Evelo Biosciences Reports Fourth Quarter and Full Year 2018 Financial Results and Business Highlights

February 14, 2019

-- First Patient Dosed in University of Chicago Phase 2a Trial of EDP1503 in Metastatic Melanoma --
-- Preclinical Studies Have Shown Non-replicating Monoclonal Microbials Maintain Activity: EDP1867 in Development --
-- Initial Clinical Data for EDP1066 in Atopic Dermatitis and Psoriasis Expected in 2Q 2019 --
-- Initial Clinical Data for EDP1815 in Atopic Dermatitis and Psoriasis Expected in 2H 2019 --
-- Management to Host Conference Call at 8:30 a.m. ET --

CAMBRIDGE, Mass., Feb. 14, 2019 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq: EVLO) ("Evelo"), a clinical stage biotechnology company developing monoclonal microbials, a potential new modality of oral biologic medicines, today reported financial results and provided a business update for the fourth quarter and full year 2018.

"Our platform opens up the potential for effective, orally delivered, safe and cost-effective medicines for improved treatments of inflammatory diseases and cancers. In 2018, we made significant progress and advanced our first three product candidates into clinical trials across multiple inflammatory diseases and cancers," said Simba Gill, Ph.D., president and chief executive officer of Evelo. "In 2019, we expect to advance our oncology clinical trials and announce clinical data from our ongoing inflammatory disease clinical trials which may signal the potential for monoclonal microbials as a broadly applicable new modality of medicines."

2018 and Recent Business Highlights:

Inflammation

- April 2018 - Evelo initiated a placebo-controlled Phase 1b clinical trial of EDP1066 in healthy volunteers and patients with atopic dermatitis or psoriasis. Following completion of each of the three dose-ascending healthy volunteer cohorts, data was reviewed by the trial's safety review committee and the trial proceeded as planned into cohorts of patients with atopic dermatitis or psoriasis
- November 2018 - Evelo initiated a placebo-controlled Phase 1b clinical trial of EDP1815 in healthy volunteers and patients with atopic dermatitis or psoriasis

Oncology

- November 2018 - Entered into clinical collaboration with Merck to evaluate EDP1503 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in multiple cancer indications
- December 2018 - Evelo initiated an open-label Phase 1/2 clinical trial of EDP1503 in combination with KEYTRUDA in microsatellite stable colorectal cancer, triple-negative breast cancer, and patients with other tumor types that have relapsed on prior PD-1/L1 inhibitor treatment
- January 2019 - The University of Chicago initiated an open-label Phase 2a clinical trial of EDP1503 in combination with KEYTRUDA in naïve melanoma patients and melanoma patients that have relapsed on prior PD-1/L1 inhibitor treatment

Non-Replicating Monoclonal Microbials

- Preclinical studies have shown that non-replicating monoclonal microbials, which have been treated to prevent growth and division, maintain activity, opening up the potential to develop non-replicating monoclonal microbial clinical candidates
- Monoclonal microbial activity is likely driven by recognition of structural motifs by immune cells in the small intestine and is not dependent on engraftment or colonization
- Nominated EDP1867 as a preclinical monoclonal microbial candidate for inflammatory diseases. EDP1867 is the first monoclonal microbial specifically developed as a non-replicating product candidate in Evelo's pipeline

Anticipated 2019 Clinical Milestones

- Initial clinical data from the ongoing Phase 1b clinical trial of EDP1066 in healthy volunteers and patients with psoriasis or atopic dermatitis in the second quarter of 2019
- Initiation of an immuno-pharmacology clinical study in healthy volunteers with EDP1066 in 1H 2019, designed to explore additional doses and formulations ahead of potential later stage trials
- Initial clinical data from the ongoing Phase 1b clinical trial of EDP1815 in healthy volunteers and patients with psoriasis or atopic dermatitis in the second half of 2019
- Initiation of clinical trials with EDP1066 and EDP1815 in additional inflammatory disease indications in the second half of 2019

Fourth Quarter and Full Year 2018 Financial Results

- **Cash Position:** As of December 31, 2018, cash, cash equivalents and investments were $147.9 million, as compared to cash and cash equivalents of $38.2 million as of December 31, 2017. This increase was due to net proceeds of $81.3

million from the issuance of Series C convertible preferred stock, net proceeds of $75.8 million from Evelo's initial public offering and $5.0 million of additional drawings from Evelo's existing debt facility, partially offset by cash used to fund operating activities for the full year 2018. Evelo expects that its cash, cash equivalents and investments will enable it to fund its planned operating expenses and capital expenditure requirements into the second half of 2020.

- **Research and Development Expenses:** R&D expenses were $11.3 million for the three months ended December 31, 2018 and $39.9 million for the full year ended December 31, 2018, compared to $6.1 million for the three months ended December 31, 2017 and $20.0 million for the full year ended December 31, 2017. The increase of $19.9 million for 2018 was due primarily to increases in costs related to Evelo's inflammation and oncology clinical development programs, and gut-body network platform expenses, as well as increased personnel costs.
- **General and Administrative Expenses:** G&A expenses were $4.7 million for the three months ended December 31, 2018 and $18.2 million for the full year ended December 31, 2018, compared to $2.0 million for the three months ended December 31, 2017 and $7.6 million for the full year ended December 31, 2017. The increase of $10.6 million for 2018 was due primarily to increased general and administrative personnel costs, professional and consulting fees, and facility expenses supporting Evelo's growing organization and public company infrastructure.
- **Net Loss Attributable to Common Stockholders:** Net loss attributable to common stockholders was $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, as compared to a net loss attributable to common stockholders of $9.9 million for the three months ended December 31, 2017 and $34.1 million for the full year ended December 31, 2017,or $(2.57) and $(9.10) per basic and diluted share, respectively.

Conference Call

Evelo will host a conference call and webcast today at 8:30a.m. ET. To access the call please dial (866) 795-3242 (domestic) and (409) 937-8909 (international) and provide the passcode 7986199. A live webcast of the call will be available on the Investors sections of the Evelo website at www.evelobio.com. The archived webcast will be available approximately two hours after the conference call and will be available for 30 days following the call.

About Evelo Biosciences

Evelo Biosciences, Inc. is a clinical-stage biotechnology company developing monoclonal microbials, a potential new modality of oral biologic medicines. Evelo's product candidates are single strains of microbes, selected for defined pharmacological properties. They are developed to activate multiple naturally evolved biological pathways by engaging immune cells that link the small intestine to the rest of the body. Evelo believes that monoclonal microbials have the potential to be broadly applicable across many immune-mediated diseases including inflammation, cancer and autoimmune diseases.

Evelo currently has three product candidates, EDP1066 and EDP1815 for the treatment of inflammatory diseases and EDP1503 for the treatment of cancer, for which ten clinical readouts are expected during 2019 and 2020. Evelo is also advancing additional candidates through preclinical development in other disease areas.

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 our objectives and anticipated clinical milestones for 2019, the promise and potential impact of any of our monoclonal microbials or preclinical or clinical trial data, the timing of and plans to initiate clinical studies, the timing and results of any clinical studies of EDP1503, EDP1066 and EDP1815 and the potential to develop non-replicating monoclonal microbial clinical 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 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, 2018 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
Stefan Riley
617-577-0300
stefan@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,	
	2018	**2017**	**2018**	**2017**
Operating Expenses(1):				
Research and development	$ 11,343	$ 6,076	$ 39,885	$ 19,957
General and administrative	4,650	1,991	18,218	7,574
Total operating expenses	15,993	8,067	58,103	27,531
Loss from operations	(15,993)	(8,067)	(58,103)	(27,531)
Other income (expense), net	550	(76)	1,157	(516)
Net loss	$ (15,443)	$ (8,143)	$ (56,946)	$ (28,047)
Preferred stock dividends	—	(1,730)	(3,937)	(6,085)
Net loss attributable to common stockholders	$ (15,443)	$ (9,873)	$ (60,883)	$ (34,132)
Net loss per share - basic and diluted	$ (0.49)	$ (2.57)	$ (2.78)	$ (9.10)
Weighted-average common shares used in computing net loss per share - basic and diluted	31,778,021	3,840,439	21,871,029	3,750,790

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

Research and development	$ 741	$ 410	$ 2,508	$ 849
General and administrative	824	226	3,551	693

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

	December 31, 2018	**December 31, 2017**
Assets:		
Cash, cash equivalents and investments	$ 147,919	$ 38,246
Property and equipment, net	6,925	3,496
Other assets	5,023	2,046
Total assets	$ 159,867	$ 43,788
Liabilities, convertible preferred stock and stockholders' equity (deficit):		
Accounts payable and current liabilities	$ 9,235	$ 3,839
Long-term debt	12,305	9,966
Other liabilities	1,378	1,004
Total liabilities	22,918	14,809
Convertible preferred stock	—	83,702
Total stockholders' equity (deficit)	136,949	(54,723)
Total liabilities, preferred stock and stockholders' equity (deficit)	$ 159,867	$ 43,788

Source: Evelo Biosciences, Inc.