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): July 29, 2021

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 2.02. Results of Operations and Financial Condition.

On July 29, 2021, Evelo Biosciences, Inc. (the "Company") announced its financial results for the quarter ended June 30, 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 No.	Description
99.1	Press Release issued on July 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.

EVELO BIOSCIENCES, INC.

Date: July 29, 2021

By: /s/ Luca Scavo

Luca Scavo

Chief Financial Officer, Senior Vice President and Treasurer

(Principal Financial Officer)

Exhibit 99.1

Evelo Biosciences Reports Second Quarter 2021 Financial Results and Business Highlights

–EDP1815 Phase 2b data in psoriasis expected in 3Q 2021–
–Finalized design of Phase 2 clinical trial of EDP1815 in atopic dermatitis; start of trial anticipated in 3Q 2021–
–Strengthened leadership team with appointment of Mark Plinio as Chief Commercial Officer–
–Multiple clinical data readouts expected over next 6-12 months–
–Management to host conference call at 8:30 a.m. ET–

CAMBRIDGE, Mass., July 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 second quarter 2021.

"We have demonstrated in multiple cohorts in a Phase 1b clinical trial the potential of our platform to create medicines that control systemic inflammation and immunity that are well-tolerated and easily administered. Over the next 6-12 months, we have a series of catalysts that will bring us closer to our mission of delivering on this promise to patients, beginning with data from our EDP1815 Phase 2 trial in psoriasis and the start of our EDP1815 Phase 2 trial in atopic dermatitis, both expected in 3Q 2021," said Simba Gill, Ph.D., Chief Executive Officer of Evelo. "Importantly, our efforts with EDP1815 and dermatological diseases are only the beginning. Consistent with our strategy and understanding of the breadth of our platform, we continue to explore ways to enhance and extend the applications of SINTAX-based medicines. We are progressing our next-generation extracellular vesicle (EV) candidates into the clinic next year. And, as we look ahead to later-stage development, we strengthened our team with the addition of Mark Plinio as Chief Commercial Officer. We have the resources and leadership in place to advance and expand our broad portfolio of product candidates that have the potential to be safe, well-tolerated, and affordable therapies for hundreds of millions of people around the world."

Second Quarter 2021 Highlights and Recent Progress

EDP1815 Phase 2 Trial in Atopic Dermatitis

- Evelo announced that it has finalized the design of the EDP1815 Phase 2 clinical trial in atopic dermatitis.
- The trial will be a 12-week, double-blind, placebo-controlled, multiple cohort trial in patients with mild, moderate, and severe atopic dermatitis.
- Approximately 198 patients will be randomized to receive EDP1815, and 66 patients will be randomized to receive placebo. Patients will receive either 1 capsule once daily, 2 capsules once daily, or 1 capsule twice daily.
- The primary endpoint will be the mean difference between EDP1815 and placebo in the percentage change from baseline in Eczema Area and Severity Index (EASI) score at week 12.
- Secondary endpoints will include a number of physician-reported outcomes, such as Investigators Global Assessment (IGA), Body Surface Area (BSA), along with numerous patient-reported outcomes, such as Dermatology Life Quality Index (DLQI), itch using the daily peak pruritus numerical rating scale, and Patient Oriented Eczema Measure (POEM).
- All trial participants who complete the 12-week trial will be eligible to enroll into an open-label extension trial where they will receive EDP1815.

EDP2939 in Inflammatory Diseases

- In May 2021, Evelo presented preclinical data for its extracellular vesicle (EV) product candidate, EDP2939, for the treatment of inflammatory diseases, at Virtual IMMUNOLOGY2021, the 104th Annual Meeting of the American Association of Immunologists (AAI).

- In the preclinical study, mice undergoing a delayed-type hypersensitivity (DTH) reaction against keyhole limpet hemagglutinin (KLH) were treated with EDP2939, EDP2939 in combination with different antibodies, or with placebo.
- These data suggest that EDP2939 requires the stimulation of both the TLR2 receptor and the IL-10 receptor, in addition to lymphocyte homing to the intestinal lymphoid tissue.
- Also, in-vitro, EDP2939 induces TLR2-dependent release of IL-10. Fluorescent biodistribution analysis showed that EDP2939 was not detected outside the gastrointestinal tract.
- The data suggest that treatment with EDP2939 resulted in broad-based resolution of inflammation and the establishment of immune homeostasis, with no apparent adverse safety or tolerability effects preclinically, providing key insights into the pharmacologic effects, mechanism of action, and biodistribution of EDP2939.

Business Highlights
- In June 2021, Evelo announced the appointment of Mark Plinio as Chief Commercial Officer and a member of the Evelo Leadership Team.

Upcoming Key Milestones
EDP1815 – Psoriasis; data anticipated to be reported in 3Q 2021
- Data from Phase 2b dose-ranging trial
- Data from Phase 1b cohorts with tablets and capsules

EDP1815 – Atopic Dermatitis
- Start of Phase 2 trial in 3Q 2021
- Data from Phase 2 trial anticipated in 3Q 2022

EDP1867 – Atopic Dermatitis
- Interim data from Phase 1b trial anticipated in 4Q 2021

EDP2939 – Inflammation
- Initiation of clinical development in 2022

EDP1908 – Oncology
- Initiation of clinical development in 2022

Second Quarter 2021 Financial Results
- **Cash Position:** As of June 30, 2021, cash and cash equivalents were $123.3 million, as compared to cash and cash equivalents of $68.9 million as of December 31, 2020.
- **Research and Development Expenses:** R&D expenses were $20.7 million for the three months ended June 30, 2021, compared to $15.2 million for the three months ended June 30, 2020. The $5.5 million increase was primarily due to increased costs related to Evelo's inflammation clinical development programs, personnel and R&D platform costs, partially offset by decrease in oncology program costs.
- **General and Administrative Expenses:** G&A expenses were $7.0 million for the three months ended June 30, 2021, compared to $5.1 million for the three months ended June 30, 2020. The $1.9 million increase was primarily due to increased personnel, facility, and other costs.
- **Net Loss:** Net loss was $31.6 million for the three months ended June 30, 2021, or $0.59 per basic and diluted share, as compared to a net loss of $20.7 million for the three months ended June 30, 2020, or $0.63 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 1658301. 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 and our other product candidates, 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 June 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 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 data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 20,655	$ 15,174	$ 42,163	$ 32,593
General and administrative	7,001	5,071	12,964	10,913
Total operating expenses	27,656	20,245	55,127	43,506
Loss from operations	(27,656)	(20,245)	(55,127)	(43,506)
Other (expense) income:				
Interest expense, net	(814)	(458)	(1,579)	(639)
Loss on extinguishment of debt	(3,226)	—	(3,226)	—
Other income, net	151	140	313	606
Total Other expense, net	(3,889)	(318)	(4,492)	(33)
Loss before income taxes	(31,545)	(20,563)	(59,619)	(43,539)
Income tax expense	(53)	(89)	(175)	(154)
Net loss	$ (31,598)	$ (20,652)	$ (59,794)	$ (43,693)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.59)	$ (0.63)	$ (1.14)	$ (1.35)
Weighted-average number of common shares outstanding, basic and diluted	53,379,415	32,634,468	52,340,608	32,442,259

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
General and administrative	$ 1,723	$ 1,010	$ 3,164	$ 1,899
Research and development	2,049	1,083	3,872	2,149
Total stock-based compensation expense	$ 3,772	$ 2,093	$ 7,036	$ 4,048

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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 123,333	$ 68,857
Prepaid expenses and other current assets	3,034	2,123
Total current assets	126,367	70,980
Property and equipment, net	7,520	7,478
Right of use asset - operating lease	9,856	10,757
Other assets	1,315	1,424
Total assets	$ 145,058	$ 90,639
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,319	$ 1,442
Accrued expenses	15,011	16,254
Operating lease liability, current portion	1,812	1,674
Other current liabilities	654	463
Total current liabilities	19,796	19,833
Noncurrent liabilities:		
Long-term debt	46,482	30,048
Operating lease liability, net of current portion	8,924	9,989
Deferred revenue	7,500	—
Other noncurrent liabilities	263	284
Total liabilities	82,965	60,154
Total stockholders' equity	62,093	30,485
Total liabilities and stockholders' equity	$ 145,058	$ 90,639