Evelo Biosciences Announces Fourth Quarter and Full Year 2022 Financial Results and Business Highlights

CAMBRIDGE, Mass., March 16, 2023 – Evelo Biosciences, Inc. (Nasdaq: EVLO), ("Evelo" or the "Company") a clinical stage biotechnology company developing a novel platform of orally delivered inflammation-resolving medicines acting on the small intestinal axis, SINTAX, today reported financial results and business highlights for the fourth quarter and full year 2022.

"We continued to progress on our SINTAX platform and our clinical pipeline in 2022. We look forward to important clinical milestones in 2023. On mechanism of action, we have shown that the action of SINTAX medicines in the small intestine generates systemically circulating regulatory T cells. These T cells have the potential to induce durable resolution of inflammation throughout the body, as observed in Part B of the EDP1815 Phase 2 study in psoriasis announced in 2022," said Simba Gill, Ph.D., Chief Executive Officer. "We also developed a faster release capsule in 2022 which we expect to improve exposure of drug substance to the target of the upper regions of the small intestine. Our first clinical testing of the faster release capsule is in a placebo controlled fourth cohort of our ongoing atopic dermatitis Phase 2 trial of EDP1815, for which we anticipate reporting results in the second quarter of this year."

Dr. Gill continued, "Additionally, we have progressed our first oral extracellular vesicle (EV) clinical program. We announced in February 2023 that our product candidate, EDP2939, also formulated with the faster release capsule, is now in the clinic. Following a Phase 1 safety review in the first cohort of our healthy human volunteers, we have started dosing in a Phase 2 study in moderate plaque psoriasis patients. The Phase 2 clinical readout is expected in the second half of 2023."

2022 Highlights

- In February 2022, the Company reported data from Part B of EDP1815 Phase 2 trial in psoriasis, demonstrating durable and deepening responses in the post-treatment period.
    - 18/30 patients maintained a PASI-50 or greater response
    - 9/20 patients experienced a deepening of response from PASI-50 to at least PASI-75
- In May 2022, the Company raised $79.2 million through a Registered Direct Offering of common stock, led by Flagship Pioneering with participation from key existing and new investors.
- In December 2022, Evelo refinanced its existing $45 million debt by executing a loan and security agreement with Horizon Technology Finance, which provides for three years of interest-only payments, followed by a two-year amortization period.
- Evelo received feedback from the U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") and Medicines and Healthcare products Regulatory Agency ("MHRA") regarding a proposed Phase 3 study of EDP1815 in psoriasis, advancement into which is funding dependent, including the following:
    - Agreement on primary endpoint of PGA 0/1 with a 2-point improvement
    - No need for active comparator in Europe, with placebo control acceptable in the mild-to-moderate population
    - Alignment on Chemistry, Manufacturing and Controls plan for release and stability testing panels
- Evelo published a peer-reviewed article in Frontiers in Immunology explaining the scientific basis of the Small Intestinal Axis ("SINTAX").

Upcoming Milestones

EDP1815 – Atopic Dermatitis

- Data from a fourth patient cohort of the Phase 2 study in atopic dermatitis evaluating the faster release capsule is anticipated in 2Q 2023.

- Cohorts one, two and three did not meet the primary endpoint of EASI-50 improvement as compared to placebo, due to an unusually high placebo response. No conclusions regarding the cause of the high placebo response have been identified.

EDP2939 – Psoriasis

- A safety and tolerability review was conducted in a first cohort of healthy volunteers in the Phase 1 portion of the trial, with no safety or tolerability concerns identified and resulting in approval to start the Phase 2 part of the trial.
- In February 2023, Evelo began dosing psoriasis patients in the Phase 2 portion of the trial, with data expected 2H 2023.
- Safety and tolerability assessment of multiple ascending dose cohorts continues, as the Company anticipates conducting additional dose-ranging studies following acceptable safety and tolerability data.

Fourth Quarter and Full Year 2022 Financial Results (Unaudited)

- **Cash Position:** As of December 31, 2022, cash and cash equivalents were $47.9 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 $16.1 million and $78.6 million for the three and twelve-month periods ended December 31, 2022, compared to $18.9 million and $83.6 million for the three and twelve-month periods ended December 31, 2021, respectively.
- **General and Administrative Expenses:** G&A expenses were $5.0 million and $29.9 million for the three and twelve-month periods ended December 31, 2022, compared to $8.7 million and $31.8 million for the three and twelve-month periods ended December 31, 2021, respectively.
- **Net Loss:** Net loss was $23.5 million and $114.5 million for the three and twelve-month periods ended December 31, 2022, compared to $28.7 million and $122.2 million for the three and twelve-month periods ended December 31, 2021, 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 2022 highlights. To listen to the conference call by phone, participants must pre-register here. 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 30 days following the event.

About Evelo Biosciences

Evelo Biosciences is a clinical stage biotechnology company developing a novel platform of orally delivered anti-inflammatory medicines acting on the small intestinal axis, SINTAX, with systemic therapeutic effects. The small intestine plays a central role in governing inflammation throughout the body. The Company's product candidates are pharmaceutical preparations of single strains of microbes or their extracellular vesicles (EVs). Evelo initially is developing EDP1815 in psoriasis and atopic dermatitis and EDP2939 in psoriasis. 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. 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 expected timing and advancement of, and data results from, trials and clinical studies involving our product candidates.

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 projected cash runway; our need for additional funding; our ability to meet our debt obligations (including restrictive and operational covenants and terms of refinanced debt); our ability to cure or satisfactorily resolve any default arising from our debt agreements; 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 operate with a reduced workforce, to manage potential growth and to retain key personnel, particularly following a significant downsizing; 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 impact of the COVID-19 pandemic on our operations, including our preclinical studies and clinical trials, and the continuity of our business; 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, 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 16,084	$ 18,881	$ 78,554	$ 83,643
General and administrative	5,003	8,678	29,912	31,753
Total operating expenses[(1)]	21,087	27,559	108,466	115,396
Loss from operations	(21,087)	(27,559)	(108,466)	(115,396)
Other income (expense):				
Interest expense, net	(1,837)	(1,010)	(4,672)	(3,612)
Loss on extinguishment of debt	(520)	—	(520)	(3,226)
Other miscellaneous income, net	447	14	61	486
Total other expenses, net	(1,910)	(996)	(5,131)	(6,352)
Loss before income taxes	(22,997)	(28,555)	(113,597)	(121,748)
Income tax expense	(544)	(97)	(930)	(428)
Net loss	$ (23,541)	$ (28,652)	$ (114,527)	$ (122,176)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.21)	$ (0.54)	$ (1.31)	$ (2.31)
Weighted average number of common shares outstanding, basic and diluted	109,839,320	53,515,636	87,168,683	52,910,982

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
General and administrative	$ 1,712	$ 2,290	$ 8,018	$ 7,842
Research and development	1,709	2,079	7,140	8,004
Total stock-based compensation expense	$ 3,421	$ 4,369	$ 15,158	$ 15,846

Evelo Biosciences, Inc.
Consolidated Balance Sheets (Unaudited)
(In thousands, except share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 47,940	$ 68,441
Prepaid expenses and other current assets	3,633	2,585
Total current assets	51,573	71,026
Property and equipment, net	4,842	6,622
Right of use asset - operating lease	6,868	8,910
Other assets	1,158	1,313
Total assets	$ 64,441	$ 87,871
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 1,764	$ 1,601
Accrued expenses	7,945	13,068
Operating lease liability, current portion	2,259	1,951
Other current liabilities	427	742
Total current liabilities	12,395	17,362
Noncurrent liabilities:		
Debt, net of current portion	43,614	46,557
Operating lease liability, net of current portion	5,265	7,785
Deferred revenue	7,500	7,500
Other noncurrent liabilities	659	—
Total liabilities	69,433	79,204
Commitments and contingencies (Note 10)		
Stockholder's (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 110,852,741 and 53,576,454 shares issued and outstanding as of December 31, 2022 and 2021, respectively	111	54
Additional paid-in capital	524,119	423,308
Accumulated deficit	(529,222)	(414,695)
Total stockholders' (deficit) equity	(4,992)	8,667
Total liabilities and stockholders' (deficit) equity	$ 64,441	$ 87,871