

Synthetic Biologics, Inc.
Form 10-Q
August 03, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

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: 001-12584

SYNTHETIC BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)(I.R.S. Employer Identification No.)

13-3808303

9605 Medical Center Drive, Suite 270

Rockville, MD

(Address of principal executive offices)

20850

(Zip Code)

(301) 417-4364

(Registrant's telephone number, including area code)

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 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 No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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
(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

As of August 1, 2016 the registrant had 91,269,586 shares of common stock, \$0.001 par value per share, outstanding.

SYNTHETIC BIOLOGICS, INC.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In particular, statements contained in this Quarterly Report on Form 10-Q, including but not limited to, statements regarding the timing of our clinical trials the development and commercialization of our pipeline products, the sufficiency of our cash, our ability to finance our operations and business initiatives and obtain funding for such activities, our future results of operations and financial position, business strategy and plan prospects, or costs and objectives of management for future research, development or operations, are forward-looking statements. These forward-looking statements relate to our future plans, objectives, expectations and intentions and may be identified by words such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “seeks,” “goals,” “estimates,” “predicts,” “potential” and “continue” or similar words. Readers are cautioned that these forward-looking statements are based on our current beliefs, expectations and assumptions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified below, under Part II, Item 1A. “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q, and those identified under Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on March 10, 2016. Therefore, actual results may differ materially and adversely from those expressed, projected or implied in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

NOTE REGARDING COMPANY REFERENCES

Throughout this Quarterly Report on Form 10-Q, “Synthetic,” the “Company,” “we,” “us” and “our” refer to Synthetic Biologics, Inc.

NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

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 and per share amounts)**

	June 30, 2016 (unaudited)	December 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	\$10,049	\$20,818
Prepaid expenses and other current assets	5,774	9,519
Total Current Assets	15,823	30,337
Property and equipment, net	482	494
Deposits and other assets	26	14
Total Assets	\$16,331	\$30,845
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$4,556	\$4,413
Accrued expenses	1,841	297
Warrant liabilities	7,552	10,567
Accrued employee benefits	1,174	277
Deferred rent	50	21
Total Current Liabilities	15,173	15,575
Long term deferred rent	227	267
Total Liabilities	15,400	15,842
Commitments and Contingencies	-	-

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Equity:

Preferred stock, \$0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, \$0.001 par value; 250,000,000 shares authorized, 91,351,068 issued and 91,269,586 outstanding and 90,908,234 issued and 90,826,752 outstanding	91	91
Additional paid-in capital	163,508	160,739
Accumulated deficit	(161,305)	(144,779)
Total Synthetic Biologics, Inc. and Subsidiaries Equity	2,294	16,051
Non-controlling interest	(1,363)	(1,048)
Total Stockholders' Equity	931	15,003
Total Liabilities and Stockholders' Equity	\$16,331	\$30,845

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,		For the six months ended June 30,	
	2016	2015	2016	2015
Operating Costs and Expenses:				
General and administrative	\$ 2,147	\$ 2,222	\$ 4,573	\$ 3,935
Research and development	7,164	7,508	15,319	14,002
Total Operating Costs and Expenses	9,311	9,730	19,892	17,937
Loss from Operations	(9,311)	(9,730)	(19,892)	(17,937)
Other Income (Expense):				
Change in fair value of warrant liability	3,513	(3,895)	3,015	(8,047)
Interest income	34	2	35	3
Total Other Income (Expense)	3,547	(3,893)	3,050	(8,044)
Net Loss	(5,764)	(13,623)	(16,842)	(25,981)
Net Loss Attributable to Non-controlling Interest	(82)	-	(315)	-
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	\$ (5,682)	\$ (13,623)	\$ (16,527)	\$ (25,981)
Net Loss Per Share - Basic	\$ (0.06)	\$ (0.19)	\$ (0.18)	\$ (0.36)
Net Loss Per Share - Dilutive	\$ (0.10)	\$ (0.19)	\$ (0.21)	\$ (0.36)
Weighted average number of shares outstanding during the period - Basic	91,015,733	72,736,829	90,921,243	72,674,650
Weighted average number of shares outstanding during the period - Dilutive	93,930,540	72,736,829	92,651,215	72,674,650

See accompanying notes to unaudited consolidated financial statements.

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

	For the six months ended June,	
	2016	2015
Cash Flows From Operating Activities:		
Net Loss	\$ (16,842)	\$ (25,981)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,959	1,413
Stock issued for milestone payments	-	1,350
Change in fair value of warrant liabilities	(3,015)	8,047
Depreciation	57	19
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,745	(5,407)
Deposits and other assets	(11)	(12)
Accounts payable	143	7,690
Accrued expenses	1,543	317
Accrued employee benefits	897	(144)
Deferred rent	(10)	-
Net Cash Used In Operating Activities	(11,534)	(12,708)
Cash Flows From Investing Activities:		
Purchases of property and equipment	(45)	(61)
Net Cash Used In Investing Activities	(45)	(61)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock for stock option exercises	810	1
Net Cash Provided By Financing Activities	810	1
Net decrease in cash	(10,769)	(12,768)
Cash at beginning of period	20,818	17,525
Cash at end of period	\$ 10,049	\$ 4,757
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 clinical stage company developing therapeutics to protect the gut microbiome while targeting pathogen-specific diseases. The Company’s lead candidates in Phase 2 development are: (1) SYN-010 which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C), and (2) SYN-004 (ribaxamase) which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. difficile* infection (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms. In collaboration with Intrexon Corporation (“Intrexon”), the Company is also developing preclinical stage monoclonal antibody therapies for the prevention and treatment of pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

Basis of Presentation

The accompanying consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) for interim financial information. Accordingly, they do not include all of the information and notes required by U.S. Generally Accepted Accounting Principles (“GAAP”) for complete financial statements. The accompanying consolidated financial statements include all adjustments, comprised 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 the Company’s Annual Report on Form 10-K for the year ended December 31, 2015 (“2015 Form 10-K”) as filed with the SEC. The interim results for the three and six months ended June 30, 2016, 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.

Recent Accounting Pronouncements and Developments

In March 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-09, *Compensation - Stock Compensation (Topic 718)*, which is part of the FASB's Simplification Initiative. The updated guidance simplifies the accounting for share-based payment transactions. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which establishes a new lease accounting model for lessees. The updated guidance requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2016-09, guidance which defines management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. This guidance is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early adoption is permitted. Management believes that the adoption of this guidance will not have a material impact on our financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, to provide guidance on revenue recognition. ASU No. 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today's guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which provided for the adoption of the new standard for fiscal years beginning after December 15, 2017. Accordingly, ASU No. 2014-09 is effective for the Company in the first quarter of 2018. Early adoption up to the first quarter of 2017 is permitted. Upon adoption, ASU No. 2014-09 can be applied retrospectively to all periods presented or only to the most current period presented with the cumulative effect of changes reflected in the opening balance of retained earnings in the most current period presented. The FASB has also issued the following standards which clarify ASU No. 2014-09 and have the same effective date as the original standard:

ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*;

ASU No. 2016-10, *Identifying Performance Obligations and Licensing (Topic 606)*;

ASU No. 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting*; and

ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*.

The Company is currently evaluating the method of adoption and the impact of adopting ASU No. 2014-09 on its results of operations, cash flows and financial position.

2. Management's Plan

The Company has incurred an accumulated deficit of \$161.3 million through June 30, 2016. With the exception of the quarter ended June 30, 2010, the Company has incurred negative cash flow from operations since its inception. The Company has spent, and expects to continue to spend, substantial amounts in connection with implementing its business strategy, including the planned product development efforts, clinical trials and research and discovery efforts.

At June 30, 2016, the Company had cash and cash equivalents of approximately \$10.0 million. Based upon our current business plans, management does not believe that the Company's current cash on hand will be sufficient to fund its operations for the next twelve months. The Company will be required to obtain additional funding in order to execute its plans, although it does not currently have commitments from any third parties to provide it with capital. The Company cannot assure that additional funding will be available on favorable terms, or at all. If the Company fails to obtain additional funding when needed, it may not be able to execute its business plans and its business may suffer, which would have a material adverse effect on its financial position, results of operations and cash flows.

The actual amount of funds the Company will need to operate is subject to many factors, some of which are beyond the Company's control. These factors include the following:

- the progress of research activities;

- the number and scope of research programs;

- the progress of preclinical and clinical development activities;

- the progress of the development efforts of parties with whom the Company has entered into research and development agreements;

- costs associated with additional clinical trials of product candidates;

- the ability to maintain current research and development licensing arrangements and to establish new research and development, and licensing arrangements;

- the ability to achieve milestones under licensing arrangements;

- the costs associated with manufacturing-related services to produce material for use in our clinical trials;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

The Company has based its estimate on assumptions that may prove to be wrong. The Company may need to obtain additional funds sooner or in greater amounts than it currently anticipates. Potential sources of financing include strategic relationships, public or private sales of the Company's shares or debt and other sources.

The Company may seek to access the public or private equity markets when conditions are favorable due to long-term capital requirements. The Company does not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when needed on terms that will be acceptable to it, or at all. If the Company raises funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of the existing stockholders will be diluted. If the Company is not able to obtain financing when needed, it may be unable to carry out its business plan. As a result, the Company may have to significantly limit its operations and its business, financial condition and results of operations would be materially harmed.

3. 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 \$1.8 million and \$5.3 million as of June 30, 2016 and December 31, 2015, respectively, that are measured using Level 1 inputs.

The warrants issued in conjunction with the registered direct offering in October 2014 include a provision that if the Company were to enter into a certain transaction, as defined in the agreement, the warrants would be purchased from the holder at a premium. Accordingly, the Company recorded the warrants as liabilities at their fair value upon issuance and re-measures the fair value at each period end with the change in fair value recorded in the Consolidated Statements of Operations. The Company uses the Black-Scholes options pricing model to estimate the fair value of the warrants. In using this model, the fair value is determined by applying Level 3 inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liability and the change in estimated fair value could be materially different.

4. Selected Balance Sheet Information

Prepaid expenses and other current assets (in thousands)