May 15, 2013

Synthetic Biologics Reports First Quarter 2013 Financial Results

ROCKVILLE, Md., May 15, 2013 /PRNewswire/ -- Synthetic Biologics, Inc. (NYSE MKT: SYN), a developer of biologics focused on the prevention and treatment of serious infectious diseases, today reported financial results for the three months ended March 31, 2013 and summarized operational highlights.

Operational Highlights

Emphasis on C. difficile (C. diff) Infection Prevention (SYN-004)

- In the U.S. each year, 24 million patients are administered IV antibiotics[1] which may be excreted into the gastrointestinal (GI) tract where they can upset the natural balance of the microbiome allowing for the overgrowth of *C. difficile* which causes diarrhea, colitis and may result in death.
- SYN-004 is being developed as an oral enzyme product to be co-administered with IV beta-lactam antibiotics. SYN-004 is expected to:
  - Remain in the GI tract to degrade certain beta-lactam antibiotics
  - Protect the healthy microflora from the overgrowth of *C. diff*
- In 2012, over 13 million patients were treated with IV beta-lactam antibiotics that may be covered by SYN-004.[1]
- Phase I and II studies of over 200 subjects treated with 1st generation candidate demonstrated safety, tolerability, and preservation of the normal GI microflora when co-administered with certain penicillins.

Infectious Disease Specialist Joins Scientific Advisory Board

- Brad Spellberg, M.D., is an Associate Professor of Medicine,David Geffen School of Medicine in the Division of General Internal Medicine at Harbor-UCLA Medical Center, and Associate Program Director for Internal Medicine Residency Training Program, Harbor-UCLA Medical Center and LA BioMed.
- Dr. Spellberg has worked closely with the Infectious Diseases Society of America (IDSA) to focus attention on the rising public health crisis caused by increasing antibiotic resistance and decreasing new antibiotic development.

Trimesta™ for Relapsing-Remitting Multiple Sclerosis (MS)

- Continuing the 164-patient, randomized, double-blind, placebo-controlled, multi-center Phase II clinical trial evaluating the efficacy and safety of oral estriol (Trimesta™) for the treatment of relapsing-remitting MS in women. The primary endpoint is relapse rate at two years.
- Through our wholly owned subsidiary, we hold the exclusive worldwide license to U.S.

Patent 8,372,826 and 6,936,599 and pending patents for multiple sclerosis and other autoimmune diseases covering the uses of its drug candidate, Trimesta™.

- During the first quarter of 2013, U.S. Patent No. 8,372,826 was issued to the Regents of the University of California which includes claims to the use of our drug candidate, Trimesta™ (oral estriol), in combination with glatiramer acetate injection (Copaxone®).
- Copaxone® is the number one selling drug for MS with approximately $4 billion in annual sales. Currently marketed exclusively by Teva Pharmaceutical Industries Ltd., Copaxone® is expected to face generic competition as certain patent terms begin to expire in 2014.[2]

Upcoming Milestones

- *C. difficile* program:
  - Initiation of cGMP manufacturing expected during 3rd quarter of 2013
  - Initiation of clinical trials expected during 2nd half of 2014
- Relapsing-remitting MS clinical trial:
  - Final patient's final visit expected in January 2014
  - Top-line results expected in the first half of 2014

"As we begin 2013, we are focused on building our infectious disease platform. We are especially excited about SYN-004, a 2nd generation preventative treatment for *C. difficile*, to be co-administered with IV beta-lactam antibiotics. While Phase I and II studies of a 1st generation candidate demonstrated safety, tolerability and preservation of the normal GI microflora when co-administered with certain penicillins, we anticipate that SYN-004 should have a broader spectrum of activity including, penicillins as well as most cephalosporins. There is great potential for SYN-004 to protect the healthy microflora in the GI tract from the overgrowth of *C. diff*," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics.

"As a novel prevention for *C. diff*, SYN-004 is a break-through candidate for Synthetic Biologics. With over 13 million patients treated with certain IV beta-lactam antibiotics in 2012, these antibiotics have become a mainstay in hospital infection management. We are working hard to accelerate the development of this program in order to provide a prophylactic treatment intended to prevent *C. diff* infections," concluded Mr. Riley.

Three Months Ended March 31, 2013 Financial Results

General and administrative expenses were $1.1 million for the three months ended March 31, 2013, compared to $1.5 million for the same period in 2012. The decrease of 24% is primarily the result of lower consultant and legal fees, and non-cash stock based compensation. Charges related to stock-based compensation were $353,000 for the three months ended March 31, 2013, compared to $499,000 for the same period in 2012.

Research and development expenses were $1.1 million for the three months ended March 31, 2013, compared to $386,000 for the same period in 2012. The increase of 190% is primarily the result of additional employee costs and increased program costs associated with our infectious disease programs. Charges related to stock-based compensation were $103,000 for the three months ended March 31, 2013, compared to $9,000 for the same period in 2012.

Other income was $12,000 for the three months ended March 31, 2013, compared to $5,000 for the same period in 2012.

Cash as of March 31, 2013 was $8.5 million compared to $9.9 million as of December 31, 2012.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a biotechnology company focused on the development of biologics for the prevention and treatment of serious infectious diseases. The Company is developing an oral enzyme for the prevention of *C. difficile* infections, and a series of monoclonal antibody therapies for the treatment of Pertussis and *Acinetobacter* infections. In addition, the Company is developing a drug candidate for the treatment of relapsing-remitting multiple sclerosis and cognitive dysfunction in multiple sclerosis. For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

Copaxone® is a registered trademark of Teva Pharmaceutical Industries Ltd.

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 our continued focus of our efforts in the field of synthetic biology and advancing our clinical programs, the opportunities in the infectious disease market, the anticipated timing and results of our development efforts and the expected size of the future market for sales of therapies for CDI , Pertussis and Acinetobacter. The forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those set forth or implied by any forward-looking statements. 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 our therapeutics, a failure of our clinical trials to be commenced or completed on time or to achieve desired results, a failure of our clinical trials to receive anticipated funding, a failure of our monoclonal antibodies for the treatment of infectious diseases to be successfully developed or commercialized, our inability to maintain our licensing agreements, including our agreement with Intrexon, or a failure by us or our strategic partners to successfully commercialize products and other factors described in Synthetic Biologics' report on Form 10-K for the year ended December 31, 2012 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.

Synthetic Biologics, Inc. and Subsidiaries

(in thousands, except share and per share amounts)

(Unaudited)

Condensed Consolidated Balance Sheets

	March 31,	**December 31,**

	2013	2012
Assets		
Cash	$ 8,520	$ 9,954
Prepaid expenses and other current assets	2,234	2,509
Note receivable, current	700	-
Property and equipment, net	215	223
Long-term note receivable	-	700
Deposits and other assets	15	37
Total assets	$ 11,684	$ 13,423
Liabilities and Stockholders' Equity		
Current liabilities	$ 196	$ 395
Stockholders' equity	11,488	13,028
Total liabilities and stockholders' equity	$ 11,684	$ 13,423

Condensed Consolidated Statements of Operations

	For the three months ended March 31,	
	2013	2012
Operating Costs and Expenses		
	$	
General and administrative	1,122	$ 1,468
Research and development	1,118	386
Total operating costs and expenses	2,240	1,854
Loss from Operations	(2,240)	(1,854)
Other Income		
Interest income	11	-
Other income	1	5
Total other income	12	5
Loss from Continuing Operations	(2,228)	(1,849)
Income from Discontinued Operations	-	649
Net Loss	$ (2,228)	$ (1,200)
Net Income (Loss) Per Share - Basic and Dilutive		
Continuing operations	$ (0.05)	$ (0.06)
Discontinued operations	-	0.02
Net Income (Loss) Per Share	$ (0.05)	$ (0.04)
Weighted average number of common shares outstanding - Basic and Dilutive	44,601,396	32,003,164

[1] This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: CDM Hospital database for full year 2012. IMS expressly reserves all rights, including rights of copying, distribution and republication.

[2] Teva Pharmaceutical Industries Ltd. Form 20-F filed with the SEC for the year ended December 31, 2012.

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