May 5, 2016

Synthetic Biologics Reports First Quarter 2016 Operational Highlights and Financial Results

-- Positioned to Initiate Phase 3 Clinical Trial for SYN-010 for the Treatment of Irritable Bowel Syndrome with Constipation (IBS-C) in 2H 2016 --

-- Two SYN-010 Posters Scheduled for Presentation at Digestive Disease Week (DDW 2016), Including Additional Positive Results from Two Phase 2 Clinical Trials --

-- Conference Call Today, May 5, 2016, at 4:30 p.m. (EDT) --

ROCKVILLE, Md., May 5, 2016 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE MKT: SYN), a clinical stage company focused on developing therapeutics to protect the gut microbiome, today provided an operational update and reported financial results for the three months ended March 31, 2016.

"Our momentum from 2015 carried into the first quarter of 2016, as we continued to make important clinical progress in our microbiome-focused programs. During the quarter, we announced positive topline results from the second Phase 2 clinical trial of SYN-010 in patients with IBS-C. We are scheduled to present detailed data supporting previously

reported positive topline data from both SYN-010 Phase 2 clinical trials in a poster presentation at DDW 2016 later this month. We also look forward to holding an end of Phase 2 meeting with the FDA this summer to discuss late-stage clinical trials of our SYN-010 program," said Jeffrey Riley, President and Chief Executive Officer of Synthetic Biologics. "With this sustained progress, we are well positioned to initiate Phase 3 clinical trials of SYN-010 during the second half of this year."

Mr. Riley continued, "We've also made important strides with our program to prevent*C. difficile* infection and antibiotic-associated diarrhea. Patient enrollment is complete in the second Phase 2a clinical trial designed to evaluate the GI antibiotic-degrading ability and the safety of SYN-004 in the presence of a proton pump inhibitor. In addition, patient recruitment in our Phase 2b proof-of-concept clinical trial for SYN-004 has been strong as we have enrolled approximately 185 patients in this global clinical trial. We look forward to further progress in our SYN-004 clinical trials and are expecting topline results from the second Phase 2a clinical trial during the second quarter of 2016 and an interim analysis of blinded data performed by an independent data monitoring committee for the Phase 2b clinical trial this summer."

Microbiome-Focused Clinical Program Progress

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

- Plan to initiate Phase 3 clinical trial(s) (2H 2016)
- Intend to hold an end of Phase 2 meeting with FDA (Summer 2016)
- Mark Pimentel, MD, FRCP(C), Director of the GI Motility Program and Laboratory at Cedars-Sinai, scheduled to present detailed data supporting previously reported positive topline data from two Phase 2 clinical trials in a poster presentation at DDW 2016 (May 2016)
- Reported positive topline data from second Phase 2 clinical trial – 8-week open-label treatment of all patients with SYN-010 (42 mg) (1Q 2016), including:
    - A statistically significant decrease in methane production ($p=0.002$) from the beginning of the first Phase 2 clinical trial to the end of the second Phase 2 clinical trial, meeting the primary endpoint
    - A statistically significant reduction in the mean IBS Symptom Severity Score (IBS-SSS; $p<0.0001$), which includes abdominal pain, bloating, stool frequency and quality of life scores, was observed for all patients from baseline of the first Phase 2 randomized clinical trial to the end of the second Phase 2 open-label clinical trial
    - An increase in the percentage of patients identified as Monthly Responders, an FDA-defined composite measure incorporating improvements in complete spontaneous bowel movements and abdominal pain[i]
    - No serious adverse events were observed
- Received Type C meeting responses from FDA regarding late-stage aspects of clinical pathway (2Q 2016)

SYN-004 – Prevention of *C. difficile* infection (CDI), antibiotic-associated diarrhea (AAD) and emergence of antibiotic-resistant organisms:

- Plan to initiate Phase 3 clinical trial(s) (1H 2017)
- Continued enrollment in Phase 2b proof-of-concept clinical trial
    - Intended to evaluate the ability of SYN-004 to prevent CDI,*C. difficile*-associated diarrhea (CDAD) and AAD in patients hospitalized with a lower respiratory tract infection and receiving intravenous (IV) ceftriaxone
    - A randomized, placebo-controlled clinical trial designed to enroll up to ~370 patients at up to 75 global clinical sites
    - Enrolled approximately 185 patients across global sites to date
    - Anticipate an interim analysis of blinded data performed by an independent data monitoring committee (Summer 2016)
- Completed enrollment in second Phase 2a clinical trial
    - Intended to evaluate the GI antibiotic-degrading ability and safety of SYN-004 in the presence of the proton pump inhibitor (PPI), esomeprazole, in healthy participants with functioning ileostomies
    - Anticipate reporting topline results (2Q 2016)

Quarter Ended March 31, 2016 Financial Results

General and administrative expenses were $2.4 million for the three months ended March 31, 2016, compared to $1.7 million for the same period in 2015. This increase was primarily the result of increased employee costs associated with the transition of the administrative and financial office to Maryland headquarters, and increased legal fees and stock-based compensation expense. Non-cash charges related to stock-based compensation were $643,000 for the three months ended March 31, 2016, compared to $582,000 for the same period in 2015.

Research and development expenses were $8.2 million for the three months ended March 31, 2016, compared to $6.5 million for the same period in 2015. This increase was primarily the result of increased Phase 2 program costs associated with expanded clinical development, manufacturing and research activities within our microbiome-focused pipeline. Non-cash charges related to stock-based compensation were $409,000 for the three months ended March 31, 2016, compared to $246,000 for the same period in 2015.

Other expense was $497,000 for the three months ended March 31, 2016, compared to $4.2 million for the same period in 2015. Other expense for the three months ended March 31, 2016 was due to non-cash expense of $498,000 from the change in fair value of warrants. The increase in the fair value of the warrants was due to the increase in the stock price from the year ended December 31, 2015. Non-cash expense related to fair value of warrants for the three months ended March 31, 2015 was $4.2 million.

Cash and cash equivalents at March 31, 2016 were $15.1 million, compared to $20.8 million at December 31, 2015.

Conference Call

Synthetic Biologics will hold a conference call today, Thursday, May 5, 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 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/1096/14380. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/14380, for 90 days after the call.

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 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 (CDI) and antibiotic-associated diarrhea (AAD). In collaboration with Intrexon Corporation, 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 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 expected initiation of Phase 3 clinical trials for SYN-010 and SYN-004 and the timing of the initiation, the reporting of additional data supporting the previously reported positive topline data from both Phase 2 clinical trials of SYN-010 at DDW, the reporting of progress in the two ongoing Phase 2 clinical trials for SYN-004, holding an end of Phase 2 meeting with the FDA regarding SYN-010, continued enrollment in Phase 2b proof-of-concept clinical trial for SYN-004 which is anticipated to enroll up to 370 patients at up to 75 global sites, anticipated interim analysis of blinded data form the Phase 2b trial this summer by an independent data monitoring committee, anticipated reporting of topline results from the second Phase 2a clinical trial of SYN-004 in the second quarter of 2016 and the potential benefits of SYN-004 and SYN-010. 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, 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

	March 31, 2016	December 31, 2015
	(unaudited)	
Assets		
Cash and cash equivalents	$ 15,100	$ 20,818
Prepaid expenses and other current assets	7,116	9,519
Property and equipment, net	501	494
Deposits and other assets	26	14
Total Assets	**$ 22,743**	**$ 30,845**
Liabilities and Stockholders' Equity		
Current liabilities	$ 17,526	$ 15,575
Long-term deferred rent	240	267
Total stockholders' equity	4,977	15,003
Total Liabilities and Stockholders' Equity	**$ 22,743**	**$ 30,845**

Condensed Consolidated Statements of Operations

	For the three months ended March 31,	
	2016	2015
	(unaudited)	
Operating Costs and Expenses		
General and administrative	$ 2,426	$ 1,713
Research and development	8,155	6,494
Total Operating Costs and Expenses	10,581	8,207
Loss from Operations	(10,581)	(8,207)
Other Income (Expense)		
Change in fair value of warrant liability	(498)	(4,152)
Interest income	1	1
Total Other Expense, net	(497)	(4,151)
Net Loss	(11,078)	(12,358)
Net Loss Attributable to Non-controlling Interest	(233)	-
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	**$ (10,845)**	**$ (12,358)**

Net Loss Per Share - Basic and Dilutive	**$ (0.12)**	**$ (0.17)**
Weighted average number of common shares outstanding during the period - Basic and Dilutive	90,826,752	72,673,959

[i] A Monthly Responder is defined as a patient who has a Weekly Response in at least 50% of the weeks of treatment during the month. A Weekly Responder is defined as a patient who experiences a decrease in weekly average score for worst abdominal pain in the past 24 hours of at least 30% compared with Study 1 Baseline and a stool frequency increase of 1 or more CSBM per week compared with Study 1 Baseline.

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/synthetic-biologics-reports-first-quarter-2016-operational-highlights-and-financial-results-300264009.html

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