

November 8, 2018



# Synthetic Biologics Reports Third Quarter 2018 Operational Highlights and Financial Results

**-- Announced Agreement with Cedars-Sinai Medical Center to Co-fund a Phase 2b Investigator-Sponsored Clinical Study of SYN-010, for the Treatment of IBS-C --**

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

**-- Conference Call Today, November 8, 2018, at 4:30 p.m. (EST) --**

ROCKVILLE, Md., Nov. 8, 2018 /PRNewswire/ -- [Synthetic Biologics, Inc.](#) (NYSE American: SYN), a late-stage clinical company developing therapeutics designed to preserve the microbiome to protect and restore the health of patients, today provided an operational update and reported financial results for the three and nine months ended September 30, 2018.



"During the third quarter, we remained sharply focused on the advancement of our portfolio of microbiome-focused assets," stated Steven A. Shallcross, Interim Chief Executive Officer and Chief Financial Officer. "We were pleased to report the expansion of our relationship with Cedars-Sinai Medical Center and announced a research agreement to co-fund an investigator-sponsored Phase 2b clinical study of SYN-010, our modified-release formulation of lovastatin lactone designed to treat an underlying cause of irritable bowel syndrome with

constipation (IBS-C). In addition to fortifying the well-established clinical data set for SYN-010, we believe results from this study will determine the optimal dose of SYN-010 for future registration studies. During the third quarter we also held an End of Phase 2 meeting with the FDA to define a clear and achievable pathway forward for SYN-004, our first-in-class therapeutic intervention designed to protect the gut microbiome from antibiotic-mediated dysbiosis. We also announced that we are evaluating opportunities that may further unlock the potential of SYN-004 through the pursuit of a second more focused indication in a specialty patient population with multiple potential disease endpoints associated with IV beta-lactam-induced gut microbiome damage, such as allogeneic hematopoietic cell transplant (HCT) recipients. This dual approach may enable us to continue the clinical advancement of SYN-004 in a cost-effective manner while targeting an area of clear unmet need and expanding upon the established data set to further validate SYN-004's use in the broader indication for the prevention of CDI."

Mr. Shallcross continued, "While remaining keenly focused on the execution of our clinical development activities, we also significantly strengthened our balance sheet by raising gross proceeds of approximately \$18.6 million from the closing of a public offering of common stock and Series B convertible preferred stock, as well as net proceeds of approximately \$11.8 million from the utilization of our "at-the-market" facility through October. As a result of these activities, our current cash position to date is approximately \$32 million and should provide ample runway to allow the Company to continue its operations into 2020 as we continue to focus on the achievement of key clinical development milestones for our two-lead assets."

### **Clinical Development and Operational Update**

- Entered into agreement with Cedars-Sinai Medical Center (CSMC) in Q3 2018 to co-fund an investigator-sponsored Phase 2b clinical study of SYN-010 to evaluate SYN-010 dose response and inform Phase 3 clinical development:
  - The Phase 2b clinical study will be conducted out of the Pimentel Laboratory at CSMC and is expected to be comprised of a 12-week, placebo-controlled, double-blind, randomized clinical trial to evaluate two dose strengths of oral SYN-010 (21 mg and 42 mg) in approximately 150 patients diagnosed with IBS-C,
  - Anticipate dosing first patient in the Phase 2b investigator-sponsored clinical study during Q4 2018, contingent upon approval of the clinical study protocol by the Cedars-Sinai Medical Center Institutional Review Board,
  - Anticipate data readout from the Phase 2b investigator-sponsored clinical study during 2H 2019;
- Held End-of-Phase 2 meeting with the FDA to solidify the remaining elements of the SYN-004 (ribaxamase) Phase 3 clinical trial in Q3 2018;
- Clarified market/partner needs and identified potential additional indications for SYN-004 in specialty patient populations such as allogeneic hematopoietic cell transplant patients in 3Q 2018;

- Plan to initiate clinical trial(s) (2H 2019), which may include a broad Phase 3 clinical trial and/or Phase 1/2 clinical trial(s) in a specialty population leading to a subsequent Phase 3 clinical trial;
- Identified three potential clinical indications for SYN-020 (intestinal alkaline phosphatase) in areas of unmet medical need including, enterocolitis associated with radiation therapy, enterocolitis associated with checkpoint inhibitor therapy for cancer, and microscopic colitis in 3Q 2018,
  - Anticipated IND filing during Q4 2019;
- Strengthened balance sheet by raising gross proceeds of approximately \$18.6 million from the closing of a public offering of common stock and Series B convertible preferred stock in support of the continued advancement of our microbiome-focused clinical programs in Q4 2018.

### **Quarter Ended September 30, 2018 Financial Results**

General and administrative expenses decreased by 12% to \$1.5 million for the three months ended September 30, 2018, from \$1.7 million for the three months ended September 30, 2017. This decrease is primarily the result of lower salary expense, stock compensation, and related benefits costs incurred during the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 due to the resignation of the prior Chief Executive Officer, along with the reduction of travel and consulting expense, offset by higher registration, investor relations and legal costs. The charge related to stock-based compensation expense was \$186,000 for the three months ended September 30, 2018, compared to \$583,000 the three months ended September 30, 2017.

Research and development expenses decreased by 32% to \$2.8 million for the three months ended September 30, 2018, from \$4.1 million for the three months ended September 30, 2017. This decrease is primarily the result of lower SYN-004 (ribaxamase) and SYN-010 program costs for the three months ended September 30, 2018 since no clinical trials were ongoing during the quarter. The research and development costs incurred during the quarter were primarily related to planning for future Phase 3 (SYN-004) and Phase 2b/3(SYN-010) clinical programs as we sought to secure the financial resources necessary for the advancement of these clinical trials. The charge related to stock-based compensation expense was \$289,000 for the three months ended September 30, 2018, compared to \$317,000 for the three months ended September 30, 2017.

Other income was \$631,000 for the three months ended September 30, 2018, compared to other expense of \$5.1 million for the three months ended September 30, 2017. Other income for the three months ended September 30, 2018 is primarily comprised of non-cash income of \$626,000 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.

Cash and cash equivalents as of September 30, 2018 totaled \$9.5 million, a decrease of \$7.6 million from December 31, 2017, which does not reflect the proceeds from the sale of our securities during October 2018. During October 2018, we raised gross proceeds of approximately \$18.6 million from the closing of a public offering of common stock and Series B Preferred Stock and received net proceeds of approximately \$5.8 million from sales of our

Common Stock in "at-the-market" equity offerings.

## **Conference Call**

Synthetic Biologics will hold a conference call today, Thursday, November 8, 2018, 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/1096/28046>. An archive of the call will be available for replay at the same URL, <https://www.webcaster4.com/Webcast/Page/1096/28046>, for 90 days after the call.

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

Synthetic Biologics, Inc. (NYSE American: 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-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's preclinical pursuits include an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases as well as 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 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 includes statements regarding our belief that results from the investigator-sponsored Phase 2b clinical study of SYN-010 will determine the optimal dose of SYN-010 for future registration studies, unlocking the potential of SYN-004 through the pursuit of a second more focused indication in a specialty patient population with multiple potential disease endpoints associated with IV beta-lactam-induced gut microbiome damage, such as allogeneic hematopoietic cell transplant (HCT) recipients, the dual approach enabling us to continue the clinical advancement of SYN-004 in a cost-effective manner while targeting an area of clear unmet need and expanding upon the established data set to further validate SYN-004's use in the broader indication for the prevention of CDI, the proceeds raised providing ample runway and allowing us to continue our operations into 2020 as we continue to focus on the achievement of key clinical development milestones for our two-lead assets, anticipated dosing first patient in the Phase 2b investigator sponsored clinical study during Q4 2018, anticipated data readout from the Phase 2b investigator sponsored clinical study during 2H 2019, plan to initiate clinical trial(s) (2H 2019), anticipated IND filing for SYN-020 during Q4 2019; 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, , Synthetic Biologics' ability to establish a path forward to develop SYN-010 and ribaxamase and conduct a robust, controlled and well-designed clinical trial that may provide sufficient efficacy and safety data to support a pathway towards marketing approval for SYN-010 and ribaxamase, Synthetic Biologics' ability to regain compliance with the continued listing standards of the NYSE American by September 2, 2019, Synthetic Biologics' ability to comply with other continued listing requirements of the NYSE American, the ability of its product candidates to demonstrate safety and effectiveness, as well as results that are consistent with prior results, Synthetic Biologics' clinical trials continuing enrollment as expected, a failure to receive the necessary regulatory approvals for commercialization of Synthetic Biologics' therapeutics, including approval of proposed trial designs, 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, Synthetic Biologics' ability to achieve 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, the continued maintenance and growth of Synthetic Biologics' patent estate, Synthetic Biologics becoming and remaining profitable, 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' Form 10-K for the year ended December 31, 2017 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)

**Consolidated Balance Sheets**

	<b>September 30, 2018</b>	<b>December 31, 2017</b>
<b>Assets</b>		
Cash and cash equivalents	\$ 9,549	\$ 17,116
Prepaid expenses and other current assets	599	827
Property and equipment, net	665	872
Deposits and other assets	23	23
<b>Total Assets</b>	<b>\$ 10,796</b>	<b>\$ 18,838</b>
<b>Liabilities and Stockholder's Deficit</b>		
Total liabilities	\$ 4,243	\$ 10,195

Series A Convertible Preferred Stock	12,234	12,053
Synthetic Biologics, Inc. and subsidiaries deficit	(5,681)	(3,410)
<b>Total Liabilities and Stockholders' Deficit</b>	<b>\$ 10,796</b>	<b>\$ 18,838</b>

**Condensed Consolidated Statements of Operations**  
(In thousands except share and per share amounts)

	For the three months ended September 30, (Unaudited)		For the nine months ended September 30, (Unaudited)	
	2018	2017	2018	2017
<b>Operating Costs and Expenses</b>				
General and administrative	\$ 1,474	\$ 1,705	\$ 4,525	\$ 5,440
Research and development	2,846	4,137	9,788	15,028
<b>Total Operating Costs and Expenses</b>	<b>4,320</b>	<b>5,842</b>	<b>14,313</b>	<b>20,468</b>
<b>Loss from Operations</b>	<b>(4,320)</b>	<b>(5,842)</b>	<b>(14,313)</b>	<b>(20,468)</b>
<b>Other Income (Expense)</b>				
Change in fair value of warrant liability	626	(5,092)	4,064	2,157
Interest income	5	4	20	7
<b>Total Other Income (Expense), net</b>	<b>631</b>	<b>(5,088)</b>	<b>4,084</b>	<b>2,164</b>
<b>Net Loss</b>	<b>(3,689)</b>	<b>(10,930)</b>	<b>(10,229)</b>	<b>(18,304)</b>
<b>Net Loss Attributable to Non-controlling Interest</b>	<b>(9)</b>	<b>(8)</b>	<b>(35)</b>	<b>(280)</b>
<b>Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries</b>	<b>\$ (3,680)</b>	<b>\$ (10,922)</b>	<b>\$ (10,194)</b>	<b>\$ (18,024)</b>
<b>Series A Preferred Dividend</b>	<b>(61)</b>	<b>(6,901)</b>	<b>(181)</b>	<b>(6,901)</b>
<b>Net Loss Attributable to Common Stockholders</b>	<b>\$ (3,741)</b>	<b>\$ (17,823)</b>	<b>\$ (10,375)</b>	<b>\$ (24,925)</b>
<b>Net Loss Per Share – Basic and Dilutive</b>	<b>\$ (0.93)</b>	<b>\$ (4.90)</b>	<b>\$ (2.73)</b>	<b>\$ (7.00)</b>
<b>Weighted average number of common shares outstanding - Basic and Diluted</b>	<b>4,028,304</b>	<b>3,665,134</b>	<b>3,802,812</b>	<b>3,512,868</b>

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