

**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 29, 2021

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 April 29, 2021, Evelo Biosciences, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2021 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	Description
No.	
99.1	Press Release issued on April 29, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: April 29, 2021

EVELO BIOSCIENCES, INC.

By: /s/ Xiaoli (Jacqueline) Liu
Xiaoli (Jacqueline) Liu
VP of Finance and Controller
(Principal Accounting Officer)



Evelo Biosciences Reports First Quarter 2021 Financial Results and Business Highlights

- Presented further positive data from Phase 1b clinical trial of EDP1815 at International Society of Atopic Dermatitis Meeting–
- Strengthened leadership team with appointments of Luca Scavo as Chief Financial Officer and Julie H. McHugh to Board of Directors–
- Announced strategic collaboration with Abdul Latif Jameel Health to develop and commercialize EDP1815 in select developing markets–
- Multiple clinical data readouts expected over next 18 months–
- Management to host conference call at 8:30 a.m. ET–

CAMBRIDGE, Mass., April 29, 2021 – 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 2021.

“Over the past year, we have executed on our research and development plans, providing critical preclinical and clinical data to help inform our late-stage development plans, and further validating our platform. We are poised to continue building on this momentum, with multiple clinical readouts expected across our inflammatory disease portfolio in the next 18 months, including our Phase 2b data from EDP1815 in psoriasis in the third quarter,” said Simba Gill, Ph.D., Chief Executive Officer of Evelo. “In order to support this rapid growth, we continue to strengthen our corporate position. We recently expanded our executive team with the addition of Luca Scavo as CFO and Julie H. McHugh to our Board of Directors, and entered into a strategic collaboration with Abdul Latif Jameel Health to potentially provide EDP1815 to the Middle East, Turkey, and Africa, representing a key step in realizing our vision of providing safe, effective, convenient, and affordable medicines to millions of people around the world.”

First Quarter 2021 Highlights and Recent Progress

EDP1815 in Atopic Dermatitis

- In April 2021, Evelo presented full clinical data from the Phase 1b clinical trial cohort evaluating EDP1815 for the treatment of mild and moderate atopic dermatitis in a poster presentation at the International Society of Atopic Dermatitis (ISAD) Hybrid Meeting 2021. The Company previously reported positive data for all 24 patients in the cohort, which is re-iterated in the presentation, together with new data on the Investigator Global Assessment (IGA) score.
- The full results reinforce the data released in January 2021, demonstrating that treatment with EDP1815 resulted in clinically meaningful improvements in both patient- and physician-reported outcomes.
- At the day 70 follow-up visit, 31% more EDP1815-treated patients achieved an IGA score of 0 or 1 greater than placebo. At this same time-point, 19% more EDP1815-treated patients reached an IGA score of 0 or 1 with a two-point improvement from baseline greater than placebo.
- These data, in addition to the treatment differences seen within the Eczema Area and Severity Index (EASI), SCORing Atopic Dermatitis (SCORAD), and IGA times Body Surface Area (IGA*BSA) clinical endpoints, suggest the potential of EDP1815 to be a safe, effective, well-tolerated, oral treatment for patients with mild and moderate atopic dermatitis.
- As previously disclosed, EDP1815 was well tolerated, with no treatment-related adverse events of moderate or severe intensity and no serious adverse events.

EDP1815 TACTIC-E Trial in COVID-19

- The planned review of interim data after the first 90 patients enrolled in the trial (including 30 patients treated with EDP1815) was conducted by the Independent Data Monitoring Committee in accordance with the protocol. No safety issues for EDP1815 were identified. The trial has therefore proceeded with continued recruitment. The next review of safety and efficacy data will be after approximately 125 patients have been enrolled into the EDP1815 arm of the trial.

Business Highlights

- In March 2021, Evelo announced a strategic collaboration with Abdul Latif Jameel Health to develop and commercialize EDP1815 in the Middle East, Turkey, and Africa. The collaboration leverages Evelo's leadership in inflammatory diseases and Abdul Latif Jameel's regional distribution expertise, with the goal of accelerating the delivery of EDP1815 as an effective, affordable medicine to people in select developing markets, many of whom suffer significant challenges in accessing medical care. Under the terms of the agreement, Evelo received an upfront payment and equity investment. Evelo will be responsible for the development and manufacturing of EDP1815, whilst Abdul Latif Jameel Health will be responsible for regulatory submissions and commercialization activities in the agreed-upon regions. Evelo and Abdul Latif Jameel Health will participate in a 50:50 profit share arrangement.
- In April 2021, Evelo announced the appointments of Luca Scavo as Chief Financial Officer and a member of the Evelo Leadership Team, effective June 1, 2021, and Julie H. McHugh to the Board of Directors, effective immediately.

Upcoming Key Milestones

EDP1815 – Psoriasis; all data anticipated to be reported in 3Q 2021

- Data from Phase 1b cohorts with tablets and capsules
- Full data from Phase 2b dose-ranging trial

EDP1815 – Atopic Dermatitis

- Subject to regulatory approval, initiation of Phase 2 trial in 3Q 2021

EDP1815 – COVID-19

- While patient accrual for both COVID-19 trials continued during the quarter, given the increase in vaccination rates, and lower number of patients hospitalized with COVID-19 at clinical trial sites, Evelo expects the trials will continue longer than originally planned. The Company is unsure when it will be able to report data, and therefore will no longer be issuing guidance related to these trials.

EDP1867 – Atopic Dermatitis

- Interim data from Phase 1b trial expected in 4Q 2021

EDP2939 – Inflammation

- Initiation of clinical development in 2022

EDP1908 – Oncology

- Initiation of clinical development in 2022

First Quarter 2021 Financial Results

- **Cash Position:** As of March 31, 2021, cash and cash equivalents were \$124.6 million, as compared to cash and cash equivalents of \$68.9 million as of December 31, 2020. This increase was primarily due to net proceeds of \$82.0 million received from the Company's issuance of common stock, partially offset by cash used to fund operating activities and capital expenditures in the first quarter of 2021.
- **Research and Development Expenses:** R&D expenses were \$21.5 million for the three months ended March 31, 2021, compared to \$17.4 million for the three months ended March 31, 2020. The increase of \$4.1 million was primarily due to increased costs related to Evelo's inflammation clinical development programs and personnel costs, partially offset by decrease in R&D platform and oncology programs.
- **General and Administrative Expenses:** G&A expenses were \$6.0 million for the three months ended March 31, 2021, compared to \$5.8 million for the three months ended March 31, 2020. The increase of \$0.1 million was primarily due to increased personnel costs and other costs.
- **Net Loss:** Net loss was \$28.2 million for the three months ended March 31, 2021, or \$(0.55) per basic and diluted share, as compared to a net loss of \$23.0 million for the three months ended March 31, 2020, or \$(0.71) per basic and diluted share.

Conference Call

Evelo will host a conference call and webcast at 8:30 a.m. ET today. To access the call please dial (866) 795-3242 (domestic) or (409) 937-8909 (international) and refer to conference ID 5856668. A live webcast of the event will also be available under "News and Events" in the Investors section of Evelo's website at <http://ir.evelobio.com>. The archived webcast will be available on Evelo's website approximately two hours after the completion of the event and will be available for 30 days following the call.

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 inflammatory diseases and cancer.

Evelo currently has four product candidates in development: EDP1815, EDP1867, and EDP2939 for the treatment of inflammatory diseases and EDP1908 for the treatment of cancer. 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 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, EDP1867, EDP2939, and EDP1908, 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 months ended March 31, 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 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.

Contact

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EVELO BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Operating Expenses ⁽¹⁾ :		
Research and development	\$ 21,508	\$ 17,419
General and administrative	5,963	5,842
Total operating expenses	27,471	23,261
Loss from operations	(27,471)	(23,261)
Other (expense) income, net	(603)	285
Loss before income taxes	(28,074)	(22,976)
Income tax expense	(122)	(65)
Net loss	<u>\$ (28,196)</u>	<u>\$ (23,041)</u>
Net loss per share - basic and diluted	<u>\$ (0.55)</u>	<u>\$ (0.71)</u>
Weighted-average common shares used in computing net loss per share - basic and diluted	51,343,923	32,250,050

⁽¹⁾ Expenses include the following amount of non-cash stock-based compensation expense.

General and administrative	\$ 1,441	889
Research and development	1,823	1,066

EVELO BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(in thousands)

	March 31, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	\$ 124,591	\$ 68,857
Property and equipment, net	7,236	7,478
Right of use asset - operating lease	10,312	10,757
Other assets	10,903	3,547
Total assets	\$ 153,042	\$ 90,639
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses and other	\$ 18,719	\$ 19,833
Long-term debt	29,258	30,048
Operating lease liability, net of current portion	9,463	9,989
Other noncurrent liabilities	7,763	284
Total liabilities	65,203	60,154
Total stockholders' equity	87,839	30,485
Total liabilities and stockholders' equity	\$ 153,042	\$ 90,639