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): March 9, 2021

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 March 9, 2021, Evelo Biosciences, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 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 March 9, 2021
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: March 9, 2021

By: /s/ Daniel S. Char
Daniel S. Char
General Counsel & Secretary

Exhibit 99.1

Evelo Biosciences Announces Fourth Quarter and Full Year 2020 Financial Results and Business Highlights

–Announced new positive data in human experimental model of inflammation of EDP1815–
–Completed enrollment in Phase 2b dose-ranging trial for EDP1815 in psoriasis; full data set accelerated and now expected in 3Q 2021–
–Initiated Phase 1b clinical trial of EDP1867 in atopic dermatitis; data expected in 4Q 2021 –
–Up to 8 clinical data readouts expected over next 18 months–
–Management to host conference call at 8:30 a.m. ET–

CAMBRIDGE, Mass., March 9, 2021 – Evelo Biosciences, Inc. (Nasdaq: EVLO), a clinical stage biotechnology company developing a new modality of orally delivered medicines, today reported financial results and business highlights for the fourth quarter and full year 2020.

“Building on a series of positive clinical data announcements and strong progress in 2020, we are pleased to begin 2021 by announcing a further positive clinical data readout with EDP1815. We have now shown positive clinical data with EDP1815 in five separate cohorts across psoriasis, atopic dermatitis, and a human experimental model of inflammation. EDP1815’s observed profile of broad inflammation resolving effects and tolerability is highly differentiated and supports the potential of EDP1815 as a foundational treatment for all stages of inflammatory disease,” said Simba Gill, Ph.D., Chief Executive Officer of Evelo. “The new EDP1815 data we are reporting today is from a healthy volunteer experimental model of inflammation. This study showed that an increase in the concentration of drug in a capsule resulted in enhanced effect for the same overall dose. We are also pleased with the accelerated recruitment of the Phase 2b trial of EDP1815 in psoriasis, and we will now report top-line data for the full cohort of patients in the third quarter of this year.”

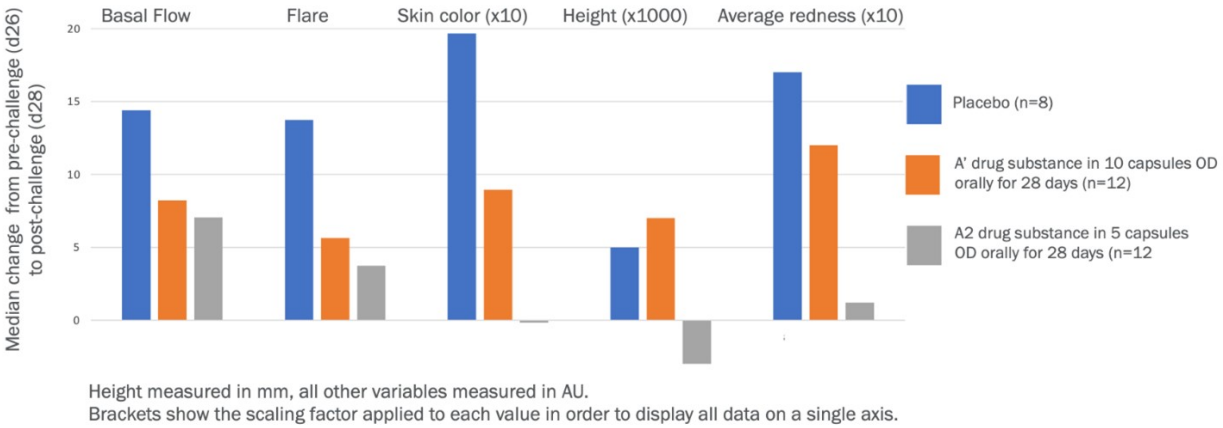
Dr. Gill continued, “The results we have observed with EDP1815 provide evidence for the entire SINTAX™ platform and support the potential of our investigational medicines to control systemic inflammation and immunity. EDP1815 and dermatological diseases are only the beginning. In February, we initiated the first clinical trial of our next anti-inflammatory candidate, EDP1867. We are progressing our two extracellular vesicle candidates, EDP2939 for inflammatory diseases and EDP1908 for oncology. In addition, we have strengthened our balance sheet with $88 million in net proceeds from recent sales of our common stock and have expanded our team with the appointments of Jonathan Zung, Ph.D., as Chief Development Officer, and John Hohneker, M.D., to our Board of Directors. We now have the resources and team in place to advance our broad portfolio to later-stage development.”

Fourth Quarter/Full Year 2020 Highlights and Recent Progress

EDP1815 in Human Experimental Model of Inflammation

- Evelo today announced positive data from a healthy volunteer experimental model of inflammation with EDP1815.
  - A total of 32 healthy volunteers were dosed daily for 28 days with either of two concentrations of EDP1815, or placebo.
  - The study was designed to investigate the relative effectiveness of two different concentrations of EDP1815 in capsules.
  - The increased concentration of drug results from improvements made in the commercial-scale manufacturing process (referred to as A2). This is the same active drug at four times the concentration compared to a prior manufacturing process (referred to as A’).
  - Healthy volunteers were immunized with the same antigen used in preclinical inflammation experiments. After 28 days of daily oral treatment with EDP1815 or placebo, subjects were given a skin challenge with the antigen which causes measurable skin inflammation a day later. 12 subjects were given A’ EDP1815. Another 12 subjects were given the higher concentration A2. The 8 subjects who received a placebo were divided between the two treatment groups.
  - As shown in the figure below, the higher concentration A2, given in fewer capsules, resulted in numerically superior reductions across the full range of skin evaluation scores compared to A’ and to placebo. A2 and A’ were given at the same total daily dose of drug.
  - These results are consistent with preclinical data showing that increased drug concentration resulted in increased effects.
  - This is a key advancement in Evelo’s understanding of how to get even more benefit from SINTAX medicine candidates.

A2 EDP1815 is more effective than A' at same total dose in human experimental model of inflammation



- Based on these data, Evelo is expanding its ongoing Phase 1b clinical trial to include additional cohorts evaluating the higher concentration A2 in both tablet and capsule formulations. Results from the Phase 1b trial and ongoing Phase 2b trial together will position the Company to go forward into Phase 3 trials with an optimized dose and formulation of EDP1815 which may further improve on the positive results already seen.

EDP1815 in Psoriasis

- Evelo has completed enrollment in its ongoing Phase 2b dose-ranging trial using A' EDP1815. Given accelerated recruitment, the Company now plans to report top-line data for all patients in the study in the third quarter of this year in place of an interim data readout on the first 113 patients.

EDP1815 in Atopic Dermatitis

- In December and January, Evelo announced positive clinical data from a cohort of patients with mild and moderate atopic dermatitis in its Phase 1b clinical trial.
- In addition to being well tolerated with no treatment-related adverse events of moderate or severe intensity and no serious adverse events, the data showed consistent improvements in percentage change from baseline compared to placebo for Eczema Area and Severity Index (EASI), Investigator's Global Assessment and Body Surface Area (IGA*BSA) and SCORing Atopic Dermatitis (SCORAD). Treatment with EDP1815 also resulted in clinically meaningful improvement in the patient-reported outcomes of Dermatology Life Quality Index (DLQI) and Patient-Oriented Eczema Measure (POEM).

EDP1867 in Atopic Dermatitis

- In February, Evelo initiated a Phase 1b trial of EDP1867 in healthy volunteers and patients with moderate atopic dermatitis.

EDP1908 in Oncology

- In November, Evelo presented preclinical data for EDP1908 at the Society for Immunotherapy of Cancer's (SITC) 35th Anniversary Annual Meeting. The data showed that orally administered EDP1908, an extracellular vesicle, resulted in superior tumor growth control versus either the parental microbial strain or anti-PD-1 therapy, with an observed dose-dependent reduction of tumor growth. The observed effects were comparable to those reported in the literature for intratumorally administered immune stimulators. Evelo subsequently announced the decision to prioritize EDP1908 as its lead clinical candidate in oncology.

Business Highlights

- In December 2020, Evelo announced the appointment of Jonathan Zung, Ph.D., as Chief Development Officer and a member of the Evelo Executive Team. Dr. Zung brings more than 25 years of global pharmaceutical development and commercialization experience to Evelo.
- In February 2021, Evelo closed an underwritten public offering of shares of its common stock at a public offering price of $15.00 per share, and a private placement of shares of its common stock at an offering price of $15.00 per share, resulting in gross proceeds of approximately $85.1 million, before underwriting discounts and commissions.
- In February 2021, Evelo announced the appointment of John A. Hohneker, M.D., to its Board of Directors.

Upcoming Key Milestones

EDP1815 – Psoriasis; all data anticipated to be reported in 3Q 2021

- Data from Phase 1b cohorts with A2 tablets and A2 capsules
- Full data from Phase 2b dose-ranging trial

EDP1815 – Atopic Dermatitis

- Subject to regulatory approval, initiation of Phase 2 trial in 3Q 2021

EDP1815 – COVID-19

- Data from Phase 2 trial with Rutgers University in 2Q 2021
- Interim safety and futility analysis from Phase 2/3 TACTIC-E trial in 2Q 2021

EDP1867 – Atopic Dermatitis

- Interim data from Phase 1b trial expected in 4Q 2021

EDP2939 – Inflammation

- Initiation of clinical development in 2022

EDP1908 – Oncology

- Initiation of clinical development in 2022

Fourth Quarter and Full Year 2020 Financial Results

- **Cash Position:** As of December 31, 2020, cash and cash equivalents were $68.9 million, as compared to cash and cash equivalents of $77.8 million as of December 31, 2019. This decrease was primarily due to cash used in operating activities, partially offset by $48.4 million in net proceeds from the Company's June 2020 follow-on offering of common stock and draw down of an additional $10 million under its existing debt facility in July 2020. During the first quarter of 2021, the Company raised net proceeds of $82.2 million from the issuance of common stock exclusive of certain other fees payable by the Company.
- **Research and Development Expenses:** R&D expenses were $22.1 million for the three months ended December 31, 2020 and $69.6 million for the full year ended December 31, 2020, compared to $16.4 million for the three months ended December 31, 2019, and $63.1 million for the full year ended December 31, 2019. The increase of $6.5 million year over year was primarily due to increased costs related to Evelo's inflammation clinical development programs, clinical development and technical operations headcount growth and platform investment, partially offset by lower oncology spend.
- **General and Administrative Expenses:** G&A expenses were $6.1 million for the three months ended December 31, 2020 and $22.3 million for the full year ended December 31, 2020, compared to $6.3 million for the three months ended December 31, 2019 and $23.2 million for the full year ended December 31, 2019. The decrease of $1.0 million year over year was primarily due to lower cost associated with legal, consulting and other professional fees, partially offset by higher IT and other office expense costs.
- **Net Loss:** Net loss was $29.1 million for the three months ended December 31, 2020 and $93.7 million for the full year ended December 31, 2020, or $(0.62) and $(2.37) per basic and diluted share, respectively, as compared to a net loss of $22.6 million for the three months ended December 31, 2019 and $85.5 million for the full year ended December 31, 2019, or $(0.70) and $(2.67) per basic and diluted share, respectively.

Conference Call

Evelo will host a conference call and webcast at 8:30 a.m. ET today to review fourth quarter and full year 2020 highlights. To access the call, please dial (866) 795-3242 (domestic) or (409) 937-8909 (international) and refer to conference ID 3094547. 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 orally delivered product candidates that are designed to act 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 first product candidates are pharmaceutical preparations of single strains of microbes selected for the potential to offer 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 and EDP1908 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, EDP1867, EDP2939, and EDP1908, the promise and potential impact of our product candidates, the timing of and plans for clinical trials, and the timing and results of clinical trial readouts.

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 Annual Report on Form 10-K for the fiscal year ended December 31, 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 December 31,		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
Operating Expenses [1]:				
Research and development	$ 22,113	$ 16,377	$ 69,616	$ 63,128
General and administrative	6,085	6,293	22,270	23,229
Total operating expenses	28,198	22,670	91,886	86,357
Loss from operations	(28,198)	(22,670)	(91,886)	(86,357)
Other (expense) income, net	(664)	261	(1,371)	1,075
Loss before income taxes	(28862)	(22,409)	(93,257)	(85,282)
Income tax expense	(188)	(190)	(409)	(190)
Net loss	$ (29,050)	$ (22,599)	$ (93,666)	$ (85,472)
Net loss per share - basic and diluted	$ (0.62)	$ (0.70)	$ (2.37)	$ (2.67)
Weighted-average common shares used in computing net loss per share - basic and diluted	46,711,281	32,098,009	39,479,197	32,031,862

[1] Expenses include the following amount of non-cash stock-based compensation expense.

Research and development	$ 1,262	$ 804	$ 4,487	$ 3,648
General and administrative	1,113	1,211	3,981	4,517

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

	December 31,	
	2020	**2019**
Assets:		
Cash and cash equivalents	$ 68,857	$ 77,833
Property and equipment, net	7,478	8,341
Right of use asset - operating lease	10,757	—
Other assets	3,547	4,746
Total assets	$ 90,639	$ 90,920
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses and other	$ 19,833	$ 9,743
Long-term debt	30,048	19,634
Operating lease liability, net of current portion	9,989	—
Other liabilities	284	1,346
Total liabilities	60,154	30,723
Total stockholders' equity	30,485	60,197
Total liabilities and stockholders' equity	$ 90,639	$ 90,920