Evelo Biosciences Announces Second Quarter Financial Results and Recent Business Highlights

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– EDP2939 Phase 2 trial in moderate psoriasis fully enrolled with topline data expected early Q4 2023
– Completed $25.5 Million Private Placement
– Restructured and reduced secured debt with Horizon Technology Finance Corporation

CAMBRIDGE, Mass., Aug. 14, 2023 (GLOBE NEWSWIRE) -- 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 announced its second quarter 2023 financial results and recent business highlights.

Simba Gill, Ph.D., Evelo's Chief Executive Officer, said, "We are on track for a top line read-out from our ongoing Phase 2 study in moderate psoriasis with EDP2939, our first medicine based on microbial extracellular vesicles, early in the fourth quarter. EDP2939 is a next generation product candidate that builds on previously reported positive Phase 2 clinical data in psoriasis with our first-generation product, EDP1815. EDP2939 has the potential, if approved, to be effective, safe and well tolerated, as well as affordably priced. We believe this target product profile is well positioned for the vast majority of the millions of patients who suffer from moderate and milder forms of inflammatory diseases and who are not well served by other medicines, including antibodies and the newer immunomodulatory small molecules."

Dr. Gill continued, "With our recent financing combined with the restructuring and reduction of our debt, we now have the financial resources to take us past the Phase 2 clinical readout of EDP2939 and into the first quarter of 2024."

Recent Business Highlights and Upcoming Milestone

- The ongoing Phase 2 study with EDP2939 in moderate psoriasis is fully enrolled and on track for top line data readout in early Q4 2023.
- The Company completed a private placement in July 2023, resulting in gross proceeds of approximately $25.5 million. At the same time, the Company restructured its debt agreement with Horizon Technology Finance Corporation, paying down $5.0 million of its existing debt, and converting a further $5.0 million from debt to equity.
- The Company effected a 1-for-20 reverse stock split of its common stock effective with trading commencing on a split-adjusted basis on June 30, 2023.
- In July 2023, the Company announced it had entered into an agreement with its landlord to terminate the lease on its office and laboratory space, previously scheduled to terminate on September 30, 2025, effective as of September 15, 2023.

Second Quarter 2023 Financial Results (Unaudited)

- **Cash Position:** As of June 30, 2023, cash and cash equivalents were $7.6 million, as compared to cash and cash equivalents of $47.9 million as of December 31, 2022.
- **Research and Development (R&D) Expenses:** R&D expenses were $13.0 million for the three months ended June 30, 2023, compared to $21.2 million for the three months ended June 30, 2022. R&D expenses were $30.9 million for the six months ended June 30, 2023, compared to $40.5 million for the six months ended June 30, 2022.
- **General and Administrative (G&A) Expenses:** G&A expenses were $4.9 million for the three months ended June 30, 2023, compared to $8.4 million for the three months ended June 30, 2022. G&A expenses were $12.0 million for the six months ended June 30, 2023, compared to $17.8 million for the six months ended June 30, 2022.
- **Net Loss:** Net loss was $21.1 million for the three months ended June 30, 2023, compared to $30.6 million for the three months ended June 30, 2022. Net loss was $46.4 million for the six months ended June 30, 2023, compared to $60.4 million for the six months ended June 30, 2022.

About the EDP2939 Trial

EDP2939-101 is a multi-center randomized, placebo-controlled, Phase 1/2 trial evaluating the safety, tolerability and clinical efficacy of EDP2939. Part A (Phase 1) of the trial is designed to determine safety and tolerability in human volunteers at multiple ascending doses. The primary endpoints of the Phase 1 are safety endpoints: AEs, SAEs, vital signs, safety laboratory tests, and ECGs.

Part B (Phase 2) is designed to determine the efficacy of EDP2939 in patients with moderate plaque psoriasis at the proposed therapeutic dose. The primary endpoint of the Phase 2 is the proportion of patients who achieve an outcome of a 50% improvement from baseline in Psoriasis Area and Severity Index (PASI) score (a PASI-50 response) after 16 weeks of daily oral administration of EDP2939 or placebo. Secondary endpoints include several physician- and patient-reported psoriasis outcomes, as well as further safety evaluation. The trial will comprise approximately 110 patients randomized 1:1 to receive a single capsule of either EDP2939 or a matching placebo.

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'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. Evelo was founded by Flagship Pioneering.

For more information, please visit www.evelobio.com.

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 regarding the development of EDP2939, the timing of and plans for clinical trials, the timing and results of clinical trial readouts, the potential benefits of the private placement and the restructuring of our debt agreement; the impact of the reverse stock split; the promise or potential of our product candidates and our anticipated financial performance, financial position and cash runway.

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 Evelo's 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 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 and conduct our clinical trials; costs and resources of operating as a public company; and unfavorable global economic or political conditions. These and other important factors discussed under the caption "Risk Factors" in Evelo's Quarterly Report on Form 10-Q filed with the SEC for the period ended June 30, 2023 and our other filings 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 Evelo may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change.

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 7,622	$ 47,940
Prepaid expenses and other current assets	3,641	3,633
Total current assets	11,263	51,573
Property and equipment, net	2,369	4,842
Right of use asset - operating lease	5,765	6,868
Other assets	1,422	1,158
Total assets	$ 20,819	$ 64,441
Liabilities and stockholders' deficit		
Current liabilities:		
Debt, current portion	$ 43,915	$ —
Accounts payable	$ 3,765	$ 1,764
Accrued expenses	5,151	7,945
Operating lease liability, current portion	2,690	2,259
Other current liabilities	20	427
Total current liabilities	55,541	12,395
Noncurrent liabilities:		
Debt, net of current portion	—	43,614
Operating lease liability, net of current portion	3,876	5,265
Deferred revenue	7,500	7,500
Other noncurrent liabilities	28	659
Total liabilities	66,945	69,433
Stockholder's deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	—	—

Common stock, $0.001 par value; 200,000,000 shares authorized; 5,599,837 and 5,542,637 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	6	6
Additional paid-in capital	529,534	524,224
Accumulated deficit	(575,666)	(529,222)
Total stockholders' deficit	(46,126)	(4,992)
Total liabilities and stockholders' deficit	$ 20,819	$ 64,441

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

	Three Months Ended June 30,		Six months ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 13,043	$ 21,221	$ 30,900	$ 40,542
General and administrative	4,915	8,366	11,958	17,783
Impairment of property and equipment	1,616	—	1,616	—
Total operating expenses	19,574	29,587	44,474	58,325
Loss from operations	(19,574)	(29,587)	(44,474)	(58,325)
Other income (expense):				
Interest expense, net	(1,369)	(1,020)	(2,480)	(2,047)
Change in fair value of warrants	4	—	631	—
Other miscellaneous income, net	69	209	257	229
Total other expenses, net	(1,296)	(811)	(1,592)	(1,818)
Loss before income taxes	(20,870)	(30,398)	(46,066)	(60,143)
Income tax expense	(233)	(163)	(378)	(279)
Net loss	$ (21,103)	$ (30,561)	$ (46,444)	$ (60,422)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.78)	$ (8.07)	$ (8.35)	$ (18.67)
Weighted average number of common shares outstanding, basic and diluted	5,578,767	3,785,954	5,562,121	3,236,520

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

	Three Months Ended June 30,		Six months ended June 30,	
	2023	**2022**	**2023**	**2022**
Research and development	$ 1,471	$ 1,701	$ 2,992	$ 3,737
General and administrative	894	2,298	2,282	4,537
Total stock-based compensation expense	$ 2,365	$ 3,999	$ 5,274	$ 8,274