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): January 31, 2023

EVELO BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38473**	**46-5594527**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

620 Memorial Drive
Cambridge, Massachusetts 02139
(Address of principal executive offices) (Zip Code)

(617) 577-0300
(Registrant's telephone number, include area code)

N/A
(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, $0.001 par value per share	EVLO	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 2.05 Costs Associated with Exit or Disposal Activities.

On January 31, 2023, the Board of Directors (the "Board") of Evelo Biosciences, Inc. (the "Company" or "Evelo") approved a plan to reduce its workforce by 48 employees, or approximately 45% of the Company's headcount as of January 31, 2023, (the "Workforce Reduction") in order to preserve cash and prioritize investment in its core clinical programs. The Company estimates that it will incur aggregate charges in connection with the Workforce Reduction of approximately $2.7 million, which relate primarily to severance payments and related continuation of benefits costs, all of which are anticipated to result in future cash expenditures, along with the payment of accrued benefits (such as paid-time-off). The Company expects the majority of these costs to be incurred during the quarter ending March 31, 2023. The Workforce Reduction and other cost savings actions being implemented are expected to extend the Company's cash runway into the third quarter of 2023.

The estimates of the charges and expenditures that the Company expects to incur in connection with the Workforce Reduction, and the timing thereof, are subject to several assumptions and the actual amounts incurred may differ materially from these estimates. In addition, the Company may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the Workforce Reduction.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 31, 2023, Stephen J. Carriere, the Company's Chief Accounting Officer, was informed that his position was being eliminated in connection with the Workforce Reduction. On the same date, the Board appointed Marella Thorell, the Company's Chief Financial Officer, Senior Vice President, Treasurer and principal financial officer, as the Company's principal accounting officer effective upon Mr. Carriere's departure. Mr. Carriere is expected to serve in his position through March 31, 2023.

On February 1, 2023, Ms. Thorell entered into a letter agreement with the Company that provides for the payment of a retention bonus in the amount of $150,000 within five business days following June 2, 2023, subject to Ms. Thorell's continued employment through such date.

Item 8.01 Other Events.

On February 1, 2023, the Company provided a clinical and business update, regarding its trials and clinical pipeline.

The Company announced interim data from its Phase 2 trial of EDP1815 in atopic dermatitis. The first three cohorts of the trial failed to meet the primary endpoint, which is the proportion of patients who achieve an outcome of at least a 50% improvement from baseline in Eczema Area and Severity Index (EASI) score, an EASI-50 response, compared to placebo at week 16. The three cohorts evaluated different concentrations, dosing regimens and manufacturing processes of EDP1815, which was generally well-tolerated in all three cohorts. The Company reported that it was evaluating the data to understand the very high placebo response rates observed in the trial, which occurred with greater prevalence in certain geographic regions. The fourth cohort of the trial, which is designed to test a faster release formulation, is fully recruited, and the Company expects to report data from this cohort in the second quarter of 2023. The results of the fourth cohort will inform the Company's path forward in atopic dermatitis.

The Company also announced that it had had recently completed interactions with the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Medicines and Healthcare products Agency Regulatory (MHRA) regarding the Company's proposed Phase 3 plans for EDP1815 in psoriasis. Based on feedback from these agencies, the Company believes it has a clear path towards a global registration program for EDP1815 in psoriasis.

The Company also reported that it had begun dosing healthy volunteers in Part A (Phase 1) of the first clinical trial of its microbial extracellular vesicle (EV) product candidate EDP2939 in psoriasis, and anticipates commencing dosing of patients in Part B (Phase 2a) later in the first quarter of 2023. The Company expects to announce Phase 2 data from the cohort of patients with psoriasis in the second half of 2023.

The Company further announced that it was implementing cost-savings initiatives in order to extend its cash runway, including the Workforce Reduction, and prioritizing investment in its core clinical programs. Additionally, the Board asked Simba Gill to remain as the Company's Chief Executive Officer, and the search for his successor was halted.

Forward-Looking Statements

This Current Report on Form 8-K (this "Current Report") contains forward-looking statements, including within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding: the expected timing of, and data results from, trials and clinical studies involving the Company's product candidates; the expected impact, cost savings and cash runway resulting from the Company's cost saving initiatives; and the timing of management changes. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "target," "predict," "project," "contemplate," "should," "will," "would," "continue" or the negative or plural of those terms or other similar expressions.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the Company has incurred significant losses, is not currently profitable and may never become profitable; the Company's projected cash runway; the Company's need for additional funding; the Company's ability to meet its debt obligations (including restrictive and operational covenants and terms of refinanced debt); the Company's ability to cure or satisfactorily resolve any default arising from its debt agreements; the Company's limited operating history; the Company's unproven approach to therapeutic intervention; the Company's ability to address regulatory questions and the likelihood of regulatory filings and approvals; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in regulatory approval; the Company's reliance on third parties and collaborators to expand its microbial library, conduct its clinical trials, manufacture its product candidates, and develop and commercialize its product candidates, if approved; the Company's lack of experience in manufacturing, selling, marketing, and distributing its product candidates; failure to compete successfully against other drug companies; protection of the Company's proprietary technology and the confidentiality of its trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of the Company's intellectual property; the Company's patents being found invalid or unenforceable; risks associated with international operations; the Company's ability to operate with a reduced workforce, to manage potential growth and to retain key personnel, particularly following a significant downsizing; the potential volatility of the Company's common stock; the Company's management and principal stockholders have the ability to control or significantly influence its business; costs and resources of operating as a public company; unfavorable or no analyst research or reports; the impact of the COVID-19 pandemic on the Company's operations, including its preclinical studies and clinical trials, and the continuity of its business; and securities class action litigation against the Company.

These and other important factors discussed under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, and the Company's other reports filed with the United States Securities and Exchange Commission, could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. While the Company may elect to update such forward-looking statements at some point in the future, except as required by law, the Company disclaims any obligation to do so, even if subsequent events cause the Company's views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report.

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.

EVELO BIOSCIENCES, INC.

Date: February 2, 2023

By: /s/ Marella Thorell
Marella Thorell
Chief Financial Officer, Senior Vice President and Treasurer