November 5, 2015

Synthetic Biologics Reports Third Quarter 2015 Financial Results and Operational Highlights

-- Initiated Phase 2b Proof-of-Concept Clinical Trial for the Prevention of C. difficile Infection and Antibiotic Associated Diarrhea --

-- Initiated Second Phase 2 Clinical Trial to Evaluate the Sustainability of Reduced Methane Production in Patients with Irritable Bowel Syndrome with Constipation --

-- Conference Call Today, November 5, 2015, at 4:30 p.m. EST --

ROCKVILLE, Md., Nov. 5, 2015 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE MKT: SYN), a clinical-stage company focused on developing therapeutics to protect the microbiome while targeting pathogen-specific diseases, reported financial results for the three and nine months ended September 30, 2015, and provided an operational update.

"Phase 2 clinical trials for our two lead gut microbiome-focused drug candidates are ongoing and demonstrate the achievement of important milestones for Synthetic Biologics," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics. "During the third quarter, we initiated the Phase 2b proof-of-concept clinical trial to evaluate the effectiveness of SYN-004 to protect the gut microbiome from the effects of certain commonly used intravenous beta-lactam antibiotics for the prevention of *C. difficile* infection and antibiotic-associated diarrhea. We also initiated the second Phase 2 clinical trial for SYN-010 to evaluate its ability to sustain reduced levels of methane in the gut of breathe-methane positive patients with irritable bowel syndrome with constipation, and to assess key clinical outcomes including the frequency of complete spontaneous bowel movements, abdominal pain and bloating."

Mr. Riley concluded, "We look forward to reporting the progress of our gut microbiome-focused Phase 2 clinical trials for SYN-004 and SYN-010, and anticipate reporting topline results from both programs by the end of this year."

Clinical Program Progress

Prevention of *C. difficile* infection and antibiotic-associated diarrhea (AAD) – SYN-004:

- ***Phase 2b parallel-group, double-blind, placebo-controlled, proof-of-concept clinical trial***
  - Initiated trial intended to evaluate effectiveness of SYN-004 to prevent*C. difficile* infection, *C. difficile* associated diarrhea and AAD in patients hospitalized for a lower respiratory tract infection and receiving intravenous (IV) ceftriaxone
  - Anticipate enrolling approximately 370 patients at up to 75 global sites
- ***First Phase 2a randomized, multi-center, open-label clinical trial***
  - Reported data from four participants in the clinical trial that demonstrated SYN-004 degraded IV ceftriaxone in the chyme of these healthy participants with functioning ileostomies without affecting the ceftriaxone in the bloodstream
  - Completed participant enrollment
  - Expect topline data from first Phase 2a clinical trial (4Q 2015)
- ***Second Phase 2a multi-center, open-label, 2-period, fixed-sequence clinical trial***
  - Continued enrollment in trial to evaluate gastrointestinal (GI) antibiotic-degrading effects and safety of SYN-004 in the presence of the proton pump inhibitor (PPI), esomeprazole, in healthy participants with functioning ileostomies and to analyze any potential drug-drug interactions
  - Expect topline data from second Phase 2a clinical trial (1H 2016)

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

- ***First Phase 2 randomized, double-blind, parallel-group, placebo-controlled, multi-dose clinical trial***
  - Completed patient enrollment in clinical trial to evaluate the ability of two dose strengths of SYN-010 to reduce production of methane in the gut of breath methane-positive IBS-C patients
  - Patients who complete the first Phase 2 clinical trial are eligible to immediately rollover into the second Phase 2 clinical trial
  - Expect topline data from first Phase 2 clinical trial (4Q 2015)
- ***Second Phase 2 multi-center, open-label clinical trial***
  - Initiated clinical trial to evaluate ability of SYN-010 to sustain reduction of breath methane in the gut of breath methane-positive IBS-C patients
  - Also evaluating key clinical outcomes including frequency of complete spontaneous bowel movements (CSBM), abdominal pain and bloating
  - Expect topline data from second Phase 2 clinical trial (1H 2016)

Trimesta™, an oral estriol drug for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS:

- Amended license and clinical trial agreements with University of California, Los Angeles (UCLA) in July 2015
- Informed by UCLA that magnetic resonance imaging (MRI) analyses are ongoing to evaluate changes in the brain that correlate with improvements seen in clinical outcomes
- Expect to report topline MRI data 30 days following receipt of this data from UCLA and

related analysis
- A separate UCLA-led, multi-center U.S. Phase 2 trial is underway focused exclusively on cognition utilizing Trimesta with a variety of currently marketed MS drugs

Pertussis (whooping cough) – SYN-005:

- Working with Intrexon Corporation through Exclusive Channel Collaboration (ECC), and academic collaborator, The University of Texas at Austin (UT Austin) to establish a monoclonal antibody (mAb) to prevent and treat Pertussis in newborns
    - The Bill & Melinda Gates Foundation awarded grant to UT Austin to generate preclinical proof-of-concept data to test the hypothesis that antibody administration at birth may also have a role in the prevention of Pertussis
    - Jennifer Maynard, Ph.D., the UT Austin principal investigator of the grant, will evaluate the potential of our mAb to prevent Pertussis in non-human primates and provide support for its potential clinical application

Phenylketonuria (PKU) – SYN-200:

- Entered into another ECC with Intrexon Corporation to pursue development and commercialization of novel biotherapeutics for the treatment of patients with PKU, a serious and debilitating metabolic disorder

Operational Update

- Strengthened balance sheet with net proceeds of $42.6 million in a successful July 2015 public offering
- Focused on preparing for late-stage clinical trials with appointment of Raymond Stapleton, PhD, as Senior Vice President, Manufacturing, who brings more than 15 years of pharmaceutical related manufacturing and operations experience with Merck

Three and Nine Months Ended September 30, 2015 Financial Results

General and administrative expenses increased to $1.6 million and $5.5 million for the three and nine months ended September 30, 2015, respectively, compared to $1.2 million and $4.2 million for the same periods in 2014. The increases of approximately 32% and 33% for the three and nine months ended September 30, 2015, respectively, are primarily the result of increased legal fees associated with SEC filings and collaborative agreements. Non-cash charges related to stock-based compensation were $387,000 and $1.3 million for the three and nine months ended September 30, 2015, respectively, compared to $377,000 and $1.3 million for the same periods in 2014.

Research and development expenses increased to $10.0 million and $24.0 million for the three and nine months ended September 30, 2015, respectively, compared to $3.7 million and $9.2 million for the same periods in 2014. The increases of approximately 172% and 160% for the three and nine months ended September 30, 2015, respectively, are primarily the result of increased program costs associated with expanded clinical development, manufacturing and research activities for our gut microbiome-focused pipeline, including the *C. difficile* prevention and IBS-C programs. During the three months ended September 30, 2015, the Company entered into an ECC with Intrexon Corporation for the development of a treatment for patients with PKU; 937,500 shares of common stock were issued to Intrexon

Corporation as payment of the technology access fee that resulted in a non-cash charge of $3.0 million. Non-cash charges related to stock-based compensation were $259,000 and $757,000 for the three and nine months ended September 30, 2015, respectively, compared to $232,000 and $550,000 for the same periods in 2014.

Other income was $4.1 million for the three months ended September 30, 2015, compared to $1,000 for the same period in 2014. This increase was primarily the result of non-cash income of $4.1 million related to the change in fair market value of warrants due to the decrease in the stock price from the previous quarter. Other expense was $3.9 million for the nine months ended September 30, 2015, compared to other income of $97,000 for the same period in 2014. This decrease was primarily the result of non-cash expense of $3.9 million related to the change in fair market value of warrants due to the increase in the stock price from December 31, 2014. There was no non-cash income or expense relating to fair value warrants for the three and nine months ended September 30, 2014.

Cash and cash equivalents as of September 30, 2015 were $31.8 million.

Conference Call

Synthetic Biologics will hold a conference call today, Thursday, November 5, 2015, at 4:30 p.m. EST. 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/1096/11196. An archive of the call will be available for approximately 90 days at the same URL https://www.webcaster4.com/Webcast/Page/1096/11196, beginning approximately one hour after the call's conclusion.

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 include: (1) 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), 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). In addition, the Company is developing a Phase 2 oral estriol drug for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS, and in collaboration with Intrexon Corporation (XON), a preclinical stage monoclonal antibody 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 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 anticipated timing of reporting topline results from both the SYN-004 and SYN-010 programs, anticipated number of patients and sites for the SYN-004 Phase 2b clinical trial, continued enrollment in the Phase 2a SYN-004 clinical trial, and expected timing of the reporting of topline MRI data. Important factors that could cause actual results to differ materially from those reflected in Synthetic Biologics' forward-looking statements 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, to be commenced or completed on time or to achieve desired results, a failure of Synthetic Biologics' clinical trials to receive anticipated funding, a failure of Synthetic Biologics' products for the prevention and treatment of diseases to be successfully developed or commercialized, Synthetic Biologics' inability to maintain its licensing agreements, a failure to successfully integrate new management and other factors described in Synthetic Biologics' report on Form 10-K for the year ended December 31, 2014 and any other filings with the SEC. 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

	September 30, 2015 *(Unaudited)*	December 31, 2014 *(Audited)*
Assets		
Cash and cash equivalents	$ 31,806	$ 17,525
Prepaid expenses and other current assets	10,331	1,548
Property and equipment, net	483	65
Deposits and other assets	14	6
Total Assets	$ 42,634	$ 19,144
Liabilities and Stockholders' Equity		
Current liabilities	$ 17,301	$ 9,588
Long-term deferred rent	198	-
Total stockholders' equity	25,135	9,556
Total Liabilities and Stockholders' Equity	$ 42,634	$ 19,144

Condensed Consolidated Statements of Operations

	For the three months ended September 30,		For the nine months ended September 30,	
	2015	**2014**	**2015**	**2014**
Operating Costs and Expenses				
	$	$	$	$
General and administrative	1,604	1,218	5,539	4,154
Research and development	10,046	3,693	24,048	9,247
Total Operating Costs and Expenses	11,650	4,911	29,587	13,401
Loss from Operations	(11,650)	(4,911)	(29,587)	(13,401)

Other Income (Expense)				
Change in fair value of warranty liability	4,141	-	(3,906)	-
Interest income	2	1	5	2
Other income (expense)	-	-	-	95
Total Other Income (Expense), net	4,143	1	(3,901)	97
Net Loss	(7,507)	(4,910)	(33,488)	(13,304)
Net Loss Attributable to Non-controlling Interest	(733)	-	(733)	-
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (6,774)	$ (4,910)	$ (32,755)	$ (13,304)
Net Loss Per Share - Basic	$ (0.08)	$ (0.08)	$ (0.42)	$ (0.23)
Net Loss Per Share - Dilutive	$ (0.12)	$ (0.08)	$ (0.42)	$ (0.23)
Weighted average number of common shares outstanding - Basic	85,974,751	58,453,528	77,300,375	58,356,025
Weighted average number of common shares outstanding - Dilutive	87,585,103	58,453,528	77,300,375	58,356,025

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/synthetic-biologics-reports-third-quarter-2015-financial-results-and-operational-highlights-300173592.html

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