

April 16, 2013



# Synthetic Biologics Reports Year End 2012 Financial Results

## -- Strengthening Infectious Disease Portfolio to Include *C. difficile*, Pertussis and Acinetobacter Targets --

ROCKVILLE, Md., April 16, 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 year ended December 31, 2012 and summarized recent operational highlights.

### Operational Highlights:

#### *Expanding Infectious Disease Portfolio*

- ***C. difficile* Infections:**

- Utilizing our portfolio of beta-lactamase enzymes we acquired in November 2012, we intend to develop a proprietary oral beta-lactamase enzyme product candidate, SYN-004 (formerly Ipsat P3A), for the prevention of *C. difficile* infections (CDI). When co-administered with certain intravenous (IV) beta-lactam antibiotics, it is expected that SYN-004 can degrade the antibiotic that is excreted in the gastrointestinal (GI) tract, thus preserving the natural balance of the patient's microflora, and preventing opportunistic infections including CDI and antibiotic-associated diarrhea (AAD).
- Animal studies of P1A (the first generation candidate) showed that *C. difficile* colonization and disease could be prevented in mouse models and that colonization by resistant bacteria could also be prevented. P1A was shown to be safe and well tolerated in a Phase I study. In addition, two Phase II clinical studies demonstrated that P1A had the ability to preserve GI microflora in hospitalized patients treated with IV ampicillin or the combination of piperacillin and tazobactam.
- Compared to P1A, we believe that SYN-004 will have activity against a broader spectrum of beta-lactam antibiotics, including both penicillins and most cephalosporins.
- According to GlobalData, an estimated 8.7 million Americans were administered IV beta-lactam antibiotics in 2011.

- **Pertussis:**

- In December 2012, in collaboration with Intrexon Corporation (Intrexon), we initiated development of a monoclonal antibody (mAb) therapy for the treatment of Pertussis infections, more commonly known as whooping cough.
- We are developing a mAb therapy, SYN-005, designed to target and neutralize the pertussis toxin, in order to reduce the mortality rate in infants and potentially

shorten the duration of chronic cough in afflicted adults.

- To further the development of this potential therapy for Pertussis, we entered into an agreement with The University of Texas at Austin to license the rights to certain research and pending patents related to pertussis antibodies.
  - According to the World Health Organization, each year, Pertussis infection causes an estimated 294,000 deaths worldwide, primarily among young, unvaccinated children.
- ***Acinetobacter* Infections:**
    - In September 2012, in collaboration with Intrexon, we initiated efforts to develop a mAb therapy for the treatment of *Acinetobacter* infections.
    - Many strains of *Acinetobacter* are multidrug-resistant and pose an increasing global threat to hospitalized patients, wounded military personnel and those affected by natural disasters.
  - **Scientific Advisory Board:**
    - Recently recruited infectious disease specialist, Brad Spellberg, M.D. to join our Scientific Advisory Board. Dr. Spellberg's NIH-funded laboratory studies highly drug-resistant infections in an effort to develop vaccines and immune therapies to prevent and treat them.
    - Dr. Spellberg is also the author of *Rising Plague: The Global Threat from Deadly Bacteria and Our Dwindling Arsenal to Fight Them*, which he wrote to inform and educate the public about the crisis in antibiotic resistant infections and lack of antibiotic development.

#### *Ongoing Phase II Multiple Sclerosis (MS) Clinical Trials*

- The U.S. Patent & Trademark Office issued U.S. Patent No. 8,372,826 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®). Through our wholly owned subsidiary, we hold the exclusive worldwide license to U.S. Patents 8,372,826 and 6,936,599 and pending patents for multiple sclerosis and other autoimmune diseases covering the uses of Trimesta™.
- Continuing the 164-patient, randomized, double-blind, placebo-controlled, multi-center Phase II clinical trial evaluating the efficacy and safety of our proprietary oral formulation of estriol (Trimesta™) for the treatment of relapsing-remitting MS in women. The primary endpoint is relapse rate at two years, with top-line results expected in the first half of 2014.
- Ongoing patient enrollment in a second randomized, double-blind, placebo-controlled Phase II clinical trial of Trimesta™ for the treatment of cognitive dysfunction in MS. An estimated 50-65% of MS patients are expected to develop disabilities due to cognitive dysfunction and there is currently no approved treatment.

#### **Corporate Highlights:**

##### *Completed Successful Capital Raise*

- Increased cash position with net proceeds of \$10.1 million from the sale of approximately 6.8 million shares of common stock to new and existing investors in a private placement financing. Existing investors and an affiliate of R.J. Kirk constituted a

majority of the participating investors in this transaction.

"During 2012, we targeted our resources toward strengthening our infectious disease portfolio, specifically to address the increasing need for therapies to prevent and treat infections caused by *C. difficile*, Pertussis and *Acinetobacter*. We believe there is a major void in the market when it comes to developing such therapies, mainly due to these bacteria becoming immune to current antibiotics and the evolving strains of bacteria that are often stronger," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics.

"We are excited about our opportunity to develop a novel therapy to prevent *C. difficile* infections. The highly-experienced Synthetic Biologics' team is driving the *C. difficile* program toward the clinic. In addition, we are working with Intrexon's comprehensive suite of proprietary technologies to move our promising early-stage programs for the treatment of Pertussis and *Acinetobacter* infections forward. We are committed to building a strong public presence and dedicate ourselves to the virtually untapped infectious disease market," concluded Mr. Riley.

### **Year Ended December 31, 2012 Financial Results**

As part of management's plan to streamline our focus, we sold the clinical reference lab on March 8, 2012. Laboratory revenues for the years ended December 31, 2012 and December 31, 2011 were charged to discontinued operations, resulting in no revenues for these periods. In addition, the gain on the sale of the clinical reference lab of \$677,000 was included in discontinued operations for the year ended December 31, 2012.

General and administrative expenses increased to \$5.0 million for the year ended December 31, 2012, compared to \$2.6 for the same period in 2011. The increase of 94% is primarily the result of additional employee costs, the expansion of our investor relation activities and legal fees. Charges related to stock-based compensation were \$1.5 million for the year ended December 31, 2012, compared to \$919,000 for the same period in 2011.

Research and development expenses were \$12.3 million for the year ended December 31, 2012, compared to \$3.3 million for the same period in 2011. The increase of 268% is primarily the result of recording the fair value of the common stock issued to Intrexon as consideration for the infectious disease collaboration (\$7.8 million) and the fair value of the common stock issued for the acquisition of the *C. difficile* program assets (\$1.2 million). Charges related to stock-based compensation were \$400,000 for the year ended December 31, 2012, compared to \$54,000 for the same periods in 2011.

Other income was \$15,000 for the year ended December 31, 2012, compared to other expense of \$1.7 million for the same period in 2011. Other expense for the year ended December 31, 2011 related to the estimated fair value of the warrants associated with the January 2011 and April 2011 financings, adjusted for the change in their fair value at December 31, 2011.

Cash as of December 31, 2012 was \$10.0 million compared to \$6.7 million as of December 31, 2011. As of March 27, 2013, our cash balance was approximately \$8.7 million.

### **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](http://www.syntheticbiologics.com).

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*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 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 agreements with Intrexon, our inability to successfully integrate new management, 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.*

-- Financial Tables to Follow --

**Synthetic Biologics, Inc. and Subsidiaries**  
*(in thousands, except share and per share amounts)*

Condensed Consolidated Balance Sheets

December 31,

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	<u>2012</u>	<u>2011</u>
<b>Assets</b>		
Cash	\$ 9,954	\$ 6,678
Accounts receivable, net	-	405
Prepaid expenses and other current assets	2,509	16
Assets of discontinued operations	-	23
Property and equipment, net	223	323
Long-term note receivable	700	-
Other assets	37	31
<b>Total assets</b>	<u>\$ 13,423</u>	<u>\$ 7,476</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities	\$ 395	\$ 417
Stockholders' equity	13,028	7,059
<b>Total liabilities and stockholders' equity</b>	<u>\$ 13,423</u>	<u>\$ 7,476</u>

#### Condensed Consolidated Statements of Operations

	<b>For the years ended</b>	
	<b>December 31,</b>	
	<u>2012</u>	<u>2011</u>
<b>Operating Costs and Expenses</b>		
General and administrative	\$ 5,012	\$ 2,588
Research and development	12,287	3,340
Total operating costs and expenses	17,299	5,928
<b>Loss from Operations</b>	(17,299)	(5,928)
<b>Other Income (Expense)</b>		
Warrant expense	-	(1,492)
Change in fair value of warrant liability	-	(242)
Interest income	33	14
Other income (expense)	(18)	22
Total other income (expense), net	15	(1,698)
<b>Loss from Continuing Operations</b>	(17,284)	(7,626)
<b>Income (Loss) from Discontinued Operations</b>	216	(523)
<b>Net Loss and Comprehensive Loss</b>	<u>\$ (17,068)</u>	<u>\$ (8,149)</u>
<b>Net Income (Loss) Per Share - Basic and Dilutive</b>		
Continuing operations	\$ (0.50)	\$ (0.27)
Discontinued operations	0.01	(0.02)
<b>Net Income (Loss) Per Share</b>	<u>\$ (0.49)</u>	<u>\$ (0.29)</u>
<b>Weighted average number of common shares outstanding - Basic and Dilutive</b>	<u>34,896,592</u>	<u>27,710,428</u>

