August 14, 2013

Synthetic Biologics Reports Second Quarter 2013 Financial Results and Operational Update

-- Progress Cited On Three Infectious Disease Programs, Including Two Programs in Collaboration with Intrexon Corporation; C. difficile Prophylactic is Lead Anti-Infective Candidate --

ROCKVILLE, Md., Aug. 14, 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 and six months ended June 30, 2013 and provided an operational update.

The Company's development portfolio includes three anti-infective product candidates, two of which are being developed in collaboration with Intrexon Corporation (NYSE: XON), and an oral multiple sclerosis (MS) product candidate in Phase II development. The relapsing-remitting MS clinical trial is expected to be completed in January 2014, with key data to be released shortly thereafter.

Conference call scheduled for 4:00pm EDT today. To participate, please call

1-800-860-2442 (U.S. toll free), 1-866-605-3852 (Canada), or +1 412-858-4600 (International),

fifteen minutes before the start of the call to register. The call will also be webcast over the Internet at

http://www.videonewswire.com/event.asp?id=95523.

"Our lead anti-infective candidate SYN-004 for the prevention of*C. difficile (C. diff)* infections, is a second generation compound designed to address a broader population than its predecessor, which successfully completed a proof-of-concept Phase II study in Europe," said Jeffrey Riley, Synthetic Biologics' CEO. "Manufacturing of SYN-004 is underway, and with completion of that we will be able to commence toxicology bridging studies, followed by the start of clinical trials in 2014."

"In addition, we are making excellent progress in our collaboration with Intrexon for antibody programs, which currently covers treatment candidates for *Pertussis* and *Acinetobacter* infections. We expect to initiate IND-enabling studies of our *Pertussis* candidate before year end," said Mr. Riley.

Mr. Riley continued, "In developing and interlinking cutting edge cellular technologies for a broad range of applications as Intrexon does, an antibody discovery platform has been

created that is powered to yield novel molecular entities intended to treat diseases for which current therapies are inadequate. Our collaboration with Intrexon is a prime example of how two innovative companies can work together to pursue significant medical advances."

"The Company's *C. diff* and *Acinetobacter* candidates may qualify for expedited review programs at the FDA for the treatment of serious conditions with unmet medical needs, such as are addressed by the GAIN Act. The expedited programs established by the FDA not only point to the urgency for new medications for devastating diseases, but also potentially shorten the time to market," concluded Mr. Riley.

The Company's core competencies in anti-infectives have been strengthened with the recent appointment of industry veteran Lewis Barrett to the post of Senior Vice President, Commercial Strategy. Mr. Barrett was formerly Assistant Vice President, Established Products at Pfizer and Vice President Global Business Manager, Infectious Diseases at Wyeth Pharmaceuticals.

Operational Highlights

SYN-004 Product Candidate for Point-of-Care Prevention for C. diff Infections

- This second generation candidate is believed to be the only product under development to prevent, rather than treat, *C. diff* infections. Healthcare-acquired infections with *C. diff* are potentially lethal and affect 1.1 million patients;[1] adding roughly $8.2 billion to U.S. hospital costs[2] annually. SYN-004 is designed to be administered along with target IV antibiotics to prevent *C. diff*. In July 2013, the SYN-004 manufacturing process was initiated with the evaluation of beta-lactamase protein expression in Fujifilm Diosynth Biotechnologies UK Limited's pAVEway™ platform. Synthetic Biologics expects to initiate a clinical program for this second generation candidate in 2014.

"We believe SYN-004 is a breakthrough candidate within a market where no approved prophylactic for *C. diff* currently exists," Mr. Riley noted. "As strange as it may seem, the only treatments available to patients are more antibiotics or fecal transplantation."

Monoclonal Antibody (mAb) Programs in Collaboration with Intrexon Corporation

- Our mAb product candidate for treatment of *Pertussis*, which is intended to neutralize the pertussis toxin, will undergo initial preclinical testing in the third quarter and is expected to enter IND-enabling studies before year end. *Pertussis*, or whooping cough, is responsible for 300,000 deaths annually worldwide[3] (primarily infants) and afflicts 41,000 people in the U.S. each year[4].
- Our mAb for *Acinetobacter* infections is currently in the discovery stage. The urgency to develop a treatment against this deadly pathogen remains high. Mortality rates as high as 43 percent have been reported[5], and incidence of the disease is reportedly increasing, especially among wounded military in field medical settings and natural disaster victims in emergency trauma units.

Phase II Study of MS Candidate, Trimesta™

- Topline results from a 164-patient relapsing-remitting MS Phase II trial at 15 centers are due in the first half of 2014.
- In June 2013, Rhonda R. Voskuhl, M.D., was the keynote speaker at our investor day focused on MS. Dr. Voskuhl holds the titles of Professor, Department of Neurology, the Jack H. Skirball Chair in MS Research, and Director of the MS Program at UCLA School of Medicine, and is the lead investigator of the Phase II Trimesta™ clinical trial for relapsing-remitting MS. During the event, Dr. Voskuhl led an in-depth discussion about the MS space and the role of oral estriol (Trimesta™) in the treatment of MS (the archived webcast of this event is available at www.syntheticbiologics.com).
- In April 2013, we announced that 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 MS drug with approximately $4.2 billion in annual sales, marketed exclusively by Teva Pharmaceutical Industries Ltd. Copaxone® is expected to face generic competition as certain patent terms begin to expire in 2014.[6]

Upcoming Milestones

- **Relapsing-remitting Phase II MS clinical trial:**
  - Final patient final visit expected January 2014
  - Top-line results expected 1H 2014
- ***C. diff* Program:**
  - Initiation of cGMP manufacturing expected 3Q 2013
  - Initiation of clinical trials expected 2H 2014
- ***Pertussis* Program:**
  - Initiation of preclinical program expected 3Q 2013
  - Initiation of IND-enabling study expected 4Q 2013
- ***Acinetobacter* Program:**
  - Discovery stage in collaboration with Intrexon

Three and Six Months Ended June 30, 2013 Financial Results

General and administrative expenses were $1.3 million and $2.4 million for the three and six months ended June 30, 2013, respectively, compared to $1.2 million and $2.6 million for the same periods in 2012. The decrease of 10% for the six month period ended June 30, 2013 is primarily the result of decreased outside legal and consulting fees. Non-cash charges related to stock-based compensation were $299,000 and $652,000 for the three and six months ended June 30, 2013, respectively, compared to $287,000 and $786,000 for the same periods in 2012.

Research and development expenses were $1.2 million and $2.3 million for the three and six months ended June 30, 2013, respectively, compared to $547,000 and $933,000 for the same periods in 2012. These increases of 120% and 149%, respectively, are primarily the result of additional employee costs and increased program costs associated with our infectious disease programs. Non-cash charges related to stock-based compensation were $109,000 and $212,000 for the three and six months ended June 30, 2013, respectively, compared to $113,000 and $122,000 for the same periods in 2012.

Other expense was $36,000 for the three months ended June 30, 2013, compared to other

income of $7,000 for the same period in 2012. Other expense was $24,000 for the six months ended June 30, 2013, compared to other income of $12,000 for the same period in 2012.

Cash at June 30, 2013 was $6.9 million compared to $10.0 million at December 31, 2012.

Conference Call

Synthetic Biologics will hold a conference call today, Wednesday, August 14, 2013, at 4:00 pm EDT. During the call, Jeffrey Riley, Synthetic Biologics' Chief Executive Officer, will provide a brief update of the Company's MS clinical program and its infectious disease pipeline, including its oral enzyme candidate for the prevention of *C. diff* infections and monoclonal antibody candidates for the treatment of *Pertussis* and *Acinetobacter* infections. Evan Ballantyne, Synthetic Biologics' Chief Financial Officer, will review the Company's financial results for the second quarter ended June 30, 2013.

Interested parties should call 1-800-860-2442 (U.S. toll free), 1-866-605-3852 (Canada), or +1 412-858-4600 (International), fifteen minutes before the start of the call to register. Registered callers on the toll free line may ask to be placed in the queue for the Question & Answer Session. The call will also be webcast over the Internet at http://www.videonewswire.com/event.asp?id=95523. If you are unable to participate during the live conference call, the webcast will be available for replay at the same URL, http://www.videonewswire.com/event.asp?id=95523 for 30 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics (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.

To download Synthetic Biologics' investor relations mobile device app, which allows users access to the Company's SEC documents, press releases and events, please click on the following links to download the IRapp on your iPhone and iPad or your Android mobile device.

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 advancing our clinical programs, the opportunities and our position in the infectious disease market, the anticipated contributions of Lewis Barrett, the anticipated timing and results of our development efforts and the expected size of the future market for

sales of therapies for C. difficile infection, 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, 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.

[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] Agency for Healthcare Research and Quality. Healthcare and Cost Utilization Project. Statistical Brief #124. *Clostridium difficile* Infections (CDI) in Hospital Stays, 2009. January 2012. Available at http://www.hcup-us.ahrq.gov/reports/statbriefs/sb124.pdf.

[3] World Health Organization. Pertussis: Immunization surveillance, assessment and monitoring. http://www.who.int/immunization_monitoring/diseases/pertussis_surveillance/en/

[4] Centers for Disease Control and Prevention. 2012 Provisional Pertussis Surveillance Report. January 4, 2013.

[5] Falagas, ME, Bliziotis, LA, and Siempos, II. Attributable mortality of *Acinetobacter baumannii* infections in critically ill patients: a systematic review of matched cohort and case-control studies. Critical Care 2006, 10:R48.

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

- Financial Tables to Follow -

Synthetic Biologics, Inc. and Subsidiaries

(in thousands, except share and per share amounts)

(Unaudited)

Condensed Consolidated Balance Sheets

	June 30, 2013	**December 31, 2012**

Assets

Cash	$ 6,877	$ 9,954
Prepaid expenses and other current assets	1,880	2,509
Note receivable, current	700	-
Property and equipment, net	155	223
Long-term note receivable	-	700
Deposits and other assets	15	37
Total assets	$ 9,627	$ 13,423

Liabilities and Stockholders' Equity

Current liabilities	$ 229	$ 395
Stockholders' equity	9,398	13,028
Total liabilities and stockholders' equity	$ 9,627	$ 13,423

Condensed Consolidated Statements of Operations

	For the three months ended June 30,		**For the six months ended June 30,**	
	2013	**2012**	**2013**	**2012**
Operating Costs and Expenses				
General and administrative	$ 1,258	$ 1,176	$ 2,380	$ 2,644
Research and development	1,203	547	2,321	933
Total operating costs and expenses	2,461	1,723	4,701	3,577
Loss from Operations	(2,461)	(1,723)	(4,701)	(3,577)
Other Income (Expense)				
Interest income	10	-	21	-
Other income (expense)	(46)	7	(45)	12

Total other income (expense), net	(36)	7	(24)	12
Loss from Continuing Operations	(2,497)	(1,716)	(4,725)	(3,565)
Income (Loss) from Discontinued Operations	-	(156)	-	493
Net Loss	$ (2,497)	$ (1,872)	$ (4,725)	$ (3,072)
Net Income (Loss) Per Share - Basic and Dilutive				
Continuing operations	$ (0.06)	$ (0.05)	$ (0.11)	$ (0.11)
Discontinued operations	-	-	-	0.02
Net Loss Per Share	$ (0.06)	$ (0.05)	$ (0.11)	$ (0.09)
Weighted average number of common shares outstanding - Basic and Dilutive	44,654,414	33,011,460	44,628,051	32,507,312

SOURCE Synthetic Biologics, Inc.