UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 11, 2023

PepGen Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-41374**	**85-3819886**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

321 Harrison Avenue **8th Floor** **Boston, Massachusetts**	**02118**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 781 797-0979

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.0001 per share	PEPG	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 11, 2023, PepGen Inc. announced its financial results for the quarter ended March 31, 2023 and other business updates. A copy of the press release is furnished as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 of this Form 8-K shall be deemed to be furnished and not filed:

99.1	Press release issued by PepGen Inc. on May 11, 2023
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PEPGEN INC.

Date: May 11, 2023

By: /s/ Noel Donnelly

Noel Donnelly, Chief Financial Officer

PepGen Reports First Quarter 2023 Financial Results and Recent Corporate Developments

– Phase 2 open-label CONNECT1-EDO51 study expected to be initiated in Canada in the first half of 2023 –
– Potentially registration-directed, randomized, double-blind, placebo-controlled Phase 2 CONNECT2-EDO51 multinational study expected to be initiated in the second half of 2023 –
– Phase 1 randomized, double-blind, placebo-controlled FREEDOM-DM1 study expected to be initiated in the first half of 2023 –
– Ended first quarter 2023 with cash, cash equivalents, and investments of $165.4 million; Cash runway expected into 2025 –

BOSTON, May 11, 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 first quarter ended March 31, 2023.

“PepGen has had an impressive start to 2023 and anticipates a meaningful year ahead. This progress builds upon the positive results we reported in Q4 2022 from our Phase 1 Healthy Volunteer (HV) clinical trial of PGN-EDO51, which exhibited the highest levels of oligonucleotide delivery and exon skipping in a clinical study following a single dose,” said James McArthur, Ph.D., President and CEO of PepGen. “Looking ahead, we anticipate initiating CONNECT1-EDO51, a Phase 2 study in Canada in the first half of 2023, which we expect will allow us to report dystrophin production, exon skipping and safety data following 4 monthly doses of PGN-EDO51 in 2024.”

Dr. McArthur continued, “We also remain focused on the balance of our Enhanced Delivery Oligonucleotide (EDO) portfolio of candidate therapeutics. Based on the encouraging non-clinical data from PGN-EDODM1, we anticipate initiating the Phase 1 FREEDOM-DM1 study in myotonic dystrophy type 1 (DM1) patients in the first half of 2023. We look forward to continuing to advance our potentially transformative therapeutics to address areas of great unmet need.”

Recent Corporate Highlights

- In March 2023, PepGen gave two oral presentations and presented a poster updating the community on the PGN-EDO51 and PGN-EDODM1 programs and shared previously reported positive PGN-EDO51 Phase 1 clinical data at the 2023 Muscular Dystrophy Association Clinical & Scientific Conference.

- In April 2023, PepGen gave an oral and poster presentation on the preclinical data supporting the development and advancement of PGN-EDODM1 into clinical studies, the design of the proposed Phase 1 clinical trial, FREEDOM-DM1, and preclinical and Phase 1 PGN-EDO51 data at the American Academy of Neurology 2023 Annual Meeting.

Anticipated Upcoming Milestones

- **PGN-EDO51:** PepGen anticipates initiating CONNECT1-EDO51; an open-label, multiple ascending dose (MAD) Phase 2 study in Canada in the first half of 2023 and CONNECT2-EDO51; a Phase 2 multinational, randomized, double-blind, placebo-controlled MAD study (RCT) in the second half of 2023 in boys and young men living with DMD. Learnings from the open-label study will inform the global RCT, which is designed to support a potential accelerated or conditional approval pathway pending alignment with regulatory authorities.
- **PGN-EDODM1:** PepGen anticipates initiating, FREEDOM-DM1, a randomized, double-blind, placebo-controlled, single ascending dose (SAD) Phase 1 Study in people living with DM1 in the first half of 2023.

Financial Results for the Three Months Ended March 31, 2023

- **Cash and cash equivalents** were $165.4 million as of March 31, 2023, which is anticipated to fund currently planned operations into early 2025.
- **Research and Development expenses** were $14.4 million for the three months ended March 31, 2023, compared to $10.7 million for the same period in 2022.
- **General and Administrative expenses** were $3.7 million for the three months ended March 31, 2023, compared to $3.2 million for the same period in 2022.
- **Net loss** was $16.3 million for the three months ended March 31, 2023, compared to $18.2 million for the same period in 2022. PepGen had approximately 23.8 million shares outstanding on March 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 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 how they may impact our programs, 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 March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 14,360	$ 10,707
General and administrative	3,671	3,186
Total operating expenses	$ 18,031	$ 13,893
Operating loss	$ (18,031)	$ (13,893)
Other income (expense)		
Interest income	$ 1,792	$ 9
Other income (expense), net	(80)	58
Total other income (expense), net	$ 1,712	$ 67
Net loss before income tax	$ (16,319)	$ (13,826)
Income tax expense	—	(4,420)
Net loss	$ (16,319)	$ (18,246)
Net loss per share, basic and diluted	$ (0.69)	$ (18.94)
Weighted-average common shares outstanding, basic and diluted	23,761,915	963,588

Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 165,403	$ 181,752
Prepaid expenses and other current assets	3,067	4,331
Total current assets	$ 168,470	$ 186,083
Property and equipment, net	$ 5,339	$ 3,335
Operating lease right-of-use asset	25,759	26,549
Other assets	1,473	1,473
Total assets	$ 201,041	$ 217,440
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,472	$ 1,362
Accrued expenses	12,900	11,913
Operating lease liability	3,655	5,553
Total current liabilities	$ 18,027	$ 18,828
Operating lease liability, net of current portion	18,171	18,981
Total liabilities	$ 36,198	$ 37,809
Stockholders' equity:		
Preferred Stock	$ —	$ —
Common stock	2	2
Additional paid-in capital	284,044	282,566
Accumulated other comprehensive (loss)	(28)	(81)
Accumulated deficit	(119,175)	(102,856)
Total stockholders' equity	$ 164,843	$ 179,631
Total liabilities and stockholders' equity	$ 201,041	$ 217,440