

**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): April 14, 2022

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.)

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:

<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.

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

EDP1815 - Psoriasis

On April 14, 2022, the Company announced that it plans to meet with health authorities to discuss the path forward to registration trials for EDP1815 in patients with psoriasis during the third quarter of 2022.

EDP1815 - Atopic Dermatitis

On April 14, 2022, the Company announced that, subject to regulatory approval, it intends to add a cohort to its on-going Phase 2 trial of EDP1815 in mild, moderate, and severe atopic dermatitis. Patients in this cohort, if approved, will receive one capsule of EDP1815 with a faster release profile once daily. The Company also announced that on-going recruitment for the Phase 2 atopic dermatitis trial is ahead of plan. The Company expects that data from the first 3 cohorts of the Phase 2 atopic dermatitis trial will be available in the first quarter of 2023 and that data from the additional fourth cohort, if approved, will be available in the first half of 2023.

EDP1867 - Atopic Dermatitis

On April 14, 2022, the Company announced that data from a Phase 1b clinical trial of EDP1867 in patients with atopic dermatitis (n=52, with 40 participants who had at least one dose of EDP1867) suggested EDP1867 was safe and well-tolerated in both healthy volunteers and patients with moderate atopic dermatitis across all doses tested. No clear evidence of clinical benefit was observed in the small set of patients (n=15) with atopic dermatitis who received the lower dose of EDP1867 and provided analyzable data at week 8. Additionally, the Company announced that it intends to put the EDP1867 program on hold to focus efforts on its lead inflammation programs EDP1815 and EDP2939.

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 concerning the development, promise and potential impact of EDP1815 and EDP2939.

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 inability 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021, 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 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EVELO BIOSCIENCES, INC.

Date: April 14, 2022

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