

November 1, 2017



# Synthetic Biologics Reports Third Quarter 2017 Operational Highlights and Financial Results

**-- Strengthened Balance Sheet in Support of Microbiome-Focused Clinical Development Programs --**

**-- Held Initial Type-B Multidisciplinary Meeting with FDA to Discuss Late-Stage Clinical Advancement for SYN-004 (ribaxamase) --**

**-- Conference Call Today, November 1, 2017, at 4:30 p.m. EDT --**

ROCKVILLE, Md., Nov. 1, 2017 /PRNewswire/ -- [Synthetic Biologics, Inc.](#) (NYSE American: SYN), a late-stage clinical company developing therapeutics that preserve the microbiome to protect and restore the health of patients, today provided an operational update and reported financial results for the three months ended September 30, 2017.



"During the third quarter, we remained keenly focused on the advancement of our two-lead microbiome-focused clinical programs," said Jeff Riley, President and Chief Executive Officer of Synthetic Biologics. "Following the successful completion of a Phase 2b proof-of-concept clinical study and the announcement of Breakthrough Therapy Designation for SYN-004 (ribaxamase), we held an initial Type-B multidisciplinary meeting with the U.S. Food and Drug Administration (FDA) to discuss the overarching, high-level drug development plan and pathway towards marketing approval for ribaxamase. We look

forward to further collaborative discussions with the FDA on the development of a regulatory pathway forward for this novel approach to preventing the onset of primary *C. difficile* infection and the emergence of antimicrobial resistance."

Mr. Riley continued, "While continuing to focus on our clinical development activities during the third quarter, we also successfully strengthened our balance sheet with the announcement of a privately placed \$12 million convertible preferred stock financing with an affiliate of MSD Partners, L.P. We intend to build upon the momentum of the third quarter and continue to seek to build value for our shareholders as part our transition from an early-stage clinical development company, to a late-stage company focused on the commercialization of our two-promising microbiome-focused drug candidates."

### **Clinical Development & Operational Update**

- Strengthened balance sheet with the closing of a \$12 million privately placed convertible preferred stock financing with an affiliate of MSD Partners, L.P. in support of the continued late-stage advancement of our microbiome-focused clinical programs (3Q 2017)
- Announced additional results from several exploratory endpoints from SYN-004 (ribaxamase) Phase 2b proof-of-concept clinical trial funded under a contract awarded to the Company from the Centers for Disease Control and Prevention (CDC), demonstrating that SYN-004 (ribaxamase) prevented significant change to the presence of certain AMR genes in the gut resistome of patients receiving SYN-004 (ribaxamase) compared to placebo (3Q 2017)
  - Expect to share additional results regarding several exploratory endpoints from Phase 2b proof-of-concept clinical trial designed to evaluate SYN-004's (ribaxamase) ability to protect the gut microbiome from opportunistic bacterial infections and prevent the emergence of antimicrobial resistance (AMR) in the gut microbiome (4Q 2017)
- Held a Type-B multidisciplinary meeting with the FDA to discuss the high-level drug development plan and regulatory pathway towards marketing approval for SYN-004 (ribaxamase) (3Q 2017)
  - Plan to continue collaborative discussions with the FDA to solidify details and components of the drug development plan and regulatory pathway towards marketing approval for SYN-004 (ribaxamase) (1Q 2018)
  - Plan to initiate Phase 3 clinical trial(s) (2018)
- Continue to solidify clinical infrastructure to support successful advancement of SYN-010, designed to treat an underlying cause of the symptoms associated with irritable bowel syndrome with constipation (IBS-C)

### **Third Quarter 2017 Financial Results**

General and administrative expenses decreased by 19% to \$1.7 million for the third

quarter of 2017, from \$2.1 million for the third quarter of 2016. This decrease is primarily the result of higher salary expense and related benefits costs incurred in 2016 in connection with the transition of the administrative and financial office to our Maryland headquarters, along with a reduction of travel, registration fees and legal expenses in 2017. The charge related to stock-based compensation expense was \$583,000 for the third quarter of 2017, compared to \$524,000 for the third quarter of 2016.

Research and development expenses decreased by 41% to \$4.1 million for the third quarter of 2017, from \$7.1 million for the third quarter of 2016. This decrease is primarily the result of lower SYN-004 (ribaxamase) and SYN-010 program costs. In addition, there were reductions in our other research and development activities, offset by an increase in indirect costs for manufacturing and medical affairs. Research and development expenses also include a charge related to stock-based compensation expense of \$317,000 for the third quarter of 2017, compared to \$422,000 for the third quarter of 2016.

Other expense was \$5.1 million for the third quarter of 2017, compared to other income of \$0.7 million for the third quarter of 2016. Other expense for the third quarter of 2017 is primarily comprised of non-cash expense of \$5.1 million from the change in the fair value of warrants. The increase in the fair value of the warrants was due to the increase in our stock price from the prior quarter.

Cash and cash equivalents as of September 30, 2017 were approximately \$21.1 million, an increase of \$2.0 million from December 31, 2016.

### **Conference Call**

Synthetic Biologics will hold a conference call today, Wednesday, November 1, 2017, 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/1096/23123>. An archive of the conference call will be available for approximately 90 days at the same URL, <https://www.webcaster4.com/Webcast/Page/1096/23123> beginning approximately one hour after the call's conclusion.

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

Synthetic Biologics, Inc. (NYSE American: SYN) is a late-stage clinical company developing therapeutics that preserve the microbiome to protect and restore the health of patients. The Company's lead candidates poised for Phase 3 development are: (1) 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), overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR), and (2) 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). 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 expectation of further collaborative discussions with the FDA on the development of a regulatory pathway forward for SYN-004 (ribaxamase), the intent to build upon the momentum of Synthetic Biologics' third quarter and continue to build value for shareholders, Synthetic Biologics' plans to initiate Phase 3 clinical trial(s) in 2018 for SYN-004 (ribaxamase), the expectation of sharing additional results regarding several exploratory endpoints from the SYN-004 Phase 2b proof-of-concept clinical trial, and the expectation of continuing to solidify Synthetic Biologics' clinical infrastructure to support successful advancement of 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, Synthetic Biologics' product candidates demonstrating safety and effectiveness, as well as results that are consistent with prior results, Synthetic Biologics' ability to initiate clinical trials and if initiated, to complete them on time and achieve desired results and benefits, Synthetic Biologics' clinical trials continuing enrollment as expected, Synthetic Biologics' ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Synthetic Biologics' ability to promote or commercialize its product candidates for specific indications, acceptance of its product candidates in the marketplace and the successful development, marketing or sale of Synthetic Biologics' products by competitors that render Synthetic Biologics' products obsolete or non-competitive, Synthetic Biologics' ability to maintain its license agreements, the continued maintenance and growth of Synthetic Biologics' patent estate, Synthetic Biologics becoming and remaining profitable, Synthetic Biologics' ability to establish and maintain collaborations, Synthetic Biologics' ability to obtain or maintain the capital or grants necessary to fund its research and development activities, a loss of any of Synthetic Biologics' key scientists or management personnel, and other factors described in Synthetic Biologics' Annual Report on Form 10-K for the year ended December 31, 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**

	September 30, 2017 (Unaudited)	December 31, 2016 (Audited)
<b>Assets</b>		
Cash and cash equivalents	\$ 21,050	\$ 19,055
Prepaid expenses and other current assets	1,263	2,515
Property and equipment, net	943	905
Deposits and other assets	23	23
<b>Total Assets</b>	<b>\$ 23,279</b>	<b>\$ 22,498</b>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Total liabilities	\$ 17,951	\$ 20,249
Series A Convertible Preferred Stock	11,992	-
Synthetic Biologics, Inc. and subsidiaries equity (deficit)	(6,664)	2,249
<b>Total Liabilities and Stockholders' Equity (Deficit)</b>	<b>\$ 23,279</b>	<b>\$ 22,498</b>

**Condensed Consolidated Statements of Operations**

	For the three months ended September 30, (Unaudited)		For the nine months ended September 30, (Unaudited)	
	2017	2016	2017	2016
<b>Operating Costs and Expenses</b>				
General and administrative	\$ 1,705	\$ 2,095	\$ 5,440	\$ 6,668
Research and development	4,137	7,061	15,028	22,380
<b>Total Operating Costs and Expenses</b>	<b>5,842</b>	<b>9,156</b>	<b>20,468</b>	<b>29,048</b>
<b>Loss from Operations</b>	<b>(5,842)</b>	<b>(9,156)</b>	<b>(20,468)</b>	<b>(29,048)</b>
<b>Other Expense (Income)</b>				
Change in fair value of warrant liability	(5,092)	666	2,157	3,681
Interest income	4	1	7	36
<b>Total Other Expense (Income), net</b>	<b>(5,088)</b>	<b>667</b>	<b>2,164</b>	<b>3,717</b>
<b>Net Loss</b>	<b>(10,930)</b>	<b>(8,489)</b>	<b>(18,304)</b>	<b>(25,331)</b>
<b>Net Loss Attributable to Non-controlling Interest</b>	<b>(8)</b>	<b>(136)</b>	<b>(280)</b>	<b>(451)</b>
<b>Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries</b>	<b>\$ (10,922)</b>	<b>\$ (8,353)</b>	<b>\$ (18,024)</b>	<b>\$ (24,880)</b>
Series A Preferred Stock Dividends	(6,901)	-	(6,901)	-
<b>Net Loss Attributable to Common</b>	<b>\$ (17,823)</b>			

<b>Stockholders</b>		\$ (8,353)	\$ (24,925)	\$ (24,880)
<b>Net Loss Per Share – Basic &amp; Dilutive</b>	\$ (0.14)	\$ (0.09)	\$ (0.20)	\$ (0.27)
<b>Weighted average number of common shares outstanding during the period – Basic &amp; Dilutive</b>	128,279,674	91,441,687	122,950,397	91,095,990

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