

November 14, 2014



Synthetic Biologics Reports Third Quarter 2014 Financial Results and Operational Highlights

-- Company Completes \$18.9 Million Net Registered Direct Offering; Finalizes Plans for Start of Clinical Trials in *C. difficile* and C-IBS --

-- Conference Call Today, November 14, 2014, at 8:30 a.m. (EST); U.S. Participants Call (888) 347-5280 or Join Webcast at <http://www.videonewswire.com/event.asp?id=100975> --

ROCKVILLE, Md., Nov. 14, 2014 /PRNewswire/ -- [Synthetic Biologics, Inc.](#) (NYSE MKT: SYN), a developer of pathogen-specific therapies for serious infections and diseases, with a focus on protecting the microbiome, today reported financial results for the three and nine months ended September 30, 2014, and provided an operational update.



"We've made meaningful progress with each of the programs in our pipeline, and we look forward to reporting the achievement of several milestones in the next six months, including the *C. difficile* and C-IBS programs entering the clinic and the MS program completing ongoing MRI brain scan analyses," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics. "With the completion of a capital raise of \$18.9 million in net proceeds with select institutional investors, we strengthened our cash position and added a new biotech investor to our strong existing shareholder base. All of these efforts strengthen Synthetic Biologics' position for future growth and success, which we believe significantly increases value for our shareholders."

Clinical Programs Update

Prevention of *C. difficile* (*C. diff*) Infections – SYN-004 Oral Beta-Lactamase Enzyme

- Clinical drug manufacturing under cGMP guidelines commenced in the third quarter with a vastly improved process utilized by supplier Evonik.
- Preclinical data further validating the SYN-004 approach were presented at two

scientific forums – IDWeek and the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC).

- U.S. Notice of Allowance for the first composition of matter patent directly related to SYN-004's unique properties was issued.
- Phase 1a and 1b clinical studies remain on track to initiate within the next 30 days.
- Topline data from Phase 1 studies expected before year-end 2014.

Relapsing-Remitting Multiple Sclerosis (RRMS) – Trimesta™ (oral estriol)

- Expanded efficacy and safety results from the investigator-initiated Phase 2 trial evaluating adjunctive Trimesta in women with RRMS including positive results on cognitive and disability scores at 12 months, attesting to Trimesta's unique neuroprotective properties, were presented at the ACTRIMS-ECTRIMS meeting in Boston in September by the trial's lead investigator.
- A separate Phase 2 trial focused exclusively on cognition utilizing Trimesta with a variety of currently marketed MS drugs, including Copaxone®, Avonex®, Betaseron®, Extavia®, Rebif®, Gilenya®, Aubagio® and Tecfidera®, is enrolling patients at four sites in the United States.
- Active discussions with a number of potential strategic partners may accelerate development of this innovative therapy for relapsing-remitting MS in women.
- MRI brain scan analyses are ongoing to evaluate changes in the brain that correlate with improvements seen in clinical outcomes; topline data expected during the first quarter of 2015.

Constipation-Predominant Irritable Bowel Syndrome (C-IBS) – SYN-010 Statin-Class Oral Compound

- Strengthened Clinical Advisory Board (CAB) to support the development of SYN-010; CAB is comprised of prominent gastrointestinal (GI) key opinion leaders: Mark Pimentel, M.D., (Chair), William Chey, M.D., Gail M. Comer, M.D., Anthony J. Lembo, M.D., and Philip Schoenfeld, M.D., MSc, MEd, MSc.
- In September, announced the SYN-010 statin-class formulation at an IBS Investor Day in New York. Keynote speaker, Dr. Pimentel, provided an overview of the clinical development strategy for clinical candidate SYN-010.
- Anticipating a 505(b)(2) regulatory pathway for SYN-010, a corporate Investigational New Drug (IND) application is expected to be filed with the FDA in the first quarter of 2015 with the initiation of a Phase 2 clinical trial of SYN-010 in C-IBS anticipated in the first half of 2015.

Pertussis (Whooping Cough) – SYN-005 Monoclonal Antibody (mAb) Combination

- SYN-005 was granted U.S. Orphan Drug Designation by the FDA for the treatment of Pertussis.
- Increased awareness of SYN-005's novel mAbs combination designed to target and neutralize pertussis toxin were the topic of an oral presentation at ICAAC. Neutralizing pertussis toxin is anticipated to decrease morbidity and mortality in critically ill infants.
- An IND is expected to be filed in 2015, with plans to initiate a Phase 1 clinical trial in second half of 2015.

Three and Nine Months Ended September 30, 2014 Financial Results

General and administrative expenses were \$1.2 million and \$4.2 million for the three and nine months ended September 30, 2014, respectively, compared to \$1.9 million and \$4.3 million for the same periods in 2013. These decreases of approximately 36% and 3%, respectively, are primarily the result of bad debt expense of \$763,000 associated with the note and interest receivables from the sale of Adeona Clinical Laboratory that were determined uncollectible during the quarter ended September 30, 2013, which, for the nine months ended September 30, 2014, was offset by supplemental compensation granted by the Board of Directors to executive officers and increased stock-based compensation expense. Non-cash charges related to stock-based compensation were \$377,000 and \$1.3 million for the three and nine months ended September 30, 2014, respectively, compared to \$264,000 and \$916,000 for the same periods in 2013.

Research and development expenses increased to \$3.7 million and \$9.2 million for the three and nine months ended September 30, 2014, respectively, compared to \$1.5 million and \$3.8 million, for the same periods in 2013. These increases of 150% and 144%, respectively, are primarily the result of increased program costs associated with expanded research, clinical development and manufacturing activities within our pathogen-specific pipeline, including the Company's *C. difficile*, C-IBS and Pertussis programs. Non-cash charges related to stock-based compensation were \$232,000 and \$550,000 for the three and nine months ended September 30, 2014, respectively, compared to \$74,000 and \$286,000 for the same periods in 2013.

Other income was \$1,000 and \$97,000 for the three and nine months ended September 30, 2014, respectively, compared to other expense of \$3,000 and \$27,000, for the same periods in 2013.

Cash at September 30, 2014 was \$3.3 million compared to \$14.6 million at December 31, 2013. In addition, on October 16, 2014, Synthetic Biologics closed a registered direct offering with select institutional investors for net proceeds of approximately \$18.9 million.

Conference Call

Synthetic Biologics will hold a conference call today, Thursday, November 14, 2014, at 8:30 a.m. EST, during which Mr. Riley will provide an operational update and C. Evan Ballantyne, Synthetic Biologics' Chief Financial Officer, will review the Company's financial results for the three and nine months ended September 30, 2014.

Interested parties should call 1-888-347-5280 (U.S. toll free), 1-855-669-9657 (Canada toll free), or +1 412-902-4280 (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=100975>. 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=100975>, for 30 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a clinical-stage biotechnology company developing pathogen-specific therapies for serious infections and diseases, with a focus on protecting the microbiome. The Company is developing an oral biologic to protect the

gastrointestinal (GI) microflora from the effects of intravenous (IV) antibiotics for the prevention of *C. difficile* infection, an oral treatment to reduce the impact of methane producing organisms on constipation-predominant irritable bowel syndrome (C-IBS) and a monoclonal antibody combination for the treatment of Pertussis. 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. 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 advancing Synthetic Biologics' clinical programs and achieving milestones, the ability to achieve future growth and success and increase shareholder value, and the anticipated timing of the Synthetic Biologics' clinical trials, filing of INDs and release of results. 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, or a failure by Synthetic Biologics or its strategic partners to successfully commercialize products and other factors described in Synthetic Biologics' report on Form 10-K for the year ended December 31, 2013 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

	September 30,	December 31,
	2014	2013
	<i>(Unaudited)</i>	<i>(Audited)</i>
Assets		
Cash and cash equivalents	\$ 3,286	\$ 14,625
Prepaid expenses and other current assets	1,382	1,591
Property and equipment, net	67	37
Deposits and other assets	6	4
Total Assets	\$ 4,741	\$ 16,257
Liabilities and Equity		
Current liabilities	\$ 984	\$ 1,027
Synthetic Biologics, Inc. and subsidiaries equity	3,757	15,230
Total Liabilities and Equity	\$ 4,741	\$ 16,257

Condensed Consolidated Statements of Operations

	For the three months ended September 30,		For the nine months ended September 30,	
	2014	2013	2014	2013
Operating Costs and Expenses				
General and administrative	\$ 1,218	\$ 1,890	\$ 4,154	\$ 4,270
Research and development	3,693	1,475	9,247	3,796
Total Operating Costs and Expenses	4,911	3,365	13,401	8,066
Loss from Operations	(4,911)	(3,365)	(13,401)	(8,066)
Other Income (Expense)				
Interest income	1	11	2	32
Other income (expense)	-	(14)	95	(59)
Total Other Income (Expense), net	1	(3)	97	(27)
Net Loss	(4,910)	(3,368)	(13,304)	(8,093)
Net Loss Attributable to Non-controlling Interest	-	-	-	-
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	\$ (4,910)	\$ (3,368)	\$ (13,304)	\$ (8,093)

Net Loss Per Share - Basic and Dilutive	\$	(0.08)	(0.08)	(0.23)	(0.18)
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Net Loss Per Share Attributable to Synthetic Biologics, Inc. and Subsidiaries	\$	(0.08)	(0.08)	(0.23)	(0.18)
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Weighted average number of common shares outstanding - Basic and Dilutive	58,453,528	44,654,414	58,356,025	44,636,935
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