PepGen Reports Third Quarter 2022 Financial Results and Recent Corporate Developments

November 10, 2022

BOSTON, Nov. 10, 2022 (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 third quarter ended September 30, 2022 and highlighted recent corporate developments.

“During the third quarter we reported results from 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 approach. These results exceeded our expectations, with PGN-EDO51 exhibiting the highest levels of oligonucleotide delivery and exon skipping in a clinical trial following a single dose when compared to publicly-available data,” commented James McArthur, Ph.D., President and CEO of PepGen. “PGN-EDO51 was generally well-tolerated, and we were particularly pleased to see consistently higher exon 51 skipping data observed at Day 28 compared to Day 10. We believe that this sustained pharmacodynamic activity observed in humans signals that PGN-EDO51 has the potential to drive accumulation of exon 51 skipped transcript and dystrophin protein in muscle following a repeat dosing regimen in people living with DMD, and we anticipate initiating a Phase 2a multiple ascending dose trial in patients in the first half of 2023.”

Dr. McArthur continued, “Alongside the success seen in our Phase 1 HNV trial, we’ve continued to further advance our Enhanced Delivery Oligonucleotide (EDO) portfolio of candidate therapeutics. We anticipate initiating a Phase 1/2 patient clinical trial of PGN-EDODM1, PepGen’s program for the treatment of myotonic dystrophy type 1 (DM1), in the first half of 2023, and, based on the results obtained in our Phase 1 trial of PGN-EDO51, we believe that PGN-EDODM1 has the potential to achieve tissue concentrations in DM1 patients that could lead to clinically meaningful outcomes. We also anticipate reporting non-human primate (NHP) data for PGN-EDO53, PepGen’s program for the treatment of DMD patients who are amenable to an exon 53 skipping approach, as well as nominating our lead investigational drug candidates for PGN-EDO45 and PGN-EDO44, for the treatment of DMD patients who are amenable to an exon 45 and exon 44 skipping approach, respectively, by the end of 2022.”

Recent Corporate Highlights

- In September, PepGen appointed Habib Dable to the Company’s Board of Directors. Mr. Dable is an industry veteran and former President and Chief Executive Officer of Acceleron Pharma where he led Acceleron’s first blockbuster launch in 2019, prior to its eventual sale to Merck & Co.
- In September, PepGen reported positive results from its Phase 1 HNV trial of PGN-EDO51 for the treatment of DMD patients whose mutations are amenable to an exon 51 skipping approach. The Phase 1 trial met its primary endpoint, providing evidence that PGN-EDO51 was generally well tolerated at pharmacologically relevant doses. A dose dependent increase in PGN-EDO51 tissue concentration and exon skipping was observed in HNV biceps:
    - In the 10 mg/kg dose cohort, PGN-EDO51 exhibited mean oligonucleotide tissue concentrations of 19 nM and 11 nM in biceps biopsies taken at Day 10 (n=6) and Day 28 (n=6), respectively. In the same 10 mg/kg dose cohort, PGN-EDO51 exhibited mean exon skipping of 1.1% and 1.4% in biceps biopsies taken at Day 10 (n=6) and Day 28 (n=6), respectively. All AEs observed at this dose level were mild.

Based on cross-trial comparisons with publicly available data, PepGen believes that these results reflect the highest levels of exon skipping and oligonucleotide delivery observed in a clinical trial following a single dose when compared to publicly available clinical data for other exon 51 skipping approaches.

- In October, PepGen presented preclinical data from its lead DMD program at the 27th Annual Congress of the World Muscle Society. The poster presentation detailed findings that a single dose of PGN-EDO23, the murine analogue of PGN-EDO51, in the *mdx* DMD model achieved up to 93.1% exon skipping and 99.7% dystrophin expression in skeletal muscle, and 62.3% exon skipping and 25.7% dystrophin expression in the heart. In non-human primates (NHPs), three doses of PGN-EDO51 achieved up to 78% exon skipping in skeletal muscle and 24% exon skipping in the left ventricle of the heart, with this repeat dosing regimen also demonstrating accumulation of exon 51 skipped transcript with successive doses in quadriceps and biceps.

Upcoming Anticipated Milestones

- **PGN-EDO51:** PepGen anticipates initiating a Phase 2a multiple ascending dose (MAD) trial evaluating PGN-EDO51 in DMD patients in the first half of 2023.
- **PGN-EDODM1:** PepGen anticipates initiating a Phase 1/2 clinical trial in DM1 patients in the first half of 2023.
- **PGN-EDO53:** PepGen anticipates reporting NHP exon skipping data by the end of 2022 for PGN-EDO53, the Company’s program for the treatment of DMD patients who are amenable to an exon 53 skipping approach.
- **Additional Pipeline Assets:** PepGen anticipates that it will nominate lead candidates for PGN-EDO45 and PGN-EDO44

by the end of 2022, which target DMD patient populations amenable to an exon 45 and exon 44 skipping approaches, respectively.

Financial Results for the Three Months Ended September 30, 2022

- **Cash and cash equivalents** were $195.8 million as of September 30, 2022.
- **Research and Development expenses** were $16.0 million for the three months ended September 30, 2022, compared to $5.7 million for the same period in 2021. The increase in research and development expenses was primarily due to increases in preclinical, manufacturing and clinical costs associated with our Phase 1 trial for PGN-EDO51, as well as an increase in personnel-related costs.
- **General and Administrative expenses** were $3.6 million for the three months ended September 30, 2022, compared to $2.4 million for the same period in 2021. The increase in general and administrative expenses was primarily due to increased costs to support public company operations.
- **Net loss** was $18.6 million for the three months ended September 30, 2022, compared to $8.1 million for the same period in 2021. PepGen had approximately 23.6 million shares outstanding on September 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 about our clinical and preclinical programs, product candidates, including their planned development and therapeutic potential, plans for future development and clinical trials in our programs, including the planned initiation of a Phase 2a MAD trial of PGN-EDO51 in DMD patients, 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 preclinical studies and clinical trials of our product candidates or to obtain regulatory approval for marketing of such products; initial clinical trial results for one or more of our product candidates may not be predictive of future trial results for such candidates; our product candidates may not be safe and effective; we may experience delays in enrolling or completing our clinical trials or incur greater than anticipated expenses in our research and development and other activities; there may be delays in regulatory clearance 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 attract and retain key employees and qualified personnel; earlier-stage trial results may not be predictive of later stage trial 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 most recent quarterly report on Form 10-Q on file 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 September 30,	
	2022	**2021**

Operating expenses:		
Research and development	$ 15,964	$ 5,712
General and administrative	3,590	2,366
Total operating expenses	$ 19,554	$ 8,078
Operating loss	$ (19,554)	$ (8,078)
Other income (expense)		
Interest income	943	—
Other income (expense), net	4	(34)
Total other income (expense), net	947	(34)
Net loss before income tax	$ (18,607)	$ (8,112)
Income tax expense	—	—
Net loss	$ (18,607)	$ (8,112)
Net loss per share, basic and diluted	$ (0.79)	$ (9.07)
Weighted-average common shares outstanding, basic and diluted	23,562,395	894,060

Condensed Consolidated Balance Sheets
(unaudited, in thousands)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 195,783	$ 132,895
Other receivables	3,881	4,744
Prepaid expenses and other current assets	4,584	2,347
Total current assets	$ 204,248	$ 139,986
Property and equipment, net	2,740	636
Other assets	1,473	3,019
Total assets	$ 208,461	$ 143,641
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 4,622	$ 3,240
Accrued expenses	10,897	7,081
Total current liabilities	15,519	10,321
Preferred stock warrant liability	—	226
Total liabilities	15,519	10,547
Commitments and contingencies		
Convertible preferred stock	—	165,176
Stockholders' equity (deficit)		
Common stock	2	—
Additional paid-in capital	280,990	1,653
Accumulated other comprehensive (loss) income	(130)	17
Accumulated deficit	(87,920)	(33,752)
Total stockholders' equity (deficit)	192,942	(32,082)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 208,461	$ 143,641