November 10, 2020

Synthetic Biologics Reports 2020 Third Quarter Operational Highlights and Financial Results

-- Received Notice from the FDA that the SYN-004 (ribaxamase) Phase 1b/2a Clinical Program in Adult Allogeneic HCT Recipients May Proceed as Planned; Trial Commencement Anticipated in Q1 2021 --

-- Received Study-May-Proceed Letter from the FDA Supporting a Phase 1 Single Ascending Dose Study of SYN-020 IAP; Phase 1 Study to Support Development of SYN-020 in Multiple Indications

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

ROCKVILLE, Md., Nov. 10, 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 quarter ended September 30, 2020.

"During the third quarter, we remained sharply focused on executing our strategy to advance our portfolio of GI-focused clinical development programs while continuing to respond to the unprecedented global health and economic crisis sparked by the COVID-19 pandemic," said Steven A. Shallcross, Chief Executive and Financial Officer of Synthetic Biologics. "We were

pleased to receive formal written notification from the U.S. Food and Drug Administration ("FDA") notifying the Company that the proposed Phase 1b/2a clinical study of SYN-004 (ribaxamase) in adult allogeneic hematopoietic cell transplant ("HCT") recipients may proceed per our originally submitted clinical program protocol. Initiation of the planned Phase 1b/2a clinical trial to be conducted by the Washington School of Medicine in St. Louis ("Washington University") is anticipated to commence during the first quarter of 2021, pandemic conditions permitting. Following the announcement of our expanded collaboration with Massachusetts General Hospital ("MGH"), we continued to make significant progress on our SYN-020 intestinal alkaline phosphatase (IAP) program, including establishing Phase 1-enabling assays and completion of the manufacturing of drug supply in support of the planned Phase 1 single ascending dose ("SAD") study in healthy volunteers. The Phase 1 SAD Study is intended to support the clinical development of SYN-020 in multiple indications, including an initial indication for the treatment of radiation enteropathy secondary to pelvic cancer therapy."

Mr. Shallcross continued, "During the third quarter, we announced the results of a planned interim futility analysis of the investigator-sponsored Phase 2b clinical study of SYN-010 being conducted by Cedars-Sinai Medical Center ("CSMC"). Although SYN-010 was well-tolerated, analysis of the interim data set concluded it was unlikely to meet its primary objective by the time enrollment was completed. On the basis of these findings, CSMC agreed to discontinue the trial and intends to conduct a comprehensive review of the final data set and publish its findings. While we're disappointed by these results, we're committed to working with our clinical development partners to advance SYN-004 and SYN-020. Both of these programs are unrelated to SYN-010, and therefore, we remain encouraged by the outlook and potential for these programs to address large, underserved markets. We continue to closely monitor the crisis caused by the spread of COVID-19 and look forward to sharing important updates and progress for our GI-focused clinical programs."

Clinical Development and Operational Update

- Received written notification from the FDA informing the Company that the SYN-004 (ribaxamase) Phase 1b/2a clinical program in adult allogeneic hematopoietic cell transplant ("HCT") recipients may proceed per the submitted clinical program protocol (Q3 2020)
    - Initiation of the proposed Phase 1b/2a clinical trial to be conducted by the Washington University School of Medicine in St. Louis in adult allogeneic HCT recipients is anticipated to commence during Q1 2021, pandemic conditions permitting,
    - The Phase 1b/2a clinical trial will comprise a single center, randomized, double-blinded, placebo-controlled clinical trial of oral SYN-004 (ribaxamase) in up to 36 evaluable adult allogeneic HCT recipients,
    - The goal of this study 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 four times per day who receive an IV beta-lactam antibiotic to treat fever;
- Received a study-may-proceed letter from the FDA to conduct a Phase 1 single ascending dose ("SAD") study in healthy volunteers, designed to evaluate SYN-020 intestinal alkaline phosphatase ("IAP") for safety, tolerability, and pharmacokinetic parameters (Q3 2020)

    - The Phase 1 clinical program is intended to support the clinical development of SYN-020 in multiple indications, including an initial indication for the treatment and prevention of radiation enteropathy secondary to cancer therapy;
- Announced the results of a planned interim futility analysis of the investigator-sponsored Phase 2b clinical study of SYN-010 being conducted by Cedars-Sinai Medical Center ("CSMC") (Q3 2020)
    - Based on the review of the interim analysis, it was concluded that although SYN-010 was well-tolerated, it is unlikely to meet its primary objective by the time enrollment is completed,
    - CSMC has discontinued the trial and will conduct a comprehensive review of the final data set and publish its findings,
    - On the basis of these results, the Company and CSMC have mutually decided to terminate the exclusive license agreement and clinical trial agreements relating to SYN-010. The patent rights previously licensed to the Company covering the use of SYN-010 will remain the property of CSMC;

Quarter Ended September 30, 2020 Financial Results

General and administrative expenses increased by 9% to $1.2 million for the three months ended September 30, 2020, from $1.1 million for the three months ended September 30, 2019. This increase is primarily due to increased insurance costs and stock registration fees, offset by a decrease in legal costs. The charge related to stock-based compensation expense was $67,000 for the three months ended September 30, 2020, compared to $68,000 the three months ended September 30, 2019.

Research and development expenses decreased by 78% to $0.9 million for the three months ended September 30, 2020, from $4.1 million for the three months ended September 30, 2019. This decrease is primarily the result of the response to the global COVID-19 pandemic by our clinical development partners which led to the postponement of the Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients, as well as the discontinuation of the Phase 2b investigator sponsored clinical trial of SYN-010. The charge related to stock-based compensation expense was $15,000 for the three months ended September 30, 2020, compared to $23,000 for the three months ended September 30, 2019.

Other income was $134 for the three months ended September 30, 2020, compared to other income of $92,000 for the three months ended September 30, 2019. Other income for the three months ended September 30, 2020 and 2019 is primarily comprised of interest income.

Cash and cash equivalents as of September 30, 2020 totaled $6.0 million, a decrease of $9.0 million from December 31, 2019.

Conference Call

Synthetic Biologics will hold a conference call today, Tuesday, November 10, 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/1096/38296. An archive of the call will be available for replay at the same URL,

https://www.webcaster4.com/Webcast/Page/1096/38296, for 90 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a diversified clinical-stage company developing 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 (a) microbiome damage, (b) *Clostridioides difficile* infection (CDI), (c) overgrowth of pathogenic organisms, (d) the emergence of antimicrobial resistance (AMR) and (e) acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-020, a recombinant oral formulation of the enzyme intestinal alkaline phosphatase (IAP) produced under cGMP conditions and intended 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 the Phase 1 single ascending dose study supporting the clinical development of SYN-020 in multiple indications, initiation of the proposed Phase 1b/2a clinical trial to be conducted by the Washington University School of Medicine in adult allogeneic HCT recipients commencing during Q1 2021. 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 to receive additional funding necessary to continue operations, a failure of Synthetic Biologics' clinical trials, and those conducted by investigators, for SYN-004, and SYN-020 to be commenced or completed on time or to achieve desired results and benefits, especially in light of COVID-19, 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, a failure to maintain its listing on the NYSE American, or a failure by Synthetic Biologics or its strategic partners to successfully commercialize products and other factors described in Synthetic Biologics' Annual Report on Form 10-K for the year ended December 31, 2019 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, 2020	December
Assets		
Cash and cash equivalents	$ 6,005	$
Prepaid expenses and other current assets	657	
Property and equipment, net	202	
Right of Use Asset	316	
Deposits and other assets	23	
Total Assets	$ 7,203	$
Liabilities and Stockholder's Deficit		
Total liabilities	$ 3,271	$
Series A Convertible Preferred Stock	12,733	
Synthetic Biologics, Inc. and Subsidiaries Equity (Deficit)	(6,051)	
Non-controlling interest	(2,750)	
Total Liabilities and Stockholders' Deficit	$ 7,203	$

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 e September 30, *(Unaudited)*	
	2020	**2019**	**2020**	
Operating Costs and Expenses				
General and administrative	$ 1,197	$ 1,098	$ 3,876	$
Research and development	914	4,144	4,152	
Total Operating Costs and Expenses	2,111	5,242	8,028	
Loss from Operations	(2,111)	(5,242)	(8,028)	
Other Income				
Interest income	-	92	44	
Total Other Income, net	-	92	44	
Net Loss	(2,111)	(5,150)	(7,984)	
Net Loss Attributable to Non-controlling Interest	(8)	(30)	(50)	
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (2,103)	$ (5,120)	$ (7,934)	$
Series A Preferred Dividends	(64)	(63)	(189)	
Series B Preferred Dividends	(519)	(70)	(1,315)	
Net Loss Attributable to Common Stockholders	$ (2,686)	$ (5,253)	$ (9,438)	$
Net Loss Per Share – Basic and Dilutive	$ (0.14)	$ (0.31)	$ (0.52)	$
Weighted average number of common shares outstanding - Basic and Diluted	19,398,339	16,805,257	18,302,585	1

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