

November 1, 2016



# Synthetic Biologics Reports Third Quarter 2016 Operational Highlights and Financial Results

**-- Completed Enrollment of Phase 2b Proof-of-Concept Clinical Trial for the Prevention of C. difficile Infection (CDI), Antibiotic-Associated Diarrhea (AAD) and the Emergence of Antibiotic-Resistant Organisms --**

**-- Awarded Research Contract from Centers for Disease Control and Prevention to Determine SYN-004's (ribaxamase) Ability to Prevent Antibiotic-Resistance in the Gut Microbiome --**

**-- Conference Call Today, November 1, 2016, at 8:30 a.m. EDT --**

ROCKVILLE, Md., Nov. 1, 2016 /PRNewswire/ --[Synthetic Biologics, Inc.](#) (NYSE MKT: SYN), a late-stage clinical company developing therapeutics focused on the gut microbiome, provided an operational update and reported financial results for the three months ended September 30, 2016.



"Clinical progress for our two lead gut microbiome-focused drug candidates represent critical milestones for the company as we continue our evolution from an early-stage development company to a late-stage clinical development company focused on commercialization," said Jeffrey Riley, President and Chief Executive Officer of Synthetic Biologics. "During the third quarter, we completed enrollment in our Phase 2b proof-of-concept clinical trial to evaluate the ability of ribaxamase to protect the gut microbiome from the effects of certain commonly

used intravenous beta-lactam antibiotics for the prevention of *C. difficile* infection (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms. We were also the only commercial company pursuing drug development to receive a government contract from the Centers for Disease Control and Prevention to investigate antimicrobial resistance. This grant will support our clinical research aimed at determining whether ribaxamase may prevent antibiotic-mediated microbial resistance in the gut microbiomes of participants in our Phase 2b study. We look forward to sharing top-line results from this trial during the first quarter of 2017."

Mr. Riley continued, "SYN-010, our therapeutic designed to reduce methane in the gut and treat the underlying cause of irritable bowel syndrome with constipation (IBS-C), continues its rapid clinical progress. We held a held an End of Phase 2 meeting with the FDA to determine the optimal clinical pathway to advance SYN-010 into pivotal trials. We continue to collaborate with the FDA and are developing a protocol for our Phase 2b/3 adaptive clinical study which we plan to initiate during the first quarter of 2017."

### **Clinical Program Progress**

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

- Completed enrollment in global Phase 2b placebo-controlled, proof-of-concept clinical trial intended to evaluate the ability of ribaxamase to prevent CDI, *C. difficile*-associated diarrhea (CDAD), AAD and the emergence of antibiotic-resistant organisms in patients hospitalized with a lower respiratory tract infection and receiving intravenous (IV) ceftriaxone
  - Enrolled 413 patients across global clinical sites
  - Anticipate announcing topline results from Phase 2b proof-of-concept clinical trial (1Q 2017)
- Awarded government contract from the Centers for Disease Control and Prevention to determine SYN-004's ability to prevent the emergence of antibiotic-resistant organisms in the gut microbiome of patients enrolled in the Company's Phase 2b proof-of-concept clinical trial

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

- Held End of Phase 2 meeting with FDA and received guidance for clinical study design and requirements for Phase 3 development
- Submitted Phase 2b/3 adaptive study protocol and corresponding statistical analysis plan to FDA for first pivotal clinical trial (3Q 2016)
- Plan to initiate Phase 2b/3 pivotal clinical trial (1Q 2017)

### **Third Quarter 2016 Financial Results**

General and administrative expenses increased to \$2.1 million for the third quarter of 2016, from \$1.6 million for the third quarter of 2015. This increase is primarily the result of increased stock-based compensation, investor relations expenses and employee salaries and benefits costs offset by lower consulting and legal expenses. The charge related to stock-based compensation expense was \$524,000 for the third quarter of 2016, compared to \$387,000 for the third quarter of 2015.

Research and development expenses decreased to \$7.0 million for the third quarter of 2016, from \$10.0 million for the third quarter of 2015. This decrease is primarily the result of charges related to our Exclusive Channel Collaboration (ECC) agreement with Intrexon that we entered into in August 2015. In 2015, we issued 937,500 shares of our common stock to Intrexon as payment of the technology access fee that resulted in a non-cash charge of \$3.0 million for the third quarter of 2015. Research and development expenses also include a charge related to non-cash stock-based compensation expense of \$422,000 for the third quarter of 2016, compared to \$259,000 for the same period last year.

Other income was \$0.7 million for the third quarter of 2016, compared to other income of \$4.1 million for the third quarter of 2015. Other income for the third quarter of 2016 is due to non-cash income of \$0.7 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 prior quarter. Non-cash income related to the decrease of fair value of warrants for the third quarter of 2015 was \$4.1 million.

Cash and cash equivalents as of September 30, 2016 were \$4.5 million.

### **Conference Call**

Synthetic Biologics will hold a conference call today, Tuesday, November 1, 2016, at 8:30 a.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/1096/17818>. An archive of the call will be available for approximately 90 days at the same URL <https://www.webcaster4.com/Webcast/Page/1096/17818>, beginning approximately one hour after the call's conclusion.

### **About Synthetic Biologics, Inc.**

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a late-stage clinical company developing therapeutics focused on the gut microbiome. 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, 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](http://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 collaboration with FDA for SYN-010, the anticipated announcement of topline results from Synthetic Biologics' ongoing Phase 2b proof-of-concept clinical trial, 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 -

<b>Synthetic Biologics, Inc. and Subsidiaries</b>		
<i>(In thousands, except share and per share amounts)</i>		
<b>Condensed Consolidated Balance Sheets</b>		
	<b>September 30, 2016 <i>(Unaudited)</i></b>	<b>December 31, 2015 <i>(Audited)</i></b>
<b>Assets</b>		
Cash and cash equivalents	\$ 4,549	\$ 20,818
Prepaid expenses and other current assets	3,091	9,519
Property and equipment, net	582	494
Deposits and other assets	26	14
<b>Total Assets</b>	<b>\$ 8,248</b>	<b>\$ 30,845</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities	\$ 14,010	\$ 15,575
Long-term deferred rent	214	267
Total stockholders' equity	(5,976)	15,003
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 8,248</b>	<b>\$ 30,845</b>

**Condensed Consolidated Statements of Operations**

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2015	2016	2015
<b>Operating Costs and Expenses</b>				
	\$			
General and administrative	2,095	\$ 1,604	\$ 6,668	\$ 5,539
Research and development	7,061	10,046	22,380	24,048
<b>Total Operating Costs and Expenses</b>	<u>9,156</u>	<u>11,650</u>	<u>29,048</u>	<u>29,587</u>
<b>Loss from Operations</b>	(9,156)	(11,650)	(29,048)	(29,587)
<b>Other Income (Expense)</b>				
Change in fair value of warranty liability	666	4,141	3,681	(3,906)
Interest income	1	2	36	5
<b>Total Other Income (Expense), net</b>	<u>667</u>	<u>4,143</u>	<u>3,717</u>	<u>(3,901)</u>
<b>Net Loss</b>	(8,489)	(7,507)	(25,331)	(33,488)
<b>Net Loss Attributable to Non-controlling Interest</b>	(136)	(773)	(451)	(733)
<b>Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries</b>	<u>\$ (8,353)</u>	<u>\$ (6,774)</u>	<u>\$ (24,880)</u>	<u>\$ (32,775)</u>
<b>Net Loss Per Share - Basic</b>	<u>\$ (0.09)</u>	<u>\$ (0.08)</u>	<u>\$ (0.27)</u>	<u>\$ (0.42)</u>
<b>Net Loss Per Share - Dilutive</b>	<u>\$ (0.09)</u>	<u>\$ (0.12)</u>	<u>\$ (0.27)</u>	<u>\$ (0.42)</u>
<b>Weighted average number of common shares outstanding - Basic</b>	<u>91,441,687</u>	<u>85,974,751</u>	<u>91,095,990</u>	<u>77,300,375</u>
<b>Weighted average number of common shares outstanding - Dilutive</b>	<u>91,441,687</u>	<u>87,585,103</u>	<u>91,095,990</u>	<u>77,300,375</u>

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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/synthetic-biologics-reports-third-quarter-2016-operational-highlights-and-financial-results-300354622.html>

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