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 14, 2022

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 November 14, 2022, Evelo Biosciences, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2022 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 dated November 14, 2022
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: November 14, 2022

By: /s/ Marella Thorell

Marella Thorell

Chief Financial Officer, Senior Vice President and Treasurer

(Principal Financial Officer)

Evelo Biosciences Reports Third Quarter 2022 Financial Results and Business Highlights

- Multiple Phase 2 readouts for EDP1815 in atopic dermatitis expected in 2023; data from first three cohorts expected in early 1Q 2023 and fourth cohort in 2Q 2023 -

- Phase 2 data for first extracellular vesicle product candidate EDP2939 in psoriasis anticipated in 2H 2023 –

- Continuing to advance regulatory discussions for registration trials for EDP1815 in psoriasis -

CAMBRIDGE, Mass., November 14, 2022 –Evelo Biosciences, Inc. (Nasdaq: EVLO), a clinical stage biotechnology company developing a novel platform of orally delivered medicines acting on the small intestinal axis, SINTAX, today announced its third quarter 2022 financial results and business highlights.

“We are on-track to deliver on three Phase 2 clinical milestones throughout 2023: first, early in the first quarter of 2023, data from the first three cohorts in the Phase 2 trial of EDP1815 in atopic dermatitis; second, in the second quarter of 2023, data from the fourth cohort - the faster release capsule – in the Phase 2 trial of EDP1815 in atopic dermatitis; and third, in the second half of 2023, data from patients in the Phase 2 trial of EDP2939, our first extracellular vesicle (EV) product candidate, in psoriasis” said Simba Gill, Ph.D., Chief Executive Officer of Evelo.

Dr. Gill continued, “We are pleased that the European Medicines Agency (EMA) and the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA), through their respective scientific advice processes, acknowledged the appropriateness of our proposed registration clinical trial design for EDP1815 in psoriasis, including the primary and secondary endpoints. We have also received initial written feedback from the United States Food and Drug Administration (FDA) on the same topics and have requested a meeting to discuss our registration trial plans. We have the technical and manufacturing operations in place that we believe will allow for registration trials and commercial launch.”

Third Quarter 2022 Highlights and Upcoming Key Milestones

EDP1815 in Atopic Dermatitis: On-Track for Phase 2 Data Read-outs in Early 1Q 2023 (cohorts 1-3) and 2Q 2023 (cohort 4)

- Recruitment for the first three cohorts in the Phase 2 trial of EDP1815 in atopic dermatitis is complete. Cohorts 1 - 3 are currently testing different concentrations, as well as twice daily administration versus once daily administration of the original capsule that had been used in previous clinical trials with EDP1815. Data are expected early in the first quarter of 2023.
- Recruitment for the fourth cohort is ahead of schedule, with data expected in the second quarter of 2023. The fourth cohort is testing a faster release capsule, which targets the upper part of the small intestine more effectively and has demonstrated greater efficacy than the original capsule in pre-clinical trials.

EDP2939 in Psoriasis: Dosing Expected in 1Q 2023; Phase 2 Data Anticipated in 2H 2023

- In November 2022, the Company received a request from the MHRA for additional information with respect to the Clinical Trial Application (CTA) submission for the EDP2939 Phase 1/2 trial. The Company is currently in the process of providing written responses to the MHRA questions, and anticipates dosing healthy volunteers in Part A of the trial in the first quarter of 2023, with Part B (the Phase 2 trial) to follow.
- Phase 2 data in the cohort of patients with psoriasis are still expected in the second half of 2023.

EDP1815 in Psoriasis: Regulatory Feedback on Proposed Registration Trials

- The Company has completed scientific advice meetings and received feedback from the EMA and MHRA on the proposed registration trial design of EDP1815 in psoriasis, including the primary and secondary endpoints. Both agencies provided supportive feedback regarding critical components of the chemistry manufacturing and control (CMC) for the proposed registration trials.
- Initial written feedback was received from the FDA. A meeting with the FDA has been requested to discuss the Company’s registration trial plan.

Recent Presentations

- In September 2022, Evelo presented a poster at the 2022 European Academy of Dermatology and Venereology (EADV) Congress. The poster included biomarker data demonstrating the broad anti-inflammatory effects of EDP1815 in a Phase 2 clinical trial in psoriasis. Treatment with EDP1815 led to a statistically significant reduction in the release of cytokines IL-6, IL-8, and TNF in stimulated blood cells compared to placebo. In addition, RNAseq analysis of skin biopsies taken from active lesions in a subset of patients who had achieved at least a 50% improvement in their Psoriasis Area and Severity Index (PASI) score (PASI-50) from baseline at week 16 showed reductions in disease relevant cytokines IL-23, IL-12b, and IL-17. This provides evidence of a systemic anti-inflammatory effect in addition to the tissue response.
- In September 2022, Evelo gave two presentations at the 5 Continent Congress (5CC). The first presentation discussed the use of extracellular vesicles for the treatment of inflammatory diseases, and the second presentation discussed the treatment of psoriasis via the small intestine.
- In October 2022, Evelo presented two posters at the 2022 Fall Clinical Dermatology Conference. The posters described the significant unmet medical need identified by dermatologists and primary care physicians in the U.S. for new treatment options for patients with mild and moderate psoriasis and atopic dermatitis.

Third Quarter 2022 Financial Results (Unaudited)

- **Cash Position:** As of September 30, 2022, cash and cash equivalents were $69.1 million, as compared to cash and cash equivalents of $68.4 million as of December 31, 2021.
- **Research and Development Expenses:** R&D expenses were $21.9 million for the three months ended September 30, 2022, compared to $22.6 million for the three months ended September 30, 2021.
- **General and Administrative Expenses:** G&A expenses were $7.1 million for the three months ended September 30, 2022, compared to $10.1 million for the three months ended September 30, 2021.
- **Net Loss:** Net loss was $30.6 million for the three months ended September 30, 2022, compared to $33.7 million for the three months ended September 30, 2021.

About Evelo Biosciences

Evelo Biosciences is a clinical stage biotechnology company developing a novel platform of orally delivered medicines acting 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 product candidates are pharmaceutical preparations of single strains of microbes or their extracellular vesicles (EVs). Evelo's vision is to create therapies that are effective, safe, well-tolerated, and affordable to improve the lives of the billions of people living with inflammatory diseases. Evelo initially is developing EDP1815 in psoriasis and atopic dermatitis and EDP2939 in psoriasis. If shown to be effective in inflammatory disease mediated by the Th1, Th2 or Th17 inflammatory pathways, these same investigational medicines could be effective in additional inflammatory diseases, such as psoriatic and other forms of arthritis, asthma, allergy, and inflammatory bowel disease.

For more information, please visit www.evelobio.com and engage with Evelo on LinkedIn.

Forward Looking Statements

This press release contains forward-looking statements, including 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 EDP2939, the promise and potential impact of our product candidates, the timing of and plans for clinical trials, the timing and results of clinical trial readouts and the timing and nature of feedback from regulatory agencies.

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 projected cash runway; our need for additional funding; our ability to meet our debt

obligations (including restrictive covenants) or refinance our debt on acceptable terms, if at all; our limited operating history; our unproven approach to therapeutic intervention; our ability to address regulatory questions and the likelihood of regulatory filings and approvals; 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; the fact that we are subject to certain restrictive covenants under the terms of our loan and security agreements; 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 period ended September 30, 2022, and our other reports filed with the United States Securities and Exchange Commission, 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.

Contacts

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Evelo Biosciences, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 21,928	$ 22,599	$ 62,470	$ 64,762
General and administrative	7,126	10,111	24,909	23,075
Total operating expenses	29,054	32,710	87,379	87,837
Loss from operations	(29,054)	(32,710)	(87,379)	(87,837)
Other income (expense):				
Interest expense, net	(788)	(1,023)	(2,835)	(2,602)
Loss on extinguishment of debt	—	—	—	(3,226)
Other miscellaneous income (expense), net	(615)	159	(386)	472
Total other expense, net	(1,403)	(864)	(3,221)	(5,356)
Loss before income taxes	(30,457)	(33,574)	(90,600)	(93,193)
Income tax expense	(107)	(156)	(386)	(331)
Net loss	$ (30,564)	$ (33,730)	$ (90,986)	$ (93,524)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.28)	$ (0.63)	$ (1.14)	$ (1.77)
Weighted-average number of common shares outstanding, basic and diluted	108,051,851	53,430,333	79,528,761	52,704,470

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 69,053	$ 68,441
Prepaid expenses and other current assets	3,274	2,585
Total current assets	72,327	71,026
Property and equipment, net	5,455	6,622
Right of use asset - operating lease	7,398	8,910
Other assets	1,156	1,313
Total assets	$ 86,336	$ 87,871
Liabilities and stockholders' equity		
Current liabilities:		
Debt, current portion	$ 10,095	$ —
Accounts payable	1,550	1,601
Accrued expenses	12,478	13,068
Operating lease liability, current portion	2,177	1,951
Other current liabilities	617	742
Total current liabilities	26,917	17,362
Noncurrent liabilities:		
Debt, net of current portion	36,650	46,557
Operating lease liability, net of current portion	5,935	7,785
Deferred revenue	7,500	7,500
Total liabilities	77,002	79,204
Stockholder's equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding as of September 30, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 108,473,091 and 53,576,454 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	108	54
Additional paid-in capital	514,907	423,308
Accumulated deficit	(505,681)	(414,695)
Total stockholders' equity	9,334	8,667
Total liabilities and stockholders' equity	$ 86,336	$ 87,871