August 3, 2016

Synthetic Biologics Reports Second Quarter 2016 Operational Highlights and Financial Results

- Held End of Phase 2 Meeting with FDA and Received Guidance for Advancement to First Pivotal Trial for SYN-010, for the Treatment of Irritable Bowel Syndrome with Constipation (IBS-C) -

- Company Provides Update on Enrollment for Phase 2b Proof-of-Concept Clinical Trial for SYN-004 (ribaxamase), for the Prevention of C. Difficile Infection (CDI) and Antibiotic-Associated Diarrhea (AAD) -

- Conference Call Today, August 3, 2016, at 4:30 p.m. EDT -

ROCKVILLE, Md., Aug. 3, 2016 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE MKT: SYN), a clinical stage company focused on developing therapeutics to protect the gut microbiome while targeting pathogen-specific diseases, today provided an operational update and reported financial results for the three months ended June 30, 2016.

"In the second quarter we continued the transition from an early-stage clinical development company to a late-stage clinical development company focused on the commercialization of our two lead GI microbiome-focused drug candidates," said Jeffrey Riley, Chief Executive Officer. "We held an End of Phase 2 meeting with FDA and received guidance for advancement to a pivotal clinical trial for SYN-010, designed to treat an underlying cause of the symptoms associated with irritable bowel syndrome with constipation (IBS-C)." Mr. Riley continued, "The approval of the generic name 'ribaxamase' for SYN-004, the announcement of positive clinical outcomes from a second Phase 2a clinical trial and robust enrollment in our global Phase 2b proof-of-concept clinical trial continued to fuel momentum for our program designed to protect the gut microbiome and prevent *C. difficile* infection (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antibiotic resistant organisms. To date, we have enrolled 374 patients and anticipate announcing topline results from our ongoing Phase 2b clinical trial

for SYN-004 in early 2017."

Microbiome-Focused Clinical Program Progress

SYN-010 – Treatment of irritable bowel syndrome with constipation (IBS-C):

- Held End of Phase 2 meeting with FDA and received guidance for clinical study design and requirements for Phase 3 development
- Plan to initiate Phase 2b/3 pivotal clinical trial (1Q 2017)
- Presented detailed data during Digestive Disease Week® 2016 supporting previously reported positive outcomes from two Phase 2 clinical trials of SYN-010, including:
    - Data demonstrating an inverse correlation between breath methane Area Under Curve (AUC) and complete spontaneous bowel movements (CSBMs) in study participants diagnosed with IBS-C
    - Data demonstrating clear improvements in abdominal pain, bloating and quality of life measures (IBS-SSS) in study participants who were administered SYN-010
- Announced results from a separate randomized, open-label Pharmacokinetic (PK) study demonstrating SYN-010 avoided desired drug release in the stomach and delivered the antimethanogenic lovastatin lactone into the lower small intestine and colon while reducing systemic exposure to the cholesterol-lowering lovastatin beta-hydroxyacid metabolite

SYN-004 (ribaxamase) - Prevention of CDI, AAD and the emergence of antibiotic-resistant organisms:

- Received approval from United States Adopted Names Council (USAN) for the generic name "ribaxamase" for SYN-004
- Continued enrollment in global Phase 2b proof-of-concept clinical trial intended to evaluate the ability of ribaxamase to prevent CDI, C. difficile-associated diarrhea (CDAD) and AAD in patients hospitalized with a lower respiratory tract infection and receiving intravenous (IV) ceftriaxone
    - Enrolled 374 patients to date across global clinical sites; enrollment expected through 3Q 2016
    - Anticipate announcing topline results from Phase 2b proof-of-concept clinical trial (1Q 2017)
- Announced positive results from second Phase 2a clinical trial demonstrating a correlation of the 150 mg dose of ribaxamase, both alone and in the presence of the proton pump inhibitor, esomeprazole and the successful degradation of IV ceftriaxone to levels that were near or below detectable without impacting ceftriaxone plasma concentrations
    - The 150 mg dose strength of ribaxamase was well tolerated by all participants

Operational Update – Expanded Leadership Team

- Deb Mathews, PharmD, joined the Company as Vice President, Medical Affairs, bringing broad experience and strong leadership of clinical and medical affairs as the Company begins to implement commercialization strategies
- Isaac J. Bright, MD, joined the Company in the newly created position of Vice President, Corporate Development, to lead all strategic corporate and business development efforts for the Company's two lead microbiome-focused drug candidates

Second Quarter 2016 Financial Results

General and administrative expenses decreased by 3% to $2.1 million for the second quarter of 2016, from $2.2 million for the second quarter of 2015. This decrease is primarily the result of lower legal fees offset by an increase in stock-based compensation and increased employee costs associated

with the transition of the administrative and financial office to our Maryland headquarters. The charge related to stock-based compensation expense was $507,000 for the second quarter of 2016, compared to $335,000 for the second quarter of 2015.

Research and development expenses decreased by 5% to $7.2 million for the second quarter of 2016, from $7.5 million for the second quarter of 2015. This decrease is primarily the result of decreased Phase 2 program costs associated with clinical development programs, manufacturing and research activities within our microbiome-focused pipeline. Research and development expenses also include a charge related to non-cash stock-based compensation expense of $400,000 for the second quarter of 2016, compared to $252,000 for the second quarter of 2015.

Other income was $3.5 million for the second quarter of 2016, compared to other expense of $3.9 million for the second quarter of 2015. Other income for the second quarter of 2016 is due to non-cash expense of $3.5 million from the change in fair value of warrants. The decrease in the fair value of the warrants was due to the decrease in our stock price from the year ended December 31, 2015. Non-cash expense related to the increase of fair value of warrants for the second quarter of 2015 was $3.9 million.

Conference Call

Synthetic Biologics will hold a conference call today, Wednesday, August 3, 2016, at 4:30 p.m. EDT. The dial-in information for the call is as follows: U.S. toll free: 1-888-347-5280 and 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/1096/16339. An archive of the conference call will be available for approximately 90 days at the same URL, https://www.webcaster4.com/Webcast/Page/1096/16339, beginning approximately one hour after the call's conclusion.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a clinical stage company developing therapeutics to protect the gut microbiome while targeting pathogen-specific diseases. The Company's lead product candidates in Phase 2 development are: (1) 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), and (2) SYN-004 (ribaxamase) which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. difficile* infection, antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms. The Company is also developing preclinical stage monoclonal antibody therapies for the prevention and treatment of pertussis and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU). For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

This press release includes forward-looking statements on Synthetic Biologics' current expectations and projections about future events. 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. These statements are based upon current beliefs, expectations and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and include statements regarding the continued transition from an early-stage clinical development company to a late-stage clinical development company, the continued momentum for Synthetic Biologics' program designed to protect the gut microbiome and prevent CDI, AAD and the emergence of antibiotic resistant organisms, the anticipated announcement of topline results from Synthetic Biologics ongoing Phase 2b proof-of–concept clinical trial of ribaxamase, timing and design of a planned Phase 2b/3 pivotal clinical trial and the results to be achieved from the products. 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 substantial risks and uncertainties, many of which are difficult to predict and could cause actual results to differ materially and adversely from current expectations and assumptions from those set forth, projected 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, the ability of Synthetic Biologics to successfully design protocols and statistical analysis plans to support the execution of its trials, 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 that was filed with the U.S. Securities and Exchange Commission (SEC) on March 10, 2016, 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 revise or 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)

Condensed Consolidated Balance Sheets

	June 30, 2016 *(Unaudited)*	December 31, 2015 *(Audited)*
Assets		
Cash and cash equivalents	$ 10,049	$ 20,818
Prepaid expenses and other current assets	5,774	9,519
Property and equipment, net	482	494
Deposits and other assets	26	14
Total Assets	$ 16,331	$ 30,845
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities	$ 15,173	$ 15,575
Synthetic Biologics, Inc. and subsidiaries equity (deficit)	2,294	16,051
Total Liabilities and Stockholders' Equity (Deficit)	$ 16,331	$ 30,845

Condensed Consolidated Statements of Operations

	For the three months ended June 30, *(Unaudited)*		For the six months ended June 30, *(Unaudited)*	
	2016	**2015**	**2016**	**2015**
Operating Costs and Expenses				
General and administrative	$ 2,147	$ 2,222	$ 4,573	$ 3,935
Research and development	7,164	7,508	15,319	14,002
Total Operating Costs and Expenses	9,311	9,730	19,892	17,937
Loss from Operations	(9,311)	(9,730)	(19,892)	(17,937)
Other Income (Expense)				

Change in fair value of warrant liability	3,513	(3,895)	3,015	(8,047)
Interest income	34	2	35	3
Total Other Income (Expense), net	3,547	(3,893)	3,050	(8,044)
Net Loss	(5,764)	(13,623)	(16,842)	(25,981)
Net Loss Attributable to Non-controlling Interest	(82)	-	(315)	-
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (5,682)	$ (13,623)	$ (16,527)	$ (25,981)
Net Loss Per Share - Basic	$ (0.06)	$ (0.19)	$ (0.18)	$ (0.36)
Net Loss Per Share - Dilutive	$ (0.10)	$ (0.19)	$ (0.21)	$ (0.36)
Weighted average number of common shares outstanding - Basic	91,015,733	72,736,829	90,921,243	72,674,650
Weighted average number of common shares outstanding - Dilutive	93,930,540	72,736,829	92,651,215	72,674,650

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/synthetic-biologics-reports-second-quarter-2016-operational-highlights-and-financial-results-300308721.html

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