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, 2017

OR

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

For the transition period from _____ to _____

Commission File Number: 001-12584

SYNTHETIC BIOLOGICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**13-3808303**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
9605 Medical Center Drive, Suite 270 **Rockville, MD**	**20850**
(Address of Principal Executive Offices)	*(Zip Code)*

(301) 417-4364
(*Registrant's Telephone Number, Including Area Code*)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ 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 file, a non-accelerated file, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer, "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

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

As of May 2, 2017 the registrant had 121,894,034 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, 2016 filed with the Securities and Exchange Commission (the "SEC") on March 2, 2017 ("2016 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)

	March 31, 2017	December 31, 2016
Assets		
Current Assets		
Cash and cash equivalents	$ 13,471	$ 19,055
Prepaid expenses and other current assets	3,366	2,515
Total Current Assets	16,837	21,570
Property and equipment, net	859	905
Deposits and other assets	23	23
Total Assets	**$ 17,719**	**$ 22,498**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 3,796	$ 1,993
Accrued expenses	2,134	2,627
Warrant liabilities	9,731	14,821
Accrued employee benefits	787	313
Deferred rent	40	3
Total Current Liabilities	16,488	19,757
Long term deferred rent	470	492
Total Liabilities	16,958	20,249
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value; 250,000,000 shares authorized, 118,017,693 issued and 117,936,211 outstanding and 117,254,196 issued and 117,172,714 outstanding, respectively	118	117
Additional paid-in capital	177,331	175,762
Accumulated deficit	(174,880)	(172,034)
Total Synthetic Biologics, Inc. and Subsidiaries Equity	2,569	3,845
Non-controlling interest	(1,808)	(1,596)
Total Stockholders' Equity	761	2,249
Total Liabilities and Stockholders' Equity	**$ 17,719**	**$ 22,498**

See accompanying notes to unaudited condensed consolidated financial statements.

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

	For the three months ended March 31,	
	2017	**2016**
Operating Costs and Expenses:		
General and administrative	$ 2,090	$ 2,426
Research and development	6,059	8,155
Total Operating Costs and Expenses	8,149	10,581
Loss from Operations	(8,149)	(10,581)
Other Income (Expense):		
Change in fair value of warrant liability	5,090	(498)
Interest income	1	1
Total Other Income (Expense)	5,091	(497)
Net Loss	(3,058)	(11,078)
Net Loss Attributable to Non-controlling Interest	(212)	(233)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	**$ (2,846)**	**$ (10,845)**
Net Loss Per Share - Basic and Dilutive	$ (0.02)	$ (0.12)
Weighted average number of shares outstanding during the period - Basic and Dilutive	117,447,260	90,826,752

See accompanying notes to unaudited condensed consolidated financial statements.

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

	For the three months ended March 31,	
	2017	**2016**
Cash Flows From Operating Activities:		
Net Loss	$ (3,058)	$ (11,078)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,135	1,052
Change in fair value of warrant liabilities	(5,090)	498
Depreciation	57	37
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(851)	2,403
Deposits and other assets	-	(12)
Accounts payable	1,803	184
Accrued expenses	(493)	649
Accrued employee benefits	474	592
Deferred rent	15	1
Net Cash Used In Operating Activities	(6,008)	(5,674)
Cash Flows From Investing Activities:		
Purchases of property and equipment	(11)	(44)
Net Cash Used In Investing Activities	(11)	(44)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock from stock option exercises	166	-
Proceeds from “at the market” stock issuance	269	-
Net Cash Provided By Financing Activities	435	-
Net decrease in cash	(5,584)	(5,718)
Cash at beginning of period	19,055	20,818
Cash at end of period	**$ 13,471**	**$ 15,100**
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ -	$ -
Cash paid for taxes	$ -	$ -

See accompanying notes to unaudited condensed consolidated financial statements.

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

1. Organization and Nature of Operations and Basis of Presentation

Description of Business

Synthetic Biologics, Inc. (the "Company" or "Synthetic Biologics") is a 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-010 which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C), and (2) SYN-004 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) and antibiotic-associated diarrhea (AAD). In collaboration with Intrexon Corporation (NYSE: XON), the Company is also developing preclinical stage monoclonal antibody therapies for the prevention and treatment of pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the SEC for interim financial information. Accordingly, they do not include all of the information and notes required by U.S. Generally Accepted Accounting Principles ("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 2016 Form 10-K. The interim results for the three months ended March 31, 2017, 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 could differ from the original estimates, requiring adjustments to these balances in future periods.

Recent Accounting Pronouncements and Developments

In August 2016, the Financial Accounting Standards Board, ("FASB") issued Accounting Standards Update ("ASU") 2016-15, *Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments*, to clarify whether the following items should be categorized as operating, investing or financing in the statement of cash flows: (i) debt prepayments and extinguishment costs, (ii) settlement of zero-coupon debt, (iii) settlement of contingent consideration, (iv) insurance proceeds, (v) settlement of corporate-owned life insurance (COLI) and bank-owned life insurance (BOLI) policies, (vi) distributions from equity method investees, (vii) beneficial interests in securitization transactions, and (viii) receipts and payments with aspects of more than one class of cash flows. Accordingly, ASU No. 2016-015 is effective for public business entities for fiscal years beginning after December 15, 2017, with early adoption permitted. The Company does not anticipate any impact in the adoption of this standard on its condensed consolidated financial statements.

In March 2016, the FASB, issued ASU, No. 2016-09, *Compensation - Stock Compensation (Topic 718)*, which is part of the FASB's Simplification Initiative. The updated guidance simplifies the accounting for share-based payment transactions. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, with early adoption permitted. The Company has adopted this standard beginning January 1, 2017. The adoption did not result in significant changes to the recognition and disclosure of stock based compensation.

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

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, to provide guidance on revenue recognition. ASU No. 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today's guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which provided for the adoption of the new standard for fiscal years beginning after December 15, 2017. Accordingly, ASU No. 2014-09 is effective for the Company in the first quarter of 2018. Early adoption up to the first quarter of 2017 is permitted. Upon adoption, ASU No. 2014-09 can be applied retrospectively to all periods presented or only to the most current period presented with the cumulative effect of changes reflected in the opening balance of retained earnings in the most current period presented. The FASB has also issued the following standards which clarify ASU No. 2014-09 and have the same effective date as the original standard:

- ASU No. 2016-10, *Identifying Performance Obligations and Licensing (Topic 606);*
- ASU No. 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting;*
- ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*;
- ASU No. 2016-20, *Technical Correction and Improvements and*
- ASU No. 2016-20, *Technical correction and improvements to Topic 606, Revenue form Contracts with Customers.*

The adoption of ASU 2014-09 may have a material effect on the recognition of future revenues. ASU 2014-09 differs from the current accounting standard in many respects, such as in the accounting for variable consideration, including milestone payments. Accordingly, we expect that our evaluation of the accounting for collaboration agreements under the new revenue standard could identify material changes from the current accounting treatment. The new accounting standard will require entities to determine an appropriate attribution method using either output or input methods and does not include a presumption that entities would default to a ratable attribution approach for upfront non-refundable fees. These factors could materially impact the amount and timing of our revenue recognition from our license and collaboration agreements under the new revenue standard. The Company will need to evaluate the impact of adoption ASU No. 2014-09 on its results of operations, cash flows and financial position.

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 2017 the Company has an accumulated deficit of approximately $174.9 million. Since inception, the Company has financed its activities principally with proceeds from the issuance of equity securities.

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

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

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

At March 31, 2017, the Company had cash and cash equivalents of approximately $13.5 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. 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, 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 "FBR Sales Agreement") that the Company entered into with FBR Capital Markets & Co. in August 2016) or debt and other sources. The Company cannot assure that it will meet the requirements for use of the FBR Sales Agreement or that additional funding will be available on favorable terms, or at all. If the Company fails to obtain additional funding in the next few months 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 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. These factors raise doubt regarding the Company's ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

- the progress of research activities;
- the number and scope of research programs;
- the progress of preclinical and clinical development activities;
- the progress of the development efforts of parties with whom the Company has entered into research and development agreements;
- costs associated with additional clinical trials of product candidates;
- the ability to maintain current research and development licensing arrangements and to establish new research and development, and licensing arrangements;
- the ability to achieve milestones under licensing arrangements;
- the costs associated with manufacturing-related services to produce material for use in 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

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

- **Level 1 inputs:** Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- **Level 2 inputs:** Inputs, other than quoted prices, included in Level 1 that are observable either directly or indirectly; and
- **Level 3 inputs:** Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

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 $1.1 million and $1.7 million as of March 31, 2017 and December 31, 2016, respectively, that are measured using Level 1 inputs.

The warrants issued in conjunction with the registered direct offering in October 2014 include a provision that if the Company were to enter into a certain transaction, as defined in the warrant agreement, the warrants would be purchased from the holder at a premium. The warrants issued in conjunction with the public offering of the Company's securities in November 2016 include a provision, that if the Company were to enter into a certain transaction, as defined in the warrant agreement, the warrants would be purchased from the holder for cash. Accordingly, the Company recorded the warrants as liabilities at their fair value upon issuance and re-measures the fair value at each period end with the change in fair value recorded in the condensed consolidated statement of operations. The Company uses a Monte Carlo simulation to estimate the fair value of the warrants. In using this model, the fair value is determined by applying Level 3 inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liability and the change in estimated fair value could be materially different.

4. Selected Balance Sheet Information

Prepaid expenses and other current assets (in thousands)

	March 31, 2017	December 31, 2016
Prepaid clinical research organizations expense	$ 2,224	$ 1,677
Prepaid travel and conference expenses	397	295
Prepaid manufacturing expenses	330	-
Prepaid insurances	240	358
Other current assets	175	185
Total	$ 3,366	$ 2,515

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 includes payments in advance of study services. The Company anticipates that the majority of the prepaid clinical research organization expenses will be applied to research and development expenses during fiscal year 2017.

Property and equipment, net (in thousands)

	March 31, 2017	December 31, 2016
Computer and office equipment	$ 652	$ 641
Leasehold improvements	439	439
Software	11	11
	1,102	1,091
Less accumulated depreciation and amortization	(243)	(186)
Total	$ 859	$ 905

Accrued expenses (in thousands)

	March 31, 2017	December 31, 2016
Accrued clinical consulting services	$ 1,812	$ 2,211
Accrued vendor payments	280	400
Accrued manufacturing expense	38	14
Other accrued expenses	4	2
Total	$ 2,134	$ 2,627

Accrued employee benefits (in thousands)

	March 31, 2017	December 31, 2016
Accrued bonus expense	$ 446	$ -
Accrued vacation expense	341	261
Other accrued employee benefits	-	52
Total	$ 787	$ 313

5. Stock-Based Compensation

Stock Incentive Plan

On March 20, 2007, the Company's Board of Directors approved the 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 2,500,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, directors, other employees 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 Stock 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, 2017, there were 743,924 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, directors, other employees and consultants of the Company and its subsidiaries. On October 22, 2013, 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 3,000,000 to 6,000,000. On May 15, 2015, 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 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. 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. There is no limit on the number or the value of the shares 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. Options become exercisable over various periods from the date of grant, and generally expire between five to ten years after the grant date. As of March 31, 2017, there were 10,745,591 options issued and outstanding under the 2010 Stock Plan.

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

The Company has applied fair value accounting for all 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. The Black-Scholes assumptions used in the three months ended March 31, 2017 and 2016 are as follows:

	Three months ended March 31, 2017	2016
Exercise price	$0.83-$0.87	$1.08-$1.31
Expected dividends	0%	0%
Expected volatility	89.93%-91.82%	117%
Risk free interest rate	1.67%-1.75%	1.40%-1.46%
Expected life of option	4.24-4.29	7 years

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

- immediate vesting;
- half vesting immediately and remaining over three years;

- quarterly over three years;
- annually over three years;
- one-third immediate vesting and remaining annually over two years;
- one half immediate vesting 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, 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. During the same period in 2016, the Company granted 150,000 options to employees having an approximate fair value of $153,000 million based upon the Black-Scholes option pricing model.

A summary of stock option activities as of March 31, 2017, and for the year ended December 31, 2016, is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance - December 31, 2015	8,941,930	$ 2.14	5.67 years	$ 2,900,000
Granted	3,861,425	0.98		
Exercised	(445,334)	1.83		137,488
Expired	(338,529)	1.96		
Forfeited	(383,265)	2.26		
Balance - December 31, 2016	11,636,227	1.77	5.49 years	$ 194,355
Granted	543,927	0.85		
Exercised	(418,773)	0.40		163,050
Expired	(271,866)	1.84		
Forfeited	-	-		
Balance -March 31, 2017 - outstanding	11,489,515	$ 1.77	5.73 years	$ 17,427
Balance - March 31, 2016 - exercisable	6,177,207	$ 2.11	4.94 years	$ 17,427
Grant date fair value of options granted - March 31, 2017		$ 308,000		
Weighted average grant date fair value - March 31, 2017		$ 0.57		
Grant date fair value of options granted - December 31, 2016		$ 3,091,000		
Weighted average grant date fair value - December 31, 2016		$ 0.80		

Stock-based compensation expense included in general and administrative expenses and research and development expenses related to stock options issued to employees and consultants for the three months ended March 31, 2017 and 2016 was $1.1 million.

As of March 31, 2017, total unrecognized stock-based compensation expense related to stock options was $5.6 million, which is expected to be expensed through February 2020.

6. Stock Purchase Warrants

On November 18, 2016, the Company completed a public offering of 25 million shares of common stock in combination with accompanying warrants to purchase an aggregate of 50 million shares of the 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 is $1.43 and the per share exercise price of the Series B warrants is $1.72, each subject to adjustment as specified in the Warrants. 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 are exercisable until December 31, 2017. 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 Statement of Operations at each subsequent period. 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 in 2017. In accordance with U.S. GAAP, the warrants were valued on the date of grant using a Monte Carlo simulation. The assumptions used by the Company are summarized in the following table:

	Series A			Series B		
	March 31, 2017	December 31, 2016	Issuance Date	March 31, 2017	December 31, 2016	Issuance Date
Closing stock price	$ 0.63	$ 0.76	$ 0.89	$ 0.63	$ 0.76	$ 0.89
Expected dividends	0%	0%	0%	0%	0%	0%
Expected volatility	90%	85%	85%	85%	90%	85%
Risk free interest rate	1.64%	1.67%	1.58%	0.97%	0.85%	0.81%
Expected life of warrant	3.64 years	3.9 years	4 years	0.75 years	1.0 years	1.1 years

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 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, 2017, the fair value of the warrant liability was $1.1 million, which resulted in non-cash income of $1.0 million in 2017. At March 31, 2016, the fair value of the warrant liability was $11.1 million, which resulted in non-cash income of $0.5 million in 2016. In accordance with guidance 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:

	March 31, 2017	December 31, 2016	Issuance Date
Closing stock price	$ 0.63	$ 0.76	$ 1.75
Expected dividends	0%	0%	0%
Expected volatility	0.85%	95%	95%
Risk free interest rate	1.4%	1.41%	1.39%
Expected life of warrant	2.55 years	2.79 years	5 years

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

Balance at December 31, 2016	$ 14,821
Change in fair value of warrant liability	(5,090)
Balance at March 31, 2017	$ 9,731

On October 25, 2012, the Company entered into a Common Stock Purchase Agreement with certain accredited investors. As part of this agreement, the Company issued warrants to purchase 635,855 shares of common stock to the placement agent, or its permitted assigns. The warrants have an exercise price of $1.60 and a life of five years. The warrants vested immediately and expire October 25, 2017. Since these warrants were granted as part of an equity raise, the Company has treated them as a direct offering cost. The result of the transaction has no effect to equity. Warrants outstanding as of March 31, 2017 were 311,834.

A summary of warrant activity for the Company for the three months ended March 31, 2017 and for the year ended December 31, 2016 is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2015	7,908,899	$ 1.79
Granted	50,000,000	1.58
Exercised	-	-
Forfeited	(567,257)	2.35
Balance at December 31, 2016	57,341,642	1.60
Granted	-	-
Exercised	-	-
Forfeited	-	-
Balance at March 31, 2017	57,341,642	$ 1.60

A summary of all outstanding and exercisable warrants as of March 31, 2017 is as follows:

Exercise Price	Warrants Outstanding	Warrants Exercisable	Weighted Average Remaining Contractual Life
$ 1.43	25,000,000	25,000,000	3.64 years
$ 1.60	311,834	311,834	0.57 years
$ 1.72	25,000,000	25,000,000	0.75 years
$ 1.75	7,029,808	7,029,808	2.53 years
$ 1.60	57,341,642	57,341,642	2.23 years

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. 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 potential 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, 2017 were 11,489,515 and 57,341,642, respectively, and for the three months ended March 31, 2016 were 8,992,428 and 7,858,899, respectively.

The following tables set forth the computation of diluted net loss per weighted average number of shares outstanding attributable to Synthetic Biologics and Subsidiaries for the three months ended March 31, 2017 and 2016 *(in thousands except share and per share amounts)*:

	Three months ended March 31, 2017			Three months ended March 31, 2016		
	Net loss (Numerator)	Shares (Denominator)	Per Share Amount	Net Loss (Numerator)	Shares (Denominator)	Per Share Amount
Net loss - Basic	$ (2,846)	117,447,260	$ (0.02)	$ (10,845)	90,826,752	$ (0.12)
Dilutive shares related to warrants	-	-	-	-	-	-
Net loss - Dilutive	$ (2,846)	117,447,260	$ (0.02)	$ (24,880)	90,826,752	$ (0.12)

8. Non-controlling Interest

The Company's non-controlling interest is accounted for under ASC 810, *Consolidation* ("ASC 810") 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 ended March 31, 2017, the accumulated net loss attributable to the non-controlling interest was $1.8 million.

9. FBR Sales Agreement

On August 5, 2016, the Company entered into the FBR Sales Agreement with FBR Capital Markets & Co., 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 FBR Capital Markets & Co. as the Company's sales agent. Sales of common stock under the 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. 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 ending March 31, 2017, the Company sold through the FBR Sales Agreement an aggregate of 344,724 shares of the Company's common stock, and received gross proceeds of approximately $269,000, before deducting issuance expenses. Subsequent to quarter end, the Company has sold approximately 3,958,000 shares of the Company's common stock, and received gross proceeds of approximately $2.2 million.

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, 2017 and 2016, the Company did not pay Cedars-Sinai Medical Center for milestone payments related this license agreement.

11. Subsequent Events

The Company evaluated subsequent events through May 4, 2017 which is the date the condensed consolidated financial statements were issued. Other than the stock sales discussed in Note 9, no subsequent events were noted that required disclosure in the condensed consolidated financial statements.

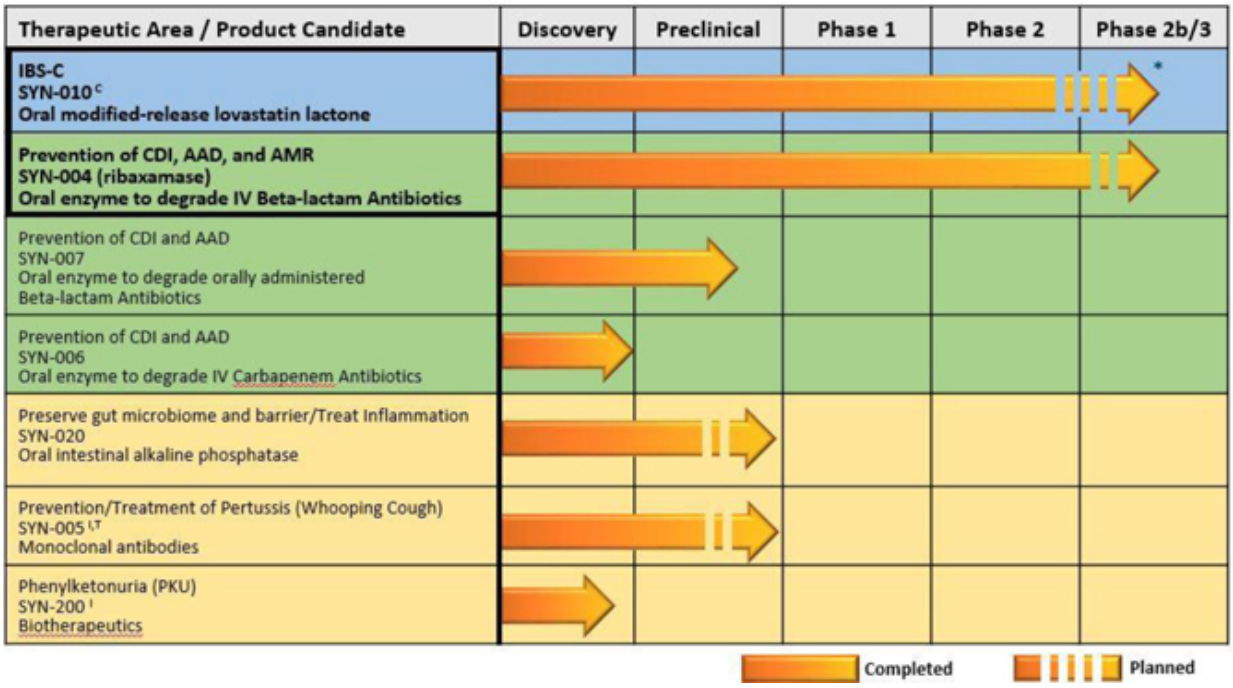
ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

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, 2016 included elsewhere in our Annual Report on Form 10-K filed with the SEC on March 2, 2017. 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, 2016 filed with the SEC on March 2, 2017.

Overview

We are a late-stage clinical stage 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-010 which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C), and (2) SYN-004 (ribaxamase) which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. difficile* infection (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antimicrobial resistance (AMR). We are also developing preclinical stage monoclonal antibody therapies for the prevention and treatment of pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

Product Pipeline:



* Two Phase 2 studies completed. Planning a Phase 2b/3 pivotal trial
C- Cedars-Sinai Medical Center Collaboration
I-Intrexon Collaboration
T- The University of Texas at Austin Collaboration

Summary of Clinical and Preclinical Programs

Therapeutic Area	Product Candidate	Status
Prevention of CDI and AAD (Degrade IV beta-lactam antibiotics)	SYN-004 (ribaxamase) (oral enzyme)	· Reported supportive Phase 1a/1b data (1Q 2015) · Initiated Phase 2b proof-of-concept clinical trial (3Q 2015) · Reported supportive topline data from first Phase 2a clinical trial (4Q 2015) · Reported supportive topline data from second Phase 2a clinical trial (2Q 2016) · Received USAN approval of the generic name “ribaxamase” for SYN -004 (July 2016) · Completed Enrollment of Phase 2b proof-of concept clinical trial (3Q 2016) · Awarded contract by the Centers for Disease Control and Prevention (CDC) (4Q 2016) · Announced positive topline data from Phase 2b proof-of-concept clinical trial, including achievement of primary endpoint of significantly reducing CDI (1Q 2017)

		· Announced additional results from Phase 2b proof-of-concept clinical trial demonstrating ribaxamase protected and maintained the naturally occurring composition of gut microbes from antibiotic-mediated dysbiosis in treated patients (Q2 2017)
		· Plan to initiate Phase 3 clinical trial(s) (1H 2018)
Treatment of IBS-C	SYN-010 (oral modified-release lovastatin lactone)	· Reported supportive topline data from two Phase 2 clinical trials (4Q 2015 & 1Q 2016)
		· Received Type C meeting responses from U.S. Food and Drug Administration (FDA) regarding late-stage aspects of clinical pathway (2Q 2016)
		· Presented detailed data supporting previously reported positive topline data from two Phase 2 clinical trials at Digestive Disease Week Conference 2016 (DDW) (May 2016)
		· Held End of Phase 2 meeting with FDA (July 2016)
		· Confirmed key elements of Pivotal Phase 2b/3 clinical trial design pursuant to consultations with FDA (1Q 2017)
		· Collaboration with Cedars-Sinai Medical Center
Prevention of CDI and AAD (Degrade oral beta-lactam antibiotics)	SYN-007 (oral enzyme)	· Preclinical work ongoing to determine ability of SYN-007 to protect the gut microbiome and degrade oral beta-lactam antibiotics
Prevention and Treatment of pertussis	SYN-005 (monoclonal antibody therapies)	· Reported supportive preclinical research findings (2014)
		· 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) · Reported supportive preclinical data demonstrating SYN-005 provided protection from pertussis five weeks in neonatal non-human primate study (Q2 2017) · Collaborations with Intrexon and UT Austin

Our Microbiome-Focused Pipeline

Our IBS-C and CDI/AAD programs are focused on protecting the healthy function of the gut microbiome, or gut flora, which is home to billions of microbial species and composed of 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. In total, we hold approximately 140 U.S. and foreign patents and have over 55 U.S. and foreign patents pending.

SYN-004 (ribaxamase) — Prevention of C. difficile infections (CDI) and antibiotic-associated diarrhea (AAD)

SYN-004 (ribaxamase) is an oral prophylactic therapy designed to degrade certain IV beta-lactam antibiotics within the gastrointestinal (GI) tract and maintain the natural balance of the gut microbiome for the prevention of CDI, AAD and emergence of antibiotic-resistant organisms. SYN-004 (ribaxamase) is a beta-lactamase enzyme which, when released in the proximal small intestine, can degrade beta-lactam antibiotics in the GI tract without altering systemic antibiotic levels. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics.

In November 2012, we acquired a series of oral beta-lactamase enzymes (P1A, P2A and P3A) and related assets targeting the prevention of CDI, the leading healthcare-associated infection that generally occurs secondary to treatment with IV antibiotics from Prev ABR LLC. The acquired assets include a pre-Investigation New Drug (IND) package for P3A, Phase 1 and Phase 2 clinical data for P1A, manufacturing processes and data, and a portfolio of issued and pending U.S. and foreign patents intended to support an IND and Biologics License Application (BLA) with the FDA. Utilizing this portfolio of assets, we developed a proprietary, second generation oral beta-lactamase enzyme product candidate that we now refer to as ribaxamase.

Compared to the first generation oral enzyme candidate of P1A, we believe that the second generation candidate, SYN-004 (ribaxamase), will have activity against a broader spectrum of beta-lactam antibiotics, including both penicillins and certain cephalosporins. Due to the structural similarities between P1A and SYN-004 (ribaxamase), and based on previous discussions with the FDA, certain preclinical data collected on P1A were used in support of an IND application for our new product candidate, SYN-004 (ribaxamase).

Specifically, P1A had been evaluated in four Phase 1 and one Phase 2 clinical trials conducted in Europe. In total, 112 patients and 143 healthy normal subjects participated in these studies.

P1A (the first generation candidate) showed acceptable safety and tolerability in a Phase 1 clinical trial. In addition, data from two Phase 2 clinical trials demonstrated that P1A had the ability to preserve GI microflora in hospitalized patients treated with IV ampicillin or the combination of piperacillin and tazobactam.

In September 2016, we completed enrollment in our randomized placebo-controlled Phase 2b proof-of-concept clinical trial intended to evaluate the ability of SYN-004 (ribaxamase) to prevent CDI, *C. difficile* associated diarrhea (CDAD) and AAD in patients hospitalized for a lower respiratory tract infection and receiving IV ceftriaxone.

On January 5, 2017, we announced positive topline data from our Phase 2b clinical trial demonstrating SYN-004 (ribaxamase) achieved its primary endpoint of significantly reducing CDI. Preliminary analysis of the data indicated seven confirmed cases of CDI in the placebo group compared to two cases in the ribaxamase treatment group. Patients receiving ribaxamase achieved a 71.4% relative risk reduction (p-value=0.045) in CDI rates compared to patients receiving placebo. Adverse events reported during this trial were comparable between treatment and placebo arms.

Preliminary analysis of the data demonstrated a significant reduction in new colonization by vancomycin-resistant enterococci (VRE) for patients receiving ribaxamase compared to placebo (p-value=0.0002). With agreement from the FDA, the study included a secondary endpoint to assess ribaxamase's capacity to decrease the incidence of antibiotic-associated diarrhea from all causes. Preliminary analysis of the data suggested a trend towards such a reduction (p-value=0.13), which was due, for the most part, to the reduction of CDI.

On April 7, 2017, we met with the CDC to share additional supportive results from several exploratory endpoints from our Phase 2b proof-of-concept clinical trial demonstrating ribaxamase successfully protected and preserved the naturally occurring composition of gut microbes in patients receiving ribaxamase from the dysbiotic effects of antibiotic-mediated intravenous ceftriaxone compared to placebo. Results indicate that patients who were administered ribaxamase in conjunction with IV ceftriaxone demonstrated significantly better maintenance of and recovery of the composition and diversity of the gut microbiome, compared to placebo. Patients receiving ribaxamase also demonstrated lower incidences of new colonization by opportunistic and potentially pathogenic microorganisms, such as VRE, compared to placebo.

We are in the process of further analyzing data from this clinical trial and expect to share results from additional exploratory endpoints as they become available later this year, including results focused on ribaxamase's ability to prevent the emergence of antimicrobial resistance in the gut microbiome.

In 2017, we also plan to continue collaborative efforts with CDC to gain public health support for ribaxamase, hold an end of Phase 2 meeting with the FDA, and expect to initiate Phase 3 trial(s) towards the first half of 2018 or later.

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

SYN-010 is our proprietary, modified-release formulation of lovastatin lactone that is intended to reduce methane production by certain microorganisms (*M. smithii*) in the gut while minimizing disruption to the microbiome. Methane produced by *M. smithii* is an underlying cause of pain, bloating and constipation associated with IBS-C, and published reports have associated higher intestinal methane production with increased constipation severity in IBS-C patients. SYN-010 is intended to act primarily in the intestinal lumen while avoiding systemic absorption, thereby targeting the major cause of IBS-C, not just the patient's symptoms.

In December 2013, through our subsidiary Synthetic Biomics, Inc. (SYN Biomics), we 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. We 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.

We believe SYN-010 may reduce the impact of methane producing organisms on IBS-C.

Overview of our two Phase 2 Clinical Trials

In 2015 and 2016, we reported supportive data from our two SYN-010 Phase 2 trials, the first study was comprised of a randomized, double-blind, placebo-controlled, 4-week study comparing SYN-010 21 mg and 42 mg dose strengths to placebo (Study 1), followed by an open-label study in which eligible patients who completed Study 1 received SYN-010 42 mg for an additional 8 weeks (Study 2). The two Phase 2 SYN-010 clinical trials evaluated the change from baseline (Day 1 of Study 1) in breath methane, stool frequency and abdominal pain and bloating at the end of weeks 1, 4, 8 and 12 (Study 2 – Day 84) in patients diagnosed with IBS-C and with breath methane levels greater than 10 parts per million (ppm) at screening.

Phase 3 Planning

On July 20, 2016, we participated in an End of Phase 2 meeting with the FDA. Following a review of data from the two Phase 2 clinical trials of SYN-010 conducted by us, a collaborative and positive discussion ensued with the FDA to determine the optimal pathway to advance SYN-010 into Phase 3 development. On January 18, 2017, and in accordance with guidance from the FDA, we confirmed our plan to conduct a Phase 2b/3 adaptive design study for our first pivotal trial of SYN-010 which we plan to initiate 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.

In accordance with collaborative discussions with the FDA, key components of the SYN-010 Phase 2b/3 adaptive pivotal trial will include:

- A 12-week, multi-center, double-blind, placebo-controlled, adaptive design clinical trial
- A study population of approximately 840 adult subjects diagnosed with IBS-C
- Evaluation of efficacy and safety of two dose strengths of SYN-010 (21 mg and 42 mg) compared to placebo
- Conducted in approximately 150 clinical sites in North America
- Study subjects will be randomized in a 1:1:1 ratio, receiving either 21 mg of SYN-010, 42 mg of SYN-010, or placebo
- Enrollment will be open to all IBS-C patients; breath-methane will be measured at baseline to ensure a comparable ratio of high-to-low breath methane IBS-C patients in each treatment arm
- An interim futility analysis may be conducted when approximately 50% of patients in each dosing arm have completed treatment

Consistent with FDA written guidance, the primary objective for this study is to determine the efficacy of SYN-010, measured as an improvement from baseline in the percentage of overall weekly responders during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses compared to placebo. Secondary efficacy endpoints for both dose strengths of SYN-010 will measure changes from baseline in abdominal pain, bloating, bowel movement frequency and stool consistency. Exploratory outcomes include adequate relief and quality of life measures using the well-validated EQ-5D-5L and PAC-SYM patient questionnaires.

Anticipated Regulatory Strategy

We believe that we will be able to utilize the regulatory approval pathway provided in Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") for SYN-010. A New Drug Application (NDA) submitted under Section 505(b)(2), referred to as a 505(b)(2) NDA, contains full safety and efficacy reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. We believe we can rely in part on the FDA's previous findings of safety for Mevacor (lovastatin) in published clinical data. We expect to rely on published clinical trials using Mevacor to provide support of efficacy.

SYN-007 — Prevention of CDI and AAD

Preclinical work is ongoing to determine the ability of SYN-007 to degrade oral beta-lactam antibiotics and protect the gut microbiome. SYN-007 comprises a reformulated version of SYN-004 for use with oral beta-lactam antibiotics versus IV beta-lactam antibiotics.

SYN-006 — Prevention of CDI and AAD

The development of SYN-006 is in the discovery stage. SYN-006 is intended to be an oral prophylactic therapy designed to degrade IV carbapenem antibiotics (a third class of beta-lactam antibiotics) within the GI tract and maintain the natural balance of the gut microbiome for the prevention of CDI and AAD. While SYN-004 (ribaxamase) is intended to degrade penicillin and certain cephalosporins in the GI tract, the SYN-006 discovery program has the potential to expand the activity to a broader spectrum of IV beta-lactam antibiotics in the GI tract to include carbapenem antibiotics.

Research Programs

Infectious disease outbreaks are increasing while intervention options are declining due to widespread multidrug-resistant bacteria, increasing numbers of immuno-compromised patients (e.g., the elderly and cancer patients) and the isolation of new pathogens.

SYN-005 — Pertussis (Whooping Cough)

Intrexon Collaboration and The University of Texas (UT) at Austin Agreement

In August 2012, we entered into a worldwide exclusive channel collaboration with Intrexon through which we intend to develop monoclonal antibody (mAb) therapies for the treatment of certain infectious diseases not adequately addressed by existing therapies. In December 2012, we initiated mAb development for the prevention and treatment of pertussis focusing on toxin neutralization. Unlike antibiotics, we are developing a mAb therapy to target and neutralize the pertussis toxin as a prophylaxis for high-risk newborns and in order to reduce the mortality rate in infected infants.

To further the development of this potential therapy for pertussis, we entered into an agreement with UT Austin to license the rights to certain research and pending patents related to pertussis antibodies. These research efforts are being conducted at the Cockrell School of Engineering in the laboratory of Associate Professor, Jennifer A. Maynard, Ph.D., the Laurence E. McMakin, Jr. Centennial Faculty Fellow in the McKetta Department of Chemical Engineering. Dr. Maynard brings to the project her expertise in the development, optimization, and application of mAbs for the treatment of pertussis.

We previously reported that SYN-005, a cocktail of two mAbs, was highly efficacious as a therapeutic in non-human primates infected with B. pertussis. The data were published in *Science Translational Medicine* in December 2015.

In October 2015, the Bill & Melinda Gates Foundation awarded a grant to UT Austin to generate preclinical proof-of-concept data in the neonatal non-human primate model to test the hypothesis that antibody administration at birth may have a role in the prevention of pertussis.

In December 2015, the non-human primate prophylaxis study was initiated by UT Austin to determine if administration of hu1B7, one component of SYN-005, at two days of age could protect animals from a subsequent pertussis infection. On April 19, 2017, we announced supportive preclinical data demonstrating hu1B7 provided five weeks of protection from pertussis in neonatal non-human primates. Control animals (n=6), infected with *Bordetella pertussis (B. pertussis)* at five weeks of age, demonstrated marked elevations in white blood cell counts and most exhibited behavioral signs of pertussis, including coughing and diminished activity. In contrast, the experimental animals (n=7), who were treated with hu1B7 at two days of age and then infected five weeks later, had significantly lower peak white blood cell counts (p=0.004) that remained within the normal range or were only slightly elevated. Importantly, all seven of the animals that received prophylactic hu1B7 appeared healthy and none exhibited any behavioral signs of pertussis. Building on this early success, we have initiated preclinical testing of a modified version of hu1B7 that has the potential to extend the plasma half-life and substantially reduce the required dose of SYN-005.

This current study expands the potential clinical utility beyond therapy to also include prophylaxis.

SYN-200 — Treatment of Phenylketonuria (PKU)

In August 2015, we initiated the SYN-200 discovery program for development and commercialization of novel biotherapeutics for the treatment of patients with PKU pursuant to an exclusive channel collaboration with Intrexon. We are utilizing Intrexon's ActoBiotics platform to provide a proprietary method of delivering therapeutic protein to the GI tract through food-grade microbes. This program is in the discovery stage.

SYN-020 — Oral Intestinal Alkaline Phosphatase

SYN-020 is in the preclinical development stage. SYN-020 is being developed as a modified-release oral dosage form of intestinal alkaline phosphatase (IAP). Published preclinical and clinical studies on IAP indicate that an oral IAP product may have efficacy in a broad range of significant therapeutic indications including inflammatory bowel disease, microbial dysbiosis and metabolic syndrome. We have generated manufacturing cell lines and processes, and are initiating preclinical animal modeling for multiple novel indications.

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 approximately 140 U.S. and foreign patents and over 55 U.S. and foreign patents pending. For instance, U.S. Patent No. 8,894,994, which has claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including ribaxamase, carries a patent term 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 ribaxamase, in protecting the microbiome, and allowed U.S. Patent No.s 9,290,754, 9,376,673, 9,404,103 and 9,464,280, which, will expire in 2035, covers further beta-lactamase compositions of matter related to ribaxamase. Also, U.S. Patent No. 9,192,618, which expires in approximately 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 approximately 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. Pending applications PCT /US2015/045140 and US 14/826,115, cover SYN-010 formulations and, if issued (after nationalization), are expected to have a term to 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 require 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 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 could 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 2016 Form 10-K.

Results of Operations

Three Months Ended March 31, 2017 and 2016

General and Administrative Expenses

General and administrative expenses decreased by 14% to $2.1 million for the three months ended March 31, 2017, from $2.4 million for the three months ended March 31, 2016. This decrease is primarily the result of lower employee salary expense and related benefits costs along with reduced travel and legal expenses. The charge related to stock-based compensation expense was $698,000 for the three months ended March 31, 2017, compared to $643,000 the three months ended March 31, 2016.

Research and Development Expenses

Research and development expenses decreased by 26% to $6.0 million for the three months ended March 31, 2017, from $8.2 million for the three months ended March 31, 2016. This decrease is primarily the result of lower ribaxamase program costs associated with its clinical development program, as well as manufacturing and research activities within our other microbiome-focused research and development activities. The charge related to non-cash stock-based compensation expense was $437,000 for the three months ended March 31, 2017, compared to $409,000 for the three months ended March 31, 2016.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the three months ended March 31, 2017 and 2016. 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.

Therapeutic Areas	March 31, 2017	March 31, 2016
SYN-010	$ 1,849	$ 2,028
Ribaxamase	633	2,480
SYN-005	14	22
Other therapeutic areas	(1)	12
SYN-010		
Total direct costs	2,495	4,542
Total indirect costs	3,564	3,613
Total Research and Development	$ 6,059	$ 8,155

Other Income (Expense)

Other income was $5.1 million for the three months ended March 31, 2017, compared to other expense of $0.5 million for the three months ended March 31, 2016. Other income for the three months ended March 31, 2017 is due to non-cash income of $5.1 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

Our net loss was $2.8 million, or $0.02 per basic and dilutive common share for the three months ended March 31, 2017, compared to a net loss of $10.8 million, or $0.12 per basic common share and dilutive common share for the three months ended March 31, 2016.

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 we expect to continue to seek to obtain the required capital in a similar manner. We have incurred an accumulated deficit of $174.9 million as of March 31, 2017 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.

Based on our current plans, our cash and cash equivalents will not be sufficient to enable us to meet our near term expected plans. Our notes to the condensed consolidated 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 cash and cash equivalents totaled $13.5 million as of March 31, 2017, a decrease of $5.6 million from December 31, 2016. During the three months ended March 31, 2017, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $3.1 million for the three months ended March 31, 2017.

Our continued operations as currently planned will primarily depend on our ability to raise additional capital from various sources, including equity (the FBR Sales Agreement as well as other equity sources) and debt financings, as well as license fees 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, our cash and cash equivalents will not be sufficient to enable us to meet our near term expected plans. Our notes to the condensed consolidated 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 will be required to obtain additional funding in order to continue the development of our current product candidates as currently planned and to continue to fund operations at the current cash expenditure levels, although we do not currently have commitments from any third parties to provide us with capital. Potential sources of financing include strategic relationships, public or private sales of our equity (including through the FBR Sales Agreement that we entered into with FBR Capital Markets & Co. in August 2016) or debt and other sources. We cannot assure that we will meet the requirements for use of the FBR Sales Agreement 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 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 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;
- 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 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. During the past several months our only source of funding was from the sale of our common stock through the FBR Sales Agreement. From August 11, 2016 through December 31, 2016, we sold through the FBR Sales Agreement an aggregate of 900,628 shares of our common stock, and received gross proceeds of approximately $1,550,197. During the quarter ended March 31, 2017, we sold through the FBR Sales Agreement an aggregate of 344,721 shares of our common stock, and received gross proceeds of approximately $218,000 and subsequent to quarter end, we sold approximately 3,958,000 shares of our common stock, and received gross proceeds of approximately $2.2 million. During the year ended December 31, 2016, our only source of funding was from the sale of our securities in our public offering of 25 million shares of common stock in combination with accompanying warrants to purchase an aggregate of 50,000,000 shares of the common stock for gross proceeds of $25,000,000 and sales of common stock through the FBR Sales Agreement. However, 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 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 financing 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.

Off-Balance Sheet Arrangements

During the three months ended March 31, 2017, 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 2016 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, 2017, 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 Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures as of March 31, 2017, 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, 2017 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 our quarter ended March 31, 2017 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 2016 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2016 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, 2017, our operating activities used net cash of approximately $6 million and as of March 31, 2017 our cash and cash equivalents were $13.5 million. With the exception of the three months ended June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. As of March 31, 2017, our accumulated deficit totaled approximately $174.9 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 significant 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 ongoing 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 fees and grants. Based upon our business plans, we do not believe that our current cash, cash equivalents and short-term investments will be sufficient to sustain our operations as currently planned. Therefore, we will need to seek additional sources of funding, such as additional financing or grant funding, and additional financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms or in a timely manner, we will be unable to complete planned preclinical and clinical trials in the periods anticipated, if at all, or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, if we do not raise additional capital in the next few months or otherwise in the future when needed we will be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. 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.

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 MKT.

Our common stock is listed on the NYSE MKT. The NYSE MKT'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 MKT. The NYSE MKT 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 MKT Exchange Company Guide. At March 31,2017, we had stockholders' equity of $761,000. The NYSE MKT 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 the total value of our market capitalization today exceeds $50.0 million and 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 a decrease in the price of our stock could result in a market capitalization below $50.0 million. There can be no assurance that the NYSE MKT will continue to list our common stock if we should continue 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 MKT. If we are delisted from the NYSE MKT 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. 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 MKT 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.

None.

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/ Jeffrey Riley
Jeffrey Riley
President and Chief Executive Officer
(Principal Executive Officer)
Date: May 4, 2017

By: /s/ Steven A. Shallcross
Steven A. Shallcross
Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: May 4, 2017

EXHIBIT INDEX

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.

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE 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, Jeffrey Riley, 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 4, 2017

By: /s/ Jeffrey Riley
Name: Jeffrey Riley
Title: President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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 4, 2017

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Title: Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION PRINCIPAL EXECUTIVE 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, 2017 (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 4, 2017

By: /s/ Jeffrey Riley
Name: Jeffrey Riley
Title: President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

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, 2017 (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 4, 2017

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Title: Chief Financial Officer
(Principal Financial Officer)