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): February 28, 2022

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, 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:

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 8.01. Other Events.

Evelo Biosciences, Inc. (the "Company") recently updated its business information as follows:

Clinical Responses Observed in Post-Treatment Period of Phase 2 Clinical Trial of Oral EDP1815 in Psoriasis

On February 28, 2022, the Company announced data from the post-treatment follow-up period of its Phase 2 trial of EDP1815 in mild and moderate psoriasis, which included durable and deeper clinical responses.

The EDP1815-201 Phase 2 trial was comprised of a Part A, when patients received either EDP1815 or placebo for 16 weeks, and a Part B, when patients were followed for up to 24 weeks after they had stopped receiving EDP1815 or placebo. Eighty-three patients who had received EDP1815 in Part A entered Part B. Thirty of these 83 patients had achieved a PASI-50 (50% reduction in Psoriasis Area and Severity Index score from baseline) or greater reduction at week 16 of Part A. Eighteen of the 30 patients remained at PASI-50 or greater at the end of Part B. Ten of the 30 patients had achieved a PASI-75 or greater at the end of Part A and 5 remained at PASI-75 or greater at the end of Part B. These durable results were achieved without any new psoriasis medication being used during this time. Nineteen of the 83 patients had achieved clear skin (PGA 0) or nearly clear skin (PGA 1) at the end of Part A and of these, 9 remained at PGA 0/1 at the end of Part B.

Of the 30 patients who had reached a PASI-50 at the end of Part A and entered Part B, 10 had already achieved a PASI-75 response at week 16 in Part A. Of the remaining 20 patients, 9 achieved a PASI-75 or greater response during the post-treatment period. These data, combined with the durability data, suggest that longer dosing could lead to further deepening of the responses in some patients.

The tolerability and safety data for EDP1815 in the trial was comparable to placebo, with the additional finding of no flare or rebound following discontinuation of therapy (which are often seen with other therapies for psoriasis).

About EDP1815-201

EDP1815-201 was a multicenter, randomized, double-blind, placebo-controlled, parallel-cohort, dose-ranging trial in adult patients with mild and moderate psoriasis. The study included a Part A (treatment phase) and Part B (extended follow-up phase, off-treatment).

In Part A of this trial, 249 patients were randomized in a 1:1:1 ratio to one of three parallel cohorts: 1 capsule, 4 capsules or 10 capsules. They then were randomized 2:1 active to placebo prior to starting dosing. Study medication was taken once daily for 16 weeks, and patients were followed for 4 weeks after treatment completion to week 20. In the trial, the PASI scores were assessed by both mean changes from baseline and responder rates. The primary endpoint was the mean percentage change in PASI between treatment and placebo. Secondary endpoints included the proportion of trial participants who achieve a PASI-50 response or greater. The 16-week primary endpoint gave probabilities that EDP1815 is superior to placebo ranging from 80% to 90% across the prespecified analyses and cohorts. 25% to 32% of patients across the three cohorts who were treated with EDP1815 achieved a PASI-50 at week 16 compared to 12% on placebo.

All patients had the option to enter Part B of the trial. The objective of Part B was to assess durability of treatment response and incidence of rebound (e.g., increase in PASI score to 125% of baseline value or above, or onset of new pustular erythrodermic psoriasis within 3 months of cessation of dosing) following cessation of dosing. Patients in Part B were assessed during follow-up visits at weeks 24 and 28. Only patients who had achieved a PASI-50 or greater at week 16 were also evaluated at week 40. Patients were not permitted to start other psoriasis treatments or trials during Part B.

Forward-Looking Statements

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 concerning the development of EDP1815 and the promise and potential impact of EDP1815.

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 impact of the COVID-19 pandemic on the Company's operations, including the Company's preclinical studies and clinical trials, and the

continuity of the Company's business; that the Company has incurred significant losses, is not currently profitable and may never become profitable; the Company's need for additional funding; the Company's limited operating history; the Company's unproven approach to therapeutic intervention; 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 the Company's microbial library, conduct clinical trials, manufacture product candidates, and develop and commercialize product candidates, if approved; the Company's lack of experience in manufacturing, selling, marketing, and distributing the Company's product candidates; failure to compete successfully against other drug companies; issues with the protection of the Company's proprietary technology and the confidentiality of the Company's 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 retain key personnel and to manage growth; the potential volatility of the Company's common stock; that the Company's management and principal stockholders have the ability to control or significantly influence the Company's business; costs and resources of operating as a public company; unfavorable or no analyst research or reports; and securities class action litigation against the Company.

These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the three months ended September 30, 2021, and our other reports filed with the SEC, 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 28, 2022

By: /s/ Daniel S. Char
Daniel S. Char
General Counsel & Secretary