
**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 31, 2018

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
Suite 200
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))

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 31, 2018, Evelo Biosciences, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2018. The full text 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 Form 8-K (including Exhibit 99.1 attached hereto) 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 (the “Securities Act”), or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

**Exhibit
No.**

Description

99.1 [Press Release issued on May 31, 2018](#)

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 31, 2018

By: /s/ Jonathan Poole
Jonathan Poole
Chief Financial Officer

Evelo Biosciences Reports First Quarter 2018 Financial Results and Recent Business Highlights

— *Dosing Underway in Phase 1 Clinical Trial of EDP1066 in Psoriasis and Atopic Dermatitis* —
 — *IND Accepted by FDA for Phase 2a Investigator-Sponsored Clinical Trial of EDP1503 in Metastatic Melanoma* —
 — *Successfully Completed Initial Public Offering, Raising \$85.0 Million in Gross Proceeds* —

CAMBRIDGE, Mass., May 31, 2018 – Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company pioneering monoclonal microbials designed to act on the gut-body network for the treatment of a wide range of diseases, today reported financial results and provided a business update for the first quarter ended March 31, 2018.

First Quarter and Recent Business Highlights:

Pipeline:

- In May 2018, the Food and Drug Administration accepted an Investigational New Drug application to begin a 70-patient Phase 2a clinical trial of EDP1503, a monoclonal microbial for the treatment of cancer. The University of Chicago will conduct this investigator-sponsored open-label clinical trial, which is designed to evaluate the safety, tolerability and efficacy of EDP1503 in combination with a PD-1 inhibitor in patients with metastatic melanoma. Evelo expects the first patient to be dosed in the second half of 2018 and to report initial clinical data in the second half of 2020. Evelo also plans to initiate a company-sponsored trial with EDP1503 in a range of cancer types in the first half of 2019.
- In April 2018, Evelo dosed the first subject in its 96-subject Phase 1 clinical trial of EDP1066, a monoclonal microbial for the treatment of inflammatory diseases. This clinical trial is designed to evaluate the safety and tolerability of a range of daily doses of EDP1066 in healthy volunteers and in psoriasis and atopic dermatitis patients. Additional exploratory endpoints to be studied in patients include the effect of EDP1066 on validated clinical measures of disease and on an integrated set of biomarkers. Evelo expects to report initial clinical data in the first half of 2019.
- Evelo expects to initiate clinical studies of its second anti-inflammatory monoclonal microbial drug candidate, EDP1815 in the fourth quarter of 2018.

Corporate:

- In May 2018, Evelo completed its initial public offering of common stock at \$16.00 per share, raising \$75.9 million in net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses.
- In February and April 2018, respectively, Evelo appointed Professor the Lord Ara Darzi of Denham and Nancy Simonian, M.D., to its board of directors.
- In March 2018, Evelo appointed Jonathan Poole as chief financial officer.
- In February 2018, Evelo entered into a strategic, multi-year manufacturing agreement with Biose Industrie (Biose). Under the terms of the agreement, Biose will reserve sufficient resources for the manufacture of Evelo's drug substance over a three-year period. In addition, the agreement with Biose gives exclusivity to Evelo for the use of Biose's facilities for the manufacture of orally delivered single strain microbial products.
- In February and March 2018, Evelo raised an aggregate of \$81.5 million from the sale of Series C convertible preferred stock.
- In February 2018, Evelo drew down an additional \$5.0 million of debt which was available under its existing debt facility.

First Quarter 2018 Financial Results:

- **Cash Position:** As of March 31, 2018, cash and cash equivalents were \$114.3 million, as compared to cash and cash equivalents of \$38.2 million as of December 31, 2017. Evelo expects that its cash and cash equivalents as of March 31, 2018 together with the proceeds from its initial public offering will enable it to fund its operating expenses and capital expenditure requirements into the second half of 2020.

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- **R&D Expenses:** R&D expenses were \$7.1 million for the three months ended March 31, 2018, as compared to \$3.8 million for the three months ended March 31, 2017. The increase of \$3.3 million was due primarily to an increase of \$1.6 million in costs for Evelo's inflammation programs, driven by external preclinical research, manufacturing costs and licensing expense, an increase of \$1.3 million in gut-body network platform expenses in line with Evelo's strategy to maximize the potential of its platform and an increase of \$0.8 million in personnel costs, including increases in salaries and bonuses of \$0.5 million and an increase of \$0.2 million in stock-based compensation expense. Oncology and other program expenses decreased slightly due to the timing of activities supporting the expected start of Evelo's clinical trial with EDP1503 in the second half of 2018.
 - **G&A Expenses:** G&A expenses were \$3.3 million for the three months ended March 31, 2018, compared to \$1.4 million for the three months ended March 31, 2017. The increase of \$1.9 million was driven by increased general and administrative and facility needs to support Evelo's growing R&D organization and was primarily due to an increase of \$0.9 million in professional fees, including legal, patent and other professional consulting fees and an increase of \$0.7 million in personnel costs, including an increase of \$0.4 million in salaries and bonus and an increase of \$0.3 million in stock-based compensation expense.
 - **Net Loss Attributable to Common Stockholders:** Net loss attributable to common stockholders was \$12.9 million for the three months ended March 31, 2018, or \$3.29 per basic and diluted share, as compared to a net loss attributable to common stockholders of \$6.6 million for the three months ended March 31, 2017, or \$1.81 per basic and diluted share.

Upcoming Events:

- JMP Securities 2018 Life Sciences Conference: June 20-21, 2018 in New York City

About Evelo Biosciences

Evelo Biosciences is a clinical-stage company pioneering the development of a new modality of medicine designed to act on the gut-body network – monoclonal microbials. Our monoclonal microbial product candidates are orally delivered and intended to modulate systemic immunology and biology by acting on multiple naturally evolved biological pathways through the gut-body network. We believe they have the potential to be broadly applicable across many diseases – including autoimmune, immunoinflammatory, metabolic, neurological, neuroinflammatory diseases and cancer. We have observed in preclinical animal models that monoclonal microbials neither circulate throughout the body, nor require gut colonization. These properties could present significant potential advantages over existing therapies, including tolerability, efficacy and convenience and allow for pharmacological intervention at all stages of disease. Evelo Biosciences was conceived and created within VentureLabs®, Flagship Pioneering's institutional innovation foundry, and launched by Flagship in 2015.

For more information, please visit 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, the promise and potential impact of any of our monoclonal microbials or clinical trial data, timing of and plans to initiate clinical studies of EDP1503 and EDP1066 and EDP1815, the timing and results of any clinical studies, 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; a significant portion of our total outstanding shares are eligible to be sold into the market in the near future; 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 final prospectus filed with the Securities and Exchange Commission, or SEC, on May 9, 2018 relating to our Registration Statement on Form S-1 and our other reports filed with the SEC, including the Quarterly Report on Form 10-Q we intend to file this week, 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, 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.

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

	March 31, 2018	December 31, 2017
Assets		
Cash and cash equivalents	\$114,311	\$ 38,246
Property and equipment, net	4,429	3,496
Other assets	3,573	2,046
Total assets	<u>\$122,313</u>	<u>\$ 43,788</u>
Liabilities and Stockholders' Equity		
Accounts payable and current liabilities	\$ 4,617	\$ 3,839
Long-term debt	14,719	9,966
Other noncurrent liabilities	1,724	1,004
Total liabilities	<u>21,060</u>	<u>14,809</u>
Preferred stock	165,778	83,702
Common stock and additional paid-in capital	2,410	1,688
Accumulated Deficit	(66,935)	(56,411)
Total stockholders' equity	<u>101,253</u>	<u>28,979</u>
Total liabilities and stockholders' equity	<u>\$122,313</u>	<u>\$ 43,788</u>

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

	Three months ended March 31,	
	2018	2017
Operating Expenses		
Research and Development	\$ 7,143	\$ 3,846
General and Administrative	3,282	1,362
Total operating expenses	<u>10,425</u>	<u>5,208</u>
Loss from operations	(10,425)	(5,208)
Other expenses, net	(75)	(162)
Net Loss	<u>\$ (10,500)</u>	<u>\$ (5,370)</u>
Preferred stock dividends	(2,417)	(1,225)
Loss attributable to stockholders	<u>(12,917)</u>	<u>(6,595)</u>
Net loss per share	<u>\$ (3.29)</u>	<u>\$ (1.81)</u>
Shares used in computing basic and diluted net loss per share	<u>3,922,152</u>	<u>3,651,833</u>

Contact

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