Evelo Biosciences Announces Second Quarter 2022 Financial Results and Business Highlights

– Health authority feedback on registration trials for EDP1815 in psoriasis expected by year-end–
– Two Phase 2 clinical read-outs with EDP1815 in atopic dermatitis expected in 1Q and 2Q 2023–
– Phase 2 data for EDP2939 in psoriasis expected in 2H 2023–
– Management will host conference call at 7:30 a.m. ET–

CAMBRIDGE, Mass., August 11, 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 reported financial results and business highlights for the second quarter 2022.

Evelo's SINTAX medicines platform and product candidates aim to disrupt how to treat the hundreds of millions of people globally who suffer with inflammatory diseases and lack access to effective treatments. This new type of medicine has the potential to resolve inflammation broadly while being safe and well-tolerated, and orally delivered. The mechanism of action of SINTAX medicines is based on the discovery that the small intestine exerts profound control over inflammation throughout the body. Orally delivered, non-live pharmaceutical preparations of commensal microbes and their extracellular vesicles have structural patterns which are recognized by immune sensory cells in the small intestine. The novel mechanism of action of SINTAX medicines leads to the induction of systemically circulating and acting regulatory T cells which resolve multiple inflammatory pathways without suppressing immunity. This is completely distinct to modifying the microbiome. The SINTAX mechanism of inflammation resolution has the potential to treat people suffering from a broad range of diseases with inflammation as an underlying driver. Evelo has previously reported positive Phase 2 results with EDP1815 in patients with mild and moderate psoriasis and in a Phase 1b trial in patients with atopic dermatitis.

"This quarter we continued to make substantial progress in our clinical development programs," said Simba Gill, Ph.D., Chief Executive Officer of Evelo. "Enrollment is progressing well in the first three cohorts of the Phase 2 trial for EDP1815 in atopic dermatitis, with data expected in the first quarter of 2023. An additional fourth cohort, in which patients will receive one capsule daily of EDP1815 with a faster release profile, is expected to read out in the second quarter of 2023. For EDP1815 in psoriasis, we expect to receive feedback from health authorities on our proposed plans for advancing into registration trials by year-end."

Second Quarter 2022 Highlights and Upcoming Key Milestones

EDP1815 in Psoriasis: Moving Towards Registration Trials

- The Company is currently engaging with health authorities in the United States and Europe to solicit feedback on its proposed plans for advancing EDP1815 into registrational trials in psoriasis. Evelo anticipates feedback by the end of 2022.

EDP1815 in Atopic Dermatitis: Phase 2 Data Expected in 1Q and 2Q 2023

- Recruitment for the first three cohorts in the Phase 2 trial of EDP1815 in atopic dermatitis is on-schedule.
- As previously shared, Evelo has added a fourth cohort to the on-going Phase 2 trial. Patients in this cohort will receive one capsule of EDP1815 with a faster release profile once daily.

EDP2939 - Inflammation: First Orally Delivered Microbial Extracellular Vesicle (EV); Phase 1/2 Data in Psoriasis Expected in 2H 2023

- Initiation of a Phase 1/2 trial in healthy volunteers and patients with psoriasis in Q3 2022, with dosing expected to commence in Q4 2022.

Business Highlights

- In May 2022, the Company completed a $79.2 million registered direct offering of common stock, led by Flagship Pioneering with additional participation from new and existing investors.
- In July 2022, the Company announced the appointment of Marella Thorell as Chief Financial Officer, effective September 1, 2022.
- The Company will present a poster at the upcoming 2022 European Academy of Dermatology and Venerology (EADV) Congress, being held in Milan, Italy from September 7-10, 2022. The poster title is "Biomarker Evidence of Anti-inflammatory Effects of EDP1815 in a Phase 2 Psoriasis Clinical Trial."

Second Quarter 2022 Financial Results (Unaudited)

- **Cash Position:** As of June 30, 2022, cash and cash equivalents were $92.0 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 $21.2 million for the three months ended June 30, 2022, compared to $20.7 million for the three months ended June 30, 2021, respectively.
- **General and Administrative Expenses:** G&A expenses were $8.4 million for the three months ended June 30, 2022, compared to $7.0 million for the three months ended June 30, 2021.
- **Net Loss:** Net loss was $30.6 million for the three months ended June 30, 2022, compared to $31.6 million for the three months ended June 30, 2021. Earnings per basic and diluted shares were $(0.40) for the three months ended June 30, 2022, compared to $(0.59) three months ended June 30, 2021. Net loss per share for the comparable quarters differs primarily as a result of the additional common shares issued during the second quarter 2022 affecting the weighted-average common shares used to compute net loss per share.

Conference Call

Evelo will host a conference call and webcast at 7:30 a.m. ET today to review second quarter 2022 highlights. To access the live conference call, please dial (800) 715-9871 (US & Canada) or +44 800 260 6466 (UK) and refer to conference ID 1143271. A live webcast can be accessed under "News & Events" in the investors section of Evelo's website, https://ir.evelobio.com/news-events. The archived webcast will be available on Evelo's website for approximately 90 days following the event.

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.

The Company is developing EDP1815, currently in late-stage development for psoriasis and atopic dermatitis, and EDP2939, about to enter the clinic to treat inflammatory diseases. Evelo is also 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 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, 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 Quarterly Report on Form 10-Q for the period ended June 30, 2022, 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.

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

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 21,221	$ 20,655	$ 40,542	$ 42,163
General and administrative	8,366	7,001	17,783	12,964
Total operating expenses [1]	29,587	27,656	58,325	55,127
Loss from operations	(29,587)	(27,656)	(58,325)	(55,127)
Other income (expense):				
Interest expense, net	(1,020)	(814)	(2,047)	(1,579)
Loss on extinguishment of debt	—	(3,226)	—	(3,226)
Other miscellaneous income, net	209	151	229	313
Total other expense, net	(811)	(3,889)	(1,818)	(4,492)
Loss before income taxes	(30,398)	(31,545)	(60,143)	(59,619)
Income tax expense	(163)	(53)	(279)	(175)
Net loss	$ (30,561)	$ (31,598)	$ (60,422)	$ (59,794)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.40)	$ (0.59)	$ (0.93)	$ (1.14)
Weighted-average number of common shares outstanding, basic and diluted	75,719,092	53,379,415	64,730,412	52,340,608

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

Research and development	$ 1,701	$ 2,049	$ 3,737	$ 3,872
General and administrative	2,298	1,723	4,537	3,164
Total stock-based compensation expense	$ 3,999	$ 3,772	$ 8,274	$ 7,036

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

(Unaudited)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 92,007	$ 68,441
Prepaid expenses and other current assets	5,003	2,585
Total current assets	97,010	71,026
Property and equipment, net	5,821	6,622
Right of use asset - operating lease	7,915	8,910
Other assets	1,155	1,313
Total assets	$ 111,901	$ 87,871
Liabilities and stockholders' equity		
Current liabilities:		
Debt, current portion	$ 5,928	$ —
Accounts payable	2,248	1,601
Accrued expenses	10,423	13,068
Operating lease liability, current portion	2,105	1,951
Other current liabilities	737	742
Total current liabilities	21,441	17,362
Noncurrent liabilities:		
Debt, net of current portion	40,746	46,557
Operating lease liability, net of current portion	6,566	7,785
Deferred revenue	7,500	7,500
Total liabilities	76,253	79,204
Commitments and contingencies (Note 10)		
Stockholder's equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding as of June 30, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 107,953,319 and 53,576,454 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	108	54
Additional paid-in capital	510,657	423,308
Accumulated deficit	(475,117)	(414,695)
Total stockholders' equity	35,648	8,667
Total liabilities and stockholders' equity	$ 111,901	$ 87,871