November 3, 2021

Synthetic Biologics Reports Third Quarter 2021 Operational Highlights and Financial Results; Conference Call to be Held Today at 4:30 PM ET

Initiated a Phase 1 Multiple Ascending Dose Clinical Trial of SYN-020 in Healthy Adult Volunteers; Topline Data Readout Expected in Q2 2022

Enrollment Remains Ongoing in Phase 1b/2a Clinical Trial of SYN-004 in Allogeneic HCT Recipients

Reports $72.1 Million of Cash on Hand to Fund Clinical Programs Through Key Milestones Beyond 2022

ROCKVILLE, Md., Nov. 3, 2021 /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 third quarter ended September 30, 2021.

Recent Developments:

- Initiated a Phase 1, placebo-controlled, multiple ascending dose clinical study of SYN-020 intestinal alkaline phosphatase ("IAP")

- Continuing enrollment in the Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant ("HCT") recipients
- Current cash position of approximately $72.1 million
- Current cash runway expected to provide funding to complete Phase 1b/2a clinical trial of SYN-004, clinical trials of SYN-020 through proof-of-concept, and other key milestones into 2023

Anticipated Milestones:

- Topline data readout from the first antibiotic cohort of the SYN-004 Phase 1b/2a clinical trial is expected during Q1 2022
- Expect to announce topline data readout from the Company's Phase 1 MAD clinical trial of SYN-020 during Q2 2022

"During the third quarter, we significantly advanced our portfolio of GI and microbiome-focused clinical programs," said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. "We were pleased to initiate a Phase 1 multiple ascending dose clinical trial of our SYN-020 IAP program during the third quarter of 2021. At this time, the first cohort of 8 study participants is nearing completion with dosing of the second cohort of 8 study participants expected to begin shortly thereafter, pending a safety review. We anticipate reporting topline data from this clinical trial during the second quarter of 2022. This study follows our recent Phase 1 single ascending dose ("SAD") clinical trial of SYN-020, in which SYN-020 was well tolerated and demonstrated a favorable safety profile at all doses. Both clinical trials are designed to support the advancement of SYN-020 in multiple potential therapeutic indications, including radiation enteropathy, celiac disease, non-alcoholic fatty liver disease (NAFLD), and age-related metabolic and inflammatory diseases. We continue to view SYN-020 as a multi-indication platform program, which has the potential to help address a considerable need for innovative new therapies targeting disorders that stem from immune and inflammatory damage to the intestine."

Mr. Shallcross continued, "We also continue to progress the SYN-004 Phase 1b/2a clinical trial in allogeneic hematopoietic cell transplant ("HCT") recipients. Patient screening and enrollment is ongoing at the Washington University School of Medicine in St. Louis ("Washington University"). As a result, we currently anticipate announcing topline results from the first of three antibiotic cohorts during the first quarter of 2022. We believe SYN-004 has the potential to address a significant unmet medical need by improving outcomes for allogeneic HCT recipients. Overall, we remain very excited about the potential for each of our clinical programs and near-term clinical milestones that we believe could drive significant value for shareholders."

Clinical Development and Operational Update

- Announced commencement of the Company's Phase 1, placebo-controlled, multiple ascending dose clinical trial of SYN-020
    - The ongoing Phase 1 MAD clinical trial is intended to evaluate the safety, tolerability and biodistribution of SYN-020 upon repeated dosing in up to 32 healthy adult volunteers.
    - The study is divided into 4 sequential cohorts of 8 participants, with SYN-020 (5 mg, 15, mg, 45 mg or 75 mg) given orally twice daily for 14 days.
    - At this time, the first cohort of 8 study participants is nearing completion and

dosing of the second cohort of 8 study participants is expected to begin shortly thereafter, pending a safety review.
    - A safety review will be conducted at the end of each cohort to determine whether progression to the next higher dose cohort is permissible.
    - A topline data readout from this clinical trial is anticipated during the second quarter of 2022, pandemic conditions permitting.
    - A previously completed Phase 1 single ascending dose clinical study of SYN-020 enrolled 24 healthy adult volunteers into four cohorts with SYN-020 given orally as a single dose ranging from 5 mg to 150 mg. Analyses of preliminary data demonstrated that SYN-020 maintained a favorable safety profile, was well tolerated at all dose levels, and no adverse events were attributed to study drug. No serious adverse events were reported.
    - Both studies are intended to support the development of SYN-020 in multiple potential clinical indications including radiation enteropathy, celiac disease, NAFLD, as well as indications supported by the Company's collaboration with Massachusetts General Hospital.
- Enrollment in the Company's Phase 1b/2a clinical trial of SYN-004 in allogeneic HCT recipients for the prevention of acute graft-versus-host-disease ("aGVHD") remains ongoing
    - The Phase 1b/2a clinical trial comprises a single center, randomized, double-blind, placebo-controlled clinical trial of oral SYN-004 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 oral SYN-004 administered to allogeneic HCT recipients who receive an IV beta-lactam antibiotic to treat fever.
    - Study 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 and 4 will receive placebo.
    - Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee ("DSMC"), which will make a recommendation on whether to proceed to the next IV beta-lactam antibiotic.
    - A topline data readout for the first of three antibiotic cohorts is anticipated during the first quarter of 2022, pandemic conditions permitting.

Quarter Ended September 30, 2021 Financial Results

General and administrative expenses increased by 9% to approximately $1.3 million for the three months ended September 30, 2021, from approximately $1.2 million for the three months ended September 30, 2020. This increase is primarily due to higher insurance costs, audit fees and registration fees offset by lower legal costs and vacation expense. The charge related to stock-based compensation expense was $83,000 for the three months ended September 30, 2021, compared to $67,000 for the three months ended September 30, 2020.

Research and development expenses increased by 116% to approximately $2.0 million for the three months ended September 30, 2021, from approximately $900,000 for the three months ended September 30, 2020. This increase is primarily the result of increased clinical trial expenses as we continued dosing patients in the Phase 1b/2a clinical trial of SYN-004 and by higher indirect program costs for the three months ended September 30, 2021,

including an increase in manufacturing costs for SYN-020. We anticipate research and development expense to increase as our ongoing clinical trials continue to enroll patients. The charge related to stock-based compensation expense was $19,000 for the three months ended September 30, 2021, compared to $15,000 related to stock-based compensation expense for the three months ended September 30, 2020.

Other income was $2,000 for the three months ended September 30, 2021, compared to other income of $134 for the three months ended September 30, 2020. Other income for the three months ended September 30, 2021 and 2020 is primarily comprised of interest income.

Cash and cash equivalents as of September 30, 2021 totaled $72.1 million, an increase of $65.9 million from December 31, 2020.

Conference Call

Synthetic Biologics will hold a conference call today, Wednesday, November 3, 2021, 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/1096/43299. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/43299, 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 (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 current cash runway providing funding to complete the Phase 1b/2a clinical trial of SYN-004, clinical trials of SYN-020 through proof-of-concept, and other key milestones into 2023, announcing topline data readout from Synthetic Biologics' Phase 1 MAD clinical trial of SYN-020 during Q2 2022, advancement of SYN-020 in multiple potential therapeutic indications, including celiac disease, non-alcoholic fatty liver disease (NAFLD), age-related metabolic and inflammatory diseases, and radiation enteropathy, the potential of SYN-020 to help address a considerable need for innovative new therapies targeting

disorders that stem from immune and inflammatory damage to the intestine, a topline data readout from the first of three antibiotic cohorts of the SYN-004 Phase 1b/2a clinical trial during the first quarter of 2022, dosing of the second cohort of 8 study participants in the SYN-020 ongoing Phase 1 MAD clinical trial to begin shortly thereafter, pending a safety review, and SYN-004 having the potential to address a significant unmet medical need by improving outcomes for allogeneic HCT recipients. 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 to advance SYN-020 in multiple potential therapeutic indications,to receive the necessary regulatory approvals for commercialization of Synthetic Biologics' therapeutics, the ability of Synthetic Biologics' clinical trials for SYN-004 and SYN-020 to be completed on time, to provide topline data when anticipatedincluding a topline data readout from Synthetic Biologics' Phase 1 MAD clinical trial of SYN-020 during Q2 2022 and a topline data readout from the first of three antibiotic cohorts of the SYN-004 Phase 1b/2a clinical trial during the first quarter of 2022 or to achieve desired results and benefits, especially in light of COVID-19, the ability of Synthetic Biologics' clinical trials to continue enrollment as expected or receive anticipated funding, the ability 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, its ability to meet its funding needs and other factors described in Synthetic Biologics' Annual Report on Form 10-K for the year ended December 31, 2020 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

	For the three months ended	
	September 30, 2021	**December 31, 2020**
Assets		
Cash and cash equivalents	$ 72,135	$ 6,227
Prepaid expenses and other current assets	1,422	1,707
Property and equipment, net	115	174
Right of Use Asset	1,426	279
Deposits and other assets	23	23
Total Assets	$ 75,121	$ 8,410
Liabilities and Stockholder's Deficit		
Total liabilities	$ 4,561	$ 3,152
Series A Convertible Preferred Stock	-	12,798
Synthetic Biologics, Inc. and Subsidiaries Equity (Deficit)	73,334	(4,767)
Non-controlling interest	(2,774)	(2,773)
Total Liabilities and Stockholders' Equity (Deficit)	$ 75,121	$ 8,410

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)*	
	2021	**2020**	**2021**	**2020**
Operating Costs and Expenses				
	$		$	$
General and administrative	1,303	1,197	3,988	3,876
Research and development	1,972	914	5,021	4,152
Total Operating Costs and Expenses	3,275	2,111	9,009	8,028
Loss from Operations	(3,275)	(2,111)	(9,009)	(8,028)
Other Income				
Interest income	2	-	4	44
Total Other Income, net	2	-	4	44
Net Loss	(3,273)	(2,111)	(9,005)	(7,984)
Net Loss Attributable to Non-controlling Interest	-	(8)	(1)	(50)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (3,273)	$ (2,103)	$ (9,004)	$ (7,934)
Series A Preferred Dividends	-	(64)	(24)	(189)
Effect of Series A Preferred Stock price adjustment	-	-	(7,402)	-
Series B Preferred Dividends	-	(519)	(1,496)	(1,315)
Net Loss Attributable to Common Stockholders	$ (3,273	$ (2,686)	$ (17,926)	$ (9,438)
Net Loss Per Share – Basic and Dilutive	$ (0.02)	$ (0.14)	$ (0.15)	$ (0.52)
Weighted average number of common shares outstanding - Basic and Diluted	132,042,538	19,398,339	118,448,633	18,302,585

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