May 15, 2012

Synthetic Biologics Reports First Quarter 2012 Financial Results

-- Preclinical and Clinical Programs Moving Forward --

ANN ARBOR, Mich., May 15, 2012 /PRNewswire/ -- Synthetic Biologics, Inc. (NYSE Amex: SYN), a developer of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses, today reported financial results for the three months ended March 31, 2012 and summarized operational highlights.

Operational Highlights

Management Team – Strengthened Clinical Development and Regulatory Affairs Functions

- Recruited former Chief Medical Officer of Clinical Data, Inc.,Carol Reed, M.D., to serve as Senior Vice President of Clinical & Regulatory Affairs. Dr. Reed, who led the design and management of two consecutive successful Phase III clinical trials and FDA approval for VIIBRYD®, is responsible for the design and implementation of all aspects of clinical development and clinical trials, as well as regulatory initiatives.

Synthetic Biologics – Focus on DNA-Based Therapeutics

- Initiated preclinical research for the development of a synthetic DNA-based therapy for pulmonary arterial hypertension (PAH), utilizing the UltraVector® platform and RheoSwitch Therapeutic System® of our collaborator, Intrexon Corporation.
- Appointed gene therapy veteran, Michael Kaleko, M.D., Ph.D., to serve as Scientific Director. Dr. Kaleko has worked in the field of gene therapy since its inception in the mid-1980s and has extensive experience developing vector platforms, inducible transcription systems and product candidates in multiple disease areas.

Multiple Sclerosis (MS) – Two Phase II Clinical Trials Ongoing

- Completed enrollment of 164 patients in a 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. According to various reports, sales of oral disease-modifying therapies for MS, of which Trimesta™, if and when approved, would be in a drug class, that is expected to reach $5 billion annually by 2017.
- Initiated patient enrollment in a second randomized, double-blind, placebo-controlled Phase II clinical trial of Trimesta™ for the treatment of cognitive dysfunction in MS. Charitable organizations have pledged to financially support a majority of this new MS clinical trial.

Board of Directors – Improved Corporate Governance

- Improved corporate governance and strengthened the Board by separating the roles of Chairman and Chief Executive Officer with the appointment of Jeffrey J. Kraws to serve as independent, non-executive Chairman of the Board. Mr. Kraws has served on the Board of Directors since January 2006.

"We continue to focus our efforts on establishing our presence in the field of 'next generation' gene therapy and on advancing our strong mid-to-late stage clinical programs," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics. "We've strengthened our management team, improved our corporate governance practices and maintained a cash position consistent with current needs."

Three Months Ended March 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 three months ended March 31, 2012 and March 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 three months ended March 31, 2012.

General and administrative expenses increased by 19% to $1.5 million for the three months ended March 31, 2012, compared to $1.2 million for the same period in 2011. This change is primarily the result of increased salary and consulting fees associated with strengthening our senior management team and expanding our emphasis on investor outreach. Non-cash charges related to stock-based compensation decreased to $499,000 for the three months ended March 31, 2012, from $759,000 for the same period in 2011.

Research and development expenses were $386,000 for the three months ended March 31, 2012, compared to $231,000 for the same period in 2011. This 67% increase is primarily driven by the expansion of our pipeline, including the initiation of our preclinical program for the treatment of PAH and our clinical trial for the treatment of cognitive dysfunction in MS.

Other income, net, was $5,000 for the three months ended March 31, 2012. Other expense, net, was $759,000 for the three months ended March 31, 2011, and included a $810,000 charge related to the estimated fair value of the warrants associated with the January 2011 financing adjusted for the change in their fair value at the end of the period, offset by other income of $63,000 related to the settlement of accounts payable previously accrued in prior periods.

Cash at March 31, 2012 was $6.8 million compared to $6.7 million at December 31, 2011. As of April 30, 2012, we had approximately $6.5 million in cash.

About Synthetic Biologics, Inc.

Synthetic Biologics is a biotechnology company focused on the development of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses. Synthetic Biologics is developing, or has partnered the development of, product candidates for the treatment of pulmonary arterial hypertension (PAH), relapsing-remitting multiple sclerosis (MS), cognitive dysfunction in MS, fibromyalgia and amyotrophic lateral sclerosis

(ALS). For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

UltraVector® and RheoSwitch Therapeutic System® are registered trademarks of Intrexon Corporation.

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 gene therapy and advancing our clinical programs and the expected size of the future market for sales of oral disease-modifying therapies for MS. 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 gene therapy to receive market acceptance, 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/A for the year ended December 31, 2011 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

	March 31, 2012 (Unaudited)	December 31, 2011 (Audited)
Assets		
Cash	$ 6,802	$ 6,678
Accounts receivable, net	440	405
Other current assets	83	16
Assets of discontinued operations	-	23
Property and equipment, net	303	323
Long-term note receivable	700	-
Deposits and other assets	21	31
Total assets	$ 8,349	$ 7,476
Liabilities and Stockholders' Equity		
Current liabilities	$ 443	$ 417
Stockholders' equity	7,906	7,059
Total liabilities and stockholders' equity	$ 8,349	$ 7,476

Condensed Consolidated Statements of Operations (Unaudited)

	For the three months ended March 31,	
	2012	**2011**
Operating Costs and Expenses		
General and administrative	$ 1,468	$ 1,233
Research and development	386	231
Total operating costs and expenses	1,854	1,464
Loss from Continuing Operations	(1,854)	(1,464)
Other Income (Expense)		
Warrant expense	-	(716)
Change in fair value of warrant liability	-	(94)
Loss on the sale of equipment	-	(5)
Other income	5	56
Total other income (expense), net	5	(759)
Net Loss from Continuing Operations	(1,849)	(2,223)
Net Income from Discontinued Operations	649	37
Net Loss	$ (1,200)	$ (2,186)
Net Income (Loss) Per Share - Basic and Dilutive		
Continuing Operations	$ (0.06)	$ (0.09)
Discontinued Operations	0.02	-
Net Loss Per Share	$ (0.04)	$ (0.09)
Weighted average number of common shares outstanding - Basic and Dilutive	32,003,164	25,220,694

SOURCE Synthetic Biologics, Inc.