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

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

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

For the transition period from _____ to _____

Commission File Number: 001-12584

SYNTHETIC BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**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 issuer: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

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

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

SYNTHETIC BIOLOGICS, INC.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

NOTE REGARDING COMPANY REFERENCES

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

NOTE REGARDING TRADEMARKS

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

SYNTHETIC BIOLOGICS, INC.

FORM 10-Q

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PART I.-FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Balance Sheets

(In thousands except share and per share amounts)

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

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

See accompanying notes to unaudited consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Statements of Operations

(In thousands except share and per share amounts)

(Unaudited)

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

See accompanying notes to unaudited consolidated financial statements.

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Synthetic Biologics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(In thousands except share and per share amounts)

(Unaudited)

	For the six months ended June,	
	2016	2015
Cash Flows From Operating Activities:		
Net Loss	$ (16,842)	$ (25,981)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,959	1,413
Stock issued for milestone payments	-	1,350
Change in fair value of warrant liabilities	(3,015)	8,047
Depreciation	57	19
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,745	(5,407)
Deposits and other assets	(11)	(12)
Accounts payable	143	7,690
Accrued expenses	1,543	317
Accrued employee benefits	897	(144)
Deferred rent	(10)	-
Net Cash Used In Operating Activities	(11,534)	(12,708)
Cash Flows From Investing Activities:		
Purchases of property and equipment	(45)	(61)
Net Cash Used In Investing Activities	(45)	(61)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock for stock option exercises	810	1
Net Cash Provided By Financing Activities	810	1
Net decrease in cash	(10,769)	(12,768)
Cash at beginning of period	20,818	17,525
Cash at end of period	$ 10,049	$ 4,757
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ -	$ -
Cash paid for taxes	$ -	$ -

See accompanying notes to unaudited consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

(Unaudited)

1. Organization and Nature of Operations and Basis of Presentation

Description of Business

Synthetic Biologics, Inc. (the "Company" or "Synthetic Biologics") is a clinical stage company developing therapeutics to protect the gut microbiome while targeting pathogen-specific diseases. The Company's lead candidates in Phase 2 development are: (1) SYN-010 which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C), and (2) SYN-004 (ribaxamase) which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. difficile* infection (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms. In collaboration with Intrexon Corporation ("Intrexon"), the Company is also developing preclinical stage monoclonal antibody therapies for the prevention and treatment of pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

Basis of Presentation

The accompanying consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all of the information and notes required by U.S. Generally Accepted Accounting Principles ("GAAP") for complete financial statements. The accompanying consolidated financial statements include all adjustments, comprised of normal recurring adjustments, considered necessary by management to fairly state our results of operations, financial position and cash flows. The operating results for the interim periods are not necessarily indicative of results that may be expected for any other interim period or for the full year. These consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015 ("2015 Form 10-K") as filed with the SEC. The interim results for the three and six months ended June 30, 2016, are not necessarily indicative of results for the full year.

The consolidated financial statements are prepared in conformity with U.S. GAAP, which requires the use of estimates, judgments and assumptions that affect the amounts of assets and liabilities at the reporting date and the

amounts of revenue and expenses in the periods presented. We believe that the accounting estimates employed are appropriate and the resulting balances are reasonable; however, due to the inherent uncertainties in making estimates, actual results could differ from the original estimates, requiring adjustments to these balances in future periods.

Recent Accounting Pronouncements and Developments

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

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

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

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

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

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

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

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

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

2. Management's Plan

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

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

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

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

· the costs associated with manufacturing-related services to produce material for use in our clinical trials;

· the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and

· the costs and timing of regulatory approvals.

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

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

3. Fair Value of Financial Instruments

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

· Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;

· Level 2 inputs: Inputs, other than quoted prices included in Level 1, that are observable either directly or indirectly; and

· Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

If the inputs used to measure fair value fall in different levels of the fair value hierarchy, the hierarchy level is based upon the lowest level of input that is significant to the fair value measurement.

Cash and cash equivalents include money market accounts of $1.8 million and $5.3 million as of June 30, 2016 and December 31, 2015, respectively, that are measured using Level 1 inputs.

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

4. Selected Balance Sheet Information

Prepaid expenses and other current assets (in thousands)

	June 30, 2016	December 31, 2015
Intrexon prepaid research and development expenses	$ 48	$ 643
Prepaid clinical research organizations	4,823	8,329
Prepaid insurances	185	339
Other prepaid expenses	718	208
Total	$ 5,774	$ 9,519

The Intrexon prepaid research and development expenses are classified as a current asset. The Company may terminate the arrangement at any time and receive a cash refund of the remaining balance minus any amounts owed to Intrexon. The Company anticipates that the majority of the prepaid will be applied to research and development expenses during the balance of 2016.

Prepaid clinical research organization 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 the balance of 2016.

Property and equipment (in thousands)

	June 30, 2016	December 31, 2015
Computer and office equipment	$ 384	$ 346
Software	11	11
Leasehold improvements	241	242
	636	599
Less accumulated depreciation and amortization	(154)	(105)
Total	$ 482	$ 494

Accrued expenses (in thousands)

	June 30, 2016	December 31, 2015
Accrued manufacturing costs	$ 203	$ -
Accrued vendor payments	486	133
Accrued clinical consulting services	1,152	164
Total	$ 1,841	$ 297

Accrued employee benefits (in thousands)

	June 30, 2016	December 31, 2015
Accrued bonus expense	$ 717	$ -
Accrued vacation expense	199	153
Other accrued employee benefits	258	124
Total	$ 1,174	$ 277

5. Stock-Based Compensation

Stock Incentive Plan

During 2001, the Company's Board of Directors and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2001 Stock Plan shall not exceed 250,000. All awards pursuant to the 2001 Stock Plan shall terminate upon the termination of the grantee's employment for any reason. Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The 2001 Stock Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined in the plan. The 2001 Stock Plan provides for a committee of the Board to grant Awards and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the Awards, including acceleration of the vesting of an Award at any time. As of June 30, 2016, there were 228,773 options issued and outstanding under the 2001 Stock 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, other employees, directors and consultants of the Company and its subsidiaries. This plan was approved by stockholders on November 2, 2007. The exercise price of stock options under the 2007 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common 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 June 30, 2016, there were 789,155 options issued and outstanding under the 2007 Stock Plan.

On November 2, 2010, the Board of Directors and stockholders adopted the 2010 Stock Incentive Plan ("2010 Stock Plan") for the issuance of up to 3,000,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. On October 22, 2013, the stockholders approved and adopted an amendment to the 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 May 31, 2016, the board of directors of the Company approved and adopted, subject to shareholder approval, 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 ten years after the grant date. As of June 30, 2016, there were 7,595,485 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 and six months ended June 30, 2016 and 2015 are as follows:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Exercise price	$2.20 - $2.66	$2.04 - $2.73	$1.08 - $2.66	$1.54 - 2.73
Expected dividends	0%	0%	0%	0%
Expected volatility	102% - 115%	88% - 128%	102% - 117%	88% - 131%
Risk free interest rate	1.41% - 1.57%	1.32% - 2.19%	1.40% - 1.57%	1.32% - 2.19%
Expected life of option	7 years	5 years - 10 years	7 years	5 years - 10 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 six months ended June 30, 2016, the Company granted 560,000 options to employees having an approximate fair value of $962,000 based upon the Black-Scholes option pricing model. During the same period in 2015, the Company granted 1,800,000 options to employees having an approximate fair value of $3.2 million based upon the Black-Scholes option pricing model.

A summary of stock option activities as of June 30, 2016, and for the year ended December 31, 2015, is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance - December 31, 2014	5,981,106	$ 2.01	5.80 years	$685,000
Granted	3,781,666	$ 2.37		
Exercised	(35,008)	$ 1.16		$44,000
Expired	(483,332)	$ 2.48		
Forfeited	(302,502)	$ 1.91		
Balance - December 31, 2015	8,941,930	$ 2.14	5.80 years	$2,900,000
Granted	560,000	$ 2.01		
Exercised	(442,834)	$ 1.83		$136,913
Expired	(249,502)	$ 1.93		
Forfeited	(196,181)	$ 2.34		
Balance -June 30, 2016 - outstanding	8,613,413	$ 2.15	5.42 years	$1,316,398
Balance - June 30, 2016 - exercisable	5,048,957	$ 2.01	4.58 years	$1,136,604
Grant date fair value of options granted - June 30, 2016		$ 962,000		
Weighted average grant date fair value - June 30, 2016		$ 1.72		
Grant date fair value of options granted - December 31, 2015		$ 7,974,000		

Weighted average grant date fair value - December 31, 2015	$ 2.12

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 June 30, 2016 and 2015 was $ 907,000 and $587,000, respectively, and $1,959,000 and $1,413,000 for the six month periods ended June 30, 2016 and 2015, respectively.

As of June 30, 2016, total unrecognized stock-based compensation expense related to stock options was $6.8 million, which is expected to be expensed through May 2018.

6. Stock Purchase Warrants

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 will be recorded as non-cash income or expense in the Consolidated Statements of Operations at each subsequent period. At June 30, 2016, the fair value of the warrant liability was $7.6 million, which resulted in non-cash income of $3.5 million and non-cash income of $3.0 million for the three and six months ended June 30, 2016, respectively. At June 30, 2015, the fair value of the warrant liability was $14.8 million, which resulted in non-cash expense of $3.9 million and $8.1 million for the three and six months ended June 30, 2015. In accordance with authoritative accounting guidance, the warrants were valued on the date of grant using the Black-Scholes valuation model. The assumptions used by the Company are summarized in the following table:

	June 30, 2016	December 31, 2015	Issuance Date
Closing stock price	$1.80	$2.29	$1.75
Expected dividends	0%	0%	0%
Expected volatility	90%	85%	95%
Risk free interest rate	0.75%	1.49%	1.39%
Expected life of warrant	3.29 years	3.79 years	5 years

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

Balance at December 31, 2015	$10,567
Change in fair value of warrant liability	(3,015)
Balance at June 30, 2016	$7,552

As of June 30, 2016, all of the warrants remained outstanding.

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 affect to equity. Warrants outstanding as of June 30, 2016 were 311,834.

A summary of warrant activity for the Company for the six months ended June 30, 2016 and for the year ended December 31, 2015 is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2014	7,974,794	$ 1.80
Granted	-	$ -
Exercised	(2,448)	$ 1.60
Forfeited	(63,447)	$ 1.79
Balance at December 31, 2015	7,908,899	$ 1.79
Granted	-	$ -
Exercised	-	$ -
Forfeited	(50,000)	$ 3.75
Balance at June 30, 2016	7,858,899	$ 1.77

A summary of all outstanding and exercisable warrants as of June 30, 2016 is as follows:

Exercise Price	Warrants Outstanding	Warrants Exercisable	Weighted Average Remaining Contractual Life
$ 1.60	311,834	311,834	1.32 years
$ 1.75	7,029,808	7,029,808	3.28 years
$ 2.22	517,257	517,257	0.41 years
$ 1.77	7,858,899	7,858,899	3.01 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 six months ended June 30, 2016 were 8,613,413 and 829,091, respectively, and for the six months ended June 30, 2015 were 7,467,762 and 7,913,587, respectively.

The following tables set forth the computation of diluted net loss per weighted average number of shares outstanding attributable to Synthetic Biologics, Inc. and Subsidiaries for the three and six months ended June 30, 2016, and 2015 *(in thousands except share and per share amounts)* :

	Three months ended June 30, 2016			Six months ended June 30, 2016		
	Net loss (Numerator)	Shares (Denominator)	Per Share Amount	Net Loss (Numerator)	Shares (Denominator)	Per Share Amount
Net loss - Basic	$ (5,764)	91,015,733	$ (0.06)	$ (16,842)	90,921,243	$ (0.18)
Change in fair value of warrant liability	$ (3,513)	-	$ -	$ (3,015)	-	$ -
Dilutive shares related to warrants	$ -	2,914,807	$ -	$ -	1,729,974	$ -
Net loss - Dilutive	$ (9,277)	93,930,540	$ (0.10)	$ (19,857)	92,651,215	$ (0.21)

	Three months ended June 30, 2015			Six months ended June 30, 2015		
	Net loss (Numerator)	Shares (Denominator)	Per Share Amount	Net Loss (Numerator)	Shares (Denominator)	Per Share Amount
Net loss - Basic	$ (13,623)	72,736,829	$ (0.19)	$ (25,981)	72,674,650	$ (0.36)
Change in fair value of warrant liability	$ -	-	$ -	$ -	-	$ -
Dilutive shares related to warrants	$ -	-	$ -	$ -	-	$ -
Net loss - Dilutive	$ (13,623)	72,736,829	$ (0.19)	$ (25,981)	72,674,650	$ (0.36)

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 Consolidated Balance Sheets and reports both net loss attributable to the non-controlling interest and net loss attributable to the Company's common shareholders on the face of the 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 and six months ended June 30, 2016, the accumulated net loss attributable to the non-controlling interest was $82,000 and $315,000, respectively.

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 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, 2015, included in our Annual Report on Form 10-K filed with the SEC on March 10, 2016. 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. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth below, under Part II, Item 1A. "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, 2015 filed with the SEC on March 10, 2016.

Overview

We are a clinical stage company developing therapeutics to protect the gut microbiome while targeting pathogen-specific diseases. Our lead product candidates in Phase 2 development are: (1) SYN-010, which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C), and (2) SYN-004 (ribaxamase), which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. difficile* infection (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms. In collaboration with Intrexon Corporation ("Intrexon"), 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:

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
Treatment of IBS-C	SYN-010 (oral modified-release lovastatin lactone)	• Reported positive topline data from two Phase 2 clinical trials (4Q 2015 & 1Q 2016) • Received Type C meeting responses from 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 DDW 2016 (May 2016) • Held End of Phase 2 meeting with FDA (Summer 2016) • Plan to initiate first Phase 2b/3 pivotal adaptive clinical trial (1Q 2017) • Collaboration with Cedars-Sinai Medical Center
Prevention of CDI and AAD (Degrade IV beta-lactam antibiotics)	SYN-004 (ribaxamase) (oral enzyme)	• Reported positive Phase 1a/1b data (1Q 2015) • Initiated Phase 2b proof-of-concept clinical trial (3Q 2015); to date, enrollment of 374 patients across global sites; anticipate interim analysis of blinded data by independent monitoring committee (2H 2016) • Reported supportive topline data from first Phase 2a clinical trial (4Q 2015) • Reported supportive topline data from second Phase 2a clinical trial (2Q 2016) • Plan to announce topline data from Phase 2b proof-of-concept clinical trial (1Q 2017) • Plan to initiate Phase 3 clinical trial(s) (end of 2017) • Received USAN approval for the generic name “ribaxamase” for SYN-004
Prevention of CDI and AAD (Degrade oral beta-lactam	SYN-007 (oral enzyme)	• Preclinical work ongoing to determine ability of SYN-007 to protect the gut microbiome and degrade oral beta-lactam antibiotics

antibiotics)

Prevention and Treatment of pertussis	SYN-005 (monoclonal antibody therapies)	• Reported positive 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) • Collaborations with Intrexon and UT Austin

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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 95 U.S. and foreign patents and have over 65 U.S. and foreign patents pending.

Our Microbiome-Focused Pipeline

Our IBS-C and CDI/AAD programs are focused on protecting the gut microbiome, or gut flora, which is home to billions of bacteria and composed of a natural balance of both “good” beneficial bacteria and potentially “bad” pathogenic bacteria. When the natural balance of these bacteria is disrupted, a person’s health can be compromised.

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 perceived as 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.

Irritable Bowel Syndrome

IBS is a functional GI disorder characterized by gas, abdominal pain, bloating and diarrhea or constipation, or alternating episodes of both. The illness affects both men and women; however, two-thirds of diagnosed sufferers are women. The onset of IBS can begin anytime from adolescence to adulthood. Four bowel patterns may be seen with IBS including: IBS-C (constipation predominant), IBS-D (diarrhea predominant), IBS-M (mixed diarrhea and constipation) and IBS-U (unsubtyped). According to GlobalData's IBS Global Drug Forecast and Market Analysis to 2023 (December 2014) stringent disease diagnosis criteria to ensure market relevance and a population most likely to receive a diagnosis and prescription drug treatment, the prevalence of IBS in adults in the U.S., Europe and Japan was expected to be 41.1 million in 2015, and it has been reported that up to 20 percent of all IBS patients have IBS-C.

Extensive studies conducted by Dr. Pimentel and collaborators have shown that overproduction of methane gas is directly associated with bloating, pain and constipation in IBS-C patients. Investigators at CSMC have discovered that inhibiting intestinal methane production may reverse constipation associated with IBS-C, and may be beneficial in treating other major diseases such as obesity, insulin resistance and type 2 diabetes.

Limitations of Current Treatments and Market Opportunity

Currently, the U.S. Food and Drug Administration (FDA)-approved therapies for the treatment of IBS-C and other treatments including prescription and over-the-counter laxatives, which provide patients with temporary symptomatic relief and often cause diarrhea, but do not treat the underlying cause of pain, bloating and constipation associated with IBS-C. According to GlobalData, IBS — Global Drug Forecast and Market Analysis to 2023 (December 2014), the estimated global sales for IBS therapeutics for 2015 was $669.3 million, and global sales are expected to be greater than $1.5 billion in 2023.

Overview of our 2 Phase 2 Clinical Trials

The two SYN-010 Phase 2 trials were 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.

First Phase 2 Clinical Trial Topline Results (4 Week Placebo-Controlled Acute Study)

In December 2015, we reported positive topline results from our first Phase 2 placebo-controlled, randomized clinical trial of SYN-010, including lowered breath methane and improved stool frequency in patients with IBS-C. This first Phase 2 clinical trial was initiated in June 2015 and enrolled 63 patients who were randomized using a 1:1:1 ratio to

one of three groups, including two different SYN-010 dose groups (21 mg and 42 mg) and a placebo group. Patients received single oral doses of SYN-010 or a placebo each day for 28 days. The primary objective of this clinical trial was to evaluate the change from baseline in the area under the curve (AUC) of breath methane, as determined by a lactulose breath test, in methane-positive patients with IBS-C after seven days of treatment with one of two dose levels of SYN-010 as compared with a placebo. The trial's secondary endpoints included improvement in the number of complete spontaneous bowel movements (CSBM) per week, and improvement in abdominal pain and bloating per standard scales required per FDA guidance. There were no serious adverse events observed.

In the first Phase 2 clinical trial of SYN-010, 65 percent of patients had no detectable plasma trough levels of lovastatin lactone or lovastatin beta-hydroxyacid after 28 days of treatment. In the few patients with detectable trough levels at day 28, concentrations of both lovastatin lactone and lovastatin beta-hydroxyacid were significantly lower than observed for commercial lovastatin formulations. Consistent with limited absorption, there were no statistically significant changes in LDL-C levels relative to placebo after 28 days.

Second Phase 2 Clinical Trial Topline Results (8 Week Open-Label Extension Study)

In January 2016, we reported positive topline data from our second Phase 2 clinical trial of SYN-010, which was initiated in October 2015. As the patients completed the first Phase 2 clinical trial, they were eligible to immediately rollover into the second Phase 2 clinical trial (multi-center, open-label) of SYN-010 that evaluated the sustainability of the effect of one dose strength of SYN-010 (42 mg) on breath methane production in 54 breath methane-positive patients with IBS-C, as well as key clinical outcomes, including frequency of CSBM, abdominal pain and bloating.

Patients in the second Phase 2 clinical trial reported compliance with the daily SYN-010 dosing regimen such that all patients in the second Phase 2 clinical trial received a minimum of 8 weeks treatment with SYN-010 42 mg. Patients who completed the second Phase 2 clinical trial demonstrated a statistically significant decrease in methane production ($p=0.002$) from the beginning of the first Phase 2 clinical trial (Baseline, Day 1, prior to any drug administration in the randomized study) to the end of the second Phase 2 clinical trial (12 weeks, Day 84), thus meeting the clinical trial's primary endpoint. Topline data from the second Phase 2 clinical trial also showed improvements in secondary efficacy endpoints, including: (1) a statistically significant reduction in the mean IBS Symptom Severity Score (IBS-SSS; $p<0.0001$), which includes abdominal pain, bloating, stool frequency and quality of life scores, for all patients from the first Phase 2 clinical trial baseline to the end of the second Phase 2 clinical trial, and (2) an increase in the percentage of patients identified as Monthly Responders, an FDA-defined composite measure incorporating improvements in CSBMs and abdominal pain. There were no serious adverse events observed.

Recent Developments

In May 2016, we presented detailed data supporting previously reported positive topline data from two Phase 2 clinical trials of two dose strengths of SYN-010 at DDW2016.

Clinical data from the 57 patients who completed Study 1 and 54 patients who completed Study 2 showed clinically meaningful improvements in measurable endpoints, including:

- Data from Study 1 demonstrating that patients on either the 21 mg or 42 mg dose strength of SYN-010 used 60% less rescue medication than patients in the placebo group.

- Data from all patients who participated in both Study 1 and Study 2 and who were administered the 42 mg dose strength of SYN-010 for at least eight weeks demonstrated an inverse correlation (p=0.0259) between breath methane AUC and complete spontaneous bowel movements (CSBM). A similar inverse correlation (p=0.0028) was observed between breath methane AUC and spontaneous bowel movements (SBM).

- Data demonstrating the 42 mg dose strength of SYN-010 had a similar overall drug response rate to comparable FDA approved and clinical stage therapies for the treatment of IBS-C with a significantly lower rate of diarrhea in study participants.

- Data demonstrating clear improvements in abdominal pain, bloating and quality of life measures (IBS-SSS) in participants who were administered SYN-010.

In May 2016, we reported results from a separate completed randomized, open-label clinical study of healthy volunteers which evaluated the pharmacokinetic (PK) profile of the active ingredient of SYN-010. The PK data in healthy volunteers supported the modified-release profile of SYN-010, which is designed to avoid drug release in the stomach and deliver the antimethanogenic drug form, lovastatin lactone, into the lower small intestine and colon while reducing systemic exposure to the cholesterol-lowering lovastatin beta-hydroxyacid metabolite. Data reported from this study demonstrate that the administration of SYN-010 did not result in adverse changes to the lipid profiles of study participants.

Phase 3 Planning

On July 20, 2016, we participated in an End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA). Following a review of data from two Phase 2 clinical trials of SYN-010 conducted by Synthetic Biologics, a collaborative and positive discussion ensued with FDA to determine the optimal pathway to advance SYN-010 into Phase 3 development. In accordance with guidance from the FDA, our plans include the development of a Phase 2b/3 adaptive design study for our first pivotal trial of SYN-010 which will address further dose exploration and sensitivity analysis of breath methane levels for trial participation. We plan to submit a study protocol design and corresponding statistical analysis plan to the FDA during the second half of 2016 and anticipate initiating this clinical trial during the first quarter of 2017.

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 (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 a currently marketed product and published clinical data. We expect to rely on published clinical trials using a similar drug product to provide support of efficacy.

Intellectual Property

The SYN-010 intellectual property portfolio includes approximately 55 issued U.S. and foreign patents, and approximately 20 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 GI tract and maintain the natural balance of the gut microbiome for the prevention of CDI, AAD and emergence of antibiotic-resistant organisms. 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 (which we now refer to as ribaxamase, formerly SYN-004), 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 call ribaxamase.

Compared to the first generation oral enzyme candidate of P1A, we believe that the second generation candidate, 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 ribaxamase, and based on previous discussions with the FDA, certain preclinical data collected on P1A was used in support of an IND application for our new product candidate, ribaxamase. P1A was 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.

Beta-lactamase enzymes have the ability to degrade beta-lactam antibiotics that may be excreted into the GI tract. 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.

C. difficile

C. *difficile* is the leading type of hospital acquired infection and is frequently associated with IV beta-lactam antibiotic treatment. According to an article published in the New England Journal of Medicine (Leffler DA et al. N Engl J Med 2015; 372: 1539-1548), CDIs more than quadruple the cost of hospitalizations, increasing annual expenditures by approximately $1.5 billion in the U.S. CDI is a rising global hospital acquired infection (HAI) problem in which the toxins produced by *C. difficile* bacteria result in AAD, and in the most serious cases, pseudomembranous colitis (severe inflammation of the lower GI tract) that can lead to death. The Centers for Disease Control and Prevention (CDC) identified *C. difficile* as an “urgent public health threat,” particularly given its resistance to many drugs used to treat other infections. CDI is a major, unintended risk associated with the prophylactic or therapeutic use of IV antibiotics, which may alter the natural balance of microflora that normally protect the GI tract, leading to *C. difficile* overgrowth and infection. Other risk factors for CDI include hospitalization, prolonged length of stay, underlying illness, immune-compromising conditions including the administration of chemotherapy and advanced age. In addition, approximately 25% of patients experience a recurrence of CDI within one to three months.

Limitations of Current Treatments and Market Opportunity

CDI is a widespread and often drug resistant infectious disease. According to an article published in the New England Journal of Medicine (Leffler DA et al. N Engl J Med 2015; 372:1539-1548), it is estimated that 453,000 patients are infected with *C. difficile* annually in the U.S., and it has been reported that approximately 29,000 patients die due to a CDI each year. CDI has surpassed methicillin-resistant staphylococcus aureus (MRSA) as the most frequent hospital acquired infection. Controlling the spread of CDI has proven challenging, as the *C. difficile* spores are easily transferred to patients via normal contact with healthcare personnel and with inanimate objects. There is currently no vaccine or approved product for the prevention of CDI.

According to data requisitioned by Synthetic Biologics, ribaxamase's significant target market is represented by the 117 million average days ribaxamase could be administered with target IV beta-lactam antibiotics to the 16.7 million hospitalized patients each year, which at a price point of $100 per day indicates a potential market size of approximately $12.0 billion. This estimate is based upon data requisitioned by Synthetic Biologics and derived from the following report: Arlington Medical Resources (AMR), a Decision Resources Group Company, 2014 Audits of Acute Care Hospital Antibiotic Utilization. Currently there are no approved treatments designed to protect the gut microbiome from the damaging effects of IV antibiotics. The worldwide market for ribaxamase could represent a multi-billion dollar opportunity for us.

Phase 1a and 1b Clinical Trial Pharmacokinetic Data

In March 2015, we reported positive pharmacokinetic data from our Phase 1a and 1b clinical trials, which suggests that ribaxamase may have no effect on the IV antibiotic in the bloodstream, allowing the antibiotic to fight the primary infection. In February 2015, we reported positive topline results from our Phase 1b clinical trial of escalating doses of oral ribaxamase, with no safety or tolerability issues reported at dose levels and dose regimens both meeting and exceeding those expected to be studied in upcoming clinical trials. The Phase 1a (40 participants) and 1b (24 participants) clinical trials of ribaxamase were initiated in December 2014.

First Phase 2a Clinical Trial Topline Results

In December 2015, we reported positive topline results from our Phase 2a clinical trial of ribaxamase, including data from ten ileostomized participants that demonstrated ribaxamase successfully degraded residual IV ceftriaxone in the chyme (digestive fluid in the small intestine) without affecting the intended level of ceftriaxone in the bloodstream. This Phase 2a clinical trial was initiated in March 2015 to evaluate the GI antibiotic-degrading effects and the safety of ribaxamase.

Second Phase 2a Clinical Trial Topline Results

In June 2015, we initiated a second Phase 2a clinical trial of ribaxamase to evaluate the GI antibiotic-degrading ability and the safety of ribaxamase, in the presence of the proton pump inhibitor (PPI), esomeprazole, in healthy participants with functioning ileostomies.

Recent Developments

In May 2016, we reported supportive topline results from our second Phase 2a clinical trial of ribaxamase, including data that demonstrated a correlation of the 150 mg dose of ribaxamase, both alone and in the presence of the proton pump inhibiter (PPI), esomeprazole, with the degradation of residual IV ceftriaxone to levels that were near or below detectable in the intestinal chyme (digestive fluid in the small intestine) of 14 healthy participants with functioning ileostomies. In addition, ceftriaxone plasma concentrations in study participants were very similar in the presence or absence of an oral PPI, suggesting limited drug-drug interactions. The 150 mg dose strength of ribaxamase was well tolerated by all participants in this clinical trial.

Data from an additional study conducted in humanized pigs demonstrated that when administered in accordance with ceftriaxone, ribaxamase prevented ceftriaxone-remediated changes in the pig fecal microflora, protecting the microbiome from antibiotic-mediated damage when compared to pigs who only received ceftriaxone.

Phase 2b Clinical Trial Design / Phase 3 Planning

In September 2015, we initiated a randomized placebo-controlled Phase 2b proof-of-concept clinical trial intended to evaluate the ability of ribaxamase to prevent CDI, *C. difficile* associated diarrhea (CDAD) and AAD in patients hospitalized for a lower respiratory tract infection and receiving IV ceftriaxone. An exploratory endpoint will be to evaluate the ability of ribaxamase to limit disruption of the gut microbiome diversity, also known as dysbiosis. Once either 120 patients complete treatment and there are 10 confirmed cases of CDI, or 186 patients complete treatment, an interim futility analysis to evaluate baseline rate of CDI in the placebo group is anticipated. We intend to have an independent monitoring committee perform an interim futility analysis of the blinded data during the second half of 2016. As a result of stronger than expected enrollment of 374 patients to date, we anticipate greater than 400 patients to enroll by the end of the third quarter and anticipate announcing topline results from our Phase 2b clinical trial during the first quarter of 2017. In 2017, we also plan to enter into strategic discussions with the CDC, hold an end of Phase 2 meeting with the FDA, and expect to initiate Phase 3 trial(s) towards the end of 2017.

SYN-007 — Prevention of CDI and AAD

Preclinical work is ongoing to determine the ability of SYN-007 to protect the gut microbiome and degrade oral beta-lactam antibiotics. 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 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.

C. difficile: Intellectual Property

The ribaxamase intellectual property portfolio includes approximately 40 issued U.S. and foreign patents, and approximately 30 U.S. and foreign patents pending.

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.

Monoclonal Antibodies for Infectious Diseases

Antibodies are proteins, generally found in the bloodstream, that provide immunity in detecting and destroying pathogens, such as viruses and bacteria and their associated toxins. Monoclonal antibodies (mAbs) can also be designed and produced as therapeutic agents, utilizing protein engineering and recombinant production technologies. The mAbs being developed under our collaboration with Intrexon are intended to supplement a patient's own immune system by providing the means to specifically and rapidly neutralize and/or clear specific pathogens and toxins of interest in a process known as "passive immunity." Many pathogens that cause infectious diseases are innately resistant to, or over time have developed increased resistance to, antibiotics and other drugs.

SYN-005 — Pertussis (Whooping Cough)

Bordetella pertussis (B. pertussis) is a gram-negative bacterium that infects the upper respiratory tract, causing uncontrollable and violent coughing. Antibiotic treatment does not have a major effect on the course of pertussis. While such treatment can eliminate the *B. pertussis* bacteria from the respiratory tract, it does not neutralize the pertussis toxin. Infants with pertussis often require hospitalization in pediatric intensive care units, frequently requiring mechanical ventilation. Pertussis in adults generally leads to a chronic cough referred to as the "cough of 100 days." The incidence of pertussis is increasing due to the declining effectiveness of the acellular vaccine introduced in the 1990s, exposure of unvaccinated and under-vaccinated individuals including infants who are not yet fully vaccinated and exposure of individuals whose immunity has diminished over time.

According to the World Health Organization (WHO), there are 50 million cases of whooping cough, and it is estimated that *B. pertussis* infection causes up to 300,000 deaths each year worldwide, primarily among unvaccinated infants. Recent news reports throughout the U.S. indicate that the pertussis vaccine introduced in the 1990s does not provide long-term protection and, as a result, whooping cough cases have increased to a 60-year high.

Intrexon Collaboration and The University of Texas at Austin Agreement

In August 2012, we entered into a worldwide exclusive channel collaboration with Intrexon through which we intend to develop 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. This program intends to utilize Intrexon's comprehensive suite of proprietary technologies, including the mAbLogix™ platform for rapid discovery of fully human mAbs and the LEAP ® cell processing station.

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 defining the key neutralizing epitopes of pertussis toxin to optimize the potential efficacy of antibody therapeutics.

Preclinical and Clinical Development

Working with our collaborator, Intrexon, and our academic collaborator, UT Austin, we have established a humanized mAb product candidate, SYN-005, designed to neutralize pertussis toxin, a major cause of pertussis-mediated infant morbidity and mortality. The two humanized mAbs, hu1B7 and hu11E6, bound tightly to the toxin and potently neutralized the toxin. In addition, the antibodies, individually or in combination, were highly efficacious in a murine model of pertussis in which they completely mitigated elevations of the white blood cell count that is characteristic of the illness. The antibodies, alone and in combination, were more potent that P-IVIG, a polyclonal IgG preparation previously used in human clinical trials.

In April 2014, and again in September 2014, we received positive preclinical research findings of SYN-005 for the treatment of pertussis in three non-human primate studies (n = 19). In the latter two pertussis studies in particular, SYN-005 rapidly stopped the rise in white blood cell count that is characteristic of the disease and accelerated its return to baseline.

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In September 2014, we received U.S. Orphan Drug Designation from the FDA for SYN-005 for the treatment of pertussis.

In April 2015, preclinical efficacy data that support advancing SYN-005 toward clinical trials were presented in two poster presentations at the European Congress of Clinical Microbiology and Infectious Diseases meeting (ECCMID) 2015 in Copenhagen, Denmark. The data suggest that SYN-005 has therapeutic potential to diminish morbidity, long-term complications and mortality from pertussis in critically ill infants. In addition, the data support a prophylactic approach for use in newborns that has the potential to save thousands of lives annually, particularly in the developing world where the unmet need is greatest.

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 evaluate the potential of our monoclonal antibody, 1B7, in the prevention of pertussis. This preclinical study is expected to provide support for the use of our 1B7 in potential clinical application.

Intellectual Property

We have patents pending on compositions and uses of SYN-005 and we have two issued U.S. patent and patents pending on other pertussis mAbs from UT Austin.

SYN-200 — Treatment of Phenylketonuria (PKU)

PKU is a genetic disease that begins at birth characterized by a deficiency in the liver enzyme that breaks down the essential amino acid phenylalanine (Phe), a building block of proteins normally obtained through the foods we eat. As a result, Phe accumulates in the body, becoming toxic and leading to serious health consequences, including profound mental retardation, brain damage, mental illness, behavioral problems, seizures, tremors, limited cognitive ability and hyperactivity. If left untreated, the most severe form of PKU leads to permanent cognitive damage. PKU affects more than 14,000 people in the U.S. and 50,000 people in developed nations globally. There is no existing cure for PKU, requiring patients to maintain a life-long treatment program and a carefully controlled diet.

Intrexon Collaboration

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 intend to utilize Intrexon's ActoBiotics platform to provide a proprietary method of delivering therapeutic protein and peptides to the GI tract through food-grade microbes. This program is in the discovery stage.

SYN-020 — Oral Intestinal Alkaline Phosphatase

The development of SYN-020 is in the discovery 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 celiac disease, inflammatory bowel disease, microbial dysbiosis and metabolic syndrome. We have identified cell systems in which IAP can be expressed and anticipate selection of an oral formulation in the 2H 2016 for evaluation in preclinical disease models.

Multiple Sclerosis Program

We discontinued our multiple sclerosis (MS) program in February 2016 and the development of a Phase 2 oral estriol drug for the treatment of relapsing-remitting multiple sclerosis (RRMS) and cognitive dysfunction in MS. Previously, our drug candidate Trimesta (oral estriol) was evaluated in investigator-sponsored Phase 2 clinical trials for RRMS in women, and cognitive dysfunction in women with MS.

On February 1, 2016, our subsidiary, Putney Drug, Inc. provided written notice to the Regents of the University of California (Regents) that we were terminating our (i) License Agreement with the Regents, dated as of July 11, 2005, as amended on November 8, 2005, January 3, 2007, August 29, 2007, December 31, 2012, July 25, 2014 and July 8, 2015 (License Agreement) and (ii) Clinical Trial Agreement with the Regents, dated April 29, 2010, as amended July 8, 2015 (CTA). Pursuant to the terms of the License Agreement, Putney Drug had licensed from the Regents certain U.S. patents for multiple sclerosis therapy related to our drug candidate, Trimesta and Trimesta-combination therapies. Based upon the independent third party analysis of the investigator-sponsored Phase 2 clinical trial that evaluated Trimesta as a treatment for relapsing-remitting MS in women, it was determined that the License Agreement and the CTA should be terminated. In accordance with the termination provisions of the License Agreement and the CTA, the License Agreement and CTA terminated on May 2, 2016.

Critical Accounting Policies

The 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 consolidated financial statements and the judgments and assumptions used are consistent with those described under Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2015.

Results of Operations

Three Months Ended June 30, 2016 and 2015

General and Administrative Expenses

General and administrative expenses decreased by 3% to $2.1 million for the three months ended June 30, 2016, from $2.2 million for the three months ended June 30, 2015. This decrease is primarily the result of lower legal fees offset by an increase in stock-based compensation and increased employee costs associated with the transition of the administrative and financial office to our Maryland headquarters. The charge related to stock-based compensation expense was $507,000 for the three months ended June 30, 2016, compared to $335,000 the three months ended June 30, 2015.

Research and Development Expenses

Research and development expenses decreased by 5% to $7.2 million for the three months ended June 30, 2016, from $7.5 million for the three months ended June 30, 2015. This decrease is primarily the result of decreased Phase 2 program costs associated with clinical development programs, manufacturing and research activities within our microbiome-focused pipeline. Research and development expenses also include a charge related to non-cash stock-based compensation expense of $400,000 for the three months ended June 30, 2016, compared to $252,000 for the three months ended June 30, 2015.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the three months ended June 30, 2016 and 2015. 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	June 30, 2016	June 30, 2015
Ribaxamase	$2,783	$2,113
SYN-010	707	3,499
Other therapeutic areas	57	234
Total direct costs	3,547	5,846
Total indirect costs	3,617	1,662
Total Research and Development	$7,164	$7,508

Other Income (Expense)

Other income was $3.5 million for the three months ended June 30, 2016, compared to other expense of $3.9 million for the three months ended June 30, 2015. Other income for the three months ended June 30, 2016 is due to non-cash income of $3.5 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 year ended December 31, 2015. Non-cash expense related to the increase of fair value of warrants for the three months ended June 30, 2015 was $3.9 million.

Net Loss

Our net loss was $5.8 million, or $0.06 per basic common share and $0.10 per dilutive common share for the three months ended June 30, 2016, compared to a net loss of $13.6 million, or $0.19 per basic and dilutive common share for the three months ended June 30, 2015.

Six Months Ended June 30, 2016 and 2015

General and Administrative Expenses

General and administrative expenses increased to $4.6 million for the six months ended June 30, 2016, from $3.9 million for the six months ended June 30, 2015. This increase of 16% is primarily the result of increased employee costs associated with the transition of the administrative and financial office to our Maryland headquarters, and an increase in stock-based compensation offset by lower consulting services. The charge relating to stock-based compensation expense was $1.2 million for the six months ended June 30, 2016, compared to $915,000 for the six months ended June 30, 2015.

Research and Development Expenses

Research and development expenses increased to $15.3 million for the six months ended June 30, 2016, from $14.0 million for the six months ended June 30, 2015. This increase of 9% is primarily the result of increased program costs associated with expanded clinical development programs, manufacturing and research activities within our pathogen-specific microbiome-focused pipeline, including our *C. difficile,* IBS-C and Pertussis programs. Research and development expenses for the six months ended June 30, 2015 also include a $1.0 million expense for achieving the third milestone as set forth in the Asset Purchase Agreement with Prev ABR LLC, dated November 28, 2012. Prev ABR LLC exercised its option to receive the milestone payment in shares of our common stock that were issued in April 2015. Research and development expenses also include a charge relating to non-cash stock-based compensation expense of $809,000 for the six months ended June, 2016, compared to $498,000 for the six months ended June 30, 2015.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the six months ended June 30, 2016 and 2015. 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	June 30, 2016	June 30, 2015
Ribaxamase	$5,264	$6,447
SYN-010	2,735	3,728
SYN-005	11	669
Other therapeutic areas	79	160
Total direct costs	8,089	11,004
Total indirect costs	7,230	2,998
Total Research and Development	$15,319	$14,002

Other Income (Expense)

Other income was $3.0 million for the six months ended June 30, 2016, compared to other expense of $8.0 million for the six months ended June 30, 2015. Other income for the six months ended June 30, 2016 is primarily due to non-cash income of $3.0 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 year ended December 31, 2015. Non-cash expense related to the change in the fair value of warrants for the three months ended June 30, 2015 was $8.0 million.

Net Loss

Our net loss was $16.8 million, or $0.18 per basic common share and $0.21 per dilutive common share for the six months ended June 30, 2016, compared to a net loss of $26.0 million, or $0.36 per basic and dilutive common share for the six months ended June 30, 2015.

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 $161.3 million as of June 30, 2016. 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 $10.0 million as of June 30, 2016, a decrease of $10.8 million from December 31, 2015. During the six months ended June 30, 2016, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $16.8 million for the six months ended June 30, 2016.

Our continued operations as currently planned will primarily depend on our ability to raise additional capital from various sources, including equity and debt financings, as well as, license fees from potential corporate partners, joint ventures and grant funding. 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

We have incurred an accumulated deficit of $161.3 million through June 30, 2016. 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, we do not believe that our cash and cash equivalents will be sufficient to enable us to meet our anticipated operating needs for the next twelve months.

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 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. 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 may be unable to carry out our business plan. 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 and six months ended June 30, 2016, 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 Annual Report on Form 10-K for the year ended December 31, 2015.

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 June 30, 2016, 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 June 30, 2016, 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 June 30, 2016 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 June 30, 2016, 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 Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the SEC on March 10, 2016. Except as disclosed below, there have been no material changes from the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

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 six months ended June 30, 2016, our operating activities used net cash of approximately $11.5 million and as of June 30, 2016 our cash and cash equivalents were $10.0 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 June 30, 2016, our accumulated deficit totaled approximately $161.3 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. With the exception of the quarter ended June 30, 2010, and limited laboratory revenues from Adeona Clinical Laboratory, which we sold in March 2012, we have generated very minimal revenues. We do not expect to derive revenue from any source in the near future until we or our potential partners successfully commercialize our products. We expect our expenses to increase in connection with our 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 for the next twelve months. 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, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. 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 June 30 2016, we had stockholders' equity of $931,000. 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 exceeds $50.0 million and we have 1,100,000 shares publicly held, a market value of publicly held shares of at least $15.0 million and 400 round lot shareholders, there can be no assurance that the NYSE MKT will continue to list our common stock if we should 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: August 3, 2016

By: /s/ Steven A. Shallcross
Steven A. Shallcross
Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: August 3, 2016

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.