

**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): **May 12, 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 2.02. Results of Operations and Financial Condition.

On May 12, 2022, Evelo Biosciences, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2022 and provided recent business highlights. A copy of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated May 12, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)



Evelo Biosciences Announces First Quarter 2022 Financial Results and Business Highlights

CAMBRIDGE, Mass., May 12, 2022 – Evelo Biosciences, Inc. (Nasdaq: EVLO), a clinical stage biotechnology company developing a new modality of orally delivered medicines, today reported financial results and business highlights for the first quarter 2022.

“This quarter we reported positive data for EDP1815 in psoriasis in three key areas: effects on systemic inflammatory cytokine markers; depth and duration of response at 6-month follow-up post dosing; and increased target site engagement with a faster release capsule. These data, together with our previously reported Phase 2 clinical efficacy data and preclinical data, demonstrate the central role of the small intestinal axis, SINTAX™, and supports the potential of EDP1815 as a new type of inflammation-resolving medicine with broad applicability,” said Simba Gill, Ph.D., Chief Executive Officer of Evelo. “We continue to advance EDP1815 towards later-stage clinical trials in psoriasis. Additionally, we are recruiting ahead of plan in our Phase 2 trial of EDP1815 in atopic dermatitis, and now expect data from the first three cohorts in the trial to be available in the first quarter of 2023, and data from a potential fourth cohort to be available in 2Q 2023.”

First Quarter 2022 Highlights

EDP1815 in Psoriasis

- In March 2022, Evelo presented a late-breaking oral abstract on data from its Phase 2 trial of EDP1815 in mild and moderate psoriasis at the 2022 American Academy of Dermatology (AAD) Annual Meeting. The Company previously released [positive clinical data](#), [confirmatory cytokine biomarker data](#), and [post-treatment follow-up findings](#) from this trial.

EDP1815 in Atopic Dermatitis

- Recruitment for the Phase 2 trial of EDP1815 in atopic dermatitis is ahead of plan.
- Evelo intends to add a fourth cohort to the on-going Phase 2 trial. Patients in this cohort, if enrolled, would receive 1 capsule of EDP1815 with a faster release profile once daily.

Business Highlights

- In April 2022, Jose-Carlos Gutiérrez-Ramos, Ph.D. and Tonya Williams, J.D. were appointed to Evelo’s Board of Directors, and John Mangalore, Ph.D. and Tassos Gianakakos were appointed as strategic advisors to the Company.

Upcoming Key Milestones

EDP1815 – Atopic Dermatitis

- Data from the first 3 cohorts of the Phase 2 atopic dermatitis trial in mild, moderate, and severe atopic dermatitis is anticipated in 1Q 2023; data from a potential additional fourth cohort is anticipated in 2Q 2023.

EDP2939 – Inflammation

- Initiation of clinical development in 3Q 2022.
- Phase 2 data from a cohort of patients with psoriasis expected 2H 2023.



First Quarter 2022 Financial Results (Unaudited)

- **Cash Position:** As of March 31, 2022, cash and cash equivalents were \$39.6 million, as compared to cash and cash equivalents of \$68.4 million as of December 31, 2021.
- **Research and Development Expenses:** R&D expenses were \$19.3 million for the three months ended March 31, 2022, compared to \$21.5 million for the three months ended March 31, 2021, respectively.
- **General and Administrative Expenses:** G&A expenses were \$9.4 million for the three months ended March 31, 2022, compared to \$6.0 million for the three months ended March 31, 2021.
- **Net Loss:** Net loss was \$29.9 million for the three months ended March 31, 2022, compared to \$28.2 million for the three months ended March 31, 2021. Earnings per basic and diluted shares were \$(0.56) for the three months ended March 31, 2022, compared to \$(0.55) three months ended March 31, 2021.

About Evelo Biosciences

Evelo Biosciences is a clinical stage biotechnology company developing orally delivered product candidates that are designed to act on the small intestinal axis, SINTAX™, with systemic therapeutic effects. SINTAX plays a central role in governing the immune, metabolic, and neurological systems. The Company's first product candidates are pharmaceutical preparations of single strains of microbes selected for their potential to offer defined pharmacological properties. Evelo's therapies have the potential to be effective, safe, and affordable medicines to improve the lives of people with a broad range of inflammatory diseases.

Evelo currently has two product candidates in development: EDP1815 and EDP2939 for the treatment of inflammatory diseases. Evelo is advancing additional product candidates in other disease areas.

For more information, please visit www.evelobio.com and engage with Evelo on LinkedIn.

Forward Looking Statements

This press release contains forward-looking statements including within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements concerning the development of EDP1815 and EDP2939, the promise and potential impact of our product candidates, the timing of and plans for clinical trials, and the timing and results of clinical trial readouts.

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 impact of the COVID-19 pandemic on our operations, including our preclinical studies and clinical trials, and the continuity of our business; we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our limited operating history; our unproven approach to therapeutic intervention; 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 retain key personnel and to manage our growth; 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 Report on Form 10-Q for the three-month period ended March 31, 2022, 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 press release. Any such forward-looking statements represent management's estimates as of the date of this press release. 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 press release.

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Evelo Biosciences, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 19,321	\$ 21,508
General and administrative	9,417	5,963
Total operating expenses ¹	28,738	27,471
Loss from operations	(28,738)	(27,471)
Other (expense) income:		
Interest expense, net	(1,027)	(765)
Other miscellaneous income, net	20	162
Total other expense, net	(1,007)	(603)
Loss before income taxes	(29,745)	(28,074)
Income tax expense	(116)	(122)
Net loss	\$ (29,861)	\$ (28,196)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.56)	\$ (0.55)
Weighted-average number of common shares outstanding, basic and diluted	53,619,635	51,343,923
¹ Expenses include the following non-cash stock-based compensation expense.		
Research and development	\$ 2,036	\$ 1,823
General and administrative	2,239	1,441
Total stock-based compensation expense	\$ 4,275	\$ 3,264

Evelo Biosciences, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except per share and share)
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 39,631	\$ 68,441
Prepaid expenses and other current assets	3,494	2,585
Total current assets	43,125	71,026
Property and equipment, net	6,126	6,622
Right of use asset - operating lease	8,419	8,910
Other assets	1,155	1,313
Total assets	\$ 58,825	\$ 87,871
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Debt, current portion	\$ 1,844	\$ —
Accounts payable	1,760	1,601
Accrued expenses	9,876	13,068
Operating lease liability, current portion	2,027	1,951
Other current liabilities	665	742
Total current liabilities	16,172	17,362
Noncurrent liabilities:		
Debt, net of current portion	44,772	46,557
Operating lease liability, net of current portion	7,183	7,785
Deferred revenue	7,500	7,500
Total liabilities	75,627	79,204
Commitments and contingencies (Note 10)		
Stockholder's (deficit) equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding as of March 31, 2022 and December 31, 2021, respectively	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized; 53,648,189 and 53,576,454 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	54	54
Additional paid-in capital	427,700	423,308
Accumulated deficit	(444,556)	(414,695)
Total stockholders' (deficit) equity	(16,802)	8,667
Total liabilities and stockholders' (deficit) equity	\$ 58,825	\$ 87,871