March 2, 2017

Synthetic Biologics Reports 2016 Year End Operational Highlights and Financial Results

-- Company Highlights Clinical Successes of Late-stage Microbiome-focused Programs, Plans for Phase 3 Development --

-- Conference Call Today, March 2, 2017, at 4:30 p.m. (EST) --

ROCKVILLE, Md., March 2, 2017 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE MKT: SYN), a late-stage clinical company developing therapeutics that preserve the microbiome to protect and restore the health of patients, today provided a clinical programs update and reported financial results for the year ended December 31, 2016.

"2016 was a transformative and momentum-building year for Synthetic Biologics," said Jeffrey Riley, President and Chief Executive Officer. "In the past 12 months, we announced positive proof-of-concept clinical results for our lead microbiome-focused programs representing significant milestones for our company. Most recently, we announced positive topline results from ribaxamase's global Phase 2b proof-of-concept clinical trial which achieved its primary endpoint by demonstrating a statistically significant reduction in the incidence of primary *C. difficile* infection (CDI) compared to placebo, positioning ribaxamase as a vanguard amongst microbiome-based therapeutics pursuing clinical development for this indication in Phase 2 trials or later. Data from this study also demonstrated that ribaxamase significantly reduced the incidence of new colonization by

vancomycin-resistant enterococci (VRE) compared to placebo, potentially expanding the utility of our compound as a first line of defense against the development of antimicrobial resistance (AMR) in the gut microbiome. We believe ribaxamase may represent a disruptive yet simple approach to antibiotic therapy that may directly lead to more effective and efficient use of antibiotics."

Mr. Riley continued, "In 2017, we will look to build upon the progress of the last year and are focused squarely on achieving the important value-building milestones that lie ahead. Toward that end, we expect to share additional results in the coming months from several exploratory endpoints from our Phase 2b study focused on ribaxamase's ability to prevent the emergence of antimicrobial resistance in the gut microbiome. We will also be focused on continuing the clinical advancement of SYN-010 for the treatment of IBS-C, with our goal of initiating the Phase 2b/3 pivotal clinical trial later this year."

Microbiome-Focused Clinical Program Progress

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

- Awarded research contract from the Centers for Disease Control and Prevention (CDC) to support research from Phase 2b clinical trial to determine ribaxamase's ability to prevent the emergence of antibiotic-mediated antimicrobial resistance (AMR) in the gut microbiome (4Q 2016)
- Reported positive topline data from global Phase 2b proof-of-concept randomized, double-blind, placebo controlled clinical trial of 412 patients (1Q 2017)
    - Achieved primary endpoint, demonstrating a statistically significant relative risk reduction of 71.4% (p=0.045) in CDI rates versus placebo
    - Demonstrated a significant reduction in new colonization by vancomycin-resistant enterococci (VRE) for patients receiving ribaxamase versus placebo (p-value=0.0002)
    - Demonstrated a positive trend (p-value=0.13) towards reducing the incidence of antibiotic- associated diarrhea (AAD) from all causes versus placebo
- Expect to share results from several exploratory endpoints designed to evaluate ribaxamase's ability to protect the gut microbiome from opportunistic bacteria and prevent the emergence of antimicrobial resistance (AMR) in the gut microbiome (1H 2017)
- Anticipate requesting end of Phase 2 meeting with FDA (2H 2017)
- Expect to initiate Phase 3 clinical trial(s) (1H 2018)

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

- Confirmed key elements of Pivotal Phase 2b/3 clinical trial pursuant to consultations with the FDA (1Q 2017)
    - A 12-week, multi-center, double-blind, placebo-controlled, adaptive design clinical trial
    - A study population of approximately 840 adult subjects diagnosed with IBS-C
    - Evaluation of efficacy and safety of two dose strengths of SYN-010 (21 mg and 42 mg) compared to placebo
    - Conducted in approximately 150 clinical sites in North America

    - Study subjects will be randomized in a 1:1:1 ratio, receiving either 21 mg of SYN-010, 42 mg of SYN-010, or placebo
    - Enrollment is open to all IBS-C patients; breath-methane will be measured at baseline to ensure a comparable ratio of high-to-low breath methane IBS-C patients in each treatment arm
    - An interim futility analysis may be conducted when approximately 50% of patients in each dosing arm have completed treatment
- Plan to initiate first Phase 2b/3 adaptive pivotal clinical trial (2017)

Operational Update

- Reinforced balance sheet with net proceeds of $23.3 million from November 2016 public offering to support the continued clinical development of SYN-010, including initiation of a planned Phase 2b/3 adaptive pivotal clinical trial

Year Ended December 31, 2016 Financial Results

General and administrative expenses were $10.1 million for the year ended December 31, 2016, compared to $8.1 million for the same period in 2015. This increase is primarily the result of bank and legal fees related to the November 2016 financing associated with the warrant liability, increased employee costs, costs associated with the transition of the administrative and financial office to our Maryland headquarters, and an increase in stock-based compensation. Non-cash charges related to stock-based compensation were $2.4 million for the year ended December 31, 2016, compared to $2.1 million for the same period in 2015.

Research and development expenses decreased to $29.1 million for the year ended December 31, 2016, from $32.9 million for the same period in 2015. This decrease is primarily the result of decreased program costs associated with clinical development programs and research activities within our pathogen-specific microbiome-focused pipeline, including our IBS-C and Pertussis programs offset by an increase in *C. difficile* program costs and an increase in manufacturing costs. In 2015, we entered into an ECC with Intrexon Corporation for the development of a treatment for patients with PKU. Pursuant to the ECC, we issued 937,500 shares of our common stock in August 2015 to Intrexon Corporation as payment for the technology access fee that resulted in a non-cash charge of $3.0 million. Research and development expenses for 2015 also include a $1.0 million non-cash expense for achieving the third milestone as set forth in the Asset Purchase Agreement with Prev ABR LLC, dated November 28, 2012. Prev ABR LLC exercised its option to receive the milestone payment in shares of our common stock that were issued in April 2015. Research and development expenses also include a charge relating to non-cash stock-based compensation expense of $1.6 million for the year ended December 31, 2016, compared to $1.1 million for the year ended December 31, 2015.

Other income was $11.4 million for the year ended December 31, 2016, compared to other expense of $3.8 million for the same period in 2015. Other income for the year ended December 31, 2016 is primarily due to non-cash income of $11.4 million from the change in fair value of warrants. The decrease in the fair value of warrants was due to the decrease in our stock price from the year ended December 31, 2015.

Cash and cash equivalents on December 31, 2016 were $19.1 million, a decrease of $1.8 million from December 31, 2015.

Conference Call

Synthetic Biologics will hold a conference call today, Thursday, March 2, 2017, 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/1096/19873. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/19873, for 90 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a late-stage clinical company developing therapeutics designed to preserve the microbiome to protect and restore the health of patients. The Company's lead candidates poised for Phase 3 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 (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antimicrobial resistance (AMR). 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 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 belief that ribaxamase may represent a disruptive yet simple approach to antibiotic therapy that may directly lead to more effective and efficient use of antibiotics, the reporting of additional results in the coming months from several exploratory endpoints from our Phase 2b study focused on ribaxamase's ability to prevent the emergence of antimicrobial resistance in the gut microbiome, anticipated request of an end of Phase 2 meeting with FDA for SYN-004 and the timing of the request, expected initiation of Phase 3 clinical trials for SYN-004 and the initiation of the first Phase 2b/3 adaptive pivotal clinical trial for SYN-010 and the timing of the initiation, 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 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-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 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)

Condensed Consolidated Balance Sheets

	December 31,	
	2016	**2015**
Assets		
Cash and cash equivalents	$ 19,055	$ 20,818
Prepaid expenses and other current assets	2,515	9,519
Property and equipment, net	905	494
Deposits and other assets	23	14
Total Assets	$ 22,498	$ 30,845
Liabilities and Equity		
Current liabilities	$ 19,757	$ 15,575
Long-term deferred rent	492	267
Total stockholders' equity	2,249	15,842
Total Liabilities and Stockholders' Equity	$ 22,498	$ 30,845

Condensed Consolidated Statements of Operations

	For the years ended December 31,	
	2016	**2015**
Operating Costs and Expenses		
General and administrative	$ 10,143	$ 8,074
Research and development	29,109	32,906
Total Operating Costs and Expenses	39,252	40,980
Loss from Operations	(39,252)	(40,980)
Other Income (Expense)		
Change in fair value of warrant liability	11,412	(3,811)

Interest income	37	6
Other income (expense)	-	-
Total Other Income (Expense), net	11,449	(3,805)
Net Loss	(27,803)	(44,785)
Net Loss Attributable to Non-controlling Interest	(548)	(1,048)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (27,255)	$ (43,737)
Net Loss Per Share - Basic and Dilutive	$ (0.29)	$ (0.54)
Weighted average number of common shares outstanding - Basic and Dilutive	94,290,436	80,705,692

To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/synthetic-biologics-reports-2016-year-end-operational-highlights-and-financial-results-300417273.html

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