Evelo Biosciences Reports Third Quarter 2020 Financial Results and Business Highlights

-- Treated first patients in Phase 2 dose-ranging trial for EDP1815 in psoriasis --
-- Six clinical readouts in psoriasis, atopic dermatitis, COVID-19, and breast cancer expected over next 3-9 months --
--Advancing newly discovered microbial extracellular vesicles as next-generation SINTAX-based medicines--
-- Data from Phase 1b trial evaluating EDP1815 in psoriasis spotlighted today at EADV Virtual Congress --
-- Management to host conference call at 8:30 a.m. ET --

CAMBRIDGE, Mass., October 29, 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 third quarter of 2020.

"We can reduce systemic inflammation in humans by oral delivery of our candidate medicines which engage SINTAX™, the small intestinal axis. We have accumulated the evidence for this from multiple cohorts of patients in two clinical trials. We are now building on these results in the next phases of development, with clinical trials across three distinct patient populations, including mid-stage studies in psoriasis and COVID-19," said Simba Gill, Ph.D., Chief Executive Officer of Evelo. "Together with our work on EDP1503 and EDP1867, we expect to announce six clinical results over the next three to nine months. In parallel, we have a remarkable discovery from our continued investment in research - microbial extracellular vesicles are a new form of SINTAX medicines that are now in preclinical development in both inflammation and oncology. Our portfolio is making significant progress towards our goal of providing therapies to patients with chronic inflammatory diseases and cancer."

Third Quarter 2020 Highlights and Recent Progress

Inflammation

EDP1815 in Psoriasis

- Today, Evelo presented data from the Phase 1b clinical trial cohorts evaluating EDP1815 for the treatment of mild to moderate psoriasis at the European Academy of Dermatology and Venereology (EADV) Virtual Congress. The poster, as well as a prerecorded presentation, are now available online on the EADV conference website. The poster was selected as one of EADV's key stories and highlighted at a virtual press conference at the event. Also at EADV, Evelo presented preclinical data, highlighting the potent anti-inflammatory effects of EDP1815 in murine models of TH1-, TH2- and TH17-mediated inflammation, including a model of chronic nervous system inflammation.
- In October, Evelo dosed the first patients in the Phase 2 dose-ranging trial evaluating EDP1815 for the treatment of mild to moderate psoriasis. The trial is evaluating three doses of EDP1815 versus placebo in approximately 225 individuals, over a 16-week treatment period. The primary endpoint is mean reduction in PASI score.

EDP1815 in Atopic Dermatitis

- In October, Evelo completed enrollment in the Phase 1b clinical trial cohort evaluating EDP1815 for the treatment of mild to moderate atopic dermatitis. The cohort is evaluating EDP1815 versus placebo in 24 individuals, over a 56-day treatment period. The primary endpoint is safety and tolerability.

EDP1815 in COVID-19

- Patient recruitment continues in two studies evaluating EDP1815 for the treatment of newly hospitalized patients with COVID-19: the Phase 2 trial in partnership with Rutgers University, and TACTIC-E, a Phase 2/3 trial sponsored by the Cambridge University Hospitals NHS Foundation Trust and led by Addenbrooke's Hospital in Cambridge, United Kingdom.
- Evelo now expects to report data from the clinical trial in partnership with Rutgers University and interim safety data and futility analysis from TACTIC-E in 2Q 2021, depending on the prevalence of hospitalized patients with COVID-19. Subject to the receipt of positive data, Evelo plans to engage in discussions with global regulatory agencies to determine an appropriate path to registration for EDP1815 in COVID-19.
- In order to expedite patient recruitment and expand access to potential therapies for COVID-19, new trial sites are being opened for TACTIC-E.

Business Highlights

- In September 2020, Evelo appointed Julie Carretero as Chief People Officer. In her role, Ms. Carretero is responsible for leading the Company's people initiatives, including talent acquisition and employee development.
- In October 2020, the U.S. Patent and Trademark Office issued to Evelo U.S. Patent No. 10,792,314, entitled "*Compositions and methods of treating cancer using Bifidobacterium animalis ssp. lactis*." The patent covers a pharmaceutical

composition formulated for oral administration comprising Bifidobacterium animalis ssp. Lactis Strain A and a pharmaceutically acceptable carrier within an enteric coating.

Upcoming Key Milestones

EDP1815

- Data from Phase 1b trial in mild to moderate atopic dermatitis in 1Q 2021
- Data from Phase 2 Rutgers University trial in COVID-19 in 2Q 2021
- Interim safety data and futility analysis from Phase 2/3 TACTIC-E trial in COVID-19 in 2Q 2021
- Interim data from Phase 2 trial in mild to moderate psoriasis by mid-2021

EDP1867

- Data from Phase 1b trial in atopic dermatitis in mid-2021

EDP1503

- Additional data from Phase 1/2 trial in triple-negative breast cancer (TNBC) accepted for poster presentation at the 2020 San Antonio Breast Cancer Symposium (SABSC), to be held virtually from December 8-11

EDP1908

- Abstract titled "Oral delivery of a microbial extracellular vesicle induces potent anti-tumor immunity in mice," accepted for poster presentation at the Society for Immunotherapy of Cancer's (SITC) 35th Anniversary Annual Meeting, to be held virtually from November 11-14

Third Quarter 2020 Financial Results

- **Cash Position:** As of September 30, 2020, cash and cash equivalents were $81.6 million, as compared to cash and cash equivalents of $77.8 million as of December 31, 2019. This increase was primarily due to $48.4 million in net proceeds from the Company's June 2020 follow-on offering and draw down of an additional $10 million under its existing debt facility in July 2020, partially offset by cash used in operating activities. Evelo expects that its cash and cash equivalents will enable it to fund its planned operating expenses and capital expenditure requirements into the beginning of the third quarter of 2021.
- **Research and Development Expenses:** R&D expenses were $14.9 million for the three months ended September 30, 2020, compared to $15.6 million for the three months ended September 30, 2019. The decrease of $0.7 million was primarily due to decrease in platform expenses and oncology program spend primarily driven by COVID-19 pandemic impact, partially offset by increases in inflammation programs and personnel costs due to advancing EDP1815 into Phase 2, additional trials and headcount increase in R&D.
- **General and Administrative Expenses:** G&A expenses were $5.3 million for the three months ended September 30, 2020, compared to $5.9 million for the three months ended September 30, 2019. The decrease of $0.6 million was primarily due to lower personnel costs associated with temporarily lower general and administrative headcount and lower professional fees, partially offset by higher facility and office costs due to the impact of the COVID-19 pandemic.
- **Net Loss:** Net loss was $20.9 million for the three months ended September 30, 2020, or $(0.45) per basic and diluted share, as compared to a net loss of $21.6 million for the three months ended September 30, 2019, or $(0.67) per basic and diluted share.

Conference Call

Evelo will host a conference call and webcast at 8:30 a.m. ET today to review third quarter 2020 highlights. To access the call, please dial (866) 795-3242 (domestic) or (409) 937-8909 (international) and refer to conference ID 5480508. 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 oral biologics that act on SINTAX™, the small intestinal axis, 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 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 five product candidates in development: EDP1815, EDP1867, and EDP2939 for the treatment of inflammatory diseases including psoriasis, atopic dermatitis, and COVID-19, and EDP1503 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, EDP1503 and EDP1908, the promise and potential impact of any of our product candidates, the timing of and plans for clinical trials of EDP1815, EDP1867 and EDP1503, the timing and results of any clinical trials 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: 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 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

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating Expenses (1):				
Research and development	$ 14,910	$ 15,610	$ 47,503	$ 46,751
General and administrative	5,272	5,886	16,185	16,936
Total operating expenses	20,182	21,496	63,688	63,687
Loss from operations	(20,182)	(21,496)	(63,688)	(63,687)
Other (expense) income, net	(674)	(137)	(707)	814
Loss before income taxes	$ (20,856)	$ (21,633)	$ (64,395)	$ (62,873)
Income tax expense	(67)	—	(221)	—
Net loss	$ (20,923)	$ (21,633)	$ (64,616)	$ (62,873)
Net loss per share - basic and diluted	$ (0.45)	$ (0.67)	$ (1.74)	$ (1.96)
Weighted-average common shares used in computing net loss per share - basic and diluted	46,168,013	32,060,747	37,050,907	32,009,571

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

Research and development	$ 1,076	$ 980	$ 3,225	$ 2,844
General and administrative	969	1,082	2,868	3,306

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

	September 30, 2020	December 31, 2019
Assets:		
Cash, cash equivalents	$ 81,580	$ 77,833
Property and equipment, net	7,586	8,341
Right of use asset - operating lease	11,192	—
Other assets	4,479	4,746
Total assets	$ 104,837	$ 90,920
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses and other	$ 11,941	$ 9,743
Long-term debt	29,924	19,634
Operating lease liability	12,110	—
Other liabilities	432	1,346
Total liabilities	54,407	30,723
Total stockholders' equity	50,430	60,197
Total liabilities and stockholders' equity	$ 104,837	$ 90,920