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): March 23, 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

PepGen Inc.
245 Main Street
Cambridge, Massachusetts 02142
(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 March 23, 2023, PepGen Inc. announced its financial results for the year ended December 31, 2022 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 March 23, 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: March 23, 2023

By: /s/ Noel Donnelly
Noel Donnelly, Chief Financial Officer

PepGen Reports Fourth Quarter and Full Year 2022 Financial Results and Recent Corporate Developments

BOSTON, March 23, 2023 – 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, 2022 and highlighted recent corporate developments.

“2022 was a truly transformative year for PepGen, as we generated first-in-human data for PGN-EDO51, our lead product candidate for the treatment of Duchenne muscular dystrophy (DMD), in a Phase 1 Healthy Volunteer (HV) trial, completed a successful initial public offering and made meaningful progress across our pipeline of Enhanced Delivery Oligonucleotide (EDO) investigational therapeutics,” commented James McArthur, Ph.D., President and CEO of PepGen. “As we look ahead in 2023, we anticipate initiating two parallel Phase 2 studies of PGN-EDO51 in patients whose disease is amenable to an exon 51 skipping approach. Building on the safety profile and high levels of exon skipping and tissue concentration observed in our Phase 1 trial, and the accumulation of exon skipped transcript in preclinical repeat dose non-human primate (NHP) studies, we believe that repeat dosing of PGN-EDO51 may lead to the accumulation of exon 51 skipped transcript and dystrophin protein in patients, which may in turn drive meaningful clinical benefit for those who live with this devastating disease.”

Dr. McArthur continued, “PepGen also expects to initiate our Phase 1, randomized, placebo controlled, single ascending dose (SAD) clinical trial of PGN-EDODM1 for the treatment of myotonic dystrophy type 1 (DM1), in the first half of this year. Based on data obtained in our Phase 1 HV study of PGN-EDO51, we believe that PGN-EDODM1 has the potential to achieve tissue concentrations that could lead to clinically meaningful outcomes. We are committed to developing transformative therapeutics to address areas of great unmet need, and in 2023 we look forward to further strengthening our relationships across the rare disease community, from patients to their families, caregivers, physicians and beyond.”

Recent Corporate Highlights

- In October 2022, PepGen presented preclinical data from its PGN-EDO51 program at the 27th Annual Congress of the World Muscle Society. The poster presentation detailed findings from a single dose study of PGN-EDO23, the murine analogue of PGN-EDO51, conducted in the *mdx* mouse model of DMD, where levels of up to 93.1% exon skipping and 99.7% dystrophin expression were observed in skeletal muscle, and levels of 62.3% exon skipping and 25.7% dystrophin expression were observed in the heart. In NHPs, exon skipping levels of up to 78% and 24% were observed in skeletal muscle and the left ventricle of the heart, respectively,

following three doses of PGN-EDO51. Furthermore, in NHPs, accumulation of exon 51 skipped transcript was observed with successive doses in quadriceps and biceps.

- In November 2022, PepGen announced positive preclinical data for PGN-EDO53, PGN-EDO45 and PGN-EDO44, three novel development candidates for the treatment of DMD patients amenable to exon 53, exon 45 and exon 44 skipping approaches, respectively. In NHPs, high levels of exon 53 skipping were observed after a single dose of PGN-EDO53, with these being almost seven times higher than those observed for a comparator peptide-phosphorodiamidate morpholino oligonucleotide (PPMO) conjugate molecule used as a positive control. For PGN-EDO45, high levels of exon skipping were observed in an *in vitro* study conducted in wild-type human myoblasts, with this development candidate outperforming a comparator PPMO used as a positive control at every dose level. Finally, high, dose-dependent exon skipping levels were also observed for PGN-EDO44 in an *in vitro* assay. We believe these data support the potential of PepGen's EDO platform in DMD, and further highlight the utility of this technology in enabling the rapid development of novel pipeline programs.
- In December 2022, PepGen announced IND-enabling preclinical data supporting the progression of PGN-EDODM1 for the treatment of DM1 into clinical studies. In the IND-enabling preclinical studies, the product candidate was well-tolerated in acute GLP studies conducted in rodents and NHPs, and while it was observed that PGN-EDODM1 corrects mis-splicing in cells with both long and short CTG repeats, the studies indicate that this product candidate does not mediate the degradation of *DMPK* transcripts. In addition, there were no off-target effects observed in other transcripts containing more than 10 CUG repeats in the HSA^{LR} mouse model of DM1 disease.
- In March 2023, PepGen gave two oral presentations and presented a poster updating the community on the PGN-EDO51 and PGN-EDODM1 programs at the 2023 Muscular Dystrophy Association Clinical & Scientific Conference in Dallas, Texas. PepGen also shared its previously reported PGN-EDO51 Phase 1 clinical data in which high levels of exon 51 skipping were observed following a single generally well-tolerated dose of 10 mg/kg of PGN-EDO51 and preclinical results which showed in NHPs that PGN-EDO51 demonstrated similar levels of exon skipping (2.5%) following a single dose at 20 mg/kg, which increased to 34.9% exon skipped transcript following 4 monthly doses. Updates were also shared on PGN-EDODM1's non-clinical pharmacology studies of PGN-EDODM1 which showed the reduction in toxic foci and nuclear MBLN1 in ex vivo patient cells leading to correction of splicing, supporting clinical studies in people living with DM1. In addition, we shared 2023 plans for the upcoming CONNECT1-EDO51 and CONNECT2-EDO51 Phase 2 multiple ascending dose studies in boys and young men living with DMD amendable to an exon 51 skipping approach and the FREEDOM-DM1 study, a SAD study in people living with DM1.

Upcoming Anticipated Milestones

- **Corporate:**
  - **American Academy of Neurology:** PepGen anticipates giving an oral presentation and poster presentations on the preclinical data supporting the development and the 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 in Boston, Massachusetts, to be held on April 22 to April 27, 2023.

- **PGN-EDO51:** PepGen anticipates initiating CONNECT1-EDO51; an open-label, multi-ascending dose (MAD) Phase 2 study to be initiated in Canada in the first half of 2023 and CONNECT2-EDO51; a Phase 2 multinational, randomized, 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 the Phase 1 FREEDOM-DM1 study, a randomized, placebo controlled, SAD study in people living with DM1 in the first half of 2023.

Financial Results for the three months and twelve months ended December 31, 2022

- **Cash and cash equivalents** were $181.8 million as of December 31, 2022, which is anticipated to fund operations into early 2025.
- **Research and Development expenses** were $13.2 million for the three months ended December 31, 2022, compared to $4.5 million for the same period in 2021. Research and Development expenses were $54.1 million for the year ended December 31, 2022, compared to $19.0 million for the same period in 2021. The increase in research and development expenses was primarily due to increased preclinical, manufacturing, and clinical trial costs associated with our PGN-EDO51 and PGN-EDODM1 programs, as well as increased personnel-related costs.
- **General and Administrative expenses** were $4.0 million for the three months ended December 31, 2022, compared to $2.7 million for the same period in 2021. General and Administrative expenses were $14.2 million for the year ended December 31, 2022, compared to $8.1 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 $14.9 million for the three months ended December 31, 2022, compared to $7.1 million for the same period in 2021. Net loss was $69.1 million for the year ended December 31, 2022, compared to $27.3 million for the same period in 2021. PepGen had approximately 23.7 million shares outstanding on December 31, 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 potential therapeutic benefits and safety profile of our candidates, initiation 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 filing of an IND application for PGN-EDODM1, scheduled participation and presentation of information in conferences 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 initiate or complete our planned clinical trials for PGN-EDO51 and 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 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 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; 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 annual report on Form 10-K to be filed with the SEC. PepGen explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

Investor Contact
Laurence Watts
Gilmartin Group
Laurence@gilmartinir.com

Media Contact
Gwendolyn Schanker
LifeSci Communications
gschanker@lifescicomms.com

Condensed Consolidated Statements of Operations

(unaudited, in thousands except share and per share amounts)

	Twelve Months Ended December 31,		Three Months Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 54,077	$ 18,999	$ 13,166	$ 4,541
General and administrative	14,224	8,110	4,047	2,670
Total operating expenses	$ 68,301	$ 27,109	$ 17,213	$ 7,211
Operating loss	$ (68,301)	$ (27,109)	$ (17,213)	$ (7,211)
Other income (expense)				
Interest income	2,793	—	1,591	—
Other income (expense), net	110	(172)	(28)	67
Total other income (expense), net	2,903	(172)	1,563	67
Net loss before income tax	$ (65,398)	$ (27,281)	$ (15,650)	$ (7,144)
Income tax expense	(3,706)	—	714	—
Net loss	$ (69,104)	$ (27,281)	$ (14,936)	$ (7,144)

Condensed Consolidated Balance Sheets
(unaudited, in thousands)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 181,752	$ 132,895
Other receivables	58	4,744
Prepaid expenses and other current assets	4,273	2,347
Total current assets	$ 186,083	$ 139,986
Property and equipment, net	3,335	636
Operating lease right-of-use assets	26,549	—
Other assets	1,473	3,019
Total assets	$ 217,440	$ 143,641
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,362	$ 3,240
Accrued expenses	11,913	7,081
Operating lease liabilities	5,553	—
Total current liabilities	18,828	10,321
Preferred stock warrant liability	—	226
Operating lease liabilities, net of current portion	18,981	—
Total liabilities	37,809	10,547
Commitments and contingencies		
Convertible preferred stock	—	165,176
Stockholders' equity (deficit)		
Common stock	2	—
Additional paid-in capital	282,566	1,653
Accumulated other comprehensive (loss) income	(81)	17
Accumulated deficit	(102,856)	(33,752)
Total stockholders' equity (deficit)	179,631	(32,082)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 217,440	$ 143,641