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): November 1, 2018

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))

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 November 1, 2018, Evelo Biosciences, Inc. (the "Company") announced its financial results for the quarter ended September 30, 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 November 1, 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: November 1, 2018

By: /s/ Jonathan Poole

Jonathan Poole

Chief Financial Officer

Exhibit 99.1

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

-- Approval to Initiate Phase 1b Trial of EDP1815 in Psoriasis and Atopic Dermatitis: Dosing of First Patient Expected in 4Q18 --
-- Initiation of Investigator-Sponsored Phase 2a Trial of EDP1503 in Metastatic Melanoma Expected in 4Q18 --

CAMBRIDGE, Mass., November 1, 2018 - Evelo Biosciences, Inc. (Nasdaq: EVLO) ("Evelo"), a clinical stage biotechnology company developing 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 third quarter ended September 30, 2018.

"Our continued progress reflects our commitment to advancing a broad portfolio of product candidates to treat multiple diseases," said Simba Gill, Ph.D., CEO of Evelo. "We are enrolling patients in our Phase 1b trial of EDP1066 for psoriasis and atopic dermatitis, and recently received approval from the MHRA to start a clinical trial of EDP1815, our second candidate for inflammatory diseases. Additionally, we expect the University of Chicago's investigator-sponsored trial of EDP1503 for the treatment of metastatic melanoma to begin enrolling patients this quarter. These activities support our goal of ten potential clinical readouts across inflammation and oncology patient groups in 2019 and 2020."

Third Quarter and Recent Business Highlights:

Pipeline:
- In September 2018, the UK Medicines and Healthcare Regulatory Agency (MHRA) accepted Evelo's Clinical Trial Authorisation application for a Phase 1b study of EDP1815 for the treatment of psoriasis and atopic dermatitis patients.

Upcoming Anticipated Milestones:
- Initiation of a Phase 1b clinical trial of EDP1815, an anti-inflammatory monoclonal microbial product candidate, in healthy volunteers and patients with psoriasis and atopic dermatitis in the fourth quarter of 2018.
- Initiation of the University of Chicago's investigator-sponsored, open-label Phase 2a clinical trial of EDP1503 in combination with a checkpoint inhibitor in patients with metastatic melanoma in the fourth quarter of 2018.
- Initiation of a company-sponsored Phase 2a clinical trial of EDP1503 in combination with a checkpoint inhibitor in patients with multiple cancer types in the first half of 2019.
- Clinical data from the ongoing Phase 1b clinical trial of EDP1066 in healthy volunteers and patients with psoriasis and atopic dermatitis in the first half of 2019.

Upcoming Events:
- Stifel 2018 Healthcare Conference on November 14, 2018 in New York, New York.
- Evercore ISI Healthcare Conference on November 27, 2018 in Boston, Massachusetts.
- BMO Prescriptions for Success Healthcare Conference on December 12, 2018 in New York, New York.

Corporate:
- In October 2018, Evelo appointed Daniel Char as general counsel. Daniel joins Evelo from Smith & Nephew, where he was the associate general counsel - commercial, responsible for advising and supporting the company's global businesses on commercial, compliance, regulatory, clinical, licensing, manufacturing and international trade matters. Daniel earned a J.D. from Harvard Law School and a B.A. in Economics from Tufts University.

Third Quarter 2018 Financial Results:
- **Cash Position:** As of September 30, 2018, cash, cash equivalents and investments were $164.3 million, as compared to cash and cash equivalents of $38.2 million as of December 31, 2017. This increase was due to net proceeds of $81.3 million from the issuance of Series C Preferred Stock, net proceeds of $75.8 million from Evelo's initial public offering and $5.0 million of additional drawings from Evelo's existing debt facility, partially offset by cash used to fund operating activities for the first nine months of 2018. 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 $11.2 million for the three months ended September 30, 2018, compared to $5.3 million for the three months ended September 30, 2017. The increase of $5.9 million was due primarily to increases in costs related to Evelo's inflammation and oncology clinical development programs, gut-body network platform expenses as well as increased personnel costs.
- **General and Administrative Expenses:** G&A expenses were $5.2 million for the three months ended September 30, 2018, compared to $2.7 million for the three months ended September 30, 2017. The increase of $2.5 million was due primarily to increased general and administrative personnel costs, professional and consulting fees, and facility expenses supporting Evelo's growing organization and public company infrastructure.
- **Net Loss Attributable to Common Stockholders:** Net loss attributable to common stockholders was $(15.9) million for the three months ended September 30, 2018, or $(0.50) per basic and diluted share, as compared to a net loss attributable to common stockholders of $(9.9) million for the three months ended September 30, 2017, or $(2.61) per basic and diluted share.

About Evelo Biosciences
Evelo Biosciences, Inc. is a clinical-stage biotechnology company developing monoclonal microbials, a new modality of medicines designed to act on the gut-body network. Evelo's product candidates are orally-delivered, single strains of microbes, selected for defined pharmacological properties. They are intended to modulate systemic immunology and biology by acting on multiple naturally evolved biological pathways that link the small intestine to the rest of the body. Evelo believes that monoclonal microbials have the potential to be broadly applicable across many diseases including inflammation, cancer and autoimmune diseases.

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 candidates through preclinical development in other disease areas.

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 preclinical or clinical trial data, timing of and plans to initiate clinical studies of EDP1503, EDP1066 and EDP1815, 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; 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 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, 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)

	September 30, 2018	December 31, 2017
Assets:		
Cash, cash equivalents and investments	$ 164,328	$ 38,246
Property and equipment, net	6,069	3,496
Other assets	5,209	2,046
Total assets	$ 175,606	$ 43,788
Liabilities, preferred stock and stockholders' equity (deficit):		
Accounts payable and current liabilities	$ 9,413	$ 3,839
Long-term debt	14,155	9,966
Other liabilities	1,278	1,004
Total liabilities	24,846	14,809
Convertible preferred stock	—	83,702
Total stockholders' equity (deficit)	150,760	(54,723)
Total liabilities, preferred stock and stockholders' equity (deficit)	$ 175,606	$ 43,788

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating Expenses(1):				
Research and development	$ 11,227	$ 5,345	$ 28,542	$ 13,881
General and administrative	5,230	2,693	13,568	5,583
Total operating expenses	16,457	8,038	42,110	19,464
Loss from operations	(16,457)	(8,038)	(42,110)	(19,464)
Other income (expense), net	600	(135)	607	(440)
Net loss	$ (15,857)	$ (8,173)	$ (41,503)	$ (19,904)
Preferred stock dividends	—	(1,708)	(3,937)	(4,355)
Net loss attributable to common stockholders	$ (15,857)	$ (9,881)	$ (45,440)	$ (24,259)
Net loss per share - basic and diluted	$ (0.50)	$ (2.61)	$ (2.45)	$ (6.52)
Weighted-average common shares used in computing net loss per share - basic and diluted	31,741,683	3,779,728	18,532,408	3,721,531

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

Research and development	$ 764	$ 224	$ 1,767	$ 439
General and administrative	831	211	2,727	467

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