

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 2, 2019

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**EVELO BIOSCIENCES, INC.**  
(Exact name of registrant as specified in its charter)

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**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, include area code)

**N/A**  
(Former Name or Former Address, if Changed Since Last Report)

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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))

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 2, 2019, Evelo Biosciences, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2019 and provided recent business highlights. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release issued on May 2, 2019</a>

**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: May 2, 2019

By: /s/ Jonathan Poole

Jonathan Poole

Chief Financial Officer

## **Evelo Biosciences Reports First Quarter 2019 Financial Results and Recent Business Highlights**

- *Novel Formulation of Monoclonal Microbials Discovered, Preclinical Potency Increased by up to 30-Fold: Plan to Introduce New Formulation into Ongoing Clinical Trials in Second Half of 2019 --*
- *Initial Clinical Data for EDP1066 Expected Early in Third Quarter of 2019 --*
- *On Track to Deliver 10 Clinical Readouts Across 2019 and 2020 --*

**CAMBRIDGE, Mass., May 02, 2019** - Evelo Biosciences, Inc. (Nasdaq: EVLO) ("Evelo"), a clinical stage biotechnology company developing oral biologics that act on cells in the small intestine with striking therapeutic effects throughout the body, today reported financial results and provided a business update for the first quarter of 2019.

"We continue to progress therapies targeting cells in the small intestine to drive systemic effects to treat major diseases. We look forward to clinical data from our first inflammatory disease trial of EDP1066 in healthy volunteers and psoriasis patients early in the third quarter and in atopic dermatitis patients shortly thereafter," said Simba Gill, Ph.D., chief executive officer of Evelo. "In addition, we have discovered novel formulations of monoclonal microbes which significantly improve potency in preclinical models. In parallel with completion of the current patient cohorts, we are advancing a novel formulation into our ongoing clinical studies, providing us with the opportunity for additional clinical readouts in the near term."

### **Business Highlights:**

#### **Platform Discovery: Novel Formulations with Increased Potency**

- Evelo has discovered a new formulation that enhances the pharmacological potency of monoclonal microbes by up to 30-fold in preclinical *in vivo* models.
- This proprietary formulation enhances the probability of translating preclinical effects into patients and can be commercialized cost effectively.
- Evelo plans to introduce this formulation into ongoing and new clinical trials beginning in the second half of 2019 across multiple monoclonal microbes.
- Evelo continues to invest in enhanced forms and formulations of oral biologics.

### **Ongoing Clinical Studies and Anticipated Milestones**

#### **Inflammation:**

##### **EDP1066 - Phase 1b**

- Healthy volunteers and psoriasis patients - Evelo expects to complete dosing this quarter and to report initial clinical data early in the third quarter of 2019.
- Atopic dermatitis patients - Following the recent addition of a new cohort of patients, Evelo expects to report initial clinical data in the third quarter of 2019.
- New formulation - Evelo expects to report initial clinical data from cohorts of psoriasis and atopic dermatitis patients during the fourth quarter of 2019 and the first quarter of 2020, respectively.

##### **EDP1815 - Phase 1b**

- Evelo completed dosing of EDP1815 in two dose-ascending healthy volunteer cohorts. Based on the data reviewed by the trial's safety committee, the trial proceeded as planned into patients.
- Following the addition of a new formulation into the trial, Evelo expects to report initial clinical data from psoriasis and atopic dermatitis patients in early 2020.

#### **Anticipated Additional Studies**

- Evelo expects to continue to conduct immuno-pharmacology studies in healthy volunteers with EDP1066 and EDP1815 to explore additional doses and formulations.
- Subject to data from ongoing trials, Evelo expects to initiate clinical trials in additional inflammatory disease indications in the second half of 2019.

#### **Oncology:**

##### **EDP1503 - Phase 1/2**

- Evelo is conducting a Phase 1/2 clinical trial of EDP1503 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in microsatellite stable colorectal cancer, triple-negative breast cancer, and patients with other tumor types that have relapsed on prior PD-1/L1 inhibitor treatment. Initial clinical data is expected in the first half of 2020.

#### **EDP1503 - Phase 2a**

- The University of Chicago is conducting a Phase 2a investigator-sponsored clinical trial of EDP1503 in combination with KEYTRUDA in naive melanoma patients and melanoma patients who have relapsed on prior PD-1/L1 inhibitor treatment. Initial clinical data expected in second half of 2020.

#### **First Quarter 2019 Financial Results**

- Cash Position:** As of March 31, 2019, cash, cash equivalents and investments were \$129.4 million, as compared to cash and cash equivalents of \$147.9 million as of December 31, 2018. This decrease was due to cash used to fund operating activities and capital expenditures for the first quarter of 2019. Evelo expects that its cash, cash equivalents and investments will enable it to fund its planned operating expenses and capital expenditure requirements into the second half of 2020.
- Research and Development Expenses:** R&D expenses were \$15.7 million for the three months ended March 31, 2019, compared to \$7.1 million for the three months ended March 31, 2018. The increase of \$8.6 million was due primarily to increases in costs related to Evelo's inflammation and oncology clinical development programs, and research platform expenses, as well as increased personnel costs.
- General and Administrative Expenses:** G&A expenses were \$5.1 million for the three months ended March 31, 2019, compared to \$3.3 million for the three months ended March 31, 2018. The increase of \$1.8 million was due primarily to increased general and administrative personnel costs, professional and consulting fees, and facility expenses supporting Evelo's growing R&D organization and public company infrastructure.
- Net Loss Attributable to Common Stockholders:** Net loss attributable to common stockholders was \$20.3 million for the three months ended March 31, 2019, or \$(0.64) per basic and diluted share, as compared to a net loss attributable to common stockholders of \$12.9 million for the three months ended March 31, 2018, or \$(3.29) per basic and diluted share.

#### **Conference Call**

Evelo will host a conference call and webcast today at 8:30a.m. ET. To access the call please dial (866) 795-3242 (domestic) and (409) 937-8909 (international) and provide the passcode 1838168. A live webcast of the call will be available on the Investors sections of the Evelo website at [www.evelobio.com](http://www.evelobio.com). The archived webcast will be available approximately two hours after the conference call and will be available for 30 days following the call.

#### **About Evelo Biosciences**

Evelo Biosciences, Inc. is a clinical stage biotechnology company developing oral biologics that act on cells in the small intestine with striking therapeutic effects throughout the body. These cells in the small intestine play a central role in governing the immune, metabolic and neurological systems. The company's first product candidates are monoclonal microbials, single strains of microbes selected for defined pharmacological properties. They have systemic dose-dependent effects, modulating multiple clinically validated pathways. Evelo's therapies have the potential to be effective, safe and affordable medicines to improve the lives of people with chronic disease and cancer.

Evelo currently has three product candidates, EDP1066 and EDP1815 for the treatment of inflammatory diseases and EDP1503 for the treatment of cancer, for which ten clinical readouts are expected during 2019 and 2020. Evelo is also advancing additional oral biologics through preclinical development in other disease areas.

For more information, please visit [www.evelobio.com](http://www.evelobio.com).

#### **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 our development plans and new formulations, the promise and potential impact of any of our monoclonal microbials or preclinical or clinical trial data, the timing of and plans to initiate clinical studies of EDP1066, EDP1815 and EDP1503, the timing and results of any clinical studies 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: 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 Annual Report on Form 10-K for the year ended December 31, 2018 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,	
	2019	2018
Operating Expenses(1):		
Research and development	\$ 15,680	\$ 7,143
General and administrative	5,124	3,282
Total operating expenses	<u>20,804</u>	<u>10,425</u>
Loss from operations	(20,804)	(10,425)
Other income (expense), net	505	(75)
Net loss	<u>\$ (20,299)</u>	<u>\$ (10,500)</u>
Preferred stock dividends	—	(2,417)
Net loss attributable to common stockholders	<u>\$ (20,299)</u>	<u>\$ (12,917)</u>
Net loss per share - basic and diluted	<u>\$ (0.64)</u>	<u>\$ (3.29)</u>
Weighted-average common shares used in computing net loss per share - basic and diluted	<u>31,925,072</u>	<u>3,922,152</u>

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

Research and development	\$ 891	\$ 242
General and administrative	1,062	410

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

	<u>March 31, 2019</u>	<u>December 31, 2018</u>
<b>Assets:</b>		
Cash, cash equivalents and investments	\$ 129,439	\$ 147,919
Property and equipment, net	7,332	6,925
Other assets	5,163	5,023
<b>Total assets</b>	<u>\$ 141,934</u>	<u>\$ 159,867</u>
<b>Liabilities and stockholders' equity:</b>		
Accounts payable and current liabilities	\$ 11,216	\$ 9,235
Long-term debt	10,458	12,305
Other liabilities	1,377	1,378
<b>Total liabilities</b>	<u>23,051</u>	<u>22,918</u>
<b>Total stockholders' equity</b>	<u>118,883</u>	<u>136,949</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 141,934</u>	<u>\$ 159,867</u>