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 30, 2020

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, include 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 30, 2020, Evelo Biosciences, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2020 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 30, 2020

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 30, 2020

By: /s/ Daniel S. Char

Daniel S. Char

General Counsel & Secretary

Exhibit 99.1

Evelo Biosciences Reports Second Quarter 2020 Financial Results and Business Highlights

– FDA authorization of IND for Phase 2 trial of EDP1815 in COVID-19 in the U.S.; data expected in 4Q 2020 –
–Achieved regulatory and ethics authorization for Phase 2 dose ranging trial for EDP1815 in moderate psoriasis in the U.S., UK, and EU; trial initiation expected in 3Q 2020 with interim data expected by mid-2021–
–Additional data from Phase 1/2 trial of EDP1503 in TNBC expected in 4Q 2020–
–Up to 6 clinical readouts expected over next 6-12 months–
–Management to host conference call at 8:30 a.m. ET–

CAMBRIDGE, Mass., July 30, 2020 – Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing a new modality of orally delivered, systemically acting biologics, today reported financial results and business highlights for the second quarter 2020.

"Our preclinical and clinical data support advancing our programs in psoriasis, COVID-19, atopic dermatitis, and triple-negative breast cancer (TNBC), with multiple clinical readouts expected over the next 6-12 months. In parallel, we continue to advance our preclinical programs in inflammation, oncology, neuroinflammation, and metabolism," said Simba Gill, Ph.D., chief executive officer of Evelo. "Our recently completed follow-on offering provides the capital to pursue these clinical activities whilst continuing to explore additional opportunities to capture the therapeutic potential of SINTAX."

Second Quarter 2020 Highlights and Recent Progress

Inflammation

EDP1815 in Moderate Psoriasis

- Evelo has received regulatory and ethics authorization for its Phase 2 dose ranging trial at sites in the U.S., UK, and EU. The Company is on-track to initiate the trial in 3Q 2020.
- The trial will evaluate three doses of EDP1815 versus placebo in approximately 225 individuals with moderate psoriasis. The primary endpoint will be mean reduction in PASI score at 16 weeks.

EDP1815 in COVID-19

- EDP1815 will be evaluated in two clinical trials for the treatment of hospitalized patients with COVID-19: a Phase 2 trial in partnership with Rutgers University and Robert Wood Johnson University Hospital, and TACTIC-E, a Phase 2/3 trial sponsored by the Cambridge University Hospitals NHS Foundation Trust and led by Addenbrooke's Hospital in Cambridge, United Kingdom.
- The U.S. Food and Drug Administration (FDA) recently authorized the Company's Investigational New Drug (IND) application for the Phase 2 trial in the U.S.

Oncology

EDP1503

- In July 2020, Evelo presented clinical data from its Phase 1/2 open-label study of EDP1503, in combination with pembrolizumab, at the ESMO World Congress on Gastrointestinal Cancer Virtual Meeting.
- The clinical trial included patients with advanced metastatic microsatellite stable colorectal carcinoma (MSS CRC), TNBC, and those with multiple tumor types who have relapsed on prior checkpoint inhibitor treatment.
- Preliminary data on 11 TNBC patients (8 on high dose and 3 on low dose EDP1503) was presented. The data showed an overall response rate (ORR) of 25% (2/8) and a disease control rate of 37.5% (3/8) across all TNBC patients receiving high dose EDP1503.

Business Highlights

- In June 2020, Evelo completed a public offering of 13.8 million shares of its common stock, including the underwriter's option to purchase additional shares, at a public offering price of $3.75 per share, before underwriting discounts and commissions, raising approximately $52 million in gross proceeds. Additionally, in July 2020, Evelo drew down an additional $10 million under its existing loan and security agreement with K2HealthVentures.
- The U.S. Patent and Trademark Office has issued to Evelo U.S. Patent No. 10,702,561 entitled "Pharmaceutical compositions comprising a Blautia strain." The patent relates to a pharmaceutical composition formulated for oral administration comprising a therapeutically effective amount of a Blautia strain. This is the second patent in this family.

Upcoming Key Milestones

EDP1815

- Data from Phase 2 trial in COVID-19 in 4Q 2020
- Interim safety data and futility analysis from Phase 2/3 TACTIC-E trial in 4Q 2020
- Data from Phase 1b trial in atopic dermatitis in 1Q 2021
- Interim data from Phase 2 trial in moderate psoriasis by mid-2021

EDP1867

- Data from Phase 1b trial in atopic dermatitis in mid-2021

EDP1503

- Additional data from Phase 1/2 trial in TNBC in 4Q 2020

Second Quarter 2020 Financial Results

- **Cash Position:** As of June 30, 2020, cash and cash equivalents were $90.2 million, as compared to cash and cash equivalents of $77.8 million as of December 31, 2019. This increase was primarily due to $48.6 million in net proceeds received from the Company's June 2020 follow-on underwritten public offering, partially offset by cash used in operating activities. Evelo now expects that its cash and cash equivalents, including the $10 million additional debt, will enable it to fund its planned operating expenses and capital expenditure requirements into the third quarter of 2021.
- **Research and Development Expenses:** R&D expenses were $15.2 million for the three months ended June 30, 2020, compared to $15.5 million for the three months ended June 30, 2019. The decrease of $0.3 million was primarily due to the impact of COVID-19, which delayed the trial initiation and patient recruitment across inflammation and oncology programs and reduced lab and external manufacturing activities, partially offset by continuous investment in R&D hiring and headcount growth.
- **General and Administrative Expenses:** G&A expenses were $5.1 million for the three months ended June 30, 2020, compared to $5.9 million for the three months ended June 30, 2019. The decrease of $0.8 million primarily reflects a $0.4 million decrease in lower travel and office expenditure due to the COVID-19 pandemic, and a $0.4 million decrease in personnel costs due to temporary lower G&A headcount.
- **Net Loss:** Net loss was $20.7 million for the three months ended June 30, 2020, or $(0.63) per basic and diluted share, as compared to a net loss of $20.9 million for the three months ended June 30, 2019, or $(0.65) 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 37208458. 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 oral biologics that act on SINTAX™, the small intestinal axis, 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 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 including psoriasis, atopic dermatitis, and COVID-19, and EDP1503 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 for the treatment of patients with COVID-19, our development plans, the promise and potential impact of any of our monoclonal microbials or preclinical or clinical trial data, the timing of and plans for clinical trials of EDP1815, EDP1867 and EDP1503, the timing and results of any clinical trials or readouts, and the sufficiency of cash to fund operations.

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 quarter ended June 30, 2020, 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 June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating Expenses (1):				
Research and development	$ 15,174	$ 15,464	$ 32,593	$ 31,141
General and administrative	5,071	5,923	10,913	11,050
Total operating expenses	20,245	21,387	43,506	42,191
Loss from operations	(20,245)	(21,387)	(43,506)	(42,191)
Other income, net	(318)	446	(33)	951
Loss before income taxes	$ (20,563)	$ (20,941)	$ (43,539)	$ (41,240)
Income tax expense	(89)	—	(154)	—
Net loss	$ (20,652)	$ (20,941)	$ (43,693)	$ (41,240)
Net loss per share - basic and diluted	$ (0.63)	$ (0.65)	$ (1.35)	$ (1.29)
Weighted-average common shares used in computing net loss per share - basic and diluted	32,634,468	32,041,401	32,442,259	31,983,558

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

Research and development	$ 1,083	$ 973	$ 2,149	$ 1,864
General and administrative	1,010	1,162	1,899	2,224

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

	June 30, 2020	December 31, 2019
Assets:		
Cash, cash equivalents	$ 90,173	$ 77,833
Property and equipment, net	8,002	8,341
Right of use asset - operating lease	11,616	—
Other assets	4,114	4,746
Total assets	$ 113,905	$ 90,920
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses and other	$ 11,820	$ 9,743
Long-term debt	19,806	19,634
Operating lease liability	12,770	—
Other liabilities	303	1,346
Total liabilities	44,699	30,723
Total stockholders' equity	69,206	60,197
Total liabilities and stockholders' equity	$ 113,905	$ 90,920