

Evelo Biosciences Reports Fourth Quarter and Full Year 2019 Financial Results and Business Highlights

- Strong 2019 marked by clinical data that validates platform—
- Lead inflammation candidate EDP1815 showed positive clinical data across two separate cohorts—
 - EDP1815 Phase 2 study initiation expected in Q2 2020—
- Multiple clinical readouts across inflammation and oncology portfolio expected throughout 2020—
 - Management to host conference call at 8:30 a.m. EST—

CAMBRIDGE, Mass., February 13, 2020 – Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing a new modality of orally delivered, systemically acting biologics, today reported financial results and business highlights for the fourth quarter and full year 2019.

“2019 was a pivotal year for Evelo. We reported positive clinical data supporting the validation of our novel platform and demonstrating that we can target SINTAX™, the small intestinal axis, to drive clinical effects in individuals with psoriasis. These data support the role of SINTAX as an important new therapeutic target with broad potential applicability,” said Simba Gill, Ph.D., chief executive officer of Evelo. “We will build on this momentum in 2020, with multiple clinical readouts planned across our inflammation and oncology portfolio. Based on the initial safety and efficacy data reported last year, we are progressing the development of EDP1815, which could benefit millions of people with mild to moderate psoriasis as well as have potential use in other inflammatory diseases. We also look forward to advancing EDP1867 into a Phase 1b trial in asthma. EDP1867 is a non-replicating monoclonal microbial product candidate for inflammatory diseases.”

Inflammation

EDP1815 – Phase 2 study in mild to moderate psoriasis

- Evelo announced that it had agreed on the design of the EDP1815 Phase 2 clinical trial with the U.S. Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). This dose ranging study will evaluate three doses of an improved formulation of EDP1815 versus placebo in approximately 180 individuals with mild to moderate psoriasis. The primary endpoint will be the mean reduction in PASI score at 16 weeks. Evelo expects to initiate the trial in the second quarter of 2020 and to announce interim data by the end of 2020.
- Clinical data from this study may enable Evelo to advance directly into Phase 3 registrational studies in 2021, subject to end of Phase 2 discussions with regulatory agencies.

EDP1815 – Phase 1b new formulation in mild to moderate psoriasis

- Initial clinical data from a cohort of up to 24 individuals with mild to moderate psoriasis treated with the new formulation of EDP1815 is expected in the second quarter of 2020.

EDP1815 – Phase 1b new formulation in mild to moderate atopic dermatitis

- Initial clinical data from a cohort of up to 24 individuals with mild to moderate atopic dermatitis treated with the new formulation of EDP1815 is expected in the second quarter of 2020.

EDP1066

- Following completion of the final cohort of the EDP1066 Phase 1b trial, Evelo has decided to discontinue development of EDP1066 and focus its efforts in inflammatory diseases on EDP1815, EDP1867, and its preclinical pipeline.
- In the EDP1066 Phase 1b trial in mild to moderate atopic dermatitis and mild to moderate psoriasis, EDP1066 was well tolerated with no overall difference reported from placebo.
- In a cohort of individuals with mild to moderate atopic dermatitis treated with the high dose of the new formulation of EDP1066, Evelo observed changes in biomarkers of inflammation consistent with a pharmacodynamic effect which were greater than those [previously observed](#) with the high dose of the original formulation in a cohort of individuals with mild to moderate psoriasis.

EDP1867 – Phase 1b clinical trial in asthma

- EDP1867 is a non-replicating monoclonal microbial candidate for the treatment of inflammatory diseases.
- In preclinical studies EDP1867 was shown to resolve TH2-dependent inflammation which underlies atopic diseases including atopic asthma.
- Initiation of a Phase 1b clinical trial evaluating EDP1867 in individuals with asthma is expected in the second half of 2020.

Oncology

EDP1503 – Phase 1/2

- Additional data from the ongoing Phase 1/2 clinical trial evaluating EDP1503 in combination with Merck's anti-PD-1, KEYTRUDA® (pembrolizumab), in individuals with microsatellite colorectal cancer, triple-negative breast cancer, or other tumor types who have relapsed on prior PD-1/L1 inhibitor treatment, are expected in the first half of 2020.

Business Highlights

- In December 2019, the U.S. Patent and Trademark Office issued U.S. Patent No. 10,493,113 to Evelo, entitled "Compositions and methods for treating disease using a *Blautia* strain." The patent covers the use of a proprietary *Blautia* strain for the treatment of immune disorders, including inflammatory diseases and cancer. The breadth of this newly issued patent, which is not restricted by form, formulation, or method of administration, covers the use of the *Blautia* strain for a wide array of indications.
- In December 2019, Evelo appointed Juan Andres to its Board of Directors. Mr. Andres is currently Chief Technical Operations and Quality Officer at Moderna, Inc. Prior to joining Moderna, he was the Global Head of Technical Operations at Novartis. Mr. Andres is currently on the Board of Directors at Avantor, Inc. Mr. Andres holds a master's degree in Pharmacy from Alcala de Henares University in Madrid, Spain and completed an advanced development program at London Business School.

Fourth Quarter and Full Year 2019 Financial Results

- **Cash Position:** Cash and cash equivalents were \$77.8 million as of December 31, 2019, as compared to cash, cash equivalents, and investments of \$147.9 million as of December 31, 2018. This decrease was due to operating spend for the full year 2019, partially offset by net proceeds from the debt refinancing with K2 HealthVentures in July 2019. Evelo expects that its cash and cash equivalents will enable it to fund its planned operating expenses and capital expenditure requirements to the end of 2020.
- **Research and Development Expenses:** R&D expenses were \$16.4 million for the three months ended December 31, 2019 and \$63.1 million for the full year ended December 31, 2019, compared to \$11.3 million for the three months ended December 31, 2018 and \$39.9 million for the full year ended December 31, 2018. The increase of \$23.2 million for 2019 was due primarily to increased costs related to Evelo's inflammation clinical development programs, R&D platform, and personnel costs.
- **General and Administrative Expenses:** G&A expenses were \$6.3 million for the three months ended December 31, 2019 and \$23.2 million for the full year ended December 31, 2019, compared to \$4.7 million for the three months ended December 31, 2018 and \$18.2 million for the full year ended December 31, 2018. The increase of \$5.0 million for 2019 was due primarily to increased personnel costs, professional and consulting fees supporting Evelo's growing R&D pipeline, and a full year of public company infrastructure costs following the Company's IPO in May 2018.
- **Net Loss Attributable to Common Stockholders:** Net loss attributable to common stockholders was \$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, as compared to a net loss attributable to common stockholders of \$15.4 million for the three months ended December 31, 2018 and \$60.9 million for the full year ended December 31, 2018, or \$(0.49) and \$(2.78) per basic and diluted share, respectively.

Conference Call

Evelo will host a conference call and webcast at 8:30 a.m. EST today. To access the call please dial (866) 795-3242 (domestic) or (409) 937-8909 (international) and refer to conference ID 5849487. 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, Inc. is a clinical stage biotechnology company developing oral biologics that act on 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 monoclonal microbials, single strains of microbes selected for defined pharmacological properties. Evelo's therapies have the potential to be effective, safe and affordable medicines to improve the lives of people with chronic diseases and cancer.

Evelo currently has four product candidates: EDP1815, EDP1867, and EDP2939 for the treatment of inflammatory diseases, and EDP1503 for the treatment of cancer. Evelo is also advancing additional oral biologics through preclinical development 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 our development plans, the promise and potential impact of any of our monoclonal microbials or preclinical or clinical trial data, the timing of and plans for clinical studies of EDP1815, EDP1867, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, 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

Evelo Biosciences
Jessica Cotrone, 978-760-5622
jcotrone@evelobio.com

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Operating Expenses(1):				
Research and development	\$ 16,377	\$ 11,343	\$ 63,128	\$ 39,885
General and administrative	6,293	4,650	23,229	18,218
Total operating expenses	22,670	15,993	86,357	58,103
Loss from operations	(22,670)	(15,993)	(86,357)	(58,103)
Other income, net	261	550	1,075	1,157
Loss before income taxes	\$ (22,409)	\$ (15,443)	\$ (85,282)	\$ (56,946)
Income tax expense	(190)	—	(190)	—
Net loss	(22,599)	(15,443)	(85,472)	(56,946)
Preferred stock dividends	—	—	—	(3,937)
Net loss attributable to common stockholders	\$ (22,599)	\$ (15,443)	\$ (85,472)	\$ (60,883)
Net loss per share - basic and diluted	\$ (0.70)	\$ (0.49)	\$ (2.67)	\$ (2.78)
Weighted-average common shares used in computing net loss per share - basic and diluted	32,098,009	31,778,021	32,031,862	21,871,029

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

Research and development	\$ 804	\$ 741	\$ 3,648	\$ 2,508
General and administrative	1,211	824	4,517	3,551

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

	December 31, 2019	December 31, 2018
Assets:		
Cash, cash equivalents and investments	\$ 77,833	\$ 147,919
Property and equipment, net	8,341	6,925
Other assets	4,746	5,023
Total assets	\$ 90,920	\$ 159,867
Liabilities and stockholders' equity:		
Accounts payable and current liabilities	\$ 9,743	\$ 9,235
Long-term debt	19,634	12,305
Other liabilities	1,346	1,378
Total liabilities	30,723	22,918
Total stockholders' equity	60,197	136,949
Total liabilities and stockholders' equity	\$ 90,920	\$ 159,867