May 8, 2019

Synthetic Biologics Reports First Quarter 2019 Operational Highlights and Financial Results

-- Enrollment is Ongoing in Phase 2b Investigator-Sponsored Clinical Study of SYN-010, for the Treatment of IBS-C; Topline Data Readout Anticipated in 2H 2019 --

-- Conference Call Today, May 8, 2019, at 4:30 p.m. (ET) --

ROCKVILLE, Md., May 8, 2019 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE American: SYN), a late-stage clinical company developing therapeutics that preserve the microbiome to protect and restore the health of patients, today provided an operational update and reported financial results for the three months ended March 31, 2019.

"During the first quarter, we remained keenly focused on executing our strategy to advance our portfolio of GI and microbiome-focused clinical programs," stated Steven A. Shallcross, Chief Executive & Financial Officer of Synthetic Biologics. "Enrollment into our investigator-sponsored Phase 2b clinical trial of SYN-010 in breath methane positive irritable bowel syndrome with constipation (IBS-C) patients is ongoing and we believe we are on track to announce a topline data-readout during the second half of 2019. Importantly, we believe dose-response data derived from this clinical study will further fortify the already well-established clinical data set for SYN-010 and enable regulatory discussions to potentially simplify future registration studies."

Mr. Shallcross continued, "During the first quarter, we continued to pursue our strategy for a potential secondary clinical indication for SYN-004 (ribaxamase) in a specialized patient population which may allow for more narrow and cost-efficient clinical development opportunities. Discussions with key opinion leaders are progressing to determine an optimal development pathway for SYN-004 to reduce the incidence and/or severity of adverse outcomes in allogeneic hematopoietic cell transplant (HCT) recipients. These adverse outcomes include acute graft-versus-host-disease (aGVHD) and colonization of opportunistic pathogens such as vancomycin resistant Enterococci (VRE), each of which are associated with poor outcomes and increased mortality in allogeneic HCT recipients. We believe SYN-004 may provide a distinct benefit to patient outcomes in allogeneic HCT recipients, where gut microbiome damage resulting from prolonged beta-lactam antibiotic use has been linked to the development of aGVHD and colonization by VRE. We look forward to sharing important updates and progress for this potential indication."

Clinical Development and Operational Update

- Commenced enrollment in Phase 2b investigator-sponsored clinical study of SYN-010, for the treatment of IBS-C
  - The Phase 2b clinical study is being conducted by the Medically Associated Science and Technology (MAST) Program at Cedars-Sinai Medical Center and is a 12-week, placebo-controlled, double-blind, randomized clinical trial evaluating two dose strengths of oral SYN-010 (21 mg and 42 mg) in

approximately 150 patients diagnosed with IBS-C,
    - The primary objective for the study will be to determine the efficacy of SYN-010, measured as an improvement from baseline in the weekly average number of complete spontaneous bowel movements (CSBMs) during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses relative to placebo,
    - Secondary efficacy endpoints for both dose strengths of SYN-010 will measure changes from baseline in abdominal pain, bloating, stool frequency as well as the use of rescue medication relative to placebo,
    - A topline data readout is anticipated in 2H 2019,
    - Cedars-Sinai Medical Center and Synthetic Biologics are co-funding the study. The patent rights covering the use of SYN-010 are owned by Cedars-Sinai Medical Center and are exclusively licensed by Cedars-Sinai Medical Center to Synthetic Biologics;
- Continued to evaluate a potential secondary indication for SYN-004 (ribaxamase) to reduce the incidence and/or severity of aGVHD and other adverse outcomes in allogeneic HCT recipients
    - Identification of key investigators and establishment of clinical protocols are ongoing,
    - Anticipate initiation of a Phase 1/2 clinical study in allogeneic HCT patients in 2H 2019, contingent upon the identification of a research partner and subsequent Institutional Review Board (IRB) approval;
- Evaluated regulatory strategies to advance SYN-020 (intestinal alkaline phosphatase) to and through clinical trials targeting areas of significant unmet medical need, including enterocolitis associated with radiation therapy for cancer
    - Submitted request for pre-IND meeting with FDA in Q1 2019,
    - Anticipate filing a US IND application in Q4 2019,
    - Plan to commence a Phase 1 clinical trial in Q1 2020;
- Continued to exercise prudent cash management and financial stewardship
    - Further reduced cash burn, extending projected cash runway to fund operations through at least the end of Q2 2020;

Quarter Ended March 31, 2019 Financial Results

General and administrative expenses decreased by 30% to $1.1 million for the three months ended March 31, 2019, from $1.6 million for the three months ended March 31, 2018. This decrease is primarily due to decreased stock-based compensation expense related to forfeitures and decreased share price, along with the reduction of investor relations, registration, and legal costs. The charge related to stock-based compensation expense was $65,000 for the three months ended March 31, 2019, compared to $349,000 the three months ended March 31, 2018.

Research and development expenses decreased by 28% to $2.4 million for the three months ended March 31, 2019, from $3.4 million for the three months ended March 31, 2018. This decrease is primarily the result of lower SYN-004 (ribaxamase) indirect program costs for the three months ended March 31, 2019, including salary and related expense reductions resulting from the 2018 restructuring and the fact that no clinical trial activity for SYN-004 (ribaxamase) was ongoing during the quarter, offset by an increase in manufacturing costs for SYN-020. The research and development costs incurred during the quarter were primarily related to the investigator-sponsored Phase 2b clinical study of SYN-010. We anticipate research and development expense to increase in association with the ongoing Phase 2b investigator-sponsored clinical study of SYN-010, a potential Phase 1/2 clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients, and the continued development of SYN-020. There was no charge related to stock-based compensation expense for the three months ended March 31, 2019 resulting from the 2018 restructuring, compared to $326,000 for the three months ended March 31, 2018.

Other income was $44,000 for the three months ended March 31, 2019, compared to other income of $2.7 million for the three months ended March 31, 2018. Other income for the three months ended March 31, 2019 is primarily comprised of interest income while the three months ended March 31, 3018 is comprised of non-cash income of $2.7 million from the change in fair value of warrants. The decrease in the fair value of the warrants was due to the decrease in our stock price.

Cash and cash equivalents as of March 31, 2019 was $24.7 million, a decrease of $4.2 million from December 31, 2018.

Conference Call

Synthetic Biologics will hold a conference call today, Wednesday, May 8, 2019, at 4:30 p.m. (ET). The dial-in information for the call is as follows, U.S. toll free: +1 888-347-5280 or International: +1 412-902-4280. Participants are asked to dial in 15 minutes before the start of the call to register. The call will also be webcast over the Internet at https://www.webcaster4.com/Webcast/Page/1096/30393. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/30393, for 90 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a clinical-stage company developing therapeutics that preserve the microbiome to protect and restore the health of patients. The Company's lead candidates are: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics within the gastrointestinal (GI) tract to prevent microbiome damage, *C. difficile* infection (CDI), overgrowth of pathogenic organisms, the emergence of antimicrobial resistance (AMR) and acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-010, which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). The Company is also advancing SYN-020, an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases, and has completed proof-of-concept studies with monoclonal antibody therapies for the prevention and treatment of pertussis. For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions, and includes statements regarding being on track to announce a topline data-readout during the second half of 2019, dose-response data derived from the investigator-sponsored Phase 2b clinical trial of SYN-010 further fortifying the already well-established clinical data set for SYN-010 and enabling regulatory discussions to potentially simplify future registration studies, a potential secondary clinical indication for SYN-004 (ribaxamase) in a specialized patient population which may allow for more narrow and cost-efficient clinical development opportunities, SYN-004 providing a distinct benefit to patient outcomes in allogeneic HCT recipients, initiation of a Phase 1/2 clinical study in allogeneic HCT patients in 2H 2019, filing of a US IND application in Q4 2019 for SYN-020, commencing a Phase 1 clinical trial for SYN-020 in Q1 2020, and extending Synthetic Biologics' projected cash runway through at least the end of Q2 2020. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from current expectations include, among others, the ability of Synthetic Biologics' product candidates to demonstrate safety and effectiveness, as well as results that are consistent with prior results, Synthetic Biologics' clinical trials continuing enrollment as expected, a failure to receive the necessary regulatory approvals for commercialization of Synthetic Biologics' therapeutics, including approval of proposed trial designs, a failure of Synthetic Biologics' clinical trials, and those conducted by investigators, for SYN-004, SYN-010 and SYN-020 to be commenced or completed on time or to achieve desired results and benefits, a failure to file INDs when anticipated, a failure of Synthetic Biologics' clinical trials to continue enrollment as expected or receive anticipated funding, a failure of Synthetic Biologics to successfully develop, market or sell its products, Synthetic Biologics' inability to maintain its material licensing agreements, or a failure by Synthetic Biologics or its strategic partners to successfully commercialize products, Synthetic Biologics' ability to achieve acceptance of its product candidates in the marketplace and the successful development, marketing or sale of Synthetic Biologics' products by competitors that render Synthetic Biologics' products obsolete or non-competitive, Synthetic Biologics' ability to regain compliance with the continued listing standards of the NYSE American by September 2, 2019, Synthetic Biologics' ability to comply with other continued listing requirements of the NYSE American, the continued maintenance and growth of Synthetic Biologics' patent estate, Synthetic Biologics becoming and remaining profitable, Synthetic Biologics' ability to obtain or maintain the capital or grants necessary to fund its research and development activities, a loss of any of Synthetic Biologics' key scientists or management personnel and other factors described in Synthetic Biologics' Form 10-K for the year ended December 31, 2018 and its other filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. The information in this release is provided only as of the date of this release, and Synthetic Biologics undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

- Financial Tables Follow -

Synthetic Biologics, Inc. and Subsidiaries
(in thousands, except share and per share amounts)

Consolidated Balance Sheets

	March 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 24,694	$ 28,918
Prepaid expenses and other current assets	860	593
Property and equipment, net	545	607

Right of use asset	510	-
Deposits and other assets	23	23
Total Assets	$ 26,632	$ 30,141
Liabilities and Stockholder's Equity		
Total liabilities	$ 3,624	$ 3,686
Series A Convertible Preferred Stock	12,357	12,296
Total stockholder's equity	10,651	14,159
Total Liabilities and Stockholders' Equity	$ 26,632	$ 30,141

Condensed Consolidated Statements of Operations	**For the three months ended March 31,**	
	2019	**2018**
Operating Costs and Expenses		
General and administrative	$ 1,154	$ 1,620
Research and development	2,418	3,370
Total Operating Costs and Expenses	3,572	4,990
Loss from Operations	(3,572)	(4,990)
Other Income		
Change in fair value of warrant liability	-	2,655
Interest income	44	9
Total Other Income	44	2,664
Net Loss	(3,528)	(2,326)
Net Loss Attributable to Non-controlling Interest	(16)	(10)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (3,512)	$ (2,316)
Series A Preferred Stock Dividends	(61)	(59)
Series B Preferred Stock Dividends	(398)	-
Net Loss Attributable to Common Stockholders	(3,971)	(2,375)
Net Loss Per Share - Basic and Dilutive	$ (0.25)	$ (0.65)
Weighted average number of common shares outstanding - Basic and Dilutive	15,656,784	3,673,340

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