Synthetic Biologics, Inc.
Form 10-Q
August 08, 2018

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, 2018

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	**13-3808303**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*

9605 Medical Center Drive, Suite 270
Rockville, MD **20850**
(Address of Principal Executive Offices) *(Zip Code)*

(301) 417-4364

(*Registrant's Telephone Number, Including Area Code*)

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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 6, 2018, the registrant had 132,969,743 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 and the timing of any such financing, 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 "continu 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, 2017 filed with the Securities and Exchange Commission (the "SEC") on February 22, 2018 ("2017 Form 10-K"). 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 Biologics," the "Company," "we," "us" and "our" refer to Synthet 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 (UNAUDITED)

Synthetic Biologics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(In thousands except share and per share amounts)

	June 30, 2018	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	$ 7,129	$ 17,116
Prepaid expenses and other current assets	535	827
Total Current Assets	7,664	17,943
Property and equipment, net	731	872
Deposits and other assets	23	23
Total Assets	$ 8,418	$ 18,838
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 1,217	$ 2,020
Accrued expenses	1,000	1,526
Warrant liabilities	645	4,083
Accrued employee benefits	1,362	2,074
Deferred rent	95	90
Total Current Liabilities	4,319	9,793
Long term deferred rent	353	402
Total Liabilities	4,672	10,195
Series A convertible preferred stock, $0.001 par value; 10,000,000 and zero shares authorized; 120,000 issued and outstanding	12,173	12,053
Stockholders' Deficit:		
	130	129

Common stock, $0.001 par value; 350,000,000 shares authorized,130,380,517 issued and 130,299,305 outstanding and 117,254,196 issued and 117,172,714 outstanding		
Additional paid-in capital	194,186	192,545
Accumulated deficit	(200,803)	(194,170)
Total Synthetic Biologics, Inc. and Subsidiaries Deficit	(6,487)	(1,496)
Non-controlling interest	(1,940)	(1,914)
Total Stockholders' Deficit	(8,427)	(3,410)
Total Liabilities and Stockholders' Deficit	$ 8,418	$ 18,838

See accompanying notes to unaudited condensed consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries

Condensed 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,	
	2018	2017	2018	2017
Operating Costs and Expenses:				
General and administrative	$ 1,431	$ 1,644	$ 3,051	$ 3,734
Research and development	3,572	4,831	6,942	10,891
Total Operating Costs and Expenses	5,003	6,475	9,993	14,625
Loss from Operations	(5,003)	(6,475)	(9,993)	(14,625)
Other Income:				
Change in fair value of warrant liability	783	2,159	3,438	7,249
Interest income	6	1	15	3
Total Other Income	789	2,160	3,453	7,252
Net Loss	(4,214)	(4,315)	(6,540)	(7,373)
Net Loss Attributable to Non-controlling Interest	(17)	(60)	(26)	(272)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (4,197)	$ (4,255)	(6,514)	(7,101)
Series A Preferred Stock Dividends	(61)		(120)	-
Net Loss Attributable to Common Stock Holders	$ (4,258)	$ (4,255)	$ (6,634)	$ (7,101)
Net Loss Per Share - Basic and Dilutive	$ (0.03)	$ (0.03)	$ (0.05)	$ (0.06)
Weighted average number of shares outstanding during the period - Basic and Dilutive	128,918,408	123,005,220	128,743,616	120,241,593

See accompanying notes to unaudited condensed consolidated financial statements.

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Synthetic Biologics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	For the six months ended June 30,	
	2018	2017
Cash Flows From Operating Activities:		
Net Loss	$ (6,540)	$ (7,373)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,233	2,006
Warrant issued to consultant	9	-
Change in fair value of warrant liabilities	(3,438)	(7,249)
Depreciation and amortization	141	116
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	292	975
Accounts payable	(803)	(271)
Accrued expenses	(526)	(877)
Accrued employee benefits	(711)	896
Deferred rent	(44)	29
Net Cash Used In Operating Activities	(10,387)	(11,748)
Cash Flows From Investing Activities:		
Purchases of property and equipment	-	(11)
Net Cash Used In Investing Activities	-	(11)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock for stock option exercises	-	166
Proceeds from "at the market" stock issuance	400	5,914
Net Cash Provided By Financing Activities	400	6,080
Net decrease in cash	(9,987)	(5,679)
Cash at beginning of period	17,116	19,055
Cash at end of period	$ 7,129	$ 13,376

See accompanying notes to unaudited condensed consolidated financial statements.

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Synthetic Biologics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Organization, Nature of Operations and Basis of Presentation

Description of Business

Synthetic Biologics, Inc. (the "Company" or "Synthetic Biologics") is a late-stage clinical company developing therapeutics designed to preserve the microbiome to protect and restore the health of patients. The Company's lead candidates poised for Phase 3 development are: (1) SYN-004 (ribaxamase) which is designed to protect the gut microbiome (gastrointestinal (GI) microflora) from the effects of certain commonly used intravenous (IV) antibiotics for the prevention of *C. difficile* infection (CDI), overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR), and (2) 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). Our preclinical pursuits include an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases as well as 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 condensed 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 Accounting Principles Generally Accepted in the United States of America ("U.S. GAAP") for complete financial statements. The accompanying condensed consolidated financial statements include all adjustments, comprised of normal recurring adjustments, considered necessary by management to fairly state the Company's 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 condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's 2017 Form 10-K. The interim results for the three and six months ended June 30, 2018 are not necessarily indicative of results for the full year.

The condensed 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. The Company believes that the accounting estimates employed are appropriate and the resulting balances are reasonable; however, due to the inherent uncertainties in making estimates, actual results may differ from the original estimates, requiring adjustments to these balances in future periods.

Recent Accounting Pronouncements and Developments

In February 2016, the Financial Accounting Standards Board, ("FASB") issued Accounting Standards Update ("ASU") 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 June 2018, FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include share-based payments issued to nonemployees, and generally aligns the accounting for nonemployee awards with the accounting for employee awards. The ASU is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

The Tax Cuts and Jobs Act (the Tax Act) was signed into law on December 22, 2017. The Tax Act changed many aspects of U.S. corporate income taxation and included reduction of the corporate income tax rate from 35% to 21%, implementation of a territorial tax system and imposition of a tax on deemed repatriated earnings of foreign subsidiaries. The Company recognized the tax effects of the Tax Act in the year ended December 31, 2017 and recorded $21.6 million in tax expense which relates almost entirely to the remeasurement of deferred tax assets to the 21% tax rate. The Company will continue to assess its provision for income taxes as future guidance is issued but does not currently anticipate significant revisions will be necessary. Accounting Standards Codification ("ASC") No. 740, *Income taxes,* requires the Company to record the effects of a tax law change in the period of enactment. However, shortly after the enactment of the Tax Act, the SEC staff issued Staff Accounting Bulletin ("SAB") 118, which allows the Company to record a provisional amount when it does not have the necessary information available, prepared, or analyzed in reasonable detail to complete its accounting for the change in the tax law. The measurement period ends when the Company has obtained, prepared and analyzed the information necessary to finalize its accounting, but cannot extend beyond one year.

2. Going Concern

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has recurring losses and, as of June 30, 2018, the Company has an accumulated deficit of approximately $200.8 million. Since inception, the Company has financed its activities principally with proceeds from the issuance of equity securities.

The Company's ability to continue as a going concern is dependent upon the Company's ability to raise additional debt or equity capital. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to the Company. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should the Company be unable to continue as a going concern.

The Company does not have sufficient capital to fund its plan of operations over the next twelve months. In order to address its capital needs, including its planned Phase 2b/3 and phase 3 clinical trials, the Company is actively pursuing additional equity or debt financing, in the form of either a private placement or a public offering. The Company has been in ongoing discussions with strategic institutional investors and investment banks with respect to such possible offerings. Such additional financing opportunities might not be available to the Company when and if needed, on acceptable terms or at all. If the Company is unable to obtain additional financing in sufficient amounts or on acceptable terms under such circumstances, the Company's operating results and prospects will be adversely affected.

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 its planned product development efforts, clinical trials, and research and discovery efforts.

At June 30, 2018, the Company had cash and cash equivalents of approximately $7.1 million. Based upon the Company's current business plans, management does not believe that the Company's current cash on hand will be sufficient to execute its near term plans. Commencement of planned clinical trials is subject to the Company's successful pursuit of opportunities that will allow it to establish the clinical infrastructure and financial resources necessary to successfully initiate and make significant progress towards completion of its plan. The Company will be required to obtain additional funding in order to continue the development of its current product candidates within the anticipated time periods (including initiation of its planned clinical trials), if at all, and to continue to fund operations at the current cash expenditure levels. Currently, the Company does not have commitments from any third parties to provide it with capital. Potential sources of financing include strategic relationships, public or private sales of equity (including through the "at-the-market" Issuance Sales Agreement (the "B. Riley FBR Sales Agreement") that the

Company entered into with FBR Capital Markets & Co. (now known as B. Riley FBR, Inc.) in August 2016 or debt and other sources. The Company cannot assure that it will meet the requirements for use of the B. Riley FBR Sales Agreement or that additional funding will be available on favorable terms, or at all. Current cash is expected to cover overhead costs, manufacturing costs for clinical supply, clinical start-up costs, business development activities and limited research efforts. If the Company fails to obtain additional funding for its clinical trials in the next few months, whether through the sale of securities or a partner or collaborator, and otherwise when needed, it will not be able to execute its business plan as planned and will be forced to cease certain development activities (including initiation of planned clinical trials) until funding is received and its business will suffer, which would have a material adverse effect on its financial position, results of operations and cash flows. Clinical development will resume once sufficient funding is available.

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 and amount of funding received from partners and collaborators;
- the Company's 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 its 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 estimates 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.

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

Fair Value of Financial Instruments

ASC 820, *Fair Value Measurement*, defines 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.

In many cases, a valuation technique used to measure fair value includes inputs from multiple levels of the fair value hierarchy described above. The lowest level of significant input determines the placement of the entire fair value measurement in the hierarchy.

The carrying amounts of the Company’s short-term financial instruments, including cash and cash equivalents, other current assets, accounts payable and accrued liabilities approximate fair value due to the relatively short period to

maturity for these instruments.

Cash and cash equivalents include money market accounts of $98,000 as of June 30, 2018 and December 31, 2017 that are measured using Level 1 inputs.

The Company uses Monte Carlo simulations to estimate the fair value of the stock 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)

	June 30, 2018	December 31, 2017
Prepaid consulting, subscriptions and other expenses	$ 230	$ 290
Prepaid insurances	170	351
Prepaid conferences and travel	130	94
At the market subscription receivable	5	-
Clinical consulting services refund receivable	-	46
Prepaid clinical research organizations	-	46
Total	$ 535	$ 827

Prepaid clinical research organizations expense is classified as a current asset. The Company makes payments to the clinical research organizations based on agreed upon terms that include payments in advance of study services.

Property and equipment, net (in thousands)

	June 30, 2018	December 31 2017
Computers and office equipment	$ 851	$ 851
Leasehold improvements	439	439
Software	11	11
	1,301	1,301
Less: accumulated depreciation and amortization	(570)	(429)
Total		