Synthetic Biologics, Inc.
Form 10-Q
August 14, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2012

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)*
617 Detroit Street, Suite 100 **Ann Arbor, MI**	**48104**
(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	¨	Smaller reporting company	x
(Do not check if a smaller reporting company)			

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 9, 2012, the registrant had 33,395,538 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 share data)

	June 30, 2012 (Unaudited)	December 31, 2011
Assets		
Current Assets:		
Cash	$ 5,932	$ 6,678
Accounts receivable – net	245	405
Other	94	16
Assets of discontinued operations	-	23
Total Current Assets	6,271	7,122
Property and equipment, net	254	323
Long-term note receivable	700	-
Deposits and other assets	20	31
Total Assets	$ 7,245	$ 7,476
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 278	$ 388
Accrued liabilities	117	29
Total Current Liabilities	395	417
Total Liabilities	395	417
Commitments and Contingencies	-	-
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, 33,382,629 issued and 33,301,147 outstanding as of June 30, 2012 and 31,374,002 issued and	33	31

31,292,520 outstanding as of December 31, 2011		
Additional paid-in capital	61,762	58,901
Accumulated deficit	(54,945)	(51,873)
Total Stockholders' Equity	6,850	7,059
Total Liabilities and Stockholders' Equity	$ 7,245	$ 7,476

See accompanying notes to unaudited consolidated financial statements

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Statements of Operations

(In thousands, except share data)

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Operating Costs and Expenses:				
General and administrative	$1,176	$524	$2,644	$1,757
Research and development	547	281	933	512
Total Operating Costs and Expenses	1,723	805	3,577	2,269
Loss from Continuing Operations	(1,723)	(805)	(3,577)	(2,269)
Other Income (Expense):				
Warrant expense	-	(776)	-	(1,492)
Change in fair value of warrant liability	-	16	-	(78)
Other income (expense)	7	(1)	12	50
Total Other Income (Expense), net	7	(761)	12	(1,520)
Loss from Continuing Operations	(1,716)	(1,566)	(3,565)	(3,789)
Income (Loss) from Discontinued Operations	(156)	(114)	493	(77)
Net Loss and Comprehensive Loss	$(1,872)	$(1,680)	$(3,072)	$(3,866)
Net Income (Loss) Per Share - Basic and Dilutive:				
Continuing operations	$(0.05)	$(0.06)	$(0.11)	$(0.14)
Discontinued operations	-	-	0.02	-
Net Loss Per Share	$(0.05)	$(0.06)	$(0.09)	$(0.14)
Weighted average number of shares outstanding during the period - Basic and Dilutive	33,011,460	27,885,479	32,507,312	26,560,448

See accompanying notes to unaudited consolidated financial statements

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six months ended June 30,	
	2012	2011
Cash Flows From Operating Activities:		
Net loss	$(3,072)	$(3,866)
Adjustments to reconcile net loss to net cash used in operating activites:		
Stock-based compensation	908	427
Stock option modification expense	-	398
Stock issued as employee compensation	-	76
Stock issued for consulting fees	-	58
Warrant expense	-	1,492
Change in fair value of warrant liability	-	78
Depreciation	39	101
Provision for uncollectible accounts receivable	165	188
Gain on the sale of discontinued operations	(677)	-
Gain on sale of equipment	-	6
Impairment on loss of equipment	30	-
Gain on the settlement of accounts payable	-	(63)
Changes in operating assets and liabilities:		
Accounts receivable	(5)	(295)
Other current assets	(78)	268
Deposits and other assets	11	50
Assets of discontinued operations	-	6
Accounts payable	(110)	54
Accrued liabilities	88	(187)
Liabilities of discontinued operations	-	(24)
Net Cash Used In Operating Activities	(2,701)	(1,233)
Cash Flows From Investing Activities:		
Proceeds from the sale of equipment	-	1
Net Cash Provided By Investing Activities	-	1
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock for stock option exercises	94	8
Proceeds from issuance of common stock for warrant exercises	1,861	-
Proceeds from issuance of common stock, net offering costs $296	-	6,961
Net Cash Provided By Financing Activities	1,955	6,969

Net increase (decrease) in cash	(746)	5,737
Cash at beginning of period	6,678	2,649
Cash at end of period	$5,932	$8,386
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

Synthetic Biologics, Inc. (the "Company" or "Synthetic Biologics"), formerly Adeona Pharmaceuticals, Inc., is a biotechnology company focused on the development of synthetic biologics and innovative medicines to address serious diseases and unmet medical needs. The Company is developing the following synthetic biologic candidates: a series of monoclonal antibodies (mAbs) for the treatment of infectious diseases not adequately addressed by existing therapies and a synthetic DNA-based therapy for the treatment of pulmonary arterial hypertension (PAH). The Company also intends to expand new and existing collaborations in the synthetic biology area. In addition, Synthetic Biologics has several clinical-stage programs that are being funded, or partially funded, by grants, charitable organizations and corporate partners. In this area we are developing, or have partnered the development of, product candidates to treat relapsing-remitting multiple sclerosis (MS), cognitive dysfunction in MS, amyotrophic lateral sclerosis (ALS) and fibromyalgia.

Medical Indication	Product Candidate	Status
Infectious disease	SYN-ID-001 (Monoclonal antibody)	Discovery; Collaboration with Intrexon
Infectious disease	SYN-ID-002 (Monoclonal antibody)	Discovery; Collaboration with Intrexon
Infectious disease	SYN-ID-003 (Monoclonal antibody)	Discovery; Collaboration with Intrexon
PAH	SYN-PAH-001 (Synthetic DNA-based therapy)	Preclinical; Collaboration with Intrexon
Relapsing-remitting MS	Trimesta (oral estriol)	All patients enrolled in Phase II clinical trial; dosing and monitoring underway
Cognitive dysfunction in MS	Trimesta (oral estriol)	Patient enrollment underway in Phase II clinical trial
ALS	AEN-100 (gastroretentive zinc acetate)	Phase II/III clinical trial preparation underway

Fibromyalgia	Effirma (oral flupirtine)	Partnered with Meda AB

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/A for the year ended December 31, 2011 ("2011 Form 10-K") as filed with the SEC. The interim results for the three and six month periods ended June 30, 2012, 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 had been met and classified the Lab as discontinued operations and its results of operations, financial position and cash flows are separately reported for all periods presented. The assets of the discontinued operations are presented separately under the caption "Assets of discontinued operations" in the accompanying Consolidated Balance Sheets at June 30, 2012, and December 31, 2011, and consist of the following *(in thousands):*

	June 30, 2012	December 31, 2011
Assets of discontinued operations:		
Property and equipment, net	$ -	$ 23
Total assets	$ -	$ 23

The summarized statement of operations data for Adeona Clinical Laboratory for the three and six months ended June 30, 2012 and June 30, 2011 are as follows *(in thousands):*

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Laboratory fees, net	$-	$356	$115	$679
Operating Costs and Expenses:				
General and administrative	156	169	183	211
Cost of laboratory services	-	301	116	545
Total operating costs and expenses	156	470	299	756
Loss from discontinued operations	(156)	(114)	(184)	(77)
Other Income:				
Gain on sale of Adeona Clinical Laboratory	-	-	677	-

Income (loss) from discontinued operations	$(156)	$(114)	$493	$(77)

4. Selected Balance Sheet Information

Accounts receivable consisted of the following at June 30, 2012 and December 31, 2011 *(in thousands):*

	June 30, 2012	December 31, 2011
Accounts receivable	$ 699	$ 692
Bad debt allowance - customer	(454)	(287)
Accounts receivable, net	$ 245	$ 405

Property and Equipment consisted of the following at June 30, 2012, and December 31, 2011 *(in thousands)* :

	June 30, 2012	December 31, 2011
Manufacturing equipment	$ 335	$ 400
Computer and office equipment	25	159
Laboratory equipment	133	136
Total	493	695
Less accumulated depreciation	(239)	(372)
Property and equipment, net	$ 254	$ 323

Depreciation expense for the six months ended June 30, 2012 and 2011 was approximately $39,000 and $101,000, respectively.

5. Stock-Based Compensation

During 2001, Pipex Therapeutics' Board of Directors and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). This plan was assumed by Pipex in the October 2006 merger with Sheffield. As of the date of the merger, there were 1,489,353 options issued and outstanding under the 2001 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 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, 2012, there were 1,066,007 options issued and outstanding under the 2001 Stock Plan.

On March 20, 2007, the Company's Board of Directors approved the Company's 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 st