

**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): October 17, 2023



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

Delaware
(State or other jurisdiction
of incorporation or organization)

001-38473
(Commission
File Number)

46-5594527
(I.R.S. Employer
Identification No.)

**One Kendal Square, 600/700, Suite 7-201
Cambridge, Massachusetts 02139**
(Address of principal executive offices) (Zip Code)

(617) 577-0300
(Registrant's telephone number, including 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 8.01 Other Events.

On October 17, 2023, Evelo Biosciences, Inc. (“Evelo” or the “Company”) announced top-line results from its Phase 2 clinical study with EDP2939 in moderate psoriasis. The study’s primary endpoint, the difference in the proportion of patients who achieved an outcome of a 50% improvement from baseline in Psoriasis Area and Severity Index (PASI) score (a PASI-50 response) between EDP2939 and placebo after 16 weeks of daily treatment, was not achieved. The Company is continuing to gather and analyze the study data. Although there was no statistically significant difference between the proportion of patients who achieved a PASI-50 response on EDP2939 compared to placebo, it was notable that such numeric proportion went from being inferior to placebo at week 16 (19.6% on EDP2939 vs. 25% on placebo) to being superior at the week 20 follow-up visit (33.9% on EDP2939 vs. 26.9% on placebo). Ongoing analysis of the secondary endpoints continues.

Overall safety data was consistent with what was previously reported in the Phase 1 portion of this study: EDP2939 was well-tolerated with adverse events (AEs) comparable to placebo. AEs classified as “gastrointestinal” were comparable between active and placebo groups, with no meaningful differences in rates of diarrhea, abdominal pain, nausea, or vomiting. There were no related serious adverse events (SAEs).

Based on these results, Evelo has initiated a process to explore strategic alternatives. There can be no assurance that this process will result in the Company pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms. The Company has not set a timetable for completion of this process and does not intend to comment further unless or until the Board of Directors has approved a definitive course of action, the process is concluded, or it is determined that other disclosure is appropriate.

Forward-Looking Statements

This Current Report on Form 8-K (the “Form 8-K”) contains forward-looking statements, including within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements concerning the expected timing and nature of further data from the Phase 2 study with EDP2939 in moderate psoriasis; our plans to conduct a review of strategic alternatives and possible outcomes; and the potential value of the Company’s EDP1815 product and platform. 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 our 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 results of our evaluation of strategic alternatives may or may not be successful; we have incurred significant losses, are not currently profitable and may never become profitable; our projected cash runway; our need for additional funding; our ability to meet our debt obligations (including restrictive and operational covenants and terms of refinanced debt); our ability to cure or satisfactorily resolve any default arising from our debt agreements; our limited operating history; our unproven approach to therapeutic intervention; our 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; our reliance on third parties and collaborators to expand our microbial library, conduct our clinical trials, manufacture our product candidates, and develop and commercialize our product candidates, if approved; our lack of experience in manufacturing, selling, marketing, and distributing our product candidates; failure to compete successfully against other drug companies; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; our patents being found invalid or unenforceable; risks associated with international operations; our 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 our common stock; our management and principal stockholders have the ability to control or significantly influence our business; costs and resources of operating as a public company; unfavorable or no analyst research or reports; and securities class action litigation against us. These and other important factors discussed under the caption “Risk Factors” in our Quarterly Results on Form 10-Q for the quarter ended June 30, 2023, and our 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 Form 8-K. Any such forward-looking statements represent management’s estimates as of the date of this Form 8-K. While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Form 8-K.

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: October 17, 2023

By:

/s/ Marella Thorell

Marella Thorell

Chief Financial Officer and Treasurer