November 4, 2019

Synthetic Biologics Reports Third 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 --

-- Conference Call Today, November 4, 2019, at 4:30 p.m. (EST) --

ROCKVILLE, Md., Nov. 4, 2019 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE American: SYN), a diversified clinical-stage company leveraging the microbiome to develop therapeutics designed to prevent and treat gastrointestinal (GI) diseases in areas of high unmet need, today provided an operational update and reported financial results for the three and nine months ended September 30, 2019.

"During the third quarter, we remained sharply focused on the advancement of our portfolio of GI-focused clinical programs which leverage the microbiome to improve the health of patients," stated Steven A. Shallcross, Chief Executive and Financial Officer. "We were pleased to announce our clinical trial collaboration with Washington University School of Medicine in St. Louis ("Washington University") to conduct a Phase 1b/2a clinical trial of SYN-004 (ribaxamase). The announcement of this agreement is an important step in our pursuit of a more cost-effective development strategy for our SYN-004 (ribaxamase) program aimed at improving clinical outcomes of high-risk patients who undergo allogeneic hematopoietic cell transplantation (HCT) and receive long courses of intravenous (IV) beta-lactam antibiotics. Looking ahead, we intend to hold a Type-C meeting with the U.S. Food &

Drug Administration ("FDA") during the fourth quarter to solidify the clinical protocol parameters for this program with the intention of initiating enrollment during the first quarter of 2020."

Mr. Shallcross continued, "Enrollment in our investigator-sponsored Phase 2b clinical study for SYN-010 in breath-methane positive irritable bowel syndrome with constipation (IBS-C) patients remains ongoing. We anticipate a data readout sometime during the first half of 2020 which we believe will further fortify the established clinical data set for SYN-010 and support regulatory discussions to potentially simplify future registration studies. For our SYN-020 intestinal alkaline phosphatase (IAP) program, preclinical activities and toxicology studies remain on track to support an Investigational New Drug Application (IND) application filing during the first quarter of 2020. We look forward to sharing important updates and progress for this and all our GI and microbiome-focused clinical programs."

Clinical Development and Operational Update

- Entered into a Clinical Trial Agreement with Washington University School of Medicine in St. Louis to conduct a Phase 1b/2a clinical trial of SYN-004 (ribaxamase)
    - Enrollment is expected to begin during the first quarter of 2020, contingent upon agreement with the FDA and approval of the clinical study protocol by Washington University's Institutional Review Board (IRB),
    - The proposed study is a Phase 1b/2a single-center, randomized, double-blinded, placebo-controlled clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of oral SYN-004 (ribaxamase) in up to 36 adult allogeneic HCT recipients,
    - Study participants will be enrolled into three sequential cohorts that will be administered a different study-assigned IV beta-lactam antibiotic. Eight participants in each cohort will receive SYN-004 (ribaxamase) and four will receive placebo,
    - Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee, which will make a recommendation on whether to proceed to the next IV beta-lactam antibiotic,
    - The proposed study will also evaluate potential protective effects of SYN-004 (ribaxamase) on the gut microbiome as well as generate preliminary information on potential therapeutic benefits and patient outcomes of SYN-004 (ribaxamase) in allogeneic HCT recipients.

- Enrollment is ongoing in the 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 data readout is anticipated in 1H 2020,
    - 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;

- Evaluated potential clinical development 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
    - Anticipate filing a US IND in Q1 2020;

- Continued to exercise prudent cash management and financial stewardship to further extend our cash runway through at least the fourth quarter of 2020.

Quarter Ended September 30, 2019 Financial Results

General and administrative expenses decreased by approximately 26% to $1.1 million for the three months ended September 30, 2019, from $1.5 million for the three months ended September 30, 2018. This decrease is primarily due to decreased stock-based compensation expense related to forfeitures and decreased option grants, along with the reduction of investor relations and consulting costs. The charge related to stock-based compensation expense was $68,000 for the three months ended September 30, 2019, compared to $186,000 the three months ended September 30, 2018.

Research and development expenses increased by approximately 46% to $4.1 million for the three months ended September 30, 2019 from $2.8 million for the three months ended September 30, 2018. This increase is primarily the result of higher manufacturing and pre-IND-enabling toxicology study costs for SYN-020 and the cost incurred to co-fund the investigator-sponsored Phase 2b clinical study of SYN-010. Research and development expenses also include a charge relating to stock-based compensation expense of $22,000 for the three months ended September 30, 2019, compared to $289,000 for the three months ended September 30, 2018.

Other income was $92,000 for the three months ended September 30, 2019, compared to other income of $631,000 for the three months ended September 30, 2018. Other income for the three months ended September 30, 2019 is primarily comprised of interest income while the three months ended September 30, 2018 is comprised of non-cash income of $626,000 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 September 30, 2019 totaled $18.7 million, a decrease of $10.3 million from December 31, 2018.

Conference Call

Synthetic Biologics will hold a conference call today, Monday, November 4, 2019, at 4:30 p.m. (EST). 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/1096/32094. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/32094, for 90 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a diversified clinical-stage company leveraging the microbiome to develop therapeutics designed to prevent and treat gastrointestinal (GI) diseases in areas of high unmet need. 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. 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 the intent to hold a Type-C meeting with the FDA during the fourth quarter to solidify the clinical protocol parameters for the SYN-004 program, the anticipated filing of an IND for SYN-020 during in the first quarter of 2020; enrollment for the Phase 1b/2a clinical trial of SYN-004 initiating during the first quarter of 2020, contingent upon agreement with the FDA and approval of the clinical study protocol by the Washington University School of Medicine's Institutional Review Board (IRB); the study design of the Phase 1b/2a clinical trial of SYN-004, a data readout for the Phase 2b investigator-sponsored clinical study of SYN-010 for the treatment of IBS-C is anticipated in 1H 2020; the data readout further fortifying the clinical data set for SYN -010 and enabling regulatory discussions to potentially simplify future registration. 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, 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 continue to comply with the 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 and 10-K/A 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

	September 30, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 18,650	$ 28,918
Prepaid expenses and other current assets	1,193	593
Property and equipment, net	425	607
Right of Use Asset	451	-
Deposits and other assets	23	23
Total Assets	$ 20,742	$ 30,141
Liabilities and Stockholder's Deficit		
Total liabilities	$ 6,172	$ 3,686
Series A Convertible Preferred Stock	12,481	12,296
Total Stockholder's Equity	2,089	14,159
Total Liabilities and Stockholders' Deficit	$ 20,742	$ 30,141

Condensed Consolidated Statements of Operations
(In thousands except share and per share amounts)

	For the three months ended September 30, *(Unaudited)*		For the nine months ended September 30, *(Unaudited)*	
	2019	**2018**	**2019**	
Operating Costs and Expenses				

General and administrative	$ 1,098	$ 1,474	$ 3,297	$
Research and development	4,144	2,846	9,156	
Total Operating Costs and Expenses	5,242	4,320	12,453	
Loss from Operations	(5,242)	(4,320)	(12,453)	
Other Income (Expense)				
Change in fair value of warrant liability	-	626	-	
Interest income	92	5	217	
Total Other Income (Expense), net	92	631	217	
Net Loss	(5,150)	(3,689)	(12,236)	
Net Loss Attributable to Non-controlling Interest	(30)	(9)	(73)	
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (5,120)	$ (3,680)	$ (12,164)	$
Series A Preferred Stock Dividend	(63)	(61)	(185)	
Series B Preferred Stock Dividend	(70)	-	(585)	
Net Loss Attributable to Common Stockholders	$ (5,253)	$ (3,741)	$ (12,934)	$
Net Loss Per Share – Basic and Dilutive	$ (0.31)	$ (0.93)	$ (0.79)	$
Weighted average number of common shares outstanding - Basic and Diluted	16,805,257	4,028,304	16,313,326	

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