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): June 13, 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 8.01 Other Events.

On June 13, 2023, PepGen Inc. issued a press release titled “PepGen Inc. Provides Update on Planned Initiation of Phase 1 Study of PGN-EDODM1 in Myotonic Dystrophy Type 1”. A copy of the press release is attached as Exhibit 99.1 to this form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release issued by PepGen Inc. on June 13, 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: June 13, 2023

By: /s/ Noel Donnelly
Chief Financial Officer

PepGen Inc. Provides Update on Planned Initiation of Phase 1 Study of PGN-EDODM1 in Myotonic Dystrophy Type 1

BOSTON, June 13, 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 announced that while it awaits receipt of an official clinical hold letter from the U.S. Food and Drug Administration (FDA), the Company is withdrawing its prior guidance with respect to the timeline for initiating a Phase 1 study of PGN-EDODM1 in patients with myotonic dystrophy type 1 (DM1) in the first half of 2023 in any geography.

“After careful consideration, we decided to pause additional regulatory filings for clearance to initiate a Phase 1 study of PGN-EDODM1 in order to address the official hold letter once received from the FDA,” said James McArthur, Ph.D., President and CEO of PepGen. “People living with DM1 are eager for innovative, potential new treatment options for this serious disease, and transparency with that community and PepGen’s shareholders is always a top priority for our team. We will continue to work closely with the FDA to lift the clinical hold whilst we remain fully committed to initiating a Phase 1 study of PGN-EDODM1 as quickly as feasible. We also remain very focused on advancing our Phase 2 CONNECT1-EDO51 study in our lead program in Duchenne muscular dystrophy, which was cleared to proceed last month by Health Canada.”

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 product candidates, initiation and timeline of the Phase 1 study of PGN-EDODM1, and the status of regulatory communications.

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; 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 by regulatory authorities with respect to our programs, including clearance to commence planned clinical studies of our product candidates, including PGN-EDO51 and PGN-EDODM1; changes in regulatory framework that are out of our control; 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 and quarterly report on Form 10-Q that are 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

Sarah Sutton

Argot Partners

pepgen@argotpartners.com