

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 March 31, 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**

(State or Other Jurisdiction of Incorporation or Organization)

**13-3808303**

(I.R.S. Employer Identification No.)

**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 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  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, 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-Accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
(Do not check if a smaller reporting company)		Emerging growth company	<input type="checkbox"/>

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

As of May 6, 2018, the registrant had 128,566,866 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 “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, 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 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 (UNAUDITED)

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

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 11,037	\$ 17,116
Prepaid expenses and other current assets	606	827
<b>Total Current Assets</b>	<u>11,643</u>	<u>17,943</u>
<b>Property and equipment, net</b>	801	872
<b>Deposits and other assets</b>	<u>23</u>	<u>23</u>
<b>Total Assets</b>	<u><b>\$ 12,467</b></u>	<u><b>\$ 18,838</b></u>
<b>Liabilities and Stockholders' Deficit</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 1,493	\$ 2,020
Accrued expenses	1,058	1,526
Warrant liabilities	1,428	4,083
Accrued employee benefits	1,016	2,074
Deferred rent	92	90
<b>Total Current Liabilities</b>	<u>5,087</u>	<u>9,793</u>
<b>Long term deferred rent</b>	<u>377</u>	<u>402</u>
<b>Total Liabilities</b>	<u>5,464</u>	<u>10,195</u>
Series A convertible preferred stock, \$0.001 par value; 10,000,000 shares authorized, 120,000 issued and outstanding	12,112	12,053
<b>Stockholders' Deficit:</b>		
Common stock, \$0.001 par value; 350,000,000 shares authorized, 128,648,365 issued and 128,566,886 outstanding	129	129
Additional paid-in capital	193,230	192,545
Accumulated deficit	(196,545)	(194,170)
<b>Total Synthetic Biologics, Inc. and Subsidiaries Deficit</b>	<u>(3,186)</u>	<u>(1,496)</u>
Non-controlling interest	(1,923)	(1,914)
<b>Total Stockholders' Deficit:</b>	<u>(5,109)</u>	<u>(3,410)</u>
<b>Total Liabilities and Stockholders' Deficit</b>	<u><b>\$ 12,467</b></u>	<u><b>\$ 18,838</b></u>

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)

	<b>For the three months ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Operating Costs and Expenses:</b>		
General and administrative	\$ 1,620	\$ 2,090
Research and development	3,370	6,059
<b>Total Operating Costs and Expenses</b>	<b>4,990</b>	<b>8,149</b>
<b>Loss from Operations</b>	<b>(4,990)</b>	<b>(8,149)</b>
<b>Other Income:</b>		
Change in fair value of warrant liability	2,655	5,090
Interest income	9	1
<b>Total Other Income</b>	<b>2,664</b>	<b>5,091</b>
<b>Net Loss</b>	<b>(2,326)</b>	<b>(3,058)</b>
<b>Net Loss Attributable to Non-controlling Interest</b>	<b>(10)</b>	<b>(212)</b>
<b>Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries</b>	<b>(2,316)</b>	<b>(2,846)</b>
Series A Preferred Stock Dividends	(59)	-
<b>Net Loss Attributable to Common Stock Holders</b>	<b>\$ (2,375)</b>	<b>\$ (2,846)</b>
<b>Net Loss Per Share - Basic and Dilutive</b>	<b>\$ (0.02)</b>	<b>\$ (0.02)</b>
<b>Weighted average number of shares outstanding during the period - Basic and Dilutive</b>	<b>128,566,883</b>	<b>117,447,260</b>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>For the three months ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash Flows From Operating Activities:</b>		
Net Loss	\$ (2,326)	\$ (3,058)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	676	1,135
Warrant issued to consultant	9	-
Change in fair value of warrant liabilities	(2,655)	(5,090)
Depreciation	71	57
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	221	(851)
Accounts payable	(527)	1,803
Accrued expenses	(468)	(493)
Accrued employee benefits	(1,058)	474
Deferred rent	(22)	15
<b>Net Cash Used In Operating Activities</b>	<b>(6,079)</b>	<b>(6,008)</b>
<b>Cash Flows From Investing Activities:</b>		
Purchases of property and equipment	-	(11)
<b>Net Cash Used In Investing Activities</b>	<b>-</b>	<b>(11)</b>
<b>Cash Flows From Financing Activities:</b>		
Proceeds from issuance of common stock for stock option exercises	-	166
Proceeds from "at the market" stock issuance	-	269
<b>Net Cash Provided By Financing Activities</b>	<b>-</b>	<b>435</b>
<b>Net decrease in cash</b>	<b>(6,079)</b>	<b>(5,584)</b>
Cash at beginning of period	17,116	19,055
<b>Cash at end of period</b>	<b>\$ 11,037</b>	<b>\$ 13,471</b>

See accompanying notes to unaudited condensed consolidated financial statements.

**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 months ended March 31, 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.

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 March 31, 2018, the Company has an accumulated deficit of approximately \$197 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 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 March 31, 2018, the Company had cash and cash equivalents of approximately \$11.0 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 B. Riley 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 March 31, 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)*

	<b>March 31, 2018</b>	<b>December 31, 2017</b>
Prepaid consulting, subscriptions and other expenses	\$ 265	\$ 290
Prepaid insurances	237	351
Prepaid conferences and travel	104	94
Clinical consulting services refund receivable	-	46
Prepaid clinical research organizations	-	46
<b>Total</b>	<b>\$ 606</b>	<b>\$ 827</b>

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)*

	<b>March 31, 2018</b>	<b>December 31 2017</b>
Computers and office equipment	\$ 851	\$ 851
Leasehold improvements	439	439
Software	11	11
	<u>1,301</u>	<u>1,301</u>
Less: accumulated depreciation and amortization	(500)	(429)
Total	<u>\$ 801</u>	<u>\$ 872</u>

*Accrued expenses (in thousands)*

	<b>March 31, 2018</b>	<b>December 31, 2017</b>
Accrued clinical consulting services	\$ 621	\$ 658
Accrued vendor payments	376	193
Accrued manufacturing costs	55	661
Other accrued expenses	6	14
Total	<u>\$ 1,058</u>	<u>\$ 1,526</u>

*Accrued employee benefits (in thousands)*

	<b>March 31, 2018</b>	<b>December 31, 2017</b>
Accrued severance	\$ 412	\$ 590
Accrued bonus expense	336	1,283
Accrued vacation expense	268	201
Total	<u>\$ 1,016</u>	<u>\$ 2,074</u>

## 5. Stock-Based Compensation

### *Stock Incentive Plans*

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 the 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 March 31, 2018, there were 712,258 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. On October 22, 2013, the stockholders approved and adopted an amendment to the Company's 2010 Incentive Stock Plan to increase the number of shares of Company's common stock reserved for issuance under the Plan from 3,000,000 to 6,000,000. On May 15, 2015, the stockholders approved and adopted an amendment to the Company's 2010 Incentive Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the Plan from 6,000,000 to 8,000,000. On August 25, 2016, the stockholders approved and adopted an amendment to the 2010 Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the 2010 Stock Plan from 8,000,000 to 14,000,000. On September 7, 2017, the stockholders approved and adopted an amendment to the 2010 Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the 2010 Stock Plan from 8,000,000 to 17,500,000. 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 expire between five and ten years after the grant date. As of March 31, 2018, there were 11,476,257 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 over the stated vesting period.

The Company has applied fair value accounting for all stock-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. There were no options granted during the three months ended March 31, 2018. The assumptions used for the three months ended March 31, 2017 are as follows:

Exercise price	\$0.83-\$0.87
Expected dividends	0%
Expected volatility	89.93%-91.82%
Risk free interest rate	1.67%-1.75%
Expected life of option	4.24-4.29 years

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

- immediate vesting;
- half vesting immediately and remaining over three years;
- in full on one-year anniversary date of grant date,
- quarterly over three years;
- annually over three years;

- one-third immediate vesting and remaining annually over two years;
- one half immediate vesting and remaining over nine months;
- one quarter immediate vesting and remaining over three years;
- one quarter immediate vesting and remaining over 33 months; and
- monthly over three years.

During the three months ended March 31, 2018, the Company did not grant options to employees. During the same period in 2017, the Company granted 543,927 options to employees having an approximate fair value of \$308,000 based upon the Black-Scholes option pricing model.

A summary of stock option activities for the three months ended March 31, 2018 is as follows:

	<u>Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Aggregate Intrinsic Value</u>
Balance - December 31, 2017	12,564,098	\$ 1.55	4.60 years	\$ <u>1,800</u>
Expired	(264,119)	\$ 1.57		
Forfeited	(111,464)	\$ 0.78		
Balance -March 31, 2018 - outstanding	<u>12,188,515</u>	<u>\$ 1.55</u>	4.40 years	<u>\$ -</u>
Balance - March 31, 2018 - exercisable	<u>8,064,487</u>	<u>\$ 1.93</u>	3.43 years	<u>\$ -</u>
Grant date fair value of options granted - March 31, 2018		<u>\$ -</u>		
Weighted average grant date fair value - March 31, 2018		<u>\$ -</u>		
Grant date fair value of options granted - December 31, 2017		<u>\$ 1,164,732</u>		
Weighted average grant date fair value - December 31, 2017		<u>\$ 0.37</u>		

Stock-based compensation expense included in operating expenses related to stock options issued to employees and consultants for the three months ended March 31, 2018 and 2017 was \$0.7 million and \$1.1 million respectively.

As of March 31, 2018, total unrecognized stock-based compensation expense related to stock options was \$2.1 million, which is expected to be expensed through September 2019.

## 6. Stock Purchase Warrants

On November 18, 2016, the Company completed a public offering of 25 million shares of common stock with accompanying warrants to purchase an aggregate of 50 million shares of common stock. The stock and warrants were sold in combination, with two warrants for each share of common stock sold, a Series A warrant and a Series B warrant, each representing the right to purchase one share of common stock. The purchase price for each share of common stock and accompanying warrants was \$1.00. The shares of common stock were immediately separable from the warrants and were issued separately. The initial per share exercise price of the Series A warrants was \$1.43 and the per share exercise price of the Series B warrants was \$1.72, each subject to adjustment as specified in the warrant agreements. The Series A and Series B warrants may be exercised at any time on or after the date of issuance. The Series A warrants are exercisable until the four year anniversary of the issuance date. The Series B warrants expired on December 31, 2017 and none were exercised prior to expiration. The warrants 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 for cash. Accordingly, the Company recorded the warrants as a liability at their estimated fair value on the issuance date, which was \$15.7 million, and changes in estimated fair value will be recorded as non-cash income or expense in the Company's Condensed Consolidated Statements of Operations at each subsequent period. At March 31, 2018, the fair value of the warrant liability was \$1.3 million, which resulted in non-cash income of \$2.3 million for the three months ended March 31, 2018. At March 31, 2017, the fair value of the warrant liability was \$8.6 million, which resulted in non-cash income of \$4.1 million for the three months ended March 31, 2017. The warrants were valued Monte Carlo simulations.

The assumptions used by the Company are summarized in the following table:

	<u>March 31, 2018</u>	<u>Series A December 31, 2017</u>	<u>Issuance Date</u>
Closing stock price	\$ 0.32	\$ 0.51	\$ 0.89

Expected dividends	80%	80%	80%
Risk free interest rate	2.35%	1.97%	1.58%
Expected life of warrant (years)	2.6	2.9	4.0

On October 10, 2014, the Company raised net proceeds of \$19.1 million through the sale of 14,059,616 units at a price of \$1.47 per unit to certain institutional investors in a registered direct offering. Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.5 shares of common stock. The warrants, exercisable for an aggregate of 7,029,808 shares of common stock, have an exercise price of \$1.75 per share and a life of five years. The warrants vested immediately and expire on October 10, 2019.

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 a liability at their estimated fair value on the issuance date, which was \$7.4 million, and changes in estimated fair value are being recorded as non-cash income or expense in the Company's Condensed Consolidated Statement of Operations at each subsequent period. At March 31, 2018, the fair value of the warrant liability was \$90,000, which resulted in non-cash income of \$326,000 for the three months ended March 31, 2018. At March 31, 2017, the fair value of the warrant liability was \$1.1 million, which resulted in non-cash income of \$1.0 million for the three months ended March 31, 2017. In accordance with U.S. GAAP, the warrants were valued on the date of grant using the Black-Scholes valuation model which approximates the value derived using a Monte Carlo simulation. The assumptions used by the Company are summarized in the following table:

	<b>March 31, 2018</b>	<b>December 31, 2017</b>	<b>Issuance Date</b>
Closing stock price	\$ 0.32	\$ 0.51	\$ 1.75
Expected dividends	0%	0%	0%
Expected volatility	80%	80%	95%
Risk free interest rate	2.19%	1.86%	1.39%
Expected life of warrant (years)	1.55	1.79	5.00

The following table summarizes the estimated fair value of the warrant liability (*in thousands*):

Balance at December 31, 2017	\$ 4,083
Change in fair value of warrant liability	(2,655)
Balance at March 31, 2018	<u>\$ 1,428</u>

On December 26, 2017 the Company entered into a consulting agreement for advisory services for a period of six months. As compensation for such services, the consultant was paid an upfront payment, is paid a monthly fee and on January 24, 2018, was issued a warrant exercisable for 25,000 shares of the Company common stock on the date of issue. The fair value of the warrant approximated \$9,000 and was measured using the Black-Scholes option pricing model. This entire expense was recorded in the quarter ended March 31, 2018. The assumptions used by the Company are summarized in the following table:

	<b>Issuance Date</b>
Closing stock price	\$ 0.53
Expected dividends	0%
Expected volatility	85%
Risk free interest rate	2.42%
Expected life of warrant (years)	4.92

A summary of warrant activity for the Company for the three months ended March 31, 2018 is as follows:

	<b>Number of Warrants</b>	<b>Weighted Average Exercise Price</b>
Balance at December 31, 2017	32,029,809	\$ 1.50
Granted	25,000	0.52
Exercised	-	-
Forfeited	-	-
Balance at March 31, 2018	<u>32,054,809</u>	<u>\$ 1.50</u>

A summary of all outstanding and exercisable warrants as of March 31, 2018 is as follows:

<b>Exercise Price</b>	<b>Warrants Outstanding</b>	<b>Warrants Exercisable</b>	<b>Weighted Average Remaining Contractual Life (years)</b>
\$ 0.52	25,000	25,000	4.74
\$ 1.43	25,000,000	25,000,000	2.64
\$ 1.75	7,029,808	7,029,809	1.53
<u>\$ 1.60</u>	<u>32,054,808</u>	<u>32,054,809</u>	<u>2.40</u>

## 7. Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding. Included in net loss is the deemed dividend from preferred shares issuance of \$59,000 for the three months ended March 31, 2018. The deemed dividend relates to the discount provided to preferred stockholders upon conversion of their preferred stock to common shares and is subtracted from net loss (see Note 9). Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding including the effect of common share equivalents. Diluted net loss per share assumes the issuance of potentially dilutive common shares outstanding for the period and adjusts for any changes in income and the repurchase of common shares that would have occurred from the assumed issuance, unless such effect is anti-dilutive. The number of options and warrants for the purchase of common stock that were excluded from the computations of net loss per common share for the three months ended March 31, 2018 were 12,188,515 and 32,054,809, respectively, and for the three months and ended March 31, 2017 were 11,489,515 and 57,341,642, respectively.

The following tables set forth the computation of diluted net loss per weighted average number of shares outstanding attributable to Synthetic Biologics, Inc. and Subsidiaries for the three months ended March 31, 2018 and 2017 (*in thousands except share and per share amounts*):

	Three months ended March 31, 2018			Three months ended March 31, 2017		
	Net loss (Numerator)	Shares (Denominator)	Per Share Amount	Net Loss (Numerator)	Shares (Denominator)	Per Share Amount
Net loss - Basic	\$ (2,316)	128,566,883	\$ (0.02)	\$ (2,846)	117,447,260	\$ (0.02)
Dilutive shares related to warrants	-	-	-	-	-	-
Net loss - Dilutive	\$ (2,316)	128,566,883	\$ (0.02)	\$ (2,846)	117,447,260	\$ (0.02)

## 8. Non-controlling Interest

The Company's non-controlling interest is accounted for under ASC 810, *Consolidation*, and represents the minority shareholder's ownership interest related to the Company's subsidiary, Synthetic Biomics, Inc. ("SYN Biomics"). In accordance with ASC 810, the Company reports its non-controlling interest in subsidiaries as a separate component of equity in the condensed consolidated balance sheets and reports both net loss attributable to the non-controlling interest and net loss attributable to the Company and its subsidiaries on the face of the condensed consolidated statements of operations. The Company's equity interest in SYN Biomics is 88.5% and the non-controlling stockholder's interest is 11.5%. For the three months March 31, 2018, the accumulated net loss attributable to the non-controlling interest was \$1.9 million.

## 9. Common and Preferred Stock

### *Series A Preferred Stock*

On September 11, 2017, the Company entered into a share purchase agreement (the "Purchase Agreement") with an investor (the "Investor"), pursuant to which the Company offered and sold in a private placement 120,000 shares of its Series A Convertible Preferred Stock, par value \$0.001 per share (the "Series A Preferred Stock") for an aggregate purchase price of \$12 million, or \$100 per share.

The Series A Preferred Stock ranks senior to the shares of the Company's common stock, and any other class or series of stock issued by the Company with respect to dividend rights, redemption rights and rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company. Holders of Series A Preferred Stock are entitled to a cumulative dividend at the rate of 2.0% per annum, payable quarterly in arrears, as set forth in the Certificate of Designation of Series A Preferred Stock. The Series A Preferred Stock is convertible at the option of the holders at any time into shares of common stock at an initial conversion price of \$0.54 per share, subject to certain customary anti-dilution adjustments.

On or at any time after (i) the VWAP (as defined in the Certificate of Designation) for at least 20 trading days in any 30 trading day period is greater than \$2.00, subject to adjustment in the case of stock split, stock dividends or the like the Company has the right, after providing notice not less than 6 months prior to the redemption date, to redeem, in whole or in part, on a pro rata basis from all holders thereof based on the number of shares of Series A Preferred Stock then held, the outstanding Series A Preferred Stock, for cash, at a redemption price per share of Series A Preferred Stock of \$225.00, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Convertible Preferred Stock, or (ii) the five year anniversary of the issue date, the Company shall have the right to redeem, in whole or in part, on a pro rata basis from all holders thereof based on the number of shares of Series A Convertible Preferred Stock then held, the outstanding Series A Preferred Stock, for cash, at a redemption price per share equal to the Liquidation Value (as defined in the Certificate of Designations).

The Series A Preferred Stock is classified as temporary equity due to the shares being (i) redeemable based on contingent events outside of the Company's control, and (ii) convertible immediately and from time to time. Since the effective conversion price of the Series A Preferred Stock is less than the fair value of the underlying common stock at the date of issuance, there is a beneficial conversion feature ("BCF") at the issuance date. Because the Series A Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the BCF is immediately charged to retained earnings as a "deemed dividend" and impacts earnings per share. During the year ended December 31, 2017, the Company recorded a discount of \$6.9 million. Because the Series A Preferred Stock is not currently redeemable, the discount arising from issuance costs was allocated to temporary equity and will not be accreted until such time that redemption becomes probable. The stated dividend rate of 2% per annum is cumulative and the Company accrues the dividend on a quarterly basis (in effect accreting the dividend regardless of declaration because the dividend is cumulative). During the year ended December 31, 2017 and the quarter ended March 31, 2018, the Company accrued dividends of \$73,000 and \$59,000, respectively. Once the dividend is declared, the Company will reclassify the declared amount from temporary equity to a dividends payable liability. When the redemption of the Series A Preferred Stock becomes probable, the temporary equity will be accreted to redemption value as a deemed dividend.

#### *B. Riley FBR Sales Agreement*

On August 5, 2016, the Company entered into the B. Riley FBR Sales Agreement with FBR Capital Markets & Co. (now known as B. Riley FBR, Inc.), which enables the Company to offer and sell shares of the Company's common stock with an aggregate sales price of up to \$40.0 million from time to time through B. Riley FBR Capital Markets & Co. as the Company's sales agent. Sales of common stock under the B. Riley FBR Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act, as amended. B. Riley FBR Capital Markets & Co. is entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of the Company's common stock sold on the Company's behalf. For the three months ended March 31, 2018, the Company did not sell stock through the FBR Sales Agreement.

#### **10. Related Party Transactions**

In December 2013, through the Company's subsidiary, Synthetic Biomics, Inc., the Company entered into a worldwide exclusive license agreement with Cedars-Sinai Medical Center ("CSMC") and acquired the rights to develop products for therapeutic and prophylactic treatments of acute and chronic diseases, including the development of SYN-010 to target IBS-C. The Company licensed from CSMC a portfolio of intellectual property comprised of several U.S. and foreign patents and pending patent applications for various fields of use, including IBS-C, obesity and diabetes. An investigational team led by Mark Pimentel, M.D. at CSMC discovered that these products may reduce the production of methane gas by certain GI microorganisms. During the three months ended March 31, 2018 and 2017, the Company did not pay Cedars-Sinai Medical Center for milestone payments related this license agreement.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion should be read in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q, and our audited consolidated financial statements and notes thereto for the year ended December 31, 2017 included in our Annual Report on Form 10-K filed with the SEC on February 22, 2018. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See "Note Regarding Forward-Looking Statements" for a discussion of the uncertainties, risks and assumptions associated with these statements. Our actual results and the timing of events could differ materially from those expressed or implied by the forward-looking statements due to important factors and risks including, but not limited to, those set forth below under "Risk Factors" and elsewhere herein, 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 SEC on February 22, 2018.

### Overview

We are a late-stage clinical company focused on developing therapeutics designed to preserve the microbiome to protect and restore the health of patients. Our lead candidates poised for Phase 3 development are: (1) 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), 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).

### Product Pipeline:

Therapeutic Area	Product Candidate	Preclinical	Phase 1	Phase 2	Phase 3
Prevention of CDI and AMR [co-administer with IV $\beta$ -lactam]	ribaxamase Oral $\beta$ -lactamase	SYN-004	→		
Prevention of CDI and AMR [co-administer with IV Carbapenem]	Oral carbapenemase	SYN-006	→		
Prevention of CDI and AMR [co-administer with Oral $\beta$ -lactam]	Oral modified-release $\beta$ -lactamase	SYN-007	→		
Treatment of IBS-C	Oral modified-release lovastatin lactone	SYN-010 <sup>C</sup>	→		
Preservation of gut barrier/Treat Inflammation/Restore Microbiome	Oral intestinal alkaline phosphatase (IAP)	SYN-020 <sup>M</sup>	→		
Treatment/Prevention of Pertussis (whooping cough)	Monoclonal antibodies	SYN-005 <sup>I,T</sup>	→		
PKU	Biotherapeutic	SYN-200 <sup>I</sup>	→		

C- Cedars-Sinai Medical Center Collaboration

I- Intrexon Collaboration

T- The University of Texas at Austin Collaboration

M- Scientific collaboration with Massachusetts General Hospital

## Summary of Clinical and Preclinical Programs

Therapeutic Area	Product Candidate	Status
Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degradate IV beta-lactam antibiotics)	SYN-004 (ribaxamase) (oral enzyme)	<ul style="list-style-type: none"> <li>· Reported supportive Phase 1a/1b data (1Q 2015)</li> <li>· Reported supportive topline data from two Phase 2a clinical trials (4Q 2015 &amp; 2Q 2016)</li> <li>· Initiated Phase 2b proof-of-concept clinical trial (3Q 2015)</li> <li>· Received USAN approval of the generic name “ribaxamase” for SYN-004 (July 2016)</li> <li>· Completed Enrollment of Phase 2b proof-of-concept clinical trial (3Q 2016)</li> <li>· Awarded contract by the CDC (4Q 2016)</li> <li>· Announced positive topline data from Phase 2b proof-of-concept clinical trial, including achievement of primary endpoint of significantly reducing CDI (1Q 2017)</li> <li>· Announced additional results from Phase 2b proof-of-concept clinical trial demonstrating SYN-004 (ribaxamase) protected and maintained the naturally occurring composition of gut microbes from antibiotic-mediated dysbiosis in treated patients (2Q 2017)</li> <li>· Announced additional results from Phase 2b proof-of-concept clinical trial funded by a contract awarded by the CDC, demonstrating that SYN-004 (ribaxamase) prevented significant change to the presence of certain AMR genes in the gut resistome of patients receiving SYN-004 compared to placebo (3Q 2017)</li> <li>· Presented additional supportive results regarding several exploratory endpoints from Phase 2b proof-of-concept clinical trial designed to evaluate SYN-004’s (ribaxamase) ability to protect the gut microbiome from opportunistic bacterial infections and prevent the emergence of antimicrobial resistance (AMR) in the gut microbiome (4Q 2017)</li> <li>· Reached preliminary agreement with the FDA on a proposed Phase 3 clinical trial synopsis, including de-coupled co-primary endpoints designed to evaluate efficacy separate from safety in a patient population being treated with a representative selection of IV-beta-lactam antibiotics (1H 2018)</li> <li>· Anticipated End of Phase 2 meeting with FDA to solidify remaining elements of planned Phase 3 clinical trial (2H 2018)</li> <li>· Plan to initiate Phase 3 clinical trial(s) (2H 2019)</li> </ul>

Treatment of IBS-C	SYN-010 (oral modified-release lovastatin lactone)	<ul style="list-style-type: none"> <li>· Collaboration with Cedars-Sinai Medical Center</li> <li>· Reported supportive topline data from two Phase 2 clinical trials (4Q 2015 &amp; 1Q 2016)</li> <li>· Received Type C meeting responses from FDA regarding late-stage aspects of clinical pathway (2Q 2016)</li> <li>· Presented detailed data supporting previously reported positive topline data from two Phase 2 clinical trials at DDW (May 2016)</li> <li>· Held End of Phase 2 meeting with FDA (July 2016)</li> <li>· Confirmed key elements of Pivotal Phase 2b/3 clinical trial design pursuant to consultations with FDA (1Q 2017)</li> <li>· Announced issuance of key U.S. composition of matter patent providing important intellectual property protection in the U.S until at least 2035 (Q2 2018)</li> </ul>
Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade IV carbapenem antibiotics)	SYN-006 (oral enzyme)	<ul style="list-style-type: none"> <li>· Identified P2A as a potent carbapenemase that is stable in the GI tract</li> <li>· Manufactured and formulated research lot for oral delivery (2017)</li> <li>· Demonstrated microbiome protection in a pig model if ertapenem administration (Q1 2018)</li> </ul>
Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade oral beta-lactam antibiotics)	SYN-007 (oral enzyme)	<ul style="list-style-type: none"> <li>· Preclinical work ongoing to expand the utility of SYN-004 (ribaxamase) for use with oral beta-lactam antibiotics</li> </ul>
Preserve gut barrier, treat local GI inflammation, restore gut microbiome	SYN-020 (oral IAP enzyme)	<ul style="list-style-type: none"> <li>· Generated high expressing manufacturing cell lines for intestinal alkaline phosphatase (IAP) (1H 2017)</li> <li>· Identified downstream process and potential tablet formulations (2H 2017)</li> <li>· Ongoing preclinical efficacy studies</li> </ul>
Prevention and treatment of pertussis	SYN-005 (monoclonal antibody therapies)	<ul style="list-style-type: none"> <li>· Reported supportive preclinical research findings (2014)</li> <li>· The University of Texas at Austin (“UT Austin”) received a grant from the Bill and Melinda Gates Foundation to support a preclinical study to evaluate the prophylactic capability of SYN-005 (4Q 2015)</li> <li>· Reported supportive preclinical data demonstrating hu1B7, a component of SYN-005, provided protection from pertussis for five weeks in neonatal non-human primate study (Q2 2017)</li> <li>· Reported supportive preclinical data demonstrating that an extended half-life version of hu1B7, a component of SYN-005, provided protection from pertussis for five weeks in a non-human neonatal primate study (Q4 2017)</li> <li>· Collaborations with Intrexon and UT Austin</li> </ul>

## Our Microbiome-Focused Pipeline

Our CDI and IBS-C programs are focused on protecting the healthy function of the gut microbiome, or gut flora, which is composed of billions of microbial organisms including a natural balance of both “good” beneficial species and potentially “bad” pathogenic species. When the natural balance or normal function of these microbial species is disrupted, a person’s health can be compromised. All of our programs are supported by our growing intellectual property portfolio. We are maintaining and building our patent portfolio through: filing new patent applications; prosecuting existing applications; and licensing and acquiring new patents and patent applications. Our plan remains focused on the advancement of our two late-stage clinical programs. We continue to actively manage resources in preparation for the late-stage clinical advancement of our two lead microbiome-focused clinical programs, including our pursuit of successful and viable opportunities that will allow us to establish the clinical infrastructure and financial resources necessary to successfully initiate and complete this plan.

### Clinical Update

#### ***SYN-004 (ribaxamase) — Prevention of *C. difficile* infections (CDI), overgrowth by pathogenic organisms, and the emergence of antimicrobial resistance (AMR)***

On April 23, 2018, we announced that we had reached preliminary agreement with the FDA on a proposed clinical trial synopsis for our planned Phase 3 clinical trial for ribaxamase. In accordance with recommendations and guidance received from the FDA, we expect the Phase 3 trial to evaluate the efficacy and safety of ribaxamase as separate, co-primary endpoints in a patient population being treated with a representative selection of intravenous (IV) beta-lactam antibiotics, which will include ceftriaxone. The inclusion of more than one beta-lactam antibiotic in this trial is intended to evaluate the potential utility of ribaxamase for co-administration with a greater number of beta-lactam antibiotics. The proposed Phase 3 clinical trial discussed with the FDA comprises a global, event-driven clinical trial with a fixed maximum number of patients and will seek to evaluate the efficacy and safety of ribaxamase in a broader patient population by enrolling patients with a variety of underlying infections. We expect the primary efficacy endpoint of the proposed Phase 3 trial will be the reduction in the incidence of CDI in the ribaxamase treatment group compared to placebo. We have also reached preliminary agreement with the FDA to evaluate mortality risk as the primary safety endpoint for this trial, which will be separate from the primary efficacy endpoint of reduction of the incidence of CDI. The designation of efficacy and safety as separate and decoupled endpoints is critical for clinical studies of this nature, where the underlying population is projected to have a comparatively high incidence of safety events that may significantly dilute the smaller number of CDI events. During our discussions with the FDA on the development of our proposed Phase 3 clinical trial synopsis, the FDA undertook an additional review of data and analysis submitted by us from the previously completed ribaxamase Phase 2b clinical trial. Following FDA’s review of the additional data, it was determined that the requirements for Breakthrough Therapy Designation were no longer met as a result of the disparities in the underlying health and comorbidities in the patient population which could not be fully evaluated due to the limited safety database, and the study’s method of statistical treatment of patients who did not complete the study for any reason. We have reached agreement with the FDA on how each of these factors will be addressed in the Phase 3 trial by evaluating safety and efficacy endpoints separately as described above. As a result, and with the consent of the FDA, we have voluntarily withdrawn the Breakthrough Therapy Designation for the ribaxamase program. The FDA stated in their official response to us that they remain committed to working with Synthetic Biologics on the development of the ribaxamase program, and the withdrawal of Breakthrough Therapy Designation will not affect interactions between us and them. We plan to continue collaborative discussions with the FDA to solidify the remaining details of the proposed Phase 3 clinical trial during an anticipated End of Phase 2 meeting with the FDA during the second half of 2018, and anticipate initiating a Phase 3 trial(s) in 2019 or later, subject to our successful pursuit of opportunities that will allow us to establish the clinical infrastructure and financial resources necessary to successfully initiate and complete this plan. If approved by the FDA, SYN-004 (ribaxamase) would be the first available drug designed to prevent primary *Clostridium difficile* infection by protecting the gut microbiome from antibiotic-mediated dysbiosis.

#### ***SYN-010 — Treatment of Irritable Bowel Syndrome with Constipation (IBS-C)***

##### *Allowance of Key U.S. Patent*

On May 1, 2018, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 9,956,292 which includes claims related to composition of matter for the use of anti-methanogenic compositions to treat IBS-C. The patent will provide key intellectual property protection in the U.S. for SYN-010 and will expire no later than 2035.

## Intellectual Property

All of our programs are supported by growing patent estates that we either own or exclusively license. Each potential product has issued patents that provide protection. In total, we have over 110 U.S. and foreign patents and over 100 U.S. and foreign patents pending. For instance, U.S. Patent Nos. 8,894,994 and 9,587,234, which include claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including SYN-004 (ribaxamase), have patent terms to at least 2031. Further, U.S. Patent 9,301,995 and 9,301,996, both of which will expire in 2031, cover various uses of beta-lactamases, including SYN-004 (ribaxamase), in protecting the microbiome, and U.S. Patent Nos. 9,290,754, 9,376,673, 9,404,103, 9,464,280, and 9,695,409 which, will expire in at least 2035, covers further beta-lactamase compositions of matter related to SYN-004 (ribaxamase). Also, U.S. Patent No. 9,192,618, which expires in at least 2023, includes claims that cover use of statins, including SYN-010, for the treatment of IBS-C. U.S. Patent No. 9,289,418, which expires in at least 2033, includes claims that cover the use of a variety of compounds, including the active agent of SYN-010, to treat constipation in certain screened patients. U.S. Patent No. 9,744,208 covers methods of use of the active agent of SYN-010 for the treatment of constipation until at least 2034. U.S. Patent No. 9,956,292 includes claims related to composition of matter for the use of anti-methanogenic compositions to treat IBS-C until at least 2035.

Our goal is to (i) obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies, (ii) preserve our trade secrets, and (iii) operate without infringing on the proprietary rights of other parties, worldwide. We seek, where appropriate, the broadest intellectual property protection for product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements and patents.

## Critical Accounting Policies

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 reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses in the periods presented. We believe that the accounting estimates employed are appropriate and resulting balances are reasonable; however, due to inherent uncertainties in making estimates, actual results may differ from the original estimates, requiring adjustments to these balances in future periods. The critical accounting estimates that affect the condensed consolidated financial statements and the judgments and assumptions used are consistent with those described under Part II, Item 7 of our 2017 Form 10-K.

## Results of Operations

### Three Months Ended March 31, 2018 and 2017

#### General and Administrative Expenses

General and administrative expenses decreased by 23% to \$1.6 million for the three months ended March 31, 2018, from \$2.1 million for the three months ended March 31, 2017. This decrease is primarily the result of lower salary expense, stock compensation, and related benefits costs incurred in 2018 due to the resignation of the Chief Executive Officer, along with the reduction of travel, consulting fees, and legal expenses in 2018 offset by higher registration fees. The charge related to stock-based compensation expense was \$349,000 for the three months ended March 31, 2018, compared to \$698,000 the three months ended March 31, 2017.

#### Research and Development Expenses

Research and development expenses decreased by 44% to \$3.4 million for the three months ended March 31, 2018, from \$6.1 million for the three months ended March 31, 2017. This decrease is primarily the result of lower SYN-004 (ribaxamase) and SYN-010 program costs for 2018 since no clinical trials were ongoing during the quarter. The research and development costs incurred during the quarter were primarily related to planning for future Phase 3 (SYN-004) and Phase 2b/3(SYN-010) clinical programs as we seek to secure the financial resources necessary for the completion of these clinical trials. The charge related to stock-based compensation expense was \$326,000 for the three months ended March 31, 2018, compared to \$437,000 for the three months ended March 31, 2017.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the three months ended March 31, 2018 and 2017. These direct expenses were external costs associated with preclinical studies and clinical trials. Indirect research and development expenses related to employee costs, facilities, stock-based compensation and research and development support services that are not directly allocated to specific drug candidates.

<b>Therapeutic Areas</b>	<b>March 31, 2018</b>	<b>March 31, 2017</b>
Ribaxamase	\$ 96	\$ 1,849
SYN-010	84	633
SYN-005	(2)	14
Other therapeutic areas	-	(1)
Total direct costs	178	2,495
Total indirect costs	3,192	3,564
<b>Total Research and Development</b>	<b>\$ 3,370</b>	<b>\$ 6,059</b>

### *Other Income/Expense*

Other income was \$2.7 million for the three months ended March 31, 2018, compared to other income of \$5.1 million for the three months ended March 31, 2017. Other income for the three months ended March 31, 2018 is primarily comprised of non-cash income of \$2.7 million from the change in fair value of warrants. The decrease in the fair value of the warrants was due to the decrease in our stock price from the prior quarter.

### *Net Loss Attributable to Common Stockholders*

Our net loss attributable to common stockholders was \$2.4 million, or \$0.02 per basic and dilutive common share for the three months ended March 31, 2018, compared to a net loss of \$2.8 million, or \$0.02 per basic common share and dilutive common share for the three months ended March 31, 2017.

### **Liquidity and Capital Resources**

With the exception of the three months ended June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. To date, we have financed our operations primarily through public and private sales of our common stock and a private placement of our preferred stock, and we expect to continue to seek to obtain the required capital in a similar manner. We have incurred an accumulated deficit of \$197 million as of March 31, 2018 and expect to continue to incur losses in the future. With the exception of the quarter ended June 30, 2010, we have incurred negative cash flow from operations since our inception. We have spent, and expect to continue to spend, a substantial amount of funds in connection with implementing our business strategy, including our planned product development efforts, our clinical trials and our research and discovery efforts.

Our cash and cash equivalents totaled \$11.0 million as of March 31, 2018, a decrease of \$6.1 million from December 31, 2017. During the three months ended March 31, 2018, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of \$2.3 million for the three months ended March 31, 2018.

The B. Riley FBR Sales Agreement enables us to offer and sell shares of our common stock, with aggregate sales of up to \$40.0 million (subject to certain SEC offering limitations), from time to time through B. Riley FBR Capital Markets & Co. as our sales agent. Sales of common stock under the B. Riley FBR Sales Agreement are made in sales deemed to be “at-the-market” equity offerings as defined in Rule 415 promulgated under the Securities Act. B. Riley FBR Capital Markets & Co. is entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of our common stock sold on our behalf. During the three months ended March 31, 2018, we did not sell our common stock through the B. Riley FBR Sales Agreement. There can be no assurance that we will be able to continue to raise funds through the sale of shares of common stock through the B. Riley FBR Sales Agreement. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain funding when needed, we will be unable to carry out our business plan and we will be forced to delay the initiation of our planned clinical trials until such time as we obtain adequate financing. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

We have spent, and expect to continue to spend, a substantial amount of funds in connection with implementing our business strategy, including our planned product development efforts, preparation for our planned clinical trials, our clinical trials and our research and discovery efforts. Based on our current plans, our cash and cash equivalents will not be sufficient to enable us to meet our near term or long-term expected plans, including initiation or completion of our planned Phase 2b/3 and Phase 3 clinical trials. Our notes to the consolidated condensed financial statements contain an explanatory paragraph referring to our recurring and continuing losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding to achieve our current business plan, obtain the required regulatory approvals for our product candidates or complete additional corporate partnering or acquisition transactions in order to commercialize such product candidates once regulatory approval is received.

Our continued operations as currently planned will primarily depend on our ability to raise additional capital from various sources, including equity (the B. Riley FBR Sales Agreement as well as other equity sources) and debt financings, as well as license fees and other funding received from potential corporate partners, joint ventures and grant funding. Although we have been awarded a contract by the CDC’s Broad Agency Announcement (BAA) 2016-N-17812, the amount of the award will not be sufficient to enable us to complete our clinical trials as planned and therefore we will be required to obtain additional capital. Such additional funds may not become available on acceptable terms or at all and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs. We will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurance that any additional capital that we are able to obtain will be sufficient to meet our needs.

### *Current and Future Financing Needs*

Based on our current plans, despite the \$12 million of proceeds we received from the sale of the Series A Preferred Stock in September 2017, our cash and cash equivalents will not be sufficient to enable us to meet our financing needs required to commence or complete our anticipated clinical trial and other expected plans. Although we continue to prepare for our clinical trials, our plan to initiate the planned clinical trials is subject to our successful pursuit of opportunities that will allow us to establish the clinical infrastructure and financial resources necessary to successfully initiate and make significant progress towards completion of this plan. Therefore, we do not intend to commence any trials until we are confident that we have funding necessary to complete the trials. In order to continue the development of our current product candidates as currently planned, including commencing our planned Phase 2b/3 and Phase 3 clinical trials, and to continue to fund operations at the current cash expenditure levels, we are required to obtain additional funding, although we do not currently have commitments from any third parties to provide us with capital. Potential sources of financing that we are pursuing include strategic relationships, public or private sales of our equity (including through the B. Riley FBR Sales Agreement) or debt and other sources. We cannot assure that we will meet the requirements for use of the B. Riley FBR Sales Agreement especially in light of the fact that we are currently limited by rules of the SEC as to the number of shares of common stock that we can sell pursuant to the B. Riley FBR Sales Agreement due to the market value of our common stock held by non-affiliates, or that additional funding will be available on favorable terms, or at all. If we fail to obtain additional funding in the next few months, we will be forced to delay the initiation of our planned clinical trials until such time as we obtain adequate financing and, even after obtaining financing we may have a delay due to long manufacturing lead times. If we fail to obtain additional funding otherwise in the future when needed, we may not be able to execute our business plan as planned and we may be forced to cease certain development activities until funding is received, including manufacturing activities, and our business will suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

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

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements and amount of funding received from partners and collaborators;
- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- our ability to achieve our 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.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares (including through the B. Riley FBR Sales Agreement, if we meet the conditions for sale thereunder) or debt and other sources. Additionally, we may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all.

### *NYSE American Noncompliance Notice and Compliance Plan*

Our common stock is listed on the NYSE American. The NYSE American's listing standards generally mandate that we meet certain requirements relating to stockholders' equity, market capitalization, aggregate market value of publicly held shares and distribution requirements. The NYSE American requires companies to meet certain continued listing criteria including a minimum stockholders' equity of \$6.0 million if an issuer has sustained losses from continuing operations and/or net losses in its five most recent years, as outlined in the NYSE American Exchange Company Guide. The NYSE American Exchange Company Guide also states that the NYSE normally will not consider removing from listing securities of an issuer with total value of market capitalization of at least \$50.0 million and 1,100,000 shares publicly held, a market value of publicly held shares of at least \$15.0 million and 400 round lot shareholders. During the first quarter of 2018, our common stock experienced a sustained a period of trading below a price of \$0.39, causing our market capitalization to fall below the \$50 million requirement needed to maintain compliance with Section 1003(iii) of the NYSE American Company Guide.

On March 7, 2018, we announced that we received written communication from NYSE American LLC (The “NYSE American”) stating the we were no longer in compliance with certain continued listing standards as set forth in the NYSE American Company Guide. Specifically, based on our 2017 Form 10-K, we are below compliance with Part 10, Section 1003(iii) of the NYSE American Company Guide since we reported stockholders’ deficit of \$1.5 million and net losses in five of our most recent fiscal years as of December 31, 2017. On April 3, 2018, we submitted a plan of compliance to the NYSE American outlining our plan to regain compliance with the continued listing standards as set forth in Part 10, Section 1003(iii) of the NYSE American Company Guide by September 2, 2018, the conclusion of the compliance plan period. Should our common stock incur and maintain a sustained increase in price above \$0.39, our market capitalization will surpass the \$50 million requirement to regain compliance with Part 10, Section 1003(iii) of the NYSE American Company Guide. The NYSE American notification does not affect the our business operations or the listing of the our shares on the NYSE American, and does not represent any change or amendment to the our consolidated financial statements or to our 2017 Form 10-K. If our common stock is delisted from the NYSE American due to our failure to regain compliance with the listing standards by the end of the compliance period or for any other reason, and the market value of our shares of common stock held by non-affiliates remain below \$15 million, we will likely no longer be eligible to sell common stock pursuant to the B. Riley FBR Sales Agreement or otherwise utilize our shelf registration statement.

#### **Off-Balance Sheet Arrangements**

During the three months ended March 31, 2018, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

#### **Contractual Obligations**

There have been no material changes to our contractual obligations during the period covered by this report from those disclosed in our 2017 Form 10-K.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents. As of March 31, 2018, our cash and cash equivalents consisted primarily of money market securities. We do not engage in any hedging activities against changes in interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions on our securities portfolio. We may, however, require additional financing to fund future obligations and no assurance can be given that the terms of future sources of financing will not expose us to material market risk.

### **ITEM 4. CONTROLS AND PROCEDURES.**

#### **(a) Evaluation of Disclosure Controls and Procedures**

The Company has adopted and maintains disclosure controls and procedures (as defined Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. The Company’s disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As required under Exchange Act Rule 13a-15, the Company’s management, including the Interim Chief Executive Officer, who also serves as the Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures as of March 31, 2018, the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that based on such evaluation, the Company’s disclosure controls and procedures are effective as of March 31, 2018 to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to the Company’s management, including the Company’s Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

#### **(b) Changes in Internal Control over Financial Reporting**

There have not been any changes in our internal controls over financial reporting during the three months ended March 31, 2018 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS.

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

### ITEM 1A. RISK FACTORS.

The following information updates, and should be read in conjunction with, the information disclosed in Part 1, Item 1A, "Risk Factors," contained in our 2017 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2017 Form 10-K.

#### RISKS RELATING TO OUR BUSINESS

*We will need to raise additional capital to operate our business and our failure to obtain funding when needed may force us to delay, reduce or eliminate our development programs or commercialization efforts.*

During the three months ended March 31, 2018, our operating activities used net cash of approximately \$6.1 million and as of March 31, 2018 our cash and cash equivalents were \$11.0 million. With the exception of the three months ended December 31, 2017 and June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. As of March 31, 2018, our accumulated deficit totaled approximately \$196 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. With the exception of the quarter ended June 30, 2010, and limited laboratory revenues from Adeona Clinical Laboratory, which we sold in March 2012, we have generated very minimal revenues. We do not expect to derive revenue from any source in the near future until we or our potential partners successfully commercialize our products. We expect our expenses to increase in connection with our anticipated activities, particularly as we continue research and development, initiate and conduct clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing and collaboration fees and grants, if any.

We will need to raise additional capital to fund our operations and meet our current timelines and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. Based on our current plans, our cash and cash equivalents will not be sufficient to enable us to meet our near term expected plans. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. Although we continued preparation for our clinical trials, our planned Phase 2b/3 clinical trials have been delayed until such time as we obtain adequate financing. A failure otherwise to raise additional funds when needed in the future could result in us being unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Our ability to raise capital through the sale of securities may be limited by the rules of the SEC and NYSE American that place limits on the number and dollar amount of securities that may be sold. There can be no assurances that we will be able to raise the funds needed, especially in light of the fact that our ability to sell securities registered on our registration statement on Form S-3 will be limited until such time the market value of our voting securities held by non-affiliates is \$75 million or more. We also may be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available.

## **RISKS RELATING TO OUR STOCK**

*We cannot assure you that the common stock will be liquid or that it will remain listed on the NYSE American. A failure to regain compliance with the NYSE American listing requirements could result in a de-listing of our common stock.*

Our common stock is listed on the NYSE American. The NYSE American's listing standards generally mandate that we meet certain requirements relating to stockholders' equity, market capitalization, aggregate market value of publicly held shares and distribution requirements. We cannot assure you that we will be able to maintain the continued listing standards of the NYSE American. The NYSE American requires companies to meet certain continued listing criteria including a minimum stockholders' equity of \$6.0 million if an issuer has sustained losses from continuing operations and/or net losses in its five most recent years, as outlined in the NYSE American Exchange Company Guide. At March 31, 2018, we had stockholders' deficit of \$197 million. The NYSE American Exchange Company Guide also states that the NYSE normally will not consider removing from listing securities of an issuer with total value of market capitalization of at least \$50.0 million and 1,100,000 shares publicly held, a market value of publicly held shares of at least \$15.0 million and 400 round lot shareholders. Although we have more than 1,100,000 shares publicly held, a market value of publicly held shares of at least \$15.0 million and 400 round lot shareholders, our stock price is volatile and, during the first quarter of 2018, the price of our common stock experienced a sustained decrease resulting in a period where our market capitalization fell below \$50.0 million.

On March 7, 2018, we announced that we received written communication from the NYSE American stating the we were no longer in compliance with certain continued listing standards as set forth in the NYSE American Company Guide. Specifically, based on our annual report on Form 10-K for the year ended December 31, 2017, and filed with the SEC on February 22, 2018, we are below compliance with Part 10, Section 1003(iii) of the NYSE American Company Guide since we reported a stockholders' deficit equity of \$1.5 million and net losses in five of our most recent fiscal years as of December 31, 2017. On April 3, 2018, we submitted a plan of compliance to the NYSE American outlining our plan to regain compliance with certain continued listing standards as set forth in Part 10, Section 1003(iii) of the NYSE American Company Guide by September 2, 2018, the conclusion of the compliance plan period. There can be no assurance that we can regain compliance with the listing standard of the NYSE American, or that the NYSE American will continue to list our common stock if we regain compliance, or if we continue to fail to maintain the minimum stockholders' equity. In addition, in the future we may not be able to maintain such minimum stockholders' equity and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE American. If we are delisted from the NYSE American then our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. If our common stock is delisted from the NYSE American due to our failure to regain compliance with the listing standards by the end of the compliance period or for any other reason, and the market value of our shares of common stock held by non-affiliates remain below \$15 million, we will likely no longer be eligible to sell common stock pursuant to the B. Riley FBR Sales Agreement or otherwise utilize our shelf registration statement. In addition, delisting of our common stock could depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the NYSE American could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities.

### **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

We did not sell any equity securities during the quarter ended March 31, 2018 in transactions that were not registered under the Securities Act, other than as previously disclosed in our filings with the SEC and as discussed below:

On January 24, 2018, we issued to a consultant as a partial payment for services, a warrant to purchase 25,000 shares of our common stock at an exercise price of \$0.53 per share. The issuance of the warrant was exempt from registration provisions of the Securities Act under the exemption provided for by the Section 4(a)(2) thereof for transactions not involving a public offering.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

Not applicable.

### **ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

### **ITEM 5. OTHER INFORMATION.**

Not applicable

### **ITEM 6. EXHIBITS**

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross

Steven A. Shallcross

Interim Chief Executive Officer, Chief Financial Officer  
(Principal Executive Officer, Principal Financial Officer and  
Principal Accounting Officer)

Date: May 8, 2018

EXHIBIT INDEX

- [4.1](#) [Warrant Agreement by and between Synthetic Biologics, Inc. and In-Site Communications\\*](#)
- [31.1](#) [Certification of Principal Executive Officer pursuant to Rule 13a-14\(a\)/15d-14\(a\) \\*](#)
- [31.2](#) [Certification of Principal Financial Officer pursuant to Rule 13a-14\(a\)/15d-14\(a\) \\*](#)
- [32.1](#) [Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 \\*](#)
- [32.2](#) [Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 \\*](#)
- 101.INS XBRL Instance Document \*
- 101.SCH XBRL Taxonomy Extension Schema \*
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase \*
- 101.DEF XBRL Taxonomy Extension Definition Linkbase \*
- 101.LAB XBRL Taxonomy Extension Label Linkbase \*
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase \*

\*Filed herewith.

NEITHER THIS WARRANT NOR THE SHARES OF COMMON STOCK ISSUABLE ON EXERCISE OF THIS WARRANT HAVE BEEN REGISTERED UNDER THE SECURITIES ACT OR ANY OTHER SECURITIES LAWS (THE "ACTS"). NEITHER THIS WARRANT NOR THE SHARES OF COMMON STOCK PURCHASABLE HEREUNDER MAY BE SOLD, TRANSFERRED, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF (A) AN EFFECTIVE REGISTRATION STATEMENT FOR THIS WARRANT OR COMMON STOCK PURCHASABLE HEREUNDER, AS APPLICABLE, UNDER THE ACTS, OR (B) AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE CORPORATION THAT REGISTRATION IS NOT REQUIRED UNDER SUCH ACTS.

**SYNTHETIC BIOLOGICS, INC.  
WARRANT**

**VOID AFTER 5:00 P.M. NEW YORK TIME**

Issue Date: December 26, 2017

1. Basic Terms. This Warrant (the "Warrant") certifies that, for value received, the registered holder specified below or its registered assigns ("Holder") is the owner of a warrant of Synthetic Biologics, Inc., a Nevada corporation (the "Corporation"), subject to adjustments as provided herein, to purchase Twenty Five Thousand (25,000) shares of the Common Stock, \$.001 par value, of the Corporation (the "Common Stock") from the Corporation at the price per share shown below (the "Exercise Price").

Holder:	In-Site Communications, Inc.
Exercise Price per share:	\$0.52

Except as specifically provided otherwise, all references in this Warrant to the Exercise Price and the number of shares of Common Stock purchasable hereunder shall be to the Exercise Price and number of shares after any adjustments are made thereto pursuant to this Warrant.

2. Method of Exercise; Fractional Shares.

(a) Method of Exercise. This Warrant is exercisable at the option of the Holder at any time by surrendering this Warrant, on any business day during the period (the "Exercise Period") beginning the business day after the issue date of this Warrant specified above and ending at 5:00 p.m. (New York time) five (5) years after the issue date. To exercise this Warrant, the Holder shall surrender this Warrant at the principal office of the Corporation or that of the duly authorized and acting transfer agent for its Common Stock, together with the executed exercise form (substantially in the form of that attached hereto) and payment in cash or by wire transfer of immediately available funds of an amount equal to the Exercise Price multiplied by the number of shares of the Common Stock being purchased under this Warrant. The principal office of the Corporation is located at 9605 Medical Center Drive, Suite 270, Rockville, Maryland 20850; provided, however, that the Corporation may change its principal office upon notice to the Holder. Payment shall be made by check payable to the order of the Corporation or by wire transfer. This Warrant is not exercisable with respect to a fraction of a share of Common Stock. In lieu of issuing a fraction of a share remaining after exercise of this Warrant as to all full shares covered by this Warrant, the Corporation shall either at its option (1) pay for the fractional share cash equal to the same fraction at the fair market price for such share; or (2) issue scrip for the fraction in the registered or bearer form which shall entitle the Holder to receive a certificate for a full share of Common Stock on surrender of scrip aggregating a full share.

3. Protection Against Dilution. If the Corporation, with respect to the Common Stock: (a) pays a dividend or makes a distribution on shares of common stock that is paid in shares of common stock or in securities convertible into or exchangeable for Common Stock (in which latter event the number of shares of common stock initially issuable upon the conversion or exchange of such securities shall be deemed to have been distributed); (b) subdivides outstanding shares of Common Stock; (c) combines outstanding shares of Common Stock into a smaller number of shares; or (d) issues by reclassification of common stock any shares of capital stock of the Corporation, the Exercise Price in effect immediately prior thereto and the number of shares of Common Stock issuable under this Warrant shall be adjusted so that each Holder thereafter shall be entitled to receive the number and kind of shares of Common Stock or other capital stock of the Corporation that it would have owned or been entitled to receive in respect of this Warrant immediately after the happening of any of the events described above had this Warrant been converted immediately prior to the happening of that event. An adjustment made in accordance with this section shall become effective immediately after the record date, in the case of a dividend, and shall become effective immediately after the effective date, in the case of a subdivision, combination, or reclassification. If, as a result of an adjustment made in accordance with this Section 4, the Holder becomes entitled to receive shares of two or more classes of capital stock or shares of common stock and other capital stock of the Corporation, the board of directors (whose determination shall be conclusive) shall determine the allocation of the adjusted Exercise Rate between or among shares of such classes of capital stock or shares of Common Stock and other capital stock.

4 . Adjustment for Reorganization, Consolidation, Merger, Etc. In the event of any consolidation or merger to which the Corporation is a party other than a consolidation or merger in which the Corporation is the continuing corporation, or the sale or conveyance to another corporation of the property of the Corporation as an entirety or substantially as an entirety or any statutory exchange of securities with another corporation (including any exchange effected in connection with a merger of a third corporation into the Corporation) (each such transaction referred to herein as “Reorganization”), the Company shall give the Holder at least ten (10) days written notice prior to the earlier of (I) the closing or effectiveness of such Reorganization and (II) the record date for receipt of such shares of stock or securities or other assets of the Corporation, and the Holder shall be permitted to exercise this Warrant in whole or in part at any time prior to the record date for the receipt of such consideration and shall be entitled to receive, for each share of Common Stock issuable to the Holder upon such exercise, the same per share consideration payable to the other holders of Common Stock in connection with such Reorganization. If and to the extent that the Holder retains this Warrant or any portion hereof following such record date, the Corporation will cause the surviving or, in the event of a sale of assets, purchasing entity, as a condition precedent to such Reorganization, to assume the obligations of the Corporation with respect to this Warrant, with such adjustments to the Exercise Price and the securities covered hereby as may be necessary in order to preserve the economic benefits of this Warrant to the Holder.

5 . Notice of Adjustment. On the happening of an event requiring an adjustment of the Exercise Price or the shares purchasable under this Warrant, the Corporation shall, within thirty (30) days, give written notice to the Holder stating the adjusted Exercise Price and the adjusted number and kind of securities or other property purchasable under this Warrant resulting from the event and setting forth in reasonable detail the method of calculation and the facts upon which the calculation is based.

6. Dissolution, Liquidation. In case of the voluntary or involuntary dissolution, liquidation or winding up of the Corporation (other than in connection with reorganization, consolidation, merger, or other transaction covered by paragraph 5 above) is at any time proposed; the Corporation shall give at least thirty (30) days prior written notice to the Holder. Such notice shall contain: (a) the date on which the transaction is to take place; (b) the record date (which shall be at least thirty (30) days after the giving of the notice) as of which holders of Common Stock will be entitled to receive distributions as a result of the transaction; (c) a brief description of the transaction; (d) a brief description of the distributions to be made to holders of Common Stock as a result of the transaction; and (e) an estimate of the fair value of the distributions. On the date of the transaction, if it actually occurs, this Warrant and all rights under this Warrant shall terminate.

7 . Rights of Holder. This Warrant does not entitle the Holder to any voting rights or, except for the foregoing notice provisions, any other rights as a shareholder of the Corporation. No dividends are payable or will accrue on this Warrant or the shares of Common Stock purchasable under this Warrant until, and except to the extent that, this Warrant is exercised. Upon the surrender of this Warrant and payment of the Exercise Price as provided above, the person or entity entitled to receive the shares of Common Stock issuable upon such exercise shall be treated for all purposes as the record holder of such shares as of the close of business on the date of the surrender of this Warrant for exercise as provided above. Upon the exercise of this Warrant, the Holder shall have all of the rights of a shareholder in the Corporation.

8. Exchange for Other Denominations. This Warrant is exchangeable, on its surrender by the Holder to the Corporation, for a new Warrant of like tenor and date representing in the aggregate the right to purchase the balance of the number of shares purchasable under this Warrant in denominations and subject to restrictions on transfer contained herein, in the names designated by the Holder at the time of surrender.

9 . Substitution. Upon receipt by the Corporation of evidence satisfactory (in the exercise of reasonable discretion) to it of the ownership of and the loss, theft or destruction or mutilation of the Warrant, and (in the case of loss, theft or destruction) of indemnity satisfactory (in the exercise of reasonable discretion) to it, and (in the case of mutilation) upon the surrender and cancellation thereof, the Corporation will issue and deliver, in lieu thereof, a new Warrant of like tenor.

10. Restrictions on Transfer. Neither this Warrant nor the shares of Common Stock issuable on exercise of this Warrant have been registered under the Securities Act or any other securities laws (the “Acts”). Neither this Warrant nor the shares of Common Stock purchasable hereunder may be sold, transferred, pledged or hypothecated in the absence of (i) an effective registration statement for this Warrant or Common Stock purchasable hereunder, as applicable, under the Acts, or (ii) an opinion of counsel reasonably satisfactory to the Corporation that registration is not required under such Acts. If the Holder seeks an opinion as to transfer without registration from Holder’s counsel, the Corporation shall provide such factual information to Holder’s counsel as Holder’s counsel reasonably requests for the purpose of rendering such opinion. Each certificate evidencing shares of Common Stock purchased hereunder will bear a legend describing the restrictions on transfer contained in this paragraph unless, in the opinion of counsel reasonably acceptable to the Corporation, the shares need no longer to be subject to the transfer restrictions.

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11. Transfer. Except as otherwise provided in this Warrant, this Warrant is transferable only on the books of the Corporation by the Holder in person or by attorney, on surrender of this Warrant, properly endorsed.

12. Recognition of Holder. Prior to due presentment for registration of transfer of this Warrant, the Corporation shall treat the Holder as the person exclusively entitled to receive notices and otherwise to exercise rights under this Warrant. All notices required or permitted to be given to the Holder shall be in writing and shall be given by facsimile, email if receipt is confirmed or first class mail, postage prepaid, addressed to the Holder at the address of the Holder appearing in the records of the Corporation.

13. Payment of Taxes. The Corporation shall pay all taxes and other governmental charges, other than applicable income taxes, that may be imposed with respect to the issuance of shares of Common Stock pursuant to the exercise of this Warrant.

14. Headings. The headings in this Warrant are for purposes of convenience in reference only, shall not be deemed to constitute a part of this Warrant and shall not affect the meaning or construction of any of the provisions of this Warrant.

15. Miscellaneous. This Warrant may not be changed, waived, discharged or terminated except by an instrument in writing signed by the Corporation and the Holder. This Warrant shall inure to the benefit of and shall be binding upon the successors and assigns of the Corporation. Under no circumstances may this Warrant be assigned by the Holder.

16. Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of Maryland without giving effect to its principles governing conflicts of law.

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**SYNTHETIC BIOLOGICS, INC.**

By: /s/ Steven A. Shallcross  
Name: Steven A. Shallcross  
Title: Interim Chief Executive Officer and  
Chief Financial Officer

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SYNTHETIC BIOLOGICS, INC.  
**Form of Transfer**

(To be executed by the Holder to transfer the Warrant)

For value received the undersigned registered holder of the attached Warrant hereby sells, assigns, and transfers the Warrant to the Assignee(s) named below:

<u>Names of Assignee</u>	<u>Address</u>	<u>Taxpayer ID No.</u>	<u>Number of shares subject to transferred Warrant</u>
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The undersigned registered holder further irrevocably appoints \_\_\_\_\_ attorney (with full power of substitution) to transfer this Warrant as aforesaid on the books of the Corporation.

Date: \_\_\_\_\_  
Signature

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SYNTHETIC BIOLOGICS, INC.

**Exercise Form**

(To be executed by the Holder to purchase  
Common Stock pursuant to the Warrant)

The undersigned holder of the attached Warrant hereby irrevocably elects to exercise purchase rights represented by such Warrant for, and to purchase, \_\_\_\_\_ shares of Common Stock of Synthetic Biologics, Inc., a Nevada corporation. The undersigned tenders payment for those shares by wire transfer or enclosed check.

The undersigned requests that (1) a certificate for the shares be issued in the name of the undersigned and (2) if the number of shares with respect to which the undersigned holder has exercised purchase rights is not all of the shares purchasable under this Warrant, that a new Warrant of like tenor for the balance of the remaining shares purchasable under this Warrant be issued.

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature

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**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Steven A. Shallcross, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Synthetic Biologics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its condensed consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2018

By: /s/ Steven A. Shallcross  
Name: Steven A. Shallcross  
Interim Chief Executive Officer, Chief Financial Officer  
(Principal Executive Officer, Principal Financial Officer and  
Principal Accounting Officer)

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**CERTIFICATION PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Synthetic Biologics, Inc. (the "Registrant") hereby certifies, to such officer's knowledge, that:

- (1) the accompanying Quarterly Report on Form 10-Q of the Registrant for the quarter ended March 31, 2018 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: May 8, 2018

By: /s/ Steven A. Shallcross  
Name: Steven A. Shallcross  
Interim Chief Executive Officer, Chief Financial Officer  
(Principal Executive Officer, Principal Financial Officer and  
Principal Accounting Officer)

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