Synthetic Biologics, Inc.
Form 10-Q
August 14, 2013

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2013

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934**

For the transition period from ____________ to ____________

Commission File Number: 1-12584

SYNTHETIC BIOLOGICS, INC.
(Name of small business issuer in its charter)

Nevada	**13-3808303**
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification Number)*
155 Gibbs Street, Suite 412 **Rockville, MD**	**20850**
(Address of principal executive offices)	*(Zip Code)*

Registrant's telephone number, including area code:
(734) 332-7800
Securities registered pursuant to Section 12(b) of the Act:
Common Stock, $0.001 par value per share

Securities registered pursuant to Section 12(g) of the Act:
None.

(Title of Class)

Indicate by check mark whether the issuer: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated file, a non-accelerated file, or a smaller reporting company. See the definitions of “large accelerated filer, “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	¨	Accelerated filer	¨
Non-Accelerated filer (Do not check if a smaller reporting company)	¨	Smaller reporting company	x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of August 12, 2013 the registrant had 44,654,414 shares of common stock outstanding.

SYNTHETIC BIOLOGICS, INC.

FORM 10-Q
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PART I.-FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Synthetic Biologics, Inc. and Subsidiaries
Consolidated Balance Sheets
(In thousands, except per share amounts)
(Unaudited)

	June 30, 2013	December 31, 2012
Assets		
Current Assets:		
Cash	$ 6,877	$ 9,954
Prepaid expenses and other current assets	1,880	2,509
Note receivable	700	-
Total Current Assets	9,457	12,463
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:		
Accounts payable	$ 213	$ 395
Accrued liabilities	16	-
Total Current Liabilities	229	395
Total Liabilities	229	395
Stockholders' Equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 44,735,896 issued and 44,654,414 outstanding and 44,444,230 issued and 44,362,748 outstanding, respectively	45	44
Additional paid-in capital	83,019	81,925
Accumulated deficit	(73,666)	(68,941)
Total Stockholders' Equity	9,398	13,028
Total Liabilities and Stockholders' Equity	$ 9,627	$ 13,423

See accompanying notes to unaudited consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries
Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	For the three months ended June 30, 2013	For the three months ended June 30, 2012	For the six months ended June 30, 2013	For the six months ended June 30, 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 shares outstanding during the period - Basic and Dilutive	44,654,414	33,011,460	44,628,051	32,507,312

See accompanying notes to unaudited consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	For six months ended June 30, 2013		For six months ended June 30, 2012	
Cash Flows From Operating Activities:				
Net loss	$	(4,725)	$	(3,072)
Adjustments to reconcile net loss to net cash used in operating activites:				
Stock-based compensation		864		908
Depreciation		23		39
Provision for uncollectible accounts receivable		-		165
Loss on sale of equipment		58		-
Impairment on loss of equipment		-		30
Gain on sale of discontinued operations		-		(677)
Changes in operating assets and liabilities:				
Accounts receivable		-		(5)
Prepaid expenses and other current assets		629		(78)
Deposits and other assets		22		11
Accounts payable		(182)		(110)
Accrued liabilities		16		88
Net Cash Used In Operating Activities		(3,295)		(2,701)
Cash Flows From Investing Activities:				
Purchase of property and equipment		(13)		-
Net Cash Used In Investing Activities		(13)		-
Cash Flows From Financing Activities:				
Proceeds from issuance of common stock for stock option exercises		231		94
Proceeds from issuance of common stock for warrant exercises		-		1,861
Net Cash Provided By Financing Activities		231		1,955
Net increase (decrease) in cash		(3,077)		(746)
Cash at beginning of period		9,954		6,678
Cash at end of period	$	6,877	$	5,932
Supplemental disclosures of cash flow information:				
Cash paid for interest	$	-	$	-
Cash paid for taxes	$	-	$	-

See accompanying notes to unaudited consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements
(Unaudited)

1. Organization and Nature of Operations and Basis of Presentation

Description of Business

Synthetic Biologics, Inc. (the "Company" or "Synthetic Biologics") 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, and has partnered the development of a treatment for fibromyalgia.

Therapeutic Area	Product Candidate	Status
Relapsing-remitting MS	Trimesta (oral estriol)	Completed enrollment in Phase II clinical trial; dosing and monitoring underway
Cognitive dysfunction in MS	Trimesta (oral estriol)	Patient enrollment underway in Phase II clinical trial
*C. difficile*infection prevention	SYN-004 (monoclonal antibody)	Series of oral enzyme candidates; first generation candidate (formerly known as P1A) is in Phase II; next generation candidate, SYN-004, (formerly known as P3A) is in preclinical
Pertussis	SYN-005 (monoclonal antibody)	Preclinical; Collaborations with Intrexon and The University of Texas at Austin
*Acinetobacter*infection	SYN-001 (monoclonal antibody)	Discovery; Collaboration with Intrexon
Fibromyalgia	Effirma (oral flupirtine)	Partnered with Meda AB

In order to further prioritize the Company's focus, it previously elected to discontinue further development of AEN-100 for the treatment of amyotrophic lateral sclerosis. However, the Company is seeking development partners for its zinc-based intellectual property and assets including, AEN-100.

2. Basis of Presentation

The accompanying consolidated financial statements have been prepared pursuant to the rules and regulations of Securities and Exchange Commission ("SEC") for interim financial information. Accordingly they do not include all of the information and notes required by U.S. GAAP for complete financial statements. The accompanying consolidated financial statements include all adjustments, composed of normal recurring adjustments, considered necessary by management to fairly state our results of operations, financial position and cash flows. The operating results for the interim periods are not necessarily indicative of results that may be expected for any other interim period or for the full year. These consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2012 (“2012 Form 10-K”) as filed with the SEC. The interim results for the three and six month periods ended June 30, 2013, are not necessarily indicative of results for the full year.

The consolidated financial statements are prepared in conformity with U.S. GAAP, which requires the use of estimates, judgments and assumptions that affect the amounts of assets and liabilities at the reporting date and the amounts of revenue and expenses in the periods presented. We believe that the accounting estimates employed are appropriate and the resulting balances are reasonable; however, due to the inherent uncertainties in making estimates actual results could differ from the original estimates, requiring adjustments to these balances in future periods.

3. Discontinued Operations of Adeona Clinical Laboratory and Note Receivable

On March 8, 2012, the Company sold all of its interest in Adeona Clinical Laboratory, LLC (the "Lab") to Hartlab, LLC, an entity controlled by the Lab's former owner. In connection with the sale of the Lab, the consideration received was (i) the immediate assignment of the Lab's outstanding accounts receivable up through the date of closing, plus (ii) $700,000 payable pursuant to the terms of a two-year promissory note bearing interest at 5.7% per annum secured by all of the assets of the Lab. The note and all unpaid interest are due on March 1, 2014.

In accordance with ASC Topic 205-20 "*Presentation of Financial Statements-Discontinued Operations*" (ASC 205-20), the Company determined that all the criteria for reporting a discontinued operation had been met. Accordingly, the Lab has been classified as a discontinued operation and its results of operations, financial position and cash flows are separately reported for all periods presented.

The summarized statement of operations data for Adeona Clinical Laboratory for the three and six months ended June 30, 2013 and 2012 are as follows *(in thousands):*

	Three Months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Laboratory fees, net	$ -	$ -	$ -	$ 115
Operating Costs and Expenses:				
General and administrative	-	156	-	183
Cost of laboratory services	-	-	-	116
Total operating costs and expenses	-	156	-	299
Loss from discontinued operations	-	(156)	-	(184)
Other Income:				
Gain on sale of Adeona Clinical Laboratory	-	-	-	677
Income (loss) from discontinued operations	$ -	$ (156)	$ -	$ 493

4. Fair Value of Financial Instruments

The fair value accounting standards define fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are rated on a three-tier hierarchy as follows:

Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;

Level 2 inputs: Inputs, other than quoted prices included in Level 1 that are observable either directly or indirectly; and

Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

If the inputs used to measure fair value fall in different levels of the fair value hierarchy, the hierarchy level is based upon the lowest level of input that is significant to the fair value measurement.

Cash and cash equivalents include money market accounts of $6.9 million and $10.0 million as of June 30, 2013 and December 31, 2012, respectively, that are measured using Level 1 inputs.

5. Selected Balance Sheet Information

Prepaid expenses and other current assets (in thousands)

	June 30, 2013		December 31, 2012	
Intrexon prepaid research and development expenses	$	1,719	$	2,412
Other receivables		53		17
Prepaid expenses		108		80
Total	$	1,880	$	2,509

The anticipated Intrexon research and development expenses for the next twelve months are classified as a current asset. The Company may terminate the arrangement at any time and receive a cash refund of the remaining balance minus any amounts owed to Intrexon.

Property and equipment (in thousands)

	June 30, 2013	December 31, 2012
Manufacturing equipment	$ 152	$ 297
Computer and office equipment	48	35
Laboratory equipment	133	133
	333	465
Less accumulated depreciation	(178)	(242)
Total	$ 155	$ 223

6. Stock-Based Compensation

Stock Incentive Plan

During 2001, the Company's Board of Directors and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2001 Stock Plan shall not exceed 250,000. All awards pursuant to the 2001 Stock Plan shall terminate upon the termination of the grantee's employment for any reason. Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The 2001 Stock Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined in the plan. The 2001 Stock Plan provides for a Committee of the Board to grant Awards and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the Awards, including acceleration of the vesting of an Award at any time. As of June 30, 2013, there were 953,507 options issued and outstanding under the 2001 Stock Plan.

On March 20, 2007, the Company's Board of Directors approved the 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 2,500,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. This plan was approved by stockholders on November 2, 2007. The exercise price of stock options under the 2007 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2007 plan shall not exceed 250,000. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of June 30, 2013, there are 443,573 options issued and outstanding under the 2007 Stock Plan.

On November 2, 2010, the Board of Directors and stockholders adopted the 2010 Stock Incentive Plan ("2010 Stock Plan") for the issuance of up to 3,000,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. The exercise price of stock options under the 2010 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of June 30, 2013, there are 2,463,056 options issued and outstanding under the 2010 Stock Plan.

In the event of an employee's termination, the Company will cease to recognize compensation expense for that employee. There is no deferred compensation recorded upon initial grant date, instead, the fair value of the stock-based payment is recognized ratably over the stated vesting period.

The Company has applied fair value accounting for all share based payment awards since inception. The fair value of each option or warrant granted is estimated on the date of grant using the Black-Scholes option pricing model. The Black-Scholes assumptions used in the three and six months ended June 30, 2013 and 2012 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Exercise price	-	$1.70- $1.75	$1.74	$1.70- $2.47
Expected dividends	-	0%	0%	0%
Expected volatility	-	171%	148%	108% - 174%
Risk free interest rate	-	1.89% - 1.92%	0.77%	0.37% - 1.98%
Expected life of option	-	7 years 10 years	5 years	7 years 10 years
Expected forfeitures	-	0%	0%	0%

The Company records stock-based compensation based upon the stated vested provisions in the related agreements. The vesting provisions for these agreements have various terms as follows:

- immediate vesting,
- half vesting immediately and the remainder over three years,
- quarterly over three years,
- annually over three years,
- one-third immediate vesting and remaining annually over two years,
- one half immediate vesting with remaining vesting over nine months,
- one quarter immediate vesting with the remaining over three years,
- one quarter immediate vesting with the remaining over 33 months; and
- monthly over three years.

During the six months ended June 30, 2013, the Company granted 117,500 options to employees and directors having an approximate fair value of $185,000 based upon the Black-Scholes option pricing model. During the same period in 2012, the Company granted 1,550,000 options to employees and consultants having an approximate fair value of $3.5 million based upon the Black-Scholes option pricing model.

A summary of stock option activities as of June 30, 2013, and for the year ended December 31, 2012, is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance - December 31, 2011	2,979,010	$ 1.34	6.01 years	$ -
Granted	2,075,000	$ 2.21		
Exercised	(374,851)	$ 0.34		
Forfeited	(225,413)	$ 2.37		
Balance - December 31, 2012	4,453,746	$ 1.78	6.43 years	$ 1,308,000
Granted	117,500	$ 1.74		

Exercised		(291,666)	$	0.79				
Forfeited		(419,444)	$	2.31				
Balance	June 30, 2013 - outstanding	3,860,136	$	1.79		6.00 years	$	976,000
Balance	June 30, 2013 - exercisable	2,779,133	$	1.66		4.34 years	$	915,000
Grant date fair value of options granted - 2013			$	185,000				
Weighted average grant date fair value - 2013			$	1.57				
Grant date fair value of options granted - 2012			$	4,468,000				
Weighted average grant date fair value - 2012			$	2.15				

Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to employees and consultants for the three months ended June 30, 2013 and 2012 were $407,000 and $400,000, respectively and $864,000 and $908,000 for the six month periods ended June 30, 2013 and 2012, respectively.

As of June 30, 2013, total unrecognized stock-based compensation expense related to stock options was $2.2 million, which is expected to be expensed through February 2016.

7. Stock Purchase Warrants

On October 25, 2012, the Company entered into a Common Stock Purchase Agreement with certain accredited investors. As part of this agreement, the Company issued warrants to purchase 635,855 shares of common stock to the placement agent, or its permitted assigns. The warrants have an exercise price of $1.60 and a life of five years. The warrants vested immediately and expire October 25, 2017. Since these warrants were granted as part of an equity raise, the Company has treated them as a direct offering cost. The result of the transaction has no affect to equity. As of June 30, 2013, all the warrants were outstanding.

On March 15, 2012, the Company entered into a consulting agreement for a financial communications program, for a period of twelve months that began on February 20, 2012. As compensation for such program, the consultant is paid a monthly fee and will be issued a performance warrant exercisable for 250,000 shares of the Company’s common stock based on achievement of certain stock price milestones. Upon initiation of the program, 50,000 of the performance warrants vested. The performance warrant is exercisable for a period of two years from the date of issuance for an exercise price equal to the price ($2.20 per share) of the Company’s common stock on the date of execution (March 15, 2012). In March 2013, the performance warrants’ vesting period was extended to March 14, 2014. All other provisions of the performance warrants remain unchanged. The incremental expense related to the modification of the warrants of approximately $76,000 will be recognized over the one year extension period.

On December 20, 2011, the Company entered into a consulting agreement for financial advisory services, for a period of twelve months. As compensation for such services, the consultant was paid a monthly fee and on February 2, 2012, was issued warrants exercisable for 100,000 shares of the Company’s common stock. The warrant is exercisable upon issuance for a period of five years from the date of issue at an exercise price equal to the price ($1.14) of the Company’s common stock on the date of issue. As of June 30, 2013, all the warrants were outstanding.

A summary of warrant activity for the Company for the six months ended June 30, 2013 and for the year ended December 31, 2012 is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2011	3,259,186	$ 1.95
Granted	985,855	1.71
Exercised	(1,768,167)	1.11
Forfeited	(844,373)	3.32
Balance at December 31, 2012	1,632,501	1.99
Granted	-	-
Exercised	-	-
Forfeited	-	-
Balance at June 30, 2013	1,632,501	$ 1.99

Stock-based compensation expense included in general and administrative expenses relating to warrants issued to consultants was $22,000 and $0 for the three months ended June 30, 2013 and 2012, respectively, and $22,000 and $270,000 for the six months ended June 30, 2013 and 2012, respectively.

A summary of all outstanding and exercisable warrants as of June 30, 2013 is as follows: