February 20, 2020

Synthetic Biologics Reports 2019 Year End Operational Highlights and Financial Results

-- Received FDA Guidance Following Type-C Meeting to Conduct a Phase 1b/2a Clinical Trial of SYN-004 (ribaxamase) in Allogeneic HCT Recipients; Enrollment Expected in Q2 2020 --

-- Enrollment is Ongoing in Phase 2b Investigator-Sponsored Clinical Study of SYN-010 for the Treatment of IBS-C

-- Conference Call Today at 4:30 p.m. (ET) --

ROCKVILLE, Md., Feb. 20, 2020 /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 a clinical programs update and reported financial results for the year ended December 31, 2019.

"2019 was a highly eventful period marked by significant progress as we continued to execute our strategy to advance and demonstrate the significant value of our portfolio of GI and microbiome-focused clinical programs," stated Steven A. Shallcross, Chief Executive and Financial Officer. "Following the announcement of our clinical trial collaboration with the Washington University School of Medicine in St. Louis ("Washington University") to advance SYN-004 in allogeneic hematopoietic cell transplant (HCT) patients, we held an extremely

productive Type-C meeting with the U.S. Food and Drug Administration ("FDA") to finalize the clinical program parameters of a Phase 1b/2a clinical trial expected to begin next quarter. Allogeneic HCT recipients who receive broad-spectrum IV beta-lactam antibiotics at onset of fever following conditioning chemotherapy are at high risk for *Clostridioides difficile* infection (CDI), colonization by vancomycin-resistant *Enterococci* (VRE) and acute graft-versus-host-disease (aGVHD). We believe SYN-004's unique mechanism of action designed to degrade IV beta-lactam antibiotics and prevent dysbiosis of the gut microbiome has the potential to significantly improve outcomes for patients who undergo allogeneic HCT, an area of significant unmet need."

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. Preclinical activities and toxicology studies are ongoing and remain on track to support a near-term Investigational New Drug Application (IND) filing for our SYN-020 Intestinal Alkaline Phosphatase (IAP) program. 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

- Received official meeting minutes from FDA following a Type-C meeting held on December 2, 2018 at the Company's request to discuss the development of a Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients. Based on the final meeting minutes,
    - Enrollment is expected to begin during the second quarter of 2020 contingent upon approval of the clinical trial protocol by the Washington University School of Medicine's Institutional Review Board (IRB) and the FDA,
    - The Phase 1b/2a clinical trial will comprise a single center, randomized, double-blind, placebo-controlled clinical trial of oral SYN-004 (ribaxamase) in up to 36 evaluable adult allogeneic HCT recipients,
    - The goal of this clinical trial is to evaluate the safety, tolerability and potential absorption into the systemic circulation (if any) of 150 mg oral SYN-004 (ribaxamase) administered to allogeneic HCT recipients who receive an IV beta-lactam antibiotic to treat fever,
    - Clinical trial participants will be enrolled into three sequential cohorts and 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;

- Enrollment is ongoing in the Phase 2b investigator-sponsored clinical study of SYN-010 for the treatment of IBS-C
    - The Phase 2b clinical trial 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 up to 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;

- Completed Pre-IND meeting with FDA to discuss advancement of SYN-020 (intestinal alkaline phosphatase) into clinical trials targeting areas of significant unmet medical need, including enterocolitis associated with radiation therapy for cancer
    - Anticipate filing a US IND in Q2 2020;

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

Year Ended December 31, 2019 Financial Results

General and administrative expenses decreased to $4.6 million for the year ended December 31, 2019, from $5.7 million for the year ended December 31, 2018. This decrease of 19% is due to decreased stock-based compensation expense related to forfeitures and decreased option grants, along with the reduction of investor relations, consulting, registration, and legal costs. The charge relating to stock-based compensation expense was $0.3 million for the year ended December 31, 2019, compared to $1.0 million for the year ended December 31, 2018.

Research and development expenses decreased to $11.1 million for the year ended December 31, 2019, from $11.8 million for the year ended December 31, 2018. This decrease of 6% is primarily the result of lower SYN-004 (ribaxamase) indirect program costs for the year ended December 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 year ended December 31, 2019, offset by an increase in manufacturing and pre IND-enabling toxicology study costs for SYN-020. Research and development expenses also include a charge relating to non-cash stock-based compensation expense of $75,000 for the year ended December 31, 2019, compared to $1.1 million for the year ended December 31, 2018.

Total other income was $283,000 for the year ended December 31, 2019, compared to other income of $4.2 million for the year ended December 31, 2018. Total other income for the year ended December 31, 2019 is primarily comprised of interest income while total other income for the year ended December 31, 2018 is comprised of non-cash income of $4.1 million from the change in fair value of warrants. The decrease in the fair value of warrants was due to the decrease in our stock price from December 31, 2017 to December 31, 2018.

Cash and cash equivalents on December 31, 2019 were $15.0 million, a decrease of $13.9 million from December 31, 2018.

Conference Call

Synthetic Biologics will hold a conference call today, Thursday, February 20, 2020, 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/1096/32979. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/32979, for 90 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a 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 clinical 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 include statements regarding anticipated initiation of a Phase 1b/2a investigator-sponsored clinical study in allogeneic HCT patients in the second quarter of 2020, the potential of SYN-004's unique mechanism of action designed to degrade IV beta-lactam antibiotics and prevent dysbiosis of the gut microbiome to significantly improve outcomes for patients who undergo allogeneic HCT, an area of significant unmet need, anticipated data readout for the investigator-sponsored Phase 2b clinical study for SYN-010 during the first half of 2020, the data readout further fortifying the established clinical data set for SYN-010 and supporting regulatory discussions to potentially simplify future registration studies, anticipated IND filing for SYN-020 in the first half of 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, a failure to receive the necessary regulatory approvals for commercialization of Synthetic Biologics' therapeutics, a failure of Synthetic Biologics' clinical trials, and those conducted by investigators, for SYN-004 and SYN-010 to be commenced or completed on

time or to achieve desired results and benefits, 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 and other factors described in Synthetic Biologics' most recent Form 10-K 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

	December 31,	
	2019	**2018**
Assets		
Cash and cash equivalents	$ 15,045	$ 28,918
Prepaid expenses and other current assets	1,381	593
Property and equipment, net	367	607
Right of Use Asset	419	-
Deposits and other assets	23	23
Total Assets	$ 17,235	$ 30,141
Liabilities and Stockholder's Equity (Deficit)		
Total liabilities	$ 5,748	$ 3,686
Series A Convertible Preferred Stock	12,544	12,296
Synthetic Biologics, Inc. and Subsidiaries Equity (Deficit)	(1,057)	14,159
Total Liabilities and Stockholders' Equity (Deficit)	$ 17,235	$ 30,141

Condensed Consolidated Statements of Operations

	For the years ended December 31,	
	2019	**2018**
Operating Costs and Expenses		
General and administrative	$ 4,580	$ 5,727
Research and development	11,083	11,844
Total Operating Costs and Expenses	15,663	17,571
Loss from Operations	(15,663)	(17,571)
Other Income		
Change in fair value of warrant liability	-	4,083

Interest income	283	67
Total Other Income	283	4,150
Net Loss	(15,380)	(13,421)
Net Loss Attributable to Non-controlling Interest	(77)	(54)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (15,303)	$ (13,367)
Series A Preferred Stock Dividends	(248)	(243)
Series B Preferred Stock Dividends	(525)	(11,681)
Net Loss Attributable to Common Stockholders	(16,076)	(25,291)
Net Loss Per Share - Basic and Dilutive	$ (0.98)	$ (4.06)
Weighted average number of common shares outstanding - Basic and Dilutive	16,438,201	6,232,442

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