

August 3, 2017



Synthetic Biologics Reports Second Quarter 2017 Operational Highlights and Financial Results

-- SYN-004 (ribaxamase) Receives Breakthrough Therapy Designation from FDA for Prevention of CDI --

-- Three Ribaxamase Presentations to be Included at Infectious Disease Week™ (ID Week) 2017 --

-- Conference Call Today, August 3, 2017, at 8:30 a.m. EDT --

ROCKVILLE, Md., Aug. 3, 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 June 30, 2017.



"During the second quarter, we achieved additional and exciting progress for our lead microbiome-focused programs," said Jeff Riley, President and Chief Executive Officer of Synthetic Biologics. "The important momentum generated during the quarter is perhaps best illustrated by the FDA's granting of a Breakthrough Therapy Designation to ribaxamase, the first ever such designation of a drug candidate for the prevention of *Clostridium difficile* infection (CDI). We have submitted a request for a Type-B multidisciplinary meeting with the FDA to discuss potential options to expedite the development and review timelines for ribaxamase's clinical advancement and path towards marketing approval. We look forward to working closely with the FDA on how to best move forward with this novel, complimentary and potentially paradigm-shifting approach which may directly lead to more effective and efficient antibiotic therapy."

Mr. Riley continued, "We also continued to be keenly focused on ensuring we have in place the

optimal timing and path forward for the clinical advancement of SYN-010, our promising candidate for the treatment of irritable bowel syndrome with constipation (IBS-C). In June, we were pleased to announce that the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance for a patent which covers the use of the active agent of SYN-010 to treat constipation until at least 2034, significantly strengthening the opportunity to build long-term value for our shareholders."

Microbiome-Focused Clinical Program Progress

SYN-004 – Prevention of *C. difficile* infection (CDI), overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR):

- Announced that the U.S. Food and Drug Administration (FDA) granted the first-ever Breakthrough Therapy Designation to SYN-004 (ribaxamase) for the prevention of *Clostridium difficile* infection
- Announced additional results from several exploratory endpoints from 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 (Q3 2017)
 - Expect to share additional results from 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 bacteria and prevent the emergence of antimicrobial resistance (AMR) in the gut microbiome (2H 2017)
- Submitted a request for a Type-B multidisciplinary meeting with the FDA to discuss the overarching, high-level drug development plan and pathway towards marketing approval for SYN-004 (ribaxamase) (2H 2017)
- Plan to initiate Phase 3 clinical trial(s) (1H 2018)

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

- Announced that the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance for a patent which covers the use of the active agent of SYN-010 for the treatment of constipation until at least 2034
- Continue to solidify infrastructure to support successful clinical advancement of SYN-010

Synthetic Biologics also announced that five abstracts have been accepted for presentation at Infectious Disease Week 2017™ taking place at the San Diego Convention Center in San Diego, CA from October 4 - 8, 2017. Members of the Synthetic Biologics team will present three posters on SYN-004, and one poster on SYN-006 and SYN-005 at ID Week™.

Infectious Disease Week™ (ID Week)

October 5, 2017

- **Presentation 136:** SYN-004 (ribaxamase) Prevents New Onset *Clostridium difficile* Infection by Protecting the Integrity of the Gut Microbiome in a Phase 2b Study
 - Session 42: The Cutting Edge in Antimicrobial Resistance Emergence Therapy from 10:30 a.m. – 10:45 a.m. CDT
 - Venue: San Diego Convention Center
- **Presentation 86:** Passive Immunization with Anti-Pertussis Toxin Humanized Monoclonal Antibody Mitigates Clinical Signs of Pertussis Infection in Newborn Baboons
 - Session 29: Identification, Treatment, and Prevention of Pediatric Bacterial Pathogens from 9:30 a.m. – 9:45 a.m. CDT
 - Venue: San Diego Convention Center

- **Poster 630:** SYN-006, a Novel Carbapenemase, Intended to Protect the Gut Microbiome from Antibiotic-Mediated Damage May Also Reduce Propagation of Carbapenem-Resistant Pathogens
 - Session: Microbiome from 12:30 p.m. – 2:00 p.m. CDT
 - Venue: San Diego Convention Center Halls CD
- **Poster 633:** Gut Antibiotic Inactivation by Beta-Lactamases Is Intended to Prevent Microbiome Damage and Attenuate Antibiotic Resistance in Large Animal Models
 - Session: Microbiome from 12:30 p.m. – 2:00 p.m. CDT
 - Venue: San Diego Convention Center Halls CD

October 7, 2017

- **Poster 1843:** SYN-004 (ribaxamase) Protects the Diversity of the Gut Microbiome in Patients Receiving Intravenous Ceftriaxone Treatment
 - Session: Clinical Study with New Antibiotics and Antifungals from 12:30 p.m. – 2:00 p.m. CDT
 - Venue: San Diego Convention Center Halls CD

Second Quarter 2017 Financial Results

General and administrative expenses decreased by 23% to \$1.6 million for the second quarter of 2017, from \$2.1 million for the second 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 and legal expenses in 2017. The charge related to stock-based compensation expense was \$539,000 for the second quarter of 2017, compared to \$507,000 for the second quarter of 2016.

Research and development expenses decreased by 33% to \$4.8 million for the second quarter of 2017, from \$7.2 million for the second quarter of 2016. This decrease is primarily the result of lower SYN-004 (ribaxamase) program costs. In addition, there were reductions in our other research and development activities, including our SYN-010 program, offset by an increase in indirect costs for medical affairs. Research and development expenses also include a charge related to stock-based compensation expense of \$331,000 for the second quarter of 2017, compared to \$400,000 for the second quarter of 2016.

Other income was \$2.2 million for the second quarter of 2017, compared to other income of \$3.5 million for the second quarter of 2016. Other income for the second quarter of 2017 is due to non-cash income of \$2.2 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.

Cash and cash equivalents as of June 30, 2017 remained relatively unchanged at \$13.4 million, a small decrease from the prior quarter.

Conference Call

Synthetic Biologics will hold a conference call today, Thursday, August 3, 2017, 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/1096/21899>. An archive of the conference call will be available for approximately 90 days at the same URL, <https://www.webcaster4.com/Webcast/Page/1096/21899>, 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.

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 potentially paradigm shifting approach which may directly lead to more effective and efficient antibiotic therapy, the expected sharing of additional results from several exploratory endpoints from Phase 2b proof-of-concept clinical trial 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, plans to initiate a Phase 3 clinical trial of SYN-004 and the potential and 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, 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

	June 30, 2017 (Unaudited)	December 31, 2016 (Audited)
Assets		
Cash and cash equivalents	\$ 13,376	\$ 19,055
Prepaid expenses and other current assets	1,540	2,515
Property and equipment, net	800	905
Deposits and other assets	24	23
Total Assets	\$ 15,740	\$ 22,498
Liabilities and Stockholders' Equity (Deficit)		
Total liabilities	\$ 12,778	\$ 20,249
Synthetic Biologics, Inc. and subsidiaries equity (deficit)	2,962	2,249
Total Liabilities and Stockholders' Equity (Deficit)	\$ 15,740	\$ 22,498

Condensed Consolidated Statements of Operations

	For the three months ended June 30, (Unaudited)		For the six months ended June 30, (Unaudited)	
	2017	2016	2017	2016
Operating Costs and Expenses				
General and administrative	\$ 1,644	\$ 2,147	\$ 3,734	\$ 4,573
Research and development	4,831	7,164	10,891	15,319
Total Operating Costs and Expenses	6,475	9,311	14,625	19,892
Loss from Operations	(6,475)	(9,311)	(14,625)	(19,892)
Other Income (Expense)				
Change in fair value of warrant liability	2,159	3,153	7,249	3,015
Interest income	1	34	3	35
Total Other Income (Expense), net	2,160	3,547	7,252	3,050
Net Loss	(4,315)	(5,764)	(7,373)	(16,842)
Net Loss Attributable to Non-controlling Interest	(60)	(82)	(272)	(315)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	\$ (4,255)	\$ (5,682)	\$ (7,101)	\$ (16,527)
Net Loss Per Share - Basic	\$ (0.03)	\$ (0.06)	\$ (0.06)	\$ (0.18)
Net Loss Per Share - Dilutive	\$ (0.03)	\$ (0.10)	\$ (0.06)	\$ (0.21)
Weighted average number of common shares outstanding - Basic	123,005,220	91,015,733	120,241,593	90,921,243
Weighted average number of common shares outstanding - Dilutive	123,005,220	93,930,540	120,241,593	92,651,215

[biologics-reports-second-quarter-2017-operational-highlights-and-financial-results-300498840.html](https://www.sec.gov/edgar/disclosure/financials-statements/exhibits/documents/000119312517000004/000119312517000004.pdf)

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