August 6, 2020

Synthetic Biologics Reports 2020 Second Quarter Operational Highlights and Financial Results

-- Announced FDA Clearance of IND Application for SYN-020 Intestinal Alkaline Phosphatase (IAP) --

-- Signed Option License Agreement with Massachusetts General Hospital to Develop SYN-020 to Treat and Prevent Metabolic and Inflammatory Diseases Associated with Aging --

-- Enrollment in the Phase 2b Investigator-Sponsored Clinical Trial of SYN-010 Has Recommenced Following COVID-19-Related Postponement --

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

ROCKVILLE, Md., Aug. 6, 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 June 30, 2020.

"During the second quarter, we remained diligently focused on advancing our portfolio of GI

and microbiome-focused clinical development programs while continuing to navigate the unprecedented global health and economic crisis sparked by the COVID-19 global pandemic," said Steven A. Shallcross, Chief Executive and Financial Officer of Synthetic Biologics. "We made significant progress positioning SYN-020, our orally delivered recombinant version of bovine intestinal alkaline phosphatase (IAP), for its first clinical trial. We were pleased to report the FDA responded to our Investigational New Drug application (IND) with a study-may-proceed letter to conduct a Phase 1 single ascending dose study of SYN-020 in healthy volunteers. Additionally, we expanded our collaboration with Massachusetts General Hospital (MGH) in the form of an exclusive option agreement to license intellectual property and technology to commercially develop SYN-020 for the treatment and prevention of metabolic and inflammatory diseases associated with aging. The Phase 1 clinical trial 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 and indications that may be developed under the MGH license agreement."

Mr. Shallcross continued, "Enrollment in the Phase 2b investigator-sponsored clinical trial of SYN-010, intended to treat irritable bowel syndrome-constipation (IBS-C) and being conducted out of Cedars-Sinai Medical Center (CSMC), has recommenced following a temporary postponement during the first and second quarter due to the impact of the COVID-19 global pandemic. A data readout in the form of an interim futility analysis is expected during the third quarter and topline data is anticipated during the first quarter of 2021, subject to potential COVID-19 complications." Mr. Shallcross concluded, "We remain in close contact with Washington University as we continue to evaluate opportunities to initiate the planned Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients in the face of the ongoing COVID-19 pandemic. We continue to closely monitor the crisis caused by the spread of the COVID-19 and look forward to sharing important updates and progress for this and all our GI and microbiome-focused clinical programs."

Clinical Development and Operational Update

- Submitted an Investigational New Drug application (IND) to the U.S. Food and Drug Administration (FDA) for SYN-020, the Company's recombinant version of bovine intestinal alkaline phosphatase (IAP) supporting an initial indication to mitigate the intestinal damage caused by radiation therapy routinely used to treat pelvic cancers (Q2 2020)
    - Received study-may-proceed letter from FDA to conduct a Phase 1 single ascending dose study in healthy volunteers, designed to evaluate SYN-020 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;
- Entered into an agreement with Massachusetts General Hospital (MGH) granting the Company an option for an exclusive license to intellectual property and technology related to the use of IAP to maintain GI and microbiome health, diminish systemic inflammation, and treat age-related diseases (Q2 2020)
    - Under the terms of the agreement, Synthetic Biologics is granted exclusive rights to negotiate a worldwide license with MGH to commercially develop SYN-020 to

treat and prevent metabolic and inflammatory diseases associated with aging,
    - If executed, the Company plans to use this license in the advancement of an expanded clinical development program for SYN-020;
- Enrollment in the investigator-sponsored Phase 2b clinical trial of SYN-010, intended to treat IBS-C, has recommenced following a temporary halt in Q1 and Q2 2020 due to the COVID-19 global pandemic; however, the ability to continue to recruit new patients into this clinical trial remains at the discretion of CSMC and contingent upon the impact of the COVID-19 global pandemic
    - A data readout in the form of an interim futility analysis is expected during the third quarter of 2020 and topline data is anticipated during the first quarter of 2021, subject to the impact of COVID-19,
    - CSMC and Synthetic Biologics are co-funding the study. The patent rights covering the use of SYN-010 are owned by CSMC and are exclusively licensed by CSMC to Synthetic Biologics;
- Received written notification from the FDA informing the Company that the FDA determined the Phase 1b/2a clinical program in adult allogeneic hematopoietic cell transplant (HCT) recipients may proceed per the submitted clinical program protocol (Q3 2020)
    - Due to the unique challenges posed by the global COVID-19 pandemic, Washington University continues to evaluate non-essential activities, which may have a direct impact on planned and ongoing clinical trials, including the SYN-004 (ribaxamase) Phase 1b/2a clinical program in allogeneic HCT recipients,
    - At this time, the Company has determined that postponing the initiation of the planned Phase 1b/2a clinical trial in allogeneic HCT recipients until at least the first quarter of 2021 remains the appropriate course of action due to continued uncertainty surrounding the ongoing global COVID-19 pandemic;
- On July 30, 2020, the Company received written communication from NYSE American LLC (the "Exchange"), the Company's current listing exchange, stating that in addition to Section 1003(iii), it is now also not in compliance with both Section 1003(i) and Section 1003(ii) of the NYSE American Company Guide since it reported a stockholders' deficit of ($4.0) million as of March 31, 2020 and losses from continuing operations and/or net losses in its five most recent fiscal years ended December 31, 2019
    - The Company has previously submitted a plan of compliance which was accepted by the Exchange addressing how it intends to regain compliance with the Exchange continued listing standards by November 25, 2020, the end of the current compliance plan period,
    - The NYSE American notification does not affect the Company's business operations or the listing of the Company's shares on the Exchange, and does not represent any change or amendment to the Company's consolidated financial statements or to its quarterly reports for the quarter ended March 30, 2020 or to its annual report on Form 10-K for the year ended December 31, 2019.

Quarter Ended June 30, 2020 Financial Results

General and administrative expenses increased by 23% to $1.3 million for the three months ended June 30, 2020, from $1.0 million for the three months ended June 30, 2019. This increase is primarily due to increased legal costs related to business development, patent execution and employee contract matters, vacation expense, and insurance costs. The

charge related to stock-based compensation expense was $67,000 for the three months ended June 30, 2020, compared to $59,000 the three months ended June 30, 2019.

Research and development expenses decreased by 38% to $1.6 million for the three months ended June 30, 2020, from $2.6 million for the three months ended June 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 and a temporary halt during the second quarter in new enrollment in the Phase 2b investigator sponsored clinical trial of SYN-010. The charge related to stock-based compensation expense was $19,000 for the three months ended June 30, 2020, compared to $31,000 for the three months ended June 30, 2019.

Other income was $6,000 for the three months ended June 30, 2020, compared to other income of $80,000 for the three months ended June 30, 2019. Other income for the three months ended June 30, 2020 and 2019 is primarily comprised of interest income.

Cash and cash equivalents as of June 30, 2020 totaled $8.1 million, a decrease of $7.0 million from December 31, 2019.

Conference Call

Synthetic Biologics will hold a conference call today, Thursday, August 6, 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/1096/35797. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/35797, 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 the Phase 1 clinical trial of SYN-020 supporting the clinical development of SYN-020 in multiple indications, a data readout in the investigator-sponsored Phase 2b clinical trial of SYN-010 in the form of an interim futility analysis during the third quarter and topline data during the first quarter of 2021, subject to potential COVID-19 complications, and use of the license with MGH in the advancement of an expanded clinical development program for SYN-020. 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, SYN-010 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 our 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

	June 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 8,059	$ 15,045
Prepaid expenses and other current assets	897	1,381
Property and equipment, net	251	367
Right of Use Asset	352	419
Deposits and other assets	23	23
Total Assets	$ 9,582	$ 17,235
Liabilities and Stockholder's Deficit		
Total liabilities	$ 3,763	$ 5,748
Series A Convertible Preferred Stock	12,669	12,544
Synthetic Biologics, Inc. and Subsidiaries Equity (Deficit)	(3,966)	1,821
Non-controlling interest	(2,884)	(2,878)
Total Liabilities and Stockholders' Deficit	$ 9,582	$ 17,235

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

	For the three months ended June 30, (Unaudited)		For the six months ended June 30, (Unaudited)	
	2020	**2019**	**2020**	**2019**
Operating Costs and Expenses				
General and administrative	$ 1,286	$ 1,044	$ 2,679	$ 2,199
Research and development	1,603	2,594	3,238	5,012
Total Operating Costs and Expenses	2,889	3,638	5,917	7,211
Loss from Operations	(2,889)	(3,638)	(5,917)	(7,211)
Other Income				
Interest income	6	80	44	125
Total Other Income, net	6	80	44	125
Net Loss	(2,883)	(3,558)	(5,873)	(7,086)
Net Loss Attributable to Non-controlling Interest	(16)	(27)	(42)	(43)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (2,867)	$ (3,531)	$ (5,831)	$ (7,043)
Series A Preferred Dividends	(63)	(61)	(125)	(122)
Series B Preferred Dividends	(392)	(117)	(796)	(515)
Net Loss Attributable to Common Stockholders	$ (3,322)	$ (3,709)	$ (6,752)	$ (7,680)
Net Loss Per Share – Basic and Dilutive	$ (0.18)	$ (0.23)	$ (0.38)	$ (0.48)
Weighted average number of common shares outstanding - Basic and Diluted	18,405,884	16,465,314	17,748,688	16,063,283

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