March 4, 2021

Synthetic Biologics Reports 2020 Year End Operational Highlights and Financial Results

-- Announced Washington University Has Begun Screening Patients for Enrollment in Phase 1b/2a Clinical Trial of SYN-004 (ribaxamase) in Allogeneic Hematopoietic Cell Transplant Recipients --

-- Reports $72.6M of Cash on Hand to Fund Clinical Programs and Extend Operations into 2023 --

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

ROCKVILLE, Md., March 4, 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 year ended December 31, 2020.

Recent developments:

- Received Institutional Review Board ("IRB") approval from Washington University School of Medicine in St. Louis for the SYN-004 (ribaxamase) Phase 1b/2a clinical trial protocol in allogeneic hematopoietic cell transplant ("HCT") recipients
- Commenced screening of patients for enrollment of the first of three sequential

antibiotic cohorts in the SYN-004 Phase 1b/2a clinical trial in allogeneic HCT recipients
- Current cash position of approximately $72.6 million
- Received $8.0 million from the exercise of warrants
- Current cash runway provides funding into 2023 and ability to fully fund Phase 1b/2a clinical trial of SYN-004 and Phase 1 safety studies of SYN-020 intestinal alkaline phosphatase ("IAP") program

Upcoming milestones:

- Expect to begin dosing patients in the first antibiotic cohort of the SYN-004 Phase 1b/2a clinical trial during Q1 2021; A topline data readout of the first antibiotic cohort is expected during Q4 2021
- Expect to commence first Phase 1 single-ascending-dose study ("SAD") of SYN-020 during Q2 2021; Topline data anticipated during Q3 2021
- Expect to commence second Phase 1 multiple-ascending-dose ("MAD") study of SYN-020 during Q3 2021; Topline data anticipated during Q2 2022

"We are more encouraged than ever by the outlook for the business as we have made important progress during the fourth quarter advancing and demonstrating the significant value of our clinical development programs. With a number of upcoming catalysts later this year, we believe there is potential to continue to deliver significant value for our shareholders," stated Steven A. Shallcross, Chief Executive and Financial Officer. "IRB approval by Washington University of the SYN-004 Phase 1b/2a clinical program protocol marks a major milestone for the Company. Looking ahead, we believe SYN-004 has the potential to address an important and underserved patient population, and may significantly improve outcomes for allogeneic HCT recipients by preventing downstream complications often associated with disruption of the gut microbiome by intravenous ("IV") beta-lactam antibiotics. We are pleased to announce that Washington University has begun screening patients for enrollment of the first of three sequential antibiotic cohorts and look forward to reporting topline data for this group towards the end of this year, pandemic conditions permitting."

Mr. Shallcross continued, "During the fourth quarter of 2020, we also made significant progress and gained additional clarity on potential clinical development pathways for our SYN-020 IAP program. Looking ahead, we intend to commence safety studies starting with a planned Phase 1 single-ascending-dose study in healthy volunteers during the second quarter of 2021; a topline data readout is expected during the third quarter of 2021. A second Phase 1 multiple-ascending-dose study is also expected to begin enrollment during the third quarter of 2021. Both studies are designed to support the advancement of SYN-020 in multiple potential therapeutic indications, including celiac disease, nonalcoholic fatty liver disease ("NAFLD") and age-related metabolic and inflammatory diseases. We are very excited about the potential for this program to be a long-term value driver for our Company and look forward to sharing important updates and progress as we continue to advance it towards clinical trials."

Mr. Shallcross concluded, "While remaining keenly focused on the execution of our clinical development activities, we also significantly strengthened our balance sheet and raised net proceeds of approximately $63.8 million, in addition to $8.0 million in proceeds from the cash exercise of warrants, which has helped to streamline our capital structure. As a result of these activities, our current cash position is approximately $72.6 million. Our fortified

financial footing will now allow the Company to continue its operations into 2023 as well as fully fund the Phase 1b/2a clinical trial of SYN-004 and our planned Phase 1 safety studies of SYN-020 IAP."

Clinical Development and Operational Update

- Announced approval by the IRB at Washington University of the SYN-004 Phase 1b/2a clinical program protocol in allogeneic HCT recipients, allowing the clinical trial to commence as planned;
- Announced Washington University has begun screening patients for enrollment of the first antibiotic cohort for 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)
    - 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 four 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 antibiotic cohort is anticipated during the fourth quarter of 2021, pandemic conditions permitting;
- A Phase 1 SAD clinical trial in healthy volunteers of the Company's SYN-020 IAP is anticipated to commence during the second quarter of 2021
    - A topline data readout is anticipated during the third quarter of 2021, pandemic conditions permitting,
    - A second Phase 1 clinical trial evaluating multiple-ascending doses of SYN-020 in healthy volunteers is expected to commence during the third quarter of 2021; topline data is anticipated during the second quarter of 2022, pandemic conditions permitting,
    - Both studies are intended to support the development of SYN-020 in multiple potential clinical indications;
- Strengthened balance sheet by raising net proceeds of $63.8 million from the sale of the common stock via the Company's At-The-Market ("ATM") facility, and $8.0 million resulting from the cash exercise of a portion of Company's 2018 warrants
    - As a result of these activities, the Company has extended its cash runway into 2023 and has the ability to fully fund its Phase 1b/2a clinical trial of SYN-004 and planned Phase 1 SAD and MAD clinical trials of SYN-020;
- Announced the appointment of senior biotech executive John Monahan, PhD, to the Company's Board of Directors
    - Dr. Monahan brings to the Company more than 45 years of executive leadership experience in the pharmaceutical and biotechnologies industries.

Year Ended December 31, 2020 Financial Results

General and administrative expenses increased to $5.0 million for the year ended December 31, 2020, from $4.6 million for the year ended December 31, 2019. This increase of 8.7% is due to increased legal costs related to business development, patent execution, employee contract matters, vacation expense, insurance costs and registration fees. The charge relating to stock-based compensation expense was $300,000 for the year ended December 31, 2020, compared to $300,000 for the year ended December 31, 2019.

Research and development expenses decreased to $5.1 million for the year ended December 31, 2020, from $11.1 million for the year ended December 31, 2019. This decrease of 54.1% is primarily due to a reduction in preclinical and manufacturing activity of SYN-020 IAP and 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 and the SYN-010 clinical trial and to a lesser extent the discontinuation of the Phase 2b investigator sponsored clinical trial of SYN-010. Research and development expenses also include a charge relating to non-cash stock-based compensation expense of $66,000 for the year ended December 31, 2020, compared to $75,000 for the year ended December 31, 2019.

Total other income was $44,000 for the year ended December 31, 2020, compared to other income of $283,000 for the year ended December 31, 2019. Total other income for the year ended December 31, 2020 and 2019 is primarily comprised of interest income from investments.

Cash and cash equivalents on December 31, 2020 were $6.2 million, a decrease of $8.8 million from December 31, 2019.

Conference Call

Synthetic Biologics will hold a conference call today, Thursday, March 4, 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/1096/39984. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/39984, 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 cash runway providing funding into 2023 and the ability to fully fund the Phase 1b/2a clinical trial of SYN-004 and planned Phase 1 safety studies of SYN-020 intestinal alkaline phosphatase, topline data of the first antibiotic cohort in the SYN-004 Phase 1b/2a clinical program being readout during Q4 2021, commencing the first Phase 1 single-ascending-dose study of SYN-020 during Q2 2021 and providing topline data during Q3 2021, commencing the second Phase 1 multiple-ascending-dose study of SYN-020 during Q3 2021 and providing topline data during Q2 2022, continuing to deliver significant value for shareholders, the potential of SYN-004 to address an important and underserved patient population, and significantly improve outcomes for allogeneic HCT recipients by preventing downstream complications often associated with disruption of the gut microbiome by intravenous beta-lactam antibiotics, and the potential for SYN-020 to be a long term value driver. 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-020 to be commenced or completed as planned, or a failure to provide topline data when anticipated 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,	
	2020	**2019**
Assets		
Cash and cash equivalents	$ 6,227	$ 15,045

Prepaid expenses and other current assets	1,707	1,381
Property and equipment, net	174	367
Right of Use Asset	279	419
Deposits and other assets	23	23
Total Assets	$ 8,410	$ 17,235
Liabilities and Stockholder's (Deficit) Equity		
Total liabilities	$ 3,152	$ 5,748
Series A Convertible Preferred Stock	12,798	12,544
Synthetic Biologics, Inc. and Subsidiaries (Deficit) Equity	(4,767)	1,821
Non-controlling interest	(2,773)	(2,878)
Total Liabilities and Stockholders' (Deficit) Equity	$ 8,410	$ 17,235

Condensed Consolidated Statements of Operations

	For the years ended December 31,	
	2020	**2019**
Operating Costs and Expenses		
General and administrative	$ 5,029	$ 4,580
Research and development	5,131	11,083
Total Operating Costs and Expenses	10,160	15,663
Loss from Operations	(10,160)	(15,663)
Other Income		
Interest income	44	283
Total Other Income	44	283
Net Loss	(10,116)	(15,380)
Net Loss Attributable to Non-controlling Interest	(73)	(77)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (10,043)	$ (15,303)
Series A Preferred Stock Dividends	(254)	(248)
Series B Preferred Stock Dividends	(1,380)	(525)
Effect of Warrant Exercise price adjustment	(880)	-
Net Loss Attributable to Common Stockholders	(12,557)	(16,076)
Net Loss Per Share - Basic and Dilutive	$ (0.66)	$ (0.98)
Weighted average number of common shares outstanding - Basic and Dilutive	19,011,362	16,438,201

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