

May 11, 2015



# Synthetic Biologics Reports First Quarter 2015 Financial Results and Operational Highlights

**-- Initiated Phase 2 for Prevention of *C. difficile*, Expected to Initiate Phase 2 for IBS-C by end of June 2015, and Expanded Leadership Team as Company Moves into Next Development Stage --**

**-- Conference Call Today, May 11, 2015, at 4:30 p.m. EDT --**

ROCKVILLE, Md., May 11, 2015 /PRNewswire/ --[Synthetic Biologics, Inc.](#) (NYSE MKT: SYN), a microbiome-focused, clinical-stage company developing therapeutics to protect the microbiome while targeting pathogen-specific diseases, reported financial results for the three months ended March 31, 2015, and provided an operational update.



"We've made great progress during the first quarter of 2015," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics. "We've advanced our *C. difficile* program into Phase 2 clinical trials, plan to initiate Phase 2 clinical trials for our irritable bowel syndrome with constipation (IBS-C) program before the end of June, and expect to have Phase 2 data from both programs focused on protecting the microbiome by year end. Due to the nature of these microbiome programs, the time spent in the clinic is less than the typical drug development program, and we are positioned to create value for our shareholders at multiple points during the remainder of 2015."

Mr. Riley added, "We've recently expanded our leadership team with the appointment of Steve Shallcross as our Chief Financial Officer beginning June 1<sup>st</sup>, and Maureen Early joining the team in the newly created position of Vice President, Commercial. We are very optimistic about the potential of Synthetic Biologics to meet unmet medical needs while generating significant returns for our shareholders."

## **Clinical Programs Update**

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

- Completed Phase 1a and 1b clinical trials; reported positive topline safety and tolerability data from both studies
- Reported positive pharmacokinetic (PK) results from both the Phase 1a and 1b clinical trials,

- with supportive evidence for no active enzyme absorption into bloodstream observed
- Initiated a Phase 2a clinical trial to evaluate gastrointestinal (GI) antibiotic-degrading effects and safety
- Presenting poster of late-breaking preclinical data for protection of microbiome at Digestive Disease Week® (May 2015)
- Presenting poster of clinical data for protection of microbiome at American Society of Microbiology 2015 (June 2015)
- Expect topline data from Phase 2a clinical trial (2Q 2015)
- Plan to initiate a Phase 2b proof-of-concept clinical trial (2H 2015); expect topline data (2H 2015)

#### **IBS-C – SYN-010:**

- Poster presentation of preclinical data by lead principal investigator of Cedars-Sinai Medical Center at Digestive Disease Week® (May 2015)
- Expect to submit an Investigational New Drug (IND) application to initiate clinical trials (2Q 2015)
- Plan to initiate Phase 2 clinical trials (2Q 2015); expect topline data (2H 2015)

#### **Pertussis (whooping cough) – SYN-005:**

- Presented two posters at ECCMID 2015 (European Congress of Clinical Microbiology and Infectious Diseases) that highlighted positive preclinical data regarding the monoclonal antibody combination, SYN-005, for the treatment and prophylaxis of whooping cough
- Seeking non-dilutive funding to support preclinical and clinical development (ongoing)

#### **RRMS – Trimesta™:**

- MRI brain scan analyses underway by University of California, Los Angeles (UCLA) to evaluate changes in the brain that correlate with improvements seen in clinical outcomes; topline data expected from UCLA (2Q 2015)
- As previously disclosed, active discussions with a number of potential strategic partners may accelerate development of Trimesta, pending data from UCLA (ongoing)
- A separate multi-center U.S. Phase 2 trial is underway focused exclusively on cognition utilizing Trimesta with a variety of currently marketed MS drugs

#### **Three Months Ended March 31, 2015 Financial Results**

General and administrative expenses increased to \$1.7 million for the three months ended March 31, 2015, compared to \$1.1 million for the same period in 2014. This increase of approximately 53% is primarily the result of increased employee costs, audit fees related to the additional procedures required under the accelerated filer status and stock compensation expense for the three months ended March 31, 2015. Non-cash charges related to stock-based compensation were \$582,000 for the three months ended March 31, 2015, compared to \$255,000 for the same period in 2014.

Research and development expenses increased to \$6.5 million for the three months ended March 31, 2015, compared to \$2.7 million for the same period in 2014. This increase of approximately 139% is primarily the result of increased program costs associated with expanded clinical development, manufacturing and research activities within our pathogen-specific, microbiome-focused pipeline, including the Company's *C. difficile*, IBS-C and Pertussis programs. 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, issued in April 2015. Non-cash charges related to stock-based compensation were \$246,000 for the three months ended March 31, 2015, compared to \$107,000 for the same period in 2014.

Other expense was \$4.2 million for the three months ended March 31, 2015, compared to other income of \$1,000 for the same period in 2014. Other expense for the three months ended March 31, 2015 is primarily the result of a non-cash charge of \$4.2 million related to the change in fair value of warrants. The increase in the fair value of the warrants was due to the increase in the stock price from the previous period. There was no non-cash income or expense relating to fair value warrants for the three months ended March 31, 2014.

Cash at March 31, 2015 was \$12.0 million compared to \$17.5 million at December 31, 2014.

### **Conference Call**

Synthetic Biologics will hold a conference call today, Monday, May 11, 2015, at 4:30 p.m. EDT. The dial-in information for the call is as follows: U.S. toll free: 1-888-347-5280, Canada toll free: 1-855-669-9657 and International: +1 412-902-4280.

Participants are asked to dial in 15 minutes before the start of the call to register. Registered callers 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=102272>.

An archive of the call will be available for approximately 90 days at the same URL, <http://www.videonewswire.com/event.asp?id=102272>, 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 is developing an oral biologic to protect the gut microbiome from intravenous (IV) antibiotics for the prevention of *C. difficile* infection and an oral statin treatment to reduce the impact of methane producing organisms on irritable bowel syndrome with constipation (IBS-C). In addition, the Company is developing a monoclonal antibody combination for the treatment of Pertussis in collaboration with Intrexon Corporation (NYSE: XON), and a Phase 2 oral estriol drug for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS. For more information, please visit Synthetic Biologics' website at [www.syntheticbiologics.com](http://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 planned Phase 2 clinical trials, expected date of data from clinical trials and the expected date of submission of IND application for SYN-010. 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 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**

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
	<i>(Unaudited)</i>	<i>(Audited)</i>
<b>Assets</b>		
Cash and cash equivalents	\$ 12,049	\$ 17,525
Prepaid expenses and other current assets	1,574	1,548
Property and equipment, net	75	65
Deposits and other assets	18	6
<b>Total Assets</b>	<b>\$ 13,716</b>	<b>\$ 19,144</b>
<b>Liabilities and Equity (Deficit)</b>		
Current liabilities	\$ 15,341	\$ 9,588

Synthetic Biologics, Inc. and subsidiaries equity (deficit)	(1,625)	9,556
<b>Total Liabilities and Equity</b>	<b>\$ 13,716</b>	<b>\$ 19,144</b>

**Condensed Consolidated Statements of Operations (Unaudited)**

	<b>For the three months ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Operating Costs and Expenses</b>		
General and administrative	\$ 1,713	\$ 1,122
Research and development	6,494	2,717
<b>Total Operating Costs and Expenses</b>	<b>8,207</b>	<b>3,839</b>
<b>Loss from Operations</b>	<b>(8,207)</b>	<b>(3,839)</b>
<b>Other Income (Expense)</b>		
Change in fair value of warrant liability	(4,152)	-
Interest income	1	1
<b>Total Other Income, net</b>	<b>(4,151)</b>	<b>1</b>
<b>Net Loss</b>	<b>(12,358)</b>	<b>(3,838)</b>
<b>Net Loss Attributable to Non-controlling Interest</b>	<b>-</b>	<b>-</b>

<b>Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries</b>	\$ (12,358)	\$ (3,838)
<b>Net Loss Per Share - Basic and Dilutive</b>	\$ (0.17)	\$ (0.07)
<b>Net Loss Per Share Attributable to Synthetic Biologics, Inc. and Subsidiaries</b>	\$ (0.17)	\$ (0.07)
<b>Weighted average number of common shares outstanding - Basic and Dilutive</b>	72,673,959	58,324,260

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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/synthetic-biologics-reports-first-quarter-2015-financial-results-and-operational-highlights-300081125.html>

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