Evelo Biosciences Reports Second Quarter 2018 Financial Results and Recent Business Highlights

August 2, 2018

-- Advancing Multiple Product Candidates into Clinical Trials with Dosing of First Patient in Phase 1 Trial of EDP1066 in Psoriasis and Atopic Dermatitis and FDA Acceptance of IND for Phase 2a Investigator-Sponsored Trial of EDP1503 in Metastatic Melanoma --
-- Entered into Research Collaboration with Harvard University to Study Gut-Body Network --

CAMBRIDGE, Mass., Aug. 02, 2018 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO) (Evelo), a clinical stage biotechnology company developing monoclonal microbials designed to act on the gut-body network for the treatment of a wide range of diseases, today reported financial results and provided a business update for the second quarter ended June 30, 2018.

"Our recent accomplishments represent important progress across our business, as we entered the clinic with our first monoclonal microbial, EDP1066, and continued to advance our broad portfolio of preclinical product candidates in a range of inflammatory and oncology indications," said Simba Gill, Ph.D., President and Chief Executive Officer of Evelo. "Looking to the second half of 2018, we are focused on advancing EDP1815 and EDP1503 into their first clinical trials in inflammatory disease and oncology, respectively, as we seek to advance our diversified portfolio of monoclonal microbials toward ten potential clinical readouts between 2019 and 2020 across different diseases and underlying biologies. We are also committed to further understanding of the gut-body network more broadly, as highlighted by our recently-signed research collaboration with world-leaders at Harvard University, which will enable us to further explore the gut's role in modulating immune activity throughout the body."

Second Quarter and Recent Business Highlights:

Pipeline:

- In May 2018, the U.S. Food and Drug Administration accepted an Investigational New Drug application to begin a 70-patient open-label Phase 2 clinical trial of EDP1503, a monoclonal microbial for the treatment of cancer. The University of Chicago will conduct this investigator-sponsored open-label clinical trial, which is designed to evaluate the safety, tolerability, and efficacy of EDP1503 in combination with a checkpoint inhibitor in patients with metastatic melanoma.
- In April 2018, Evelo dosed the first subject in its 96-subject Phase 1 clinical trial of EDP1066, a monoclonal microbial for the treatment of inflammatory diseases. This clinical trial is designed to evaluate the safety and tolerability of a range of daily doses of EDP1066 in healthy volunteers and in patients with psoriasis and atopic dermatitis. Additional exploratory endpoints include the effect of EDP1066 on validated clinical measures of disease and on an integrated set of biomarkers.

Harvard University Research Collaboration:

- In June 2018, Evelo entered into a research collaboration with scientists at Harvard University to study the gut-body network. Evelo will work with three of the world's leading experts in immunology and microbiology at Harvard Medical School: Diane Mathis, Ph.D., the Morton Grove-Rasmussen Professor of Microbiology and Immunobiology, Christophe Benoist, M.D., Ph.D., the Morton Grove-Rasmussen Professor of Immunohematology, and Dennis Kasper, M.D., the William Ellery Channing Professor of Medicine and Professor of Microbiology and Immunobiology. The collaboration aims to further elucidate the mechanisms by which microbes acting on cells in the gut have the potential to treat disease elsewhere in the body. Under the multi-year agreement, Evelo has an exclusive option to license from Harvard intellectual property rights that may arise from this research collaboration.

Corporate:

- In June 2018, Evelo was added to the Russell 3000®, Russell 2000® and Russell Microcap® Indexes as part of the Russell Investments' annual reconstitution.
- In May 2018, Evelo completed its initial public offering of common stock at $16.00 per share, raising $75.8 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses.

Upcoming Anticipated Milestones:

- Initiation of the University of Chicago's investigator-sponsored, open-label Phase 2 clinical trial of EDP1503 in combination with a PD-1 inhibitor in patients with metastatic melanoma expected in the second half of 2018.
- Initiation of a Phase 1 clinical trial of EDP1815, an anti-inflammatory monoclonal microbial product candidate, in patients with psoriasis and atopic dermatitis in the fourth quarter of 2018.
- Initiation of a Phase 2 clinical trial of EDP1503 in combination with a checkpoint inhibitor in patients with multiple cancer types in the first half of 2019.
- Initial clinical data from ongoing Phase 1 clinical trial of EDP1066 in patients with psoriasis and atopic dermatitis in the first half of 2019.

Second Quarter 2018 Financial Results:

- **Cash Position:** As of June 30, 2018, cash and cash equivalents were $178.9 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 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 first half of 2018. Evelo expects that its cash and cash equivalents 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 $10.2 million for the three months ended June 30, 2018, compared to $4.7 million for the three months ended June 30, 2017. The increase of $5.5 million was due primarily to increases in costs related to Evelo's inflammation and gut-body network platform expenses as well as increased personnel costs.
- **General and Administrative Expenses:** G&A expenses were $5.1 million for the three months ended June 30, 2018, compared to $1.5 million for the three months ended June 30, 2017. The increase of $3.6 million 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 $16.7 million for the three months ended June 30, 2018, or $0.85 per basic and diluted share, as compared to a net loss attributable to common stockholders of $7.8 million for the three months ended June 30, 2017, or $2.09 per basic and diluted share.

About Evelo Biosciences

Evelo Biosciences, Inc. is a clinical-stage biotechnology company developing a new modality of medicine, monoclonal microbials, which are designed to act on the gut-body network. Evelo's product candidates are orally-delivered, single strains of microbes, selected for their defined pharmacological properties. They are intended to modulate systemic immunology and biology by acting on multiple naturally evolved biological pathways through the gut-body network. Evelo believes that monoclonal microbials have the potential to be broadly applicable across many diseases including immunoinflammatory, cancer, autoimmune, metabolic, neurological and neuroinflammatory 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 our development plans, the promise and potential impact of any of our monoclonal microbials or preclinical or clinical trial data, timing of and plans to initiate clinical studies of EDP1503, EDP1066 and EDP1815, the timing and results of any clinical studies 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: 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; a significant portion of our total outstanding shares are eligible to be sold into the market in the near future; 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 March 31, 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, 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.

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

	June 30, 2018	December 31, 2017
Assets:		
Cash and cash equivalents	$ 178,902	$ 38,246
Property and equipment, net	5,912	3,496

Other assets	3,474	2,046
Total assets	$ 188,288	$ 43,788
Liabilities, preferred stock and stockholders' equity:		
Accounts payable and current liabilities	$ 7,517	$ 3,839
Long-term debt	14,753	9,966
Other noncurrent liabilities	970	1,004
Total liabilities	23,240	14,809
Convertible preferred stock	-	83,702
Common stock and additional paid-in capital	247,128	1,688
Accumulated deficit	(82,080)	(56,411)
Total stockholders' equity	165,048	(54,723)
Total liabilities, preferred stock and stockholders' equity	$ 188,288	$ 43,788

EVELO BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2018	**2017**	**2018**	**2017**
Operating Expenses(1)				
Research and Development	$ 10,172	$ 4,690	$ 17,315	$ 8,536
General and Administrative	5,056	1,528	8,338	2,890
Total operating expenses	15,228	6,218	25,653	11,426
Loss from operations	(15,228)	(6,218)	(25,653)	(11,426)
Other expenses, net	82	(143)	7	(305)
Net Loss	$ (15,146)	$ (6,361)	$ (25,646)	$ (11,731)
Preferred stock dividends	(1,520)	(1,422)	(3,937)	(2,647)
Loss attributable to shareholders	(16,666)	(7,783)	(29,583)	(14,378)
Net loss per share	$ (0.85)	$ (2.09)	$ (2.50)	$ (3.89)
Shares used in computing basic and diluted net loss per share	19,626,985	3,730,882	11,818,302	3,691,951

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

Research and development	$ 761	$ 123	$ 1,003	$ 215
General and administrative	1,486	145	1,869	256

Contact
Evelo Biosciences
Stefan Riley
617-704-2333
stefan@evelobio.com

Primary Logo

Source: Evelo Biosciences, Inc.