

March 10, 2016



Synthetic Biologics Reports 2015 Year End Operational Highlights and Financial Results

-- Reported Positive Topline Data from Phase 2 Clinical Trials of SYN-010 for Irritable Bowel Syndrome with Constipation and SYN-004 for Prevention of C. difficile Infection and Antibiotic-Associated Diarrhea --

-- Expect to Initiate Phase 3 Clinical Trials in 2016 --

-- Conference Call Today, March 10, 2016, at 4:30 p.m. (EST) --

ROCKVILLE, Md., March 10, 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 year ended December 31, 2015.



"2015 was a milestone year for Synthetic Biologics. We made important clinical progress in our lead microbiome-focused programs, including the announcement of positive topline results from the second Phase 2 clinical trial for SYN-010 which demonstrated statistical significance in both primary and secondary endpoints in patients suffering from irritable bowel syndrome with constipation (IBS-C)," said Jeffrey Riley, President and Chief Executive Officer Synthetic Biologics. "We also reported positive topline results from the first Phase 2a clinical trial demonstrating that SYN-004 successfully degraded residual

intravenous (IV) ceftriaxone in study participants without affecting the intended level of antibiotic in the bloodstream."

Mr. Riley concluded, "We anticipate continued momentum in the clinic during 2016 and look forward to reporting progress in two ongoing Phase 2 clinical trials for SYN-004, including topline data from the second Phase 2a clinical trial and an interim analysis of blinded data by an independent monitor committee for the Phase 2b proof-of-concept global study in the first half of 2016. Of significant importance during 2016 is scheduling an end of Phase 2 meeting with the FDA regarding the SYN-010 IBS-C program, and our plans to initiate Phase 3 clinical trials during the second half of the year."

Microbiome-Focused Clinical Program Progress

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

- Expect to initiate Phase 3 clinical trial(s) (2H 2016)
- Anticipate requesting end of Phase 2 meeting with FDA (Summer 2016)
- Reported positive topline data from second Phase 2 clinical trial – 8-week extension study (1Q 2016)
 - All patients who completed the second study showed a statistically significant decrease in methane production ($p=0.002$) from the beginning of the first Phase 2 study (Study 1 baseline; Day 1) to the end of the second Phase 2 study (12 weeks of treatment; Day 84), thus meeting the study's primary endpoint
 - Topline data also showed improvements in secondary efficacy endpoints, including:
 - 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 Study 1 baseline to the end of the second Phase 2 study
 - 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 pain¹
 - No serious adverse events were observed
- Reported positive topline data from first Phase 2 clinical trial – 4-week acute study (4Q 2015)
 - SYN-010 met its primary endpoint of lowering breath methane compared to baseline in breath methane-positive IBS-C patients
 - Improvement in clinical outcomes including stool frequency and weekly abdominal pain

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

- Expect to initiate Phase 3 clinical trial(s) (2H 2016)
- Continued enrollment in Phase 2b proof-of-concept clinical trial
 - Intended to evaluate the effectiveness of SYN-004 to prevent CDI, *C. difficile*-

- associated diarrhea (CDAD) and AAD in patients hospitalized with a lower respiratory tract infection and receiving ceftriaxone for at least 5 days
- Anticipate enrolling approximately 370 patients at up to 75 global sites
- Anticipate an interim analysis of blinded data by an independent monitor committee (1H 2016)
- Continued enrollment in second Phase 2a clinical trial
 - Intended to evaluate the IV antibiotic-degrading effects 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 (1H 2016)
- Reported positive topline data from first Phase 2a clinical trial (4Q 2015)
 - SYN-004 successfully degraded residual IV ceftriaxone in the chyme of ten patients with functioning ileostomies without affecting the intended level of IV ceftriaxone in the bloodstream

Year Ended December 31, 2015 Financial Results

General and administrative expenses were \$8.1 million for the year ended December 31, 2015, compared to \$6.0 million for the same period in 2014. This increase was primarily the result of increased employee costs, audit fees related to additional procedures required under the accelerated filer status, legal fees associated with SEC filings and collaborative agreements, and stock-based compensation expense. Non-cash charges related to stock-based compensation were \$2.1 million for the year ended December 31, 2015, compared to \$1.6 million for the same period in 2014.

Research and development expenses increased to \$32.9 million for the year ended December 31, 2015, from \$14.5 million for the same period in 2014. This increase of 127% was primarily the result of increased program costs associated with expanded clinical development, manufacturing and research activities within our microbiome-focused pipeline, including the Company's Phase 2 *C. difficile* and IBS-C clinical programs. In August 2015, Synthetic Biologics entered into an Exclusive Channel Collaboration (ECC) with Intrexon Corporation for the development of a treatment for patients with phenylketonuria (PKU) and issued 937,500 shares of common stock to Intrexon as payment of the technology access fee, which resulted in a non-cash charge of \$3.0 million. Research and development expenses also included a \$1.0 million non-cash expense for achieving the third milestone set forth in the Prev ABR LLC agreement with regard to the Company's *C. difficile* program. Non-cash charges related to stock-based compensation were \$1.1 million for the year ended December 31, 2015, compared to \$803,000 for the same period in 2014.

Other income was \$3.8 million for the year ended December 31, 2015, compared to other income of \$718,000 for the same period in 2014. Other expense for the year ended December 31, 2015 was primarily due to non-cash expense of \$3.8 million from the change in fair value of warrants. The increase in fair value of the warrants was due to the increase in our stock price from the year ended December 31, 2014.

Cash at December 31, 2015 was \$20.8 million compared to \$17.5 million at December 31, 2014.

Conference Call

Synthetic Biologics will hold a conference call today, Thursday, March 10, 2016, 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/1096/13874>. An archive of the call will be available for replay at the same URL, <https://www.webcaster4.com/Webcast/Page/1096/13874>, for 60 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a clinical stage company developing therapeutics to protect the microbiome while targeting pathogen-specific diseases. The Company's lead 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) antibiotics for the prevention of *C. difficile* infection and antibiotic-associated diarrhea (AAD). In collaboration with Intrexon Corporation (NYSE: XON), the Company is also developing preclinical stage monoclonal antibody therapies for the prevention and treatment of Pertussis and 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 expected initiation of Phase 3 clinical trials for SYN-010 and SYN-004 and the timing of the initiation, the anticipated continued momentum in the clinic during 2016, the reporting of progress in the two ongoing Phase 2 clinical trials for SYN-004, the scheduling of an end of Phase 2 meeting with the FDA regarding SYN-010, continued enrollment in Phase 2b proof-of-concept clinical trial for SYN-010, anticipated enrollment of 370 patients at up to 75 global sites, anticipated interim analysis of blinded data by an independent monitor committee in the first half of 2016, continued enrollment in the second Phase 2a clinical trial of SYN-004, anticipated reporting of topline results from the Phase 2a clinical trial of SYN-004 in the first half of 2016 and the potential benefits of SYN-004 and SYN-010. These forward-looking statements are based 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,	
	2015	2014
Assets		
Cash and cash equivalents	\$ 20,818	\$ 17,525
Prepaid expenses and other current assets	9,519	1,548
Property and equipment, net	494	65
Deposits and other assets	14	6
Total Assets	\$ 30,845	\$ 19,144
Liabilities and Equity		
Current liabilities	\$ 15,575	\$ 9,588
Long-term deferred rent	267	-
Total stockholders' equity	15,003	9,556
Total Liabilities and Stockholders' Equity	\$ 30,845	\$ 19,144

Condensed Consolidated Statements of Operations

	For the years ended December 31,	
	2015	2014
Operating Costs and Expenses		
General and administrative	\$ 8,074	\$ 6,013
Research and development	32,906	14,489
Total Operating Costs and Expenses	40,980	20,502
Loss from Operations	(40,980)	(20,502)
Other Income (Expense)		
Change in fair value of warrant liability	(3,811)	620
Interest income	6	3
Other income (expense)	-	95
Total Other Income (Expense), net	(3,805)	718
Net Loss	(44,785)	(19,784)
Net Loss Attributable to Non-controlling Interest	(1,048)	-
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	\$ (43,737)	\$ (19,784)
Net Loss Per Share - Basic and Dilutive	\$ (0.54)	\$ (0.32)

Weighted average number of common shares outstanding - Basic and Dilutive	<u>80,705,692</u>	<u>61,945,356</u>
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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-2015-year-end-operational-highlights-and-financial-results-300234362.html>

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