August 10, 2015

Synthetic Biologics Reports Second Quarter 2015 Financial Results and Operational Highlights

ROCKVILLE, Md., Aug. 10, 2015 /PRNewswire/ --

- ***Achieved Planned Milestones for Company's Lead Microbiome Drug Candidates***
- ***Enhanced Senior Management Team to Maximize Strategic Opportunities***
- ***Strengthens Balance Sheet to Support Microbiome Clinical Trials***
- ***Conference Call Today, August 10, 2015, at 8:30 a.m. EDT***

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 six months ended June 30, 2015, and provided an operational update.

"We continue to successfully execute against our planned milestones and are encouraged by the progress of our two lead microbiome drug candidates," said Jeffrey Riley, Chief Executive Officer. "We initiated Phase 2a clinical trials for 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). We also initiated a Phase 2 clinical trial for SYN-010 to evaluate the efficacy in reducing the production of methane in the gut which is perceived as the underlying cause of pain, bloating and constipation associated with irritable bowel syndrome and constipation (IBS-C)."

Mr. Riley added, "This continued progress combined with investor interest related to the microbiome enabled us to strengthen our balance sheet with net proceeds of $42.6 million in a successful July public offering. Our increased cash position provides resources to support our lead microbiome drug candidates' continued progress in the clinic. And, with the recent additions of industry veterans with proven track records to our management team, we are better positioned to develop operational and commercial strategies as we navigate through clinical trials. Looking ahead, we feel confident that we will achieve our milestones and look forward to reporting important microbiome program developments including, topline data from the two SYN-004 Phase 2a trials and topline data from the first SYN-010 Phase 2 trial.

Accomplishing each of these milestones would position us to create value for our shareholders while we work to address significant unmet medical needs with our novel microbiome drug candidates."

Clinical Program Progress

Prevention of *C. difficile* infection and AAD – SYN-004:

- Dosed first participant in second Phase 2a clinical trial to evaluate the GI antibiotic-degrading effects and safety of SYN-004 in the presence of the proton pump inhibitor (PPI), esomeprazole
- Reported data from first four of 12 expected participants in first Phase 2a open-label clinical trial; data showed that SYN-004 degraded IV ceftriaxone in the chyme of the four healthy participants with functioning ileostomies without affecting ceftriaxone in the bloodstream
- Expect topline data from first Phase 2a clinical trial (3Q 2015)
- Plan to initiate a Phase 2b proof-of-concept clinical trial (3Q 2015); anticipate enrolling approximately 370 patients at up to 75 global sites; anticipate interim analysis of blinded data (2H 2015)
- Expect topline data from second Phase 2a clinical trial (2H 2015)

IBS-C – SYN-010:

- Initiated first Phase 2 clinical trial to evaluate change from baseline in breath methane, as determined by a lactulose breath test, in methane-positive patients with IBS-C after seven days of treatment with one of two formulations of SYN-010 compared with placebo
- Expect topline data from first Phase 2 clinical trial (2H 2015)
- Plan to initiate second Phase 2 clinical trial (2H 2015); expect topline data (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 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
- 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:

- Seeking non-dilutive funding to support preclinical and clinical development (ongoing)

Operational Update – Expanded Leadership Team

- Steven A. Shallcross named Chief Financial Officer, Treasurer and Secretary, bringing operational, financial and international biotech industry experience, as well as an established track record of leading the financial development and strategy for several

publicly traded biotech companies
- Klaus Gottlieb, MD, FACG, joined the Company as Vice President, Clinical & Regulatory Affairs, bringing his knowledge of clinical pathways to commercialize products for the treatment of GI diseases
- Maureen Early joined the team in a newly created position of Vice President, Commercial, to lead all commercial and marketing efforts

Three and Six Months Ended June 30, 2015 Financial Results

General and administrative expenses increased to $2.2 million and $3.9 million for the three and six months ended June 30, 2015, respectively, compared to $1.8 million and $2.9 million for the same periods in 2014. The increase of approximately 22% for the three months ended June 30, 2015 is primarily the result of increased employee costs and legal fees, offset by a decrease in stock-based compensation expense. The increase of approximately 34% for the six months ended June 30, 2015 is primarily the result of increased employee costs, legal fees and audit fees related to the additional procedures required under the accelerated filer status. Non-cash charges related to stock-based compensation were $335,000 and $915,000 for the three and six months ended June 30, 2015, respectively, compared to $645,000 and $899,000 for the same periods in 2014.

Research and development expenses increased to $7.5 million and $14.0 million for the three and six months ended June 30, 2015, respectively, compared to $2.8 million and $5.6 million for the same periods in 2014. The increases of approximately 165% and 152% for the three and six months ended June 30, 2015, respectively, are primarily the result of increased program costs associated with expanded clinical development, manufacturing and research activities for our microbiome-focused pipeline, including the Company's *C. difficile* and IBS-C programs. For the six months ended June 30, 2015, research and development expenses also include a $1.0 million expense for achieving the third milestone as set forth in the Asset Purchase Agreement with Prev ABR LLC, dated November 28, 2012, related to the *C. difficile* program. Prev ABR LLC exercised its option to receive the milestone payments in shares of Synthetic Biologics' common stock that were issued in April 2015. Non-cash charges related to stock-based compensation were $252,000 and $498,000 for the three and six months ended June 30, 2015, respectively, compared to $210,000 and $318,000 for the same periods in 2014.

Other expense was $3.9 million and $8.0 million for the three and six months ended June 30, 2015, respectively, compared to other income of $95,000 and $96,000 for the same periods in 2014. Other expense for the three and six months ended June 30, 2015 was primarily the result of a non-cash charge of $3.9 million and $8.0 million, respectively, related to the change in fair value of warrants due to the increase in the stock price from the previous quarter. There was no non-cash income or expense relating to fair value warrants for the three and six months ended June 30, 2014.

Cash and cash equivalents at June 30, 2015 was $4.8 million. Subsequent to the end of the second quarter, a public offering was completed for net proceeds of approximately $42.6 million. The strengthened balance sheet provides the Company with the resources to fund its clinical development programs.

Conference Call

Synthetic Biologics will hold a conference call today, Monday, August 10, 2015, 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/1096/9809. An archive of the call will be available for approximately 90 days at the same URL, https://www.webcaster4.com/Webcast/Page/1096/9809, beginning approximately one hour after the call's conclusion.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a microbiome-focused, clinical-stage company developing therapeutics to protect the microbiome while targeting pathogen-specific diseases. The Company's lead candidates in Phase 2 development include 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 SYN-010 which is intended to reduce the impact of methane producing organisms in the gut microbiome to treat the 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 a monoclonal antibody combination for the treatment of Pertussis. 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 the timing of planned Phase 2 clinical trials and expected date of data from clinical trials, continued successful execution against planned milestones, expected achievement of milestones and impact of achievement of milestones. 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

	June 30, 2015 *(Unaudited)*	December 31, 2014 *(Audited)*
Assets		
Cash and cash equivalents	$ 4,757	$ 17,525
Prepaid expenses and other current assets	6,955	1,548
Property and equipment, net	107	65
Deposits and other assets	18	6
Total Assets	$ 11,837	$ 19,144
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities	$ 25,498	$ 9,588
Synthetic Biologics, Inc. and subsidiaries equity (deficit)	(13,661)	9,556
Total Liabilities and Stockholders' Equity (Deficit)	$ 11,837	$ 19,144

Condensed Consolidated Statements of Operations

	For the three months ended June 30, *(Unaudited)*		For the six months ended June 30, *(Unaudited)*	
	2015	**2014**	**2015**	**2014**
Operating Costs and Expenses	$	$	$	$
General and administrative	2,222	1,814	3,935	2,936
Research and development	7,508	2,837	14,002	5,554
Total Operating Costs and Expenses	9,730	4,651	17,937	8,490
Loss from Operations	(9,730)	(4,651)	(17,937)	(8,490)
Other Income (Expense)				
Change in fair value of warrant liability	(3,895)	-	(8,047)	-
Interest income	2	-	3	1
Other income (expense)	-	95	-	95
Total Other Income (Expense), net	(3,893)	95	(8,044)	96
Net Loss	(13,623)	(4,556)	(25,981)	(8,394)
Net Loss Attributable to Non-controlling Interest	-	-	-	-
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (13,623)	$ (4,556)	$ (25,981)	$ (8,394)
Net Loss Per Share - Basic and Dilutive	$ (0.19)	$ (0.08)	$ (0.36)	$ (0.14)
Net Loss Per Share Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (0.19)	$ (0.08)	$ (0.36)	$ (0.14)
Weighted average number of common shares outstanding - Basic and Dilutive	73,736,829	58,453,528	72,674,650	58,348,153

Logo - https://photos.prnewswire.com/prnh/20130522/MM19465LOGO

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-

releases/synthetic-biologics-reports-second-quarter-2015-financial-results-and-operational-highlights-300125848.html

SOURCE Synthetic Biologics, Inc.