Synthetic Biologics, Inc.
Form 10-Q
August 10, 2015

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, 2015

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: 1-12584

SYNTHETIC BIOLOGICS, INC.

(Name of small business issuer in its charter)

Nevada	**13-3808303**
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification Number)*
9605 Medical Center Drive, Suite 270 **Rockville, MD**	**20850**
(Address of principal executive offices)	*(Zip Code)*

617 Detroit Street, Suite 100
Ann Arbor, MI **48104**
(Mailing Address) *(Zip Code)*

Registrant's telephone number, including area code:

(734) 332-7800

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, $0.001 par value per share

Securities registered pursuant to Section 12(g) of the Act:

None.

(Title of Class)

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 6, 2015 the registrant had 88,515,086 shares of common stock outstanding.

SYNTHETIC BIOLOGICS, INC.

FORM 10-Q

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PART I.-FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Balance Sheets

(In thousands except share and per share amounts)

	June 30, 2015 (Unaudited)	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	$ 4,757	$ 17,525
Prepaid expenses and other current assets	6,955	1,548
Total Current Assets	11,712	19,073
Property and equipment, net	107	65
Deposits and other assets	18	6
Total Assets	$ 11,837	$ 19,144
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable	$ 8,686	$ 996
Accrued expenses	1,615	1,298
Warrant liabilities	14,803	6,756
Accrued employee benefits	394	538
Total Current Liabilities	25,498	9,588
Total Liabilities	25,498	9,588
Commitments and Contingencies		
Stockholders' Equity (Deficit):		
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, 73,260,787 issued and 73,179,305 outstanding and 72,594,626 issued and 72,513,144 outstanding	73	72

Additional paid-in capital	113,289	110,526
Accumulated deficit	(127,023)	(101,042)
Total Synthetic Biologics, Inc. and Subsidiaries Equity (Deficit)	(13,661)	9,556
Non-controlling interest	-	-
Total Stockholders' Equity (Deficit)	(13,661)	9,556
Total Liabilities and Stockholders' Equity (Deficit)	$ 11,837	$ 19,144

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,	
	2015	**2014**	**2015**	**2014**
Operating Costs and Expenses:				
General and administrative	$ 2,222	$ 1,814	$ 3,935	$ 2,936
Research and development	7,508	2,837	14,002	5,554
Total Operating Costs and Expenses	9,730	4,651	17,937	8,490
Loss from Operations	(9,730)	(4,651)	(17,937)	(8,490)
Other Income (Expense):				
Change in fair value of warrant liability	(3,895)	-	(8,047)	-
Other income	-	95	-	95
Interest income	2	-	3	1
Total Other Income (Expense)	(3,893)	95	(8,044)	96
Net Loss	(13,623)	(4,556)	(25,981)	(8,394)
Net Loss Attributable to Non-controlling Interest	-	-	-	-
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	**$ (13,623)**	**$ (4,556)**	**$ (25,981)**	**$ (8,394)**
Net Loss Per Share - Basic and Dilutive	$ (0.19)	$ (0.08)	$ (0.36)	$ (0.14)
Net Loss Per Share Attributable to Synthetic Biologics, Inc. and Subsidiaries	**$ (0.19)**	**$ (0.08)**	**$ (0.36)**	**$ (0.14)**
Weighted average number of shares outstanding during the period - Basic and Dilutive	72,736,829	58,453,528	72,674,650	58,348,153

See accompanying notes to unaudited consolidated financial statements.

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Synthetic Biologics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	For the six months ended June 30,	
	2015	2014
Cash Flows From Operating Activities:		
Net loss	$ (25,981)	$ (8,394)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,413	1,217
Stock issued for milestone payments	1,350	-
Change in fair value of warrant liabilities	8,047	-
Depreciation	19	7
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,407)	202
Deposits and other assets	(12)	(2)
Accounts payable	7,690	937
Accrued liabilities	317	(732)
Accrued employee benefits	(144)	-
Net Cash Used In Operating Activities	(12,708)	(6,765)
Cash Flows From Investing Activities:		
Purchases of property and equipment	(61)	(21)
Net Cash Used In Investing Activities	(61)	(21)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock for stock option exercises	1	4
Net Cash Provided By Financing Activities	1	4
Net decrease in cash	(12,768)	(6,782)
Cash at beginning of period	17,525	14,625
Cash at end of period	$ 4,757	$ 7,843
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ -	$ -
Cash paid for taxes	$ -	$ -

See accompanying notes to unaudited consolidated financial statements.

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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 microbiome while targeting pathogen-specific diseases. The Company's lead candidates in Phase 2 development include SYN-004 which is designed to protect the gut microbiome (gastrointestinal (GI) microflora) from the effects of certain commonly used intravenous (IV) antibiotics for the prevention of *C. difficile* infection and antibiotic-associated diarrhea (AAD), and SYN-010 which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat the underlying cause of irritable bowel syndrome with constipation (IBS-C). In addition, the Company is developing a Phase 2 oral estriol drug, Trimesta™, for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS, and in collaboration with Intrexon Corporation (NYSE:XON), a preclinical stage monoclonal antibody combination for the treatment of Pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

Therapeutic Area	Product Candidate	Status
C. difficile infection and AAD prevention	SYN-004 (oral enzyme)	Phase 2
IBS-C	SYN-010 (oral compound)	Phase 2
Relapsing-remitting MS	Trimesta (oral estriol)	Phase 2
Cognitive dysfunction in MS	Trimesta (oral estriol)	Phase 2
Pertussis (whooping cough)	SYN-005	Preclinical

(monoclonal antibodies)

Basis of Presentation

The accompanying consolidated financial statements have been prepared pursuant to the rules and regulations of 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 our Annual Report on Form 10-K for the year ended December 31, 2014 ("2014 Form 10-K") as filed with the SEC. The interim results for the three and six months ended June 30, 2015, 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.

2. Management's Plan

The Company has incurred an accumulated deficit of $127.0 million through June 30, 2015. With the exception of the quarter ended June 30, 2010, the Company has incurred negative cash flow from operations since it started the business. 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.

The actual amount of funds the Company will need to operate is subject to many factors, some of which are beyond our 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 the 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 $3.6 million and $13.6 million as of June 30, 2015 and December 31, 2014, 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 certain transactions, 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 Statement 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, 2015	December 31, 2014
Intrexon prepaid research and development expenses	$ 1,049	$ 1,067
Prepaid Clinical Research Organization expenses	5,458	-
Prepaid insurance	133	228
Other prepaid expenses	315	253
Total	$ 6,955	$ 1,548

The anticipated Intrexon research and development expenses for the next twelve months 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.

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Property and equipment (in thousands)

	June 30, 2015	December 31, 2014
Computer and office equipment	$ 154	$ 93
Software	11	11
	165	104
Less accumulated depreciation	(58)	(39)
Total	$ 107	$ 65

Accrued Expenses (in thousands)

	June 30, 2015	December 31, 2014
Accrued manufacturing costs	$ 105	$ 247
Accrued vendor payments	470	176
Accrued milestone payments	-	350
Accrued clinical consulting services	1,040	525
Total	$ 1,615	$ 1,298

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, 2015, there were 671,607 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 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, 2015, there were 428,657 options issued and outstanding under the 2007 Stock Plan.

On November 2, 2010, the Board of Directors and stockholders adopted the 2010 Stock Incentive Plan ("2010 Stock Plan") for the issuance of up to 3,000,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. On October 22, 2013, the stockholders approved and adopted an amendment to the Company's 2010 Incentive Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the Plan from 3,000,000 to 6,000,000. On May 15, 2015, the stockholders approved and adopted an amendment to the Company's 2010 Incentive Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the Plan from 6,000,000 to 8,000,000. 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, 2015, there were 6,367,498 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 share 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, 2015 and 2014 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Exercise price	$2.04 - $2.73	$2.52 - $2.91	$1.54 - $2.73	$2.52 - $2.91
Expected dividends	0%	0%	0%	0%
Expected volatility	88% - 128%	106% - 150%	88% - 131%	106% - 150%
Risk free interest rate	1.32% - 2.19%	1.73% - 2.73%	1.32% - 2.19%	1.57% - 2.73%
Expected life of option	5 years - 10 years	5 years - 10 years	5 years - 10 years	5 years - 10 years
Expected forfeitures	0%	0%	0%	0%

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, 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. During the same period in 2014, the Company granted 1,732,500 options to employees having an approximate fair value of $4.1 million based upon the Black-Scholes option pricing model.

A summary of stock option activities as of June 30, 2015, and for the year ended December 31, 2014, is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance - December 31, 2013	3,909,580	$ 1.78	5.59 years	$785,000
Granted	2,382,500	$ 2.36		
Exercised	(6,583)	$ 0.58		
Forfeited	(304,391)	$ 1.93		

Balance - December 31, 2014	5,981,106	$ 2.01	5.80 years	$685,000
Granted	1,800,000	$ 2.00		
Exercised	(10,842)	$ 0.09		
Forfeited	(302,502)	$ 1.92		
Balance – June 30, 2015 - outstanding	7,467,762	$ 2.01	5.79 years	$6,319,000
Balance – June 30, 2015 - exercisable	4,515,532	$ 1.92	5.51 years	$4,283,000
Grant date fair value of options granted - June 30, 2015		$ 3,245,000		
Weighted average grant date fair value - June 30, 2015		$ 1.80		
Grant date fair value of options granted - December 31, 2014		$ 4,974,000		
Weighted average grant date fair value - December 31, 2014		$ 2.09		

Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to employees and consultants for the three months ended June 30, 2015 and 2014 was $587,000 and $855,000, respectively and $1,413,000 and $1,217,000 for the six month periods ended June 30, 2015 and 2014, respectively.

As of June 30, 2015, total unrecognized stock-based compensation expense related to stock options was $5.3 million, which is expected to be expensed through October 2017.

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 and changes in estimated fair value will be recorded as non-cash income or expense in the Company's statement of operations at each subsequent period. At June 30, 2015, the fair value of the warrant liability was $14.8 million, which represented non-cash expense of $3.9 million and $8.1 million for the three months and six months ended June 30, 2015, respectively. In accordance with authoritative accounting guidance, the warrant was valued on the date of grant and in subsequent periods using the Black-Scholes valuation model. The assumptions used by the Company are summarized in the following table:

	June 30, 2015	**March 31, 2015**	**December 31, 2014**	**Issuance Date**
Closing stock price	$2.85	$2.19	$ 1.46	$1.75
Expected dividends	0 %	0 %	0 %	0 %
Expected volatility	90 %	90 %	90 %	95 %
Risk free interest rate	1.41 %	1.26 %	1.59 %	1.39 %
Expected life of warrant	4.30 years	4.55 years	4.79 years	5 years

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

Balance at December 31, 2014	$6,756
Change in fair value of warrant liability	8,047
Balance at June 30, 2015	$14,803

As of June 30, 2015, 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, 2015 were 316,522.

A summary of warrant activity for the Company for the six months ended June 30, 2015 and for the year ended December 31, 2014 is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2013	1,632,501	$ 1.99
Granted	7,029,808	$ 1.75
Exercised	(232,619)	$ 1.47
Forfeited	(454,896)	$ 1.88
Balance at December 31, 2014	7,974,794	$ 1.80
Granted	-	$ -
Exercised	-	$ -
Forfeited	(61,207)	$ 3.30
Balance at June 30, 2015	7,913,587	$ 1.79

A summary of all outstanding and exercisable warrants as of June 30, 2015 is as follows:

Exercise Price	Warrants Outstanding	Warrants Exercisable	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
$ 1.60	316,522	316,522	2.32 years	$ 396,000
$ 1.75	7,029.808	7,029,808	4.28 years	$ 7,732,000
$ 2.22	517,257	517,257	1.41 years	$ 326,000
$ 3.75	50,000	50,000	0.63 years	$ -
$ 1.79	7,913,587	7,913,587	3.99 years	$ 8,454,000

7. Stockholders' Equity (Deficit)

During the six months ended June 30, 2015, the Company issued 655,321 shares of common stock to Prev ABR LLC, with a fair value of $1,350,000, that was recorded as research and development expense, in consideration for achieving the first three milestones as set forth in the Asset Purchase Agreement dated November 28, 2012. In lieu of receiving any cash payment for achieving the first three milestones, Prev ABR LLC exercised its option to receive the milestone payments in shares of the Company's common stock. The number of shares of common stock issued upon achievement of each milestone was based upon the average of the opening and closing prices of the Company's stock on the date each milestone was achieved as specified in the Asset Purchase Agreement. Also, during the six months ended June 30, 2015, the Company issued 10,842 shares of common stock, in connection with the exercise of stock options, for proceeds of approximately $1,000.

8. Net Loss per Share

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted 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. All common equivalent shares were anti-dilutive at June 30, 2015 and 2014, as such there is no separate computation for diluted loss per share. 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, 2015 were 7,467,762 and 7,913,587, respectively, and for the six months ended June 30, 2014 were 5,331,106 and 944,986, respectively.

9. Subsequent Event

On August 10, 2015, Synthetic Biologics, Inc. expanded its relationship with Intrexon Corporation ("Intrexon") and entered into an Exclusive Channel Collaboration Agreement (the "Channel Agreement") with Intrexon that governs a "channel collaboration" arrangement in which the Company will use Intrexon's technology relating to the development

and commercialization of novel biotherapeutics (a “Collaboration Product”) for the treatment of patients with phenylketonuria (PKU). The Company has agreed to pay Intrexon a technology access fee by the issuance of 937,500 shares of common stock, having a value equal to $3 million as of August 7, 2015, within ten days of approval of the issuance by the NYSE MKT. In addition, upon the achievement of the certain milestones, the Company agreed to pay Intrexon milestone payments of up to $27 million for each product developed. The Company will pay Intrexon royalties on annual net sales of Collaboration Products, calculated on a product-by-product basis equal to a percent of net sales (ranging from mid-single digits on the first $100 million of net sales to mid-teen digits on net sales in excess of $750 million).

On July 21, 2015, the Company completed a public offering of 15.3 million shares of common stock, including the fully exercised over-allotment option by the underwriters covering 2.0 million shares, at an offering price of $3.00 per share. The total gross proceeds of the offering, including the exercise in full of the over-allotment option, were approximately $46.0 million. Net proceeds to the Company, after deducting the underwriters' discount and other estimated expenses, were approximately $42.6 million.

On July 8, 2015, Putney Drug Corp, a subsidiary of the Company, and The Regents of the University of California (“The Regents”), entered into an amendment to their License Agreement, dated July 11, 2005 (as amended previously), and an amendment to their Clinical Trial Agreement (“CTA”), dated as of April 29, 2010.The amended License Agreement grants Licensee licenses under additional patent rights and other intellectual property of The Regents, including related know-how, not currently licensed to the Licensee, which is related to the use of Estriol (and related compounds) for the treatment, prevention or palliation of any autoimmune disease, condition or indication, including, without limitation, multiple sclerosis (the “Field of Use”). In addition, The Regents agreed in the CTA Amendment to provide to the Licensee and, as directed by the Licensee, to its third party consultants, all data and results (redacted for patient-identifying information) from the prior clinical trial study under the CTA (the “Documentation”). The Licensee agreed to fund the costs of the analysis by a third party contractor of the data it receives and to reimburse The Regents for its costs, including overhead, in preparing the databases and materials for access by Licensee. The Licensee has also agreed to use commercially reasonable efforts to seek and obtain a development and commercialization partner for Estriol in the Field of Use, within twelve months of the Effective Date.

The Licensee was also granted certain rights of first negotiation to expand the Field of Use to other indications and uses. If the Licensee does not find a development partner that is a pharmaceutical company with annual net sales of at least $100 million (a “Development Partner”) to develop Licensed Products (as defined in the License Agreement) in at least the U.S or Europe within 12 months of the Effective Date, the Licensee will continue to retain rights to the Licensed Products in the Field of Use, and will have 25 months after the Effective Date to initiate a Phase 3 clinical trial. If the Licensee licenses its rights in the Licensed Products (as defined in the License Agreement) to a Development Partner within 12 months of the Effective Date then the diligence obligations will be adjusted as follows: (a) within 24 months of the delivery to Licensee of all patient name redacted MRI image and electronic data created under the clinical study on Estriol conducted under the CTA the Development Partner shall complete all clinical trials requested by the U.S. Food and Drug Administration (the “FDA”) to be completed prior to initiating Phase 3 clinical trials; and (b) the Development Partner must initiate a Phase 3 clinical trial on a Licensed Product within 6 months of completing the trials covered in (a) above. The above time frames are subject to reasonable extensions for delays caused by regulatory issues out of the Development Partners’ control. In consideration of the rights received, Licensee agreed to additional one-time milestone payments (for Licensee’s achievement of certain milestone events) of (i) $2 million upon dosing the first patient in the first Phase 3 clinical trial; (ii) $3 million upon filing a New Drug Application (an “NDA”) with the FDA for a Licensed product; (iii) $1.5 million upon approval by the FDA of the NDA;

(iv) $1.5 million upon achievement of $50 million in annual Net Sales (as defined in the License Agreement) for a License Product; and (v) $3 million upon achievement of $100 million in annual Net Sales for a Licensed Product. The Licensee also agreed to pay to The Regents 40% of sublicensing income payments received based on sublicensing, which includes all consideration received from a Sublicensee (as defined in the License Agreement) including milestone payments, sales-based payments, upfront license payments, but subject to certain exceptions; provided , however sublicensing fee payments will not be less than 5% of the Net Sales of the Licensed Products or Licensed Methods (as defined in the License Agreement) by the Sublicensee or other specified entities. The Licensee agreed to pay The Regents an earned royalty equal to 7% of the Net Sales (as defined in the License Agreement) for Licensee's sales of Licensed Products and Licensed Methods. If the Licensee incurs Development Costs (as defined in the License Amendment) in the aggregate of $14 million following the Effective Date, then thereafter the Sublicense Percentage (as defined in the License Amendment) will be reduced by one percentage point for each $4 million of additional Development Costs incurred, provided, that the Sublicense Percentage may never fall below 25%. The parties also entered into a mutual release.

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

The following discussion should be read in conjunction with the attached unaudited consolidated financial statements and notes thereto, and with our audited consolidated financial statements and notes thereto for the fiscal year ended December 31, 2014, found in our Annual Report on Form 10-K. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward looking statements by using words such as "anticipate," "believe," "intends," or similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in this 10-Q and as applicable in Part I, Item 1A of our Annual Report on Form 10-K.

Overview

We are a clinical-stage company developing therapeutics to protect the microbiome while targeting pathogen-specific diseases. Our lead candidates in Phase 2 development include SYN-004 which is designed to protect the gut microbiome (gastrointestinal (GI) microflora) from the effects of certain commonly used intravenous (IV) antibiotics for the prevention of *C. difficile* infection and antibiotic-associated diarrhea (AAD), and SYN-010 which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat the underlying cause of irritable bowel syndrome with constipation (IBS-C). In addition, we are developing a Phase 2 oral estriol drug, Trimesta™, for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS, and in collaboration with Intrexon Corporation (NYSE:XON), a preclinical stage monoclonal antibody combination for the treatment of Pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

Product Pipeline:

Summary of Microbiome Programs:

- ***C. difficile* infections (CDI):** We are in clinical development of a novel second-generation oral enzyme, SYN-004, to degrade commonly used IV beta-lactam antibiotics in the GI tract, intended to protect the microbiome and prevent the development of and severe effects from CDI and AAD. CDIs are a leading type of hospital acquired infection (HAI) and are frequently associated with IV antibiotic treatment. Designed to be given orally and co-administered with certain IV beta-lactam antibiotics (e.g., penicillins and cephalosporins), SYN-004 is intended to protect the gut

while the IV antibiotics fight the primary infection. SYN-004 is believed to not only have a similar profile to its first-generation predecessor, which demonstrated protection of the microbiome (gut flora) during treatment with certain penicillins, but also has the potential to protect the gut from a broader spectrum of IV beta-lactam antibiotics. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics. SYN-004's target market is significant and represented by annual U.S. hospitals purchases of approximately 118 million doses of IV beta-lactam antibiotics which are administered to approximately 14 million patients.* Currently there are no approved treatments designed to protect the gut microbiome from the damaging effects of IV antibiotics. This worldwide market could represent a multi-billion dollar opportunity for us. In November 2014, the U.S. Patent and Trademark Office (USPTO) issued Patent No. 8,894,994 that has claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including SYN-004, and carries a patent term to at least 2031. We also have an extensive patent estate on other aspects of this program which includes patent applications that could carry a term to at least 2035. In the fourth quarter of 2014, we initiated our randomized, double-blind placebo-controlled Phase 1a clinical trial, reported positive topline safety and tolerability results from the Phase 1a clinical trial, and initiated the Phase 1b clinical trial evaluating multiple ascending doses of SYN-004. In February 2015, we reported positive topline results from the Phase 1b clinical trial of escalating doses of oral SYN-004, 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. In March 2015, we reported positive pharmacokinetics data from both Phase 1 clinical trials, with supportive evidence that SYN-004 should have no effect on the IV antibiotic in the bloodstream, allowing the antibiotic to fight the primary infection. In March 2015, we also initiated a Phase 2a clinical trial to evaluate the GI antibiotic-degrading effects and the safety of SYN-004. In June 2015, the first participant was dosed in a second Phase 2a clinical trial of SYN-004, to evaluate the GI antibiotic-degrading effects and the safety of SYN-004, in the presence of the proton pump inhibitor (PPI), esomeprazole. Topline data is expected from the first Phase 2a clinical trial during the third quarter of 2015, and from the second Phase 2a clinical trial during the second half of 2015. In July 2015, we reported data from the first four of 12 expected participants in the first Phase 2a open-label clinical trial; the data showed that SYN-004 degraded IV ceftriaxone in the chyme of the four healthy participants with functioning ileostomies without affecting the ceftriaxone in the bloodstream. The initiation of a Phase 2b proof-of-concept clinical trial of SYN-004 is expected in the third quarter of 2015. This randomized, placebo-controlled clinical trial is expected to enroll approximately 370 patients at up to 75 global clinical sites. An interim analysis of blinded data from the Phase 2b clinical trial is anticipated during the second half of 2015. The initiation of pivotal Phase 3 clinical trial(s) are anticipated during 2016.

* This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: CDM Hospital database for full year 2012. IMS expressly reserves all rights, including rights of copying, distribution and republication.

IBS-C: In December 2013, through our majority-owned subsidiary, Synthetic Biomics, Inc., we entered into a worldwide exclusive license agreement with Cedars-Sinai Medical Center (CSMC) for the right to develop products for therapeutic and prophylactic treatments of acute and chronic diseases, including the development of SYN-010 to target IBS-C. SYN-010 is our proprietary modified-release formulation of the classic statin, lovastatin, that is intended to reduce methane-production by certain microorganisms (*M. smithii*) in the gut while minimizing disruption to the microbiome. SYN-010 is intended to act primarily in the intestinal lumen while avoiding systemic absorption, thereby targeting the cause of IBS-C, not just the symptoms. An investigational team led by Mark Pimentel, M.D. at CSMC discovered that lovastatin may reduce the production of methane gas by certain gastrointestinal (GI) microorganisms. Methane produced by these organisms is perceived as an underlying cause of pain, bloating, and constipation associated with IBS-C, and may contribute to the pathology of other diseases. In May 2015, preclinical results were presented in a poster at Digestive Disease Week® (DDW) 2015 demonstrating that lovastatin prevented proliferation of methanogens in the small intestines of rats with minimal impact on remaining microbiome. In his practice, Dr. Pimentel translated the use of statins to reduce methane in humans by evaluating commercial lovastatin formulations in select IBS-C patients, demonstrating that lovastatin prevented methane production by methanogens in human stool. Using stringent disease diagnosis criteria to ensure market relevance and a population most likely to receive a diagnosis and prescription drug treatment, there are an estimated 40.7 million cases of IBS reported in the U.S., Europe and Japan, and it has been reported that up to 20 percent of all IBS patients have IBS-C. The estimated global sales for IBS therapeutics for 2015 are $669.3 million, and global sales are expected to be greater than $1.5 billion in 2023*. A 505(b)(2) regulatory pathway is anticipated for the development of SYN-010. We licensed an intellectual property portfolio from CSMC including granted use patents and pending patent applications for SYN-010. Additional worldwide patent filings having composition of matter claims, which were recently filed by CSMC and licensed to us, could extend patent protection of SYN-010 to 2035. Our Investigational New Drug (IND) application was submitted to the U.S. Food and Drug Administration (FDA) in May 2015. In June 2015, we initiated our first Phase 2 placebo-controlled clinical trial of SYN-010. This clinical trial is expected to enroll approximately 60 patients who will be randomly assigned in a 1:1:1 ratio to one of three groups, including two different SYN-010 dose groups and a placebo group. Patients are scheduled to receive single oral doses of SYN-010 each day for 28 days. The primary objective of this clinical trial is to evaluate the change from baseline in 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 formulations of SYN-010 compared with placebo. Secondary endpoints include 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. We anticipate reporting topline results from the first Phase 2 clinical trial during the second half of 2015. We also anticipate initiating the second SYN-010 Phase 2 clinical trial during the second half of 2015, with topline results from this trial expected during the first half of 2016. The primary endpoint of the second Phase 2 is to evaluate the ability of SYN-010 to sustain the reduction in breath methane levels, and secondary endpoints include evaluating pain, bloating and CSBM. The initiation of pivotal Phase 3 clinical trial(s) are anticipated during 2016.

* GlobalData, Irritable Bowel Syndrome - Global Drug Forecast and Market Analysis to 2023, December 2014

Summary of Multiple Sclerosis Program:

Relapsing-Remitting MS: We have licensed issued method of treatment patents in the U.S. for MS therapy with estriol and estriol combination therapies (including estriol with Copaxone®) from University of California, Los Angeles (UCLA). In April 2014, positive Phase 2 topline efficacy and safety results was presented by the lead principal investigator of the UCLA Phase 2 investigator initiated randomized (n=158) double-blinded placebo trial which evaluated our drug candidate, Trimesta, in woman with relapsing remitting MS at 16 sites in the U.S. In September 2014, the lead principal investigator presented additional Phase 2 clinical outcome data, including more detailed results on improvements in cognitive and disability measures, at the 2014 Joint Americas and European Committees for Treatment and Research in Multiple Sclerosis Meeting (ACTRIMS-ECTRIMS) in Boston. The data as reported by the lead principal investigator for the UCLA-led Phase 2 study supported the potential of Trimesta to have a novel dual mechanism of action for both the anti-inflammatory effects that improve relapse rate, and a neuroprotective effect that improves standard measures of disability and cognition. Numerous new provisional patent applications have been filed based on the Phase 2 clinical results. This investigator-initiated Phase 2 clinical trial was supported by grants exceeding $8 million, awarded primarily by the National Multiple Sclerosis Society (NMSS) in partnership with the NMSS's Southern California chapter, and the National Institutes of Health. Annual worldwide sales of MS therapies are forecasted to be approximately $17.8 billion in 2019. In July 2015, through our wholly owned subsidiary, we entered into amended license and clinical trial agreements with The Regents of UCLA. We were also informed by UCLA that MRI analyses are ongoing to evaluate changes in the brain that correlate with improvements seen in clinical outcomes, and we expect to report topline MRI data 30 days following our receipt of this data from UCLA. We continue to engage the neurology community and potential strategic partners, as we determine next steps for Trimesta.

Cognitive Dysfunction in MS: Trimesta is also being developed for the treatment of cognitive dysfunction in female MS patients. This 12-month, UCLA-led, randomized, double-blind, placebo-controlled investigator-initiated Phase 2 clinical trial is being conducted at four sites in the United States. The primary endpoint is the effect on cognitive function as assessed by Paced Auditory Serial Addition Test (PASAT). Patient enrollment is ongoing. The majority of the costs of this trial are being funded by grants from foundations and charitable organizations through direct funding to the lead principal investigator and we have pledged approximately $500,000 to UCLA to partially fund this trial, payable over three years. An estimated 50 - 65% of MS patients are expected to develop disabilities due to cognitive dysfunction and there is currently no approved treatment for this indication.

Summary of Pathogen-Specific Therapy Programs:

- **Pertussis:** In December 2012, in collaboration with Intrexon Corporation, we initiated development of a monoclonal antibody (mAb) therapy for the treatment of Pertussis infections, more commonly known as whooping cough. Combining two mAbs, SYN-005 is designed to target and neutralize pertussis toxin as a prophylaxis for high-risk newborns and in order to reduce the mortality rate in infected infants. To further the development of this potential therapy for Pertussis, we entered into an agreement with The University of Texas at Austin (UT) to license the rights to certain research and pending patents related to pertussis antibodies. We have patents pending on compositions and uses of SYN-005 and we have an issued U.S. patent on other pertussis mAbs from UT. According to the World Health Organization, each year, *B. pertussis* infection is estimated to cause up to 300,000 deaths

worldwide, primarily among unvaccinated infants. Positive preclinical research findings for SYN-005 were reported in April 2014, and again in September 2014, for our proprietary mAb combination therapy for treating Pertussis, in non-human primate studies. In September 2014 we received a U.S. Orphan Drug designation for SYN-005 for the treatment of Pertussis. In April 2015, positive preclinical findings were reported in two posters at ECCMID 2015 (European Congress of Clinical Microbiology and Infectious Diseases). We are seeking non-dilutive funding to support preclinical and clinical development of SYN-005 for prophylaxis and treatment of Pertussis, including the anticipated filing of an IND application and the anticipated initiation of a Phase 1 clinical trial.

- **Phenylketonuria (PKU):** In August 2015, we entered into a third worldwide exclusive channel collaboration with Intrexon through which we intend to develop and commercialize novel biotherapeutics for the treatment of patients with PKU. We will utilize Intrexon's ActoBiotics™ platform providing a proprietary method of delivering therapeutic protein and peptides to the gastrointestinal tract through food-grade microbes. This program is in the discovery stage.

- **Acinetobacter infections:** In September 2012, in collaboration with Intrexon, we initiated efforts to develop a mAb therapy for the treatment of *Acinetobacter* infections. Many strains of *Acinetobacter* are multidrug-resistant and pose an increasing global threat to hospitalized patients, wounded military personnel and those affected by natural disasters. A treatment for *Acinetobacter* infections represents a billion dollar market opportunity. This program is in the discovery stage and the generation of a panel of antibodies to treat this infection is ongoing.

All of our programs are supported by growing patent estates that we either own or exclusively license. Each potential product has issued patents that provide protection. In total, we have approximately 100 U.S. and foreign patents and over 55 U.S. and foreign patents pending.

Recent Developments

On August 10, 2015, we expanded our relationship with Intrexon and entered into an Exclusive Channel Collaboration Agreement (the "Channel Agreement") with Intrexon that governs a "channel collaboration" arrangement in which we will use Intrexon's technology relating to the development and commercialization of novel biotherapeutics (a "Collaboration Product") for the treatment of patients with PKU. We have agreed to pay Intrexon a technology access fee by the issuance of 937,500 shares of common stock, having a value equal to $3 million as of August 7, 2015, within ten days of approval of the issuance by the NYSE MKT. In addition, upon the achievement of certain milestones, we agreed to pay Intrexon milestone payments of up to $27 million for each product developed. We will pay Intrexon royalties on annual net sales of Collaboration Products, calculated on a product-by-product basis equal to a percent of net sales (ranging from mid-single digits on the first $100 million of net sales to mid-teen digits on net sales in excess of $750 million).

On July 21, 2015, we completed a public offering of 15.3 million shares of common stock, including the fully exercised over-allotment option by the underwriters covering 2.0 million shares, at an offering price of $3.00 per share. The total gross proceeds of the offering, including the exercise in full of the over-allotment option, were approximately $46.0 million. Net proceeds, after deducting the underwriters' discount and other estimated expenses, were approximately $42.6 million.

On July 8, 2015, Putney Drug Corp., our subsidiary, and The Regents of UCLA, entered into an amendment to the License Agreement, dated July 11, 2005 (as amended previously), and an amendment to the Clinical Trial Agreement, dated as of April 29, 2010.

Since our inception in January 2001, our efforts and resources have been focused primarily on acquiring and developing our product candidates, our clinical trials, raising capital, manufacturing and recruiting personnel. 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 $127.0 million through June 30, 2015. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

Pipeline Programs and Therapeutic Areas

Microbiome-Focused Programs

We are developing therapeutics to protect the microbiome while targeting pathogen-specific diseases. Our lead candidates in Phase 2 development include SYN-004 which is designed to protect the gut microbiome (GI microflora) from the effects of certain commonly used IV antibiotics for the prevention of *C. difficile* infection and AAD, and SYN-010 which is intended to reduce the impact of methane producing organisms in the gut microbiome to treat the underlying cause of IBS-C.

Our *C. difficile* and IBS-C programs are focused on protecting the microbiome, or our gut flora, which is home to billions of bacteria and composed of a natural balance of both "good" beneficial bacteria and "bad" pathogenic bacteria. When that natural balance of all of these bacteria is disrupted, a person's health can be compromised.

***C. difficile – SYN-004*:**

According to the Agency for Healthcare Research and Quality, aggregate costs associated with CDI related stays in the hospital were $8.2 billion in the U.S. during 2009. CDI is a rising global HAI problem in which the toxins produced by *C. difficile* bacteria result in antibiotic-associated diarrhea (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.

CDI is a widespread and often drug resistant infectious disease. It is estimated that 1.1 million patients are infected with *C. difficile* annually in the U.S.*, and it has been reported that 30,000 patients die with a *C. difficile* infection 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.

* This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: CDM Hospital database for full year 2012. IMS expressly reserves all rights, including rights of copying, distribution and republication.

C. difficile: Acquisition of Clinical-Stage Program

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 HAI that generally occurs secondary to treatment with IV antibiotics. The acquired assets include a pre-IND package for P3A (now known as 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, SYN-004.

When co-administered with certain IV beta-lactam antibiotics, it is expected that SYN-004 can degrade the antibiotic that is excreted in the GI tract, thus preserving the natural balance of the patient's microflora, and preventing opportunistic infections including CDI. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics. SYN-004's target market is significant and represented by annual U.S. hospitals purchases of approximately 118 million doses of IV beta-lactam antibiotics which are administered to approximately 14 million patients.* Currently there are no approved treatments designed to protect the microbiome from the damaging effects of IV antibiotics. The worldwide market for SYN-004 could represent a multi-billion dollar opportunity for us.

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C. difficile: Oral Enzyme Background

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 study. In addition, two Phase 2 clinical studies 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: Preclinical and Clinical Development

Compared to the first generation oral enzyme candidate, P1A, we believe that the second generation candidate, SYN-004, will have activity against a broader spectrum of beta-lactam antibiotics, including both penicillins and

certain cephalosporins. Due to the structural similarities between P1A and SYN-004, and based on previous discussions with the FDA, certain preclinical data collected on P1A was used in support of an IND for our new product candidate, SYN-004.

In June 2014, we formed a Clinical Advisory Board (CAB) to support development of SYN-004. The CAB is comprised of industry leaders Mark Wilcox, M.D., (Chairman), Curtis Donskey, M.D., Ciarán Kelly, M.D. and Tom Louie, M.D., all of whom are providing expertise and guidance on aspects of the *C. difficile* clinical program.

In August 2014, we announced an agreement with Evonik Corporation for Good Manufacturing Practices (GMP) manufacturing of our proprietary oral beta-lactamase enzyme, SYN-004. Evonik formulated and encapsulated enterically coated SYN-004 for oral delivery for use in our Phase 1a, 1b and planned Phase 2a clinical trials, using material generated by our API manufacturer FUJIFILM Diosynth Biotechnologies UK Limited. In January 2015, we entered into an agreement with Halo Pharmaceutical (Whippany, NJ) to formulate and encapsulate enterically coated SYN-004 for oral delivery for use in our planned Phase 2b and other future clinical trials, using material generated by our Active Pharmaceutical Ingredient (API) manufacturer FUJIFILM Diosynth Biotechnologies UK Limited.

In December 2014, we initiated Phase 1a and 1b clinical trials of SYN-004, and also reported positive topline safety and tolerability results from the Phase 1a study. In February 2015, we reported positive topline results from the Phase 1b clinical trial of escalating doses of oral SYN-004, 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.

In March 2015, we reported positive pharmacokinetic data from both Phase 1 clinical trials, with supportive evidence that SYN-004 should have no effect on the IV antibiotic in the bloodstream, allowing the antibiotic to fight the primary infection.

In March 2015, we also initiated a Phase 2a clinical trial to evaluate the GI antibiotic-degrading effects and the safety of SYN-004. In July 2015, we reported data from the first four of 12 expected participants in the first Phase 2a open-label clinical trial; the data showed that SYN-004 degraded IV ceftriaxone in the chyme of the four healthy participants with functioning ileostomies without affecting the ceftriaxone in the bloodstream. Topline data is expected from the first Phase 2a clinical trial during the third quarter of 2015.

In June 2015, the first participant was dosed in a second Phase 2a clinical trial of SYN-004, to evaluate the GI antibiotic-degrading effects and the safety of SYN-004, in the presence of the proton pump inhibitor (PPI), esomeprazole. Topline data is expected from the second Phase 2a clinical trial during the second half of 2015.

The initiation of a Phase 2b proof-of-concept clinical trial of SYN-004 is expected in the third quarter of 2015. This randomized, placebo-controlled clinical trial is expected to enroll approximately 370 patients at up to 75 global clinical sites. An interim analysis (IA) of blinded data from the Phase 2b clinical trial is anticipated during the second half of 2015, and will be conducted as soon as prespecified criteria are fulfilled. The IA will be performed by an independent data monitoring committee.

The initiation of pivotal Phase 3 clinical trial(s) are anticipated during 2016.

C. difficile: *Intellectual Property*

In November 2014, the USPTO issued U.S. Patent 8,894,994 that has claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including SYN-004, and carries a patent term to at least 2031. In addition to this newly granted patent, we have numerous related granted and pending U.S. and foreign patent applications that are central to our intellectual property estate. Further, we continue to grow our intellectual property estate with new filings, many of which would expire in at least 2035, if granted.

In June 2015, we presented a poster at the 115th General Meeting of the American Society of Microbiology (ASM2015) that summarized the identification of a novel pipeline beta-lactamase, P2A, which has the ability to protect the gut microbiome from a third class of beta-lactam antibiotics, carbapenems. Adding P2A to the franchise platform expands our intellectual property claims to cover all three beta-lactam antibiotic classes, penicillins, cephalosporins, and carbapenems.

IBS-C – SYN-010:

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; 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-A (alternating diarrhea and constipation). Using stringent disease diagnosis criteria to ensure market relevance and a population most likely to receive a diagnosis and prescription drug treatment, there are an estimated 40.7 million cases of IBS reported in the U.S., Europe and Japan, and it has been reported that up to 20 percent of all IBS patients have IBS-C.

SYN-010 is our proprietary modified-release formulation of the classic statin, lovastatin, that is intended to reduce methane-production by certain microorganisms (*M. smithii*) in the gut, thereby treating IBS-C while minimizing disruption to the microbiome. SYN-010 is intended to act primarily in the intestinal lumen while avoiding systemic absorption, thereby targeting the cause of IBS-C, not just the symptoms.

Current FDA-approved therapies for the treatment of IBS-C include AMITIZA® (lubiprostone) and LINZESS® (linaclotide). Prescription and over-the-counter laxatives are also used by IBS-C patients for symptomatic relief. The estimated global sales for IBS therapeutics for 2015 are $669.3 million, and global sales are expected to be greater than $1.5 billion in 2023*.

*GlobalData, Irritable Bowel Syndrome - Global Drug Forecast and Market Analysis to 2023, December 2014

IBS-C: Acquisition of Clinical-Stage Program

In December 2013, we entered into a worldwide exclusive license agreement with CSMC for the right to develop products for therapeutic and prophylactic treatments for acute and chronic diseases. 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 has discovered that these products may reduce the production of methane gas by certain GI microorganisms. Methane produced by these microorganisms is perceived as the underlying cause of pain, bloating, and constipation associated with IBS-C, and may contribute to the pathology of other diseases. Initially we will focus on the development of SYN-010, an oral treatment being designed to reduce the impact of methane producing organisms on IBS-C.

IBS: Gas Producing Organisms Background

In the 1990's, research showed that IBS patients (over a given time) produced five times more gas than did people without IBS. Since the only source of those gases was bacterial, the initial presumption was that IBS patients had excessive bacteria in the colon. Subsequent studies showed that IBS patients had excessive quantities of gas in the small bowel; these data were the catalyst for studying small bowel bacteria in IBS. Normally the small intestine contains a very small quantity of bacteria. In published studies, indirect measures of small bowel bacteria suggest that 84% of IBS sufferers have excessive quantities of bacteria typically found in the colon. The CSMC investigational team led by Dr. Pimentel is researching a recent theory that defines IBS as a bacterial disease. Gut microflora that should normally be confined to the large intestine inappropriately colonize the small intestine. This process is referred to as small intestine bacterial overgrowth (SIBO), which results in gas, bloating, abdominal pain and altered stool habits characterized by IBS.

IBS-C: Methane Producing Organisms Background

Further research by the CSMC investigational team led by Dr. Pimentel is focused on the IBS-C patient population. 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. CSMC investigators have discovered that inhibiting intestinal methane production may reverse constipation associated with IBS-C, and can be beneficial in other major diseases such as obesity and type 2 diabetes.

IBS-C: Preclinical and Clinical Development

Efforts led by Dr. Pimentel included formulating and testing non-antibiotic FDA-approved oral drug candidates for ultimate product registration via potential expedited pathways. Such candidates are intended for the reduction or elimination of methane gas production within the intestines, with the goal of having little or no unintended impact on a patient's normal GI microflora.

In April 2014, we formed a CAB to support development of SYN-010, and also announced that gastroenterologist and lead investigator for the IBS-C program, Dr. Mark Pimentel, is the Chair of the CAB. In October 2014, we announced the expansion of the IBS-C CAB to include William Chey, M.D., Gail M. Comer, M.D., Anthony J. Lembo, M.D., and, Philip Schoenfeld, M.D., MSEd, MSc.

In September 2014, we announced that our candidate, SYN-010, is a modified release formulation of a statin being designed to reduce the impact of methane producing organisms on IBS-C. A 505(b)(2) regulatory pathway is anticipated for the development of SYN-010.

In May 2015, preclinical results were presented in a poster at DDW 2015 demonstrating that lovastatin prevented proliferation of methanogens in the small intestines of rats with minimal impact on remaining microbiome. In his practice, Dr. Pimentel translated the use of statins to reduce methane in humans by evaluating commercial lovastatin formulations in select IBS-C patients, demonstrating that lovastatin prevented methane production by methanogens in human stool.

In May 2015, our IND application was submitted to the FDA. In June 2015, we initiated our first Phase 2 placebo-controlled clinical trial of SYN-010. This clinical trial is expected to enroll approximately 60 patients who will be randomly assigned in a 1:1:1 ratio to one of three groups, including two different SYN-010 dose groups and a placebo group. Patients are scheduled to receive single oral doses of SYN-010 each day for 28 days. The primary objective of this clinical trial is to evaluate the change from baseline in 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 compared with placebo. Secondary endpoints include improvement in the number of CSBM per week, and improvement in abdominal pain and bloating per standard scales required per FDA guidance. We anticipate reporting topline results from the first Phase 2 clinical trial during the second half of 2015.

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We also anticipate initiating the second SYN-010 Phase 2 clinical trial during the second half of 2015, with topline results from this trial expected during the first half of 2016. The primary endpoint of the second Phase 2 is to evaluate the ability of SYN-010 to sustain the reduction in breath methane levels, and secondary endpoints include evaluating pain, bloating and CSBM.

The initiation of pivotal Phase 3 clinical trial(s) are anticipated during 2016.

IBS-C: Intellectual Property

An intellectual property portfolio including granted use patents and pending patent applications for SYN-010 has been licensed to us by CSMC. Additional worldwide patent filings, including composition of matter claims, among other claims, recently filed by CSMC and licensed to us could extend patent protection of SYN-010 to 2035.

Multiple Sclerosis Program

Relapsing-Remitting MS – Trimesta:

MS is a progressive neurological disease in which the body loses the ability to transmit messages along the central nervous system, leading to pain, loss of muscle control, paralysis, cognitive impairment and in some cases death. According to the NMSS, more than 2.3 million people worldwide (approximately 400,000 patients in the U.S. of which approximately 65% are women) have been diagnosed with MS. The diagnosis is typically made in young adults, ages 20 to 50. According to the NMSS, approximately 85% of MS patients are initially diagnosed with the relapsing-remitting form, and 10 - 15% with other progressive forms.

There are nine FDA-approved therapies for the treatment of relapsing-remitting MS: Betaseron®, Rebif®, Avonex®, Copaxone®, Tysabri®, Gilenya®, Extavia®, Aubagio® and Tecfidera®. Many of these therapies provide only a modest benefit for patients with relapsing-remitting MS. All of these drugs except Gilenya®, Aubagio® and Tecfidera® require frequent (daily, weekly & monthly) injections (or infusions) on an ongoing basis and can be associated with unpleasant side effects (such as flu-like symptoms) and high rates of non-compliance among users. Despite the availability of therapies for the treatment of relapsing-remitting MS, the disease is highly underserved and exacts a heavy personal and economic toll. Annual worldwide sales of MS therapies have been forecasted to reach approximately $17.8 billion in 2019.

Relapsing-Remitting MS: Background

Research has shown that pregnant women with MS tend to experience a spontaneous reduction of disease symptoms during pregnancy, particularly in the third trimester. The PRIMS (Pregnancy In MS) study published in 1998, a landmark observational clinical study published in the *New England Journal of Medicine* followed 254 women with MS during 269 pregnancies and for up to one year after delivery. The PRIMS study demonstrated that relapse rates were significantly reduced by 71% ($p < 0.001$) through the third trimester of pregnancy compared to pre-pregnancy-rates, and that relapse rates increased by 120% ($p < 0.001$) during the first three months after birth (post-partum) and then return to pre-pregnancy rates. It has been hypothesized that the female hormone, estriol, produced by the placenta during pregnancy, plays a role in “fetal immune privilege”, a process that prevents a mother’s immune system from attacking and rejecting the fetus. The maternal levels of estriol increase linearly through the third trimester of pregnancy until birth, whereupon it abruptly returns to low circulating levels. The anti-autoimmune effects of estriol are thought to be responsible for the therapeutic effects experienced by MS patients during pregnancy.

Rhonda Voskuhl, M.D., Director, UCLA MS program, UCLA Department of Neurology, has published that estriol at plasma levels found during pregnancy has immunomodulatory effects. Dr. Voskuhl further postulated that oral doses of estriol may have a therapeutic benefit when administered to non-pregnant female MS patients, and performed a pilot clinical study (see below).

Estriol has been approved and marketed for over 40 years throughout Europe and Asia for the oral treatment of post-menopausal symptoms. It has never been approved by the U.S. FDA for any indication.

Relapsing-Remitting MS: Clinical Development

Trimesta (oral estriol) is being developed as an adjunctive once-daily treatment for relapsing-remitting MS in women. An investigator-initiated, 10-patient, 22-month, single-agent, crossover clinical trial to study the therapeutic effects of 8 mg of oral Trimesta taken daily in non-pregnant female relapsing-remitting MS patients was completed in the U.S. The total volume and number of gadolinium-enhancing lesions were measured by brain MRI (an established neuroimaging measure of disease activity in MS). Over the next three months of treatment with Trimesta, the median total enhancing lesion volumes decreased by 79% ($p = 0.02$) and the number of lesions decreased by 82% ($p = 0.09$). They remained decreased during the next 3 months of treatment, with lesion volumes decreased by 82% ($p = 0.01$), and numbers decreased by 82% ($p = 0.02$). Following a six-month drug holiday during which the patients were not on any drug therapies, median lesion volumes and numbers returned to near baseline pretreatment levels. Trimesta therapy was reinitiated during a four-month retreatment phase of this clinical trial. The relapsing-remitting MS patients again demonstrated a decrease in enhancing lesion volumes of 88% ($p = 0.008$) and a decrease in the number of lesions by 48% ($p = 0.04$) compared with original baseline scores. The study was published by the lead principal investigator in Ann Neurol. 2002 Oct;52(4):421-8.

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Patient follow-up is complete in the UCLA-led Phase 2, investigator-initiated, randomized (n = 158), double-blinded, placebo-controlled trial which evaluated our drug candidate, Trimesta, in women with relapsing-remitting MS at 16 sites across the U.S. Positive Phase 2 topline efficacy and safety results were presented in April 2014 by lead principal investigator, Dr. Rhonda Voskuhl of UCLA at the 66thAmerican Academy of Neurology Annual Meeting. Dr. Voskuhl presented additional Phase 2 clinical outcome data, including more detailed results on improvements in cognitive and disability measures, at the 2014 Joint ACTRIMS-ECTRIMS in Boston in September 2014. The data as reported by Dr. Voskuhl for the UCLA-led Phase 2 study demonstrated the potential of Trimesta to have a novel dual mechanism of action for both the anti-inflammatory effects that lowers the relapse rate, and a neuroprotective effect that improves standard measures of disability and cognition.

Specifically, Dr. Voskuhl reported the following results:

(i) *Annualized relapse rate:* A 47% reduction in annualized relapse rate in the Trimesta+Copaxone® arm as compared to the placebo+Copaxone® arm (active control arm) at 12 months of therapy ($p = 0.02$), meeting the primary endpoint of the trial. These improvements in annualized relapse rate were sustained during the 24 months of therapy. When compared to the placebo+Copaxone® arm at 24 months, the Trimesta+Copaxone ® arm demonstrated a 32% lower relapse rate ($p = 0.11$).

(ii) *Cognitive disability:* Patients in the Trimesta+Copaxone® arm who had Paced Auditory Serial Addition Test (PASAT) scores lower than 55 before treatment (PASAT scale maximum of 60) experienced an approximately 12%, or 6 point, improvement in cognitive scores within 12 months of treatment ($p < 0.05$). This improvement from baseline was sustained throughout the 24 month study. In addition, a significantly larger proportion of patients in the Trimesta+Copaxone® arm demonstrated sustained improvement in cognition during the entire 24 month period, as approximately 33% of the patients showed sustained improvement of at least 3 points during this time period, compared to only about 21% in the placebo+ Copaxone® arm ($p < 0.05$).

(iii) *Physical disability:* Expanded Disability Status Scale (EDSS) scores in the Trimesta+Copaxone® arm significantly improved during 24 month follow-up by at least 0.5 point ($p = 0.03$) compared to the placebo+Copaxone® arm which experienced no change in EDSS scores. The between group difference was not statistically significant but showed a positive trend ($p = 0.25$). The 25 foot walk test showed a significant difference, while the patients in the Trimesta+Copaxone® arm were stable during the study, those in the active control arm did worse. The between group difference was ($p = 0.02$).

In addition, adjunctive oral Trimesta plus injectable standard of care Copaxone® demonstrated a reassuring safety profile and was well tolerated by women in the study.

This investigator-initiated Phase 2 clinical trial was supported by grants exceeding $8 million, awarded primarily by the NMSS in partnership with the NMSS's Southern California chapter, and the National Institutes of Health.

In July 2015, through our wholly owned subsidiary, we entered into amended license and clinical trial agreements with The Regents of UCLA. We were also informed by UCLA that MRI analyses are ongoing to evaluate changes in the brain that correlate with improvements seen in clinical outcomes, and we expect to report topline MRI data 30 days following our receipt of this data from UCLA. We continue to engage the neurology community and potential strategic partners, as we determine next steps for Trimesta.

Relapsing-Remitting MS: Intellectual Property

In April 2013, we announced that the USPTO issued U.S. Patent No. 8,372,826 entitled, *Estriol Therapy for Multiple Sclerosis and Other Autoimmune Diseases*, to the Regents of the University of California which includes claims to the use of our drug candidate, Trimesta, in combination with glatiramer acetate injection (Copaxone®). According to Teva Pharmaceutical Industries Ltd.'s Form 20-F for the year ended December 31, 2014, filed with the SEC on February 9, 2015, Copaxone® continued to be the leading MS therapy in the U.S, and globally, with approximately $4.2 billion in global net revenues. Currently marketed exclusively by Teva Pharmaceutical Industries Ltd., U.S. Orange Book patents on Copaxone® expired in May 2014 and, subject to further judicial review, in September 2015.

In March 2014, we announced that the USPTO issued U.S. Patent No. 8,658,627 entitled, *Pregnancy Hormone Combination for Treatment of Autoimmune Diseases*, to the Regents of the University of California. The patent includes claims to the use of our drug candidate, Trimesta, in conjunction with a gestagen for the treatment of MS and other autoimmune diseases. The patent also includes a claim for the administration of Trimesta, a gestagen and a third standard of care MS agent, such as glatiramer acetate injection (Copaxone®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®) or sphingosine-1-phosphate receptor modulator (Gilenya®).

Through our wholly owned subsidiary, we hold the exclusive worldwide license to issued U.S. Patents 8,895,539, 8,658,627, 8,372,826 and 6,936,599, as well as pending patents for MS and other autoimmune diseases covering the uses of our drug candidate, Trimesta. Numerous new provisional patent applications have been filed based on the Phase 2 clinical results.

Cognitive Dysfunction in MS – Trimesta:

According to the NMSS and the Multiple Sclerosis Society of Canada publication, *Hold that Thought! Cognition and MS*, it is fairly common for people with MS to complain of cognitive difficulties, such as remembering things, finding the right words and the ability to concentrate. Among MS patients, 50 - 65% have some degree of cognitive dysfunction.

The major areas of cognition that may be affected include complex attention and executive functions. Complex attention involves multitasking, the speed with which information can be processed, learning and memory, and perceptual skills; executive functions include problem solving, organizational skills, the ability to plan, and word finding. Just as the nature, frequency, and severity of MS-related physical problems can widely vary, not all people with MS will have cognitive dysfunction, and no two people will experience exactly the same type or severity.

Cognitive Dysfunction in MS: Background

In the investigator-initiated, 10-patient, 22-month, single-agent, crossover clinical trial conducted by Dr. Rhonda Voskuhl, a statistically significant 14% improvement from baseline in the PASAT cognitive testing scores ($p = 0.04$) was observed in relapsing-remitting MS patients after six months of Trimesta therapy. PASAT is a routine cognitive test performed in patients with a wide variety of neuropsychological disorders such as MS. The PASAT scores are expressed as a mean percent change from baseline.

Cognitive Dysfunction in MS: Clinical Development

Our Trimesta drug candidate is also being developed for the treatment of cognitive dysfunction in female MS patients. This randomized, double-blind, placebo-controlled Phase 2 clinical trial to evaluate Trimesta's potential neuroprotective and therapeutic effect on cognitive dysfunction in female MS patients is currently enrolling relapsing-remitting or secondary-progressive female MS patients at four clinical sites in the United States, including UCLA. Up to 64 patients between the ages of 18 and 50 will be randomized 1:1 into the treatment and placebo groups. Investigators will administer either oral Trimesta or a matching placebo, in addition to an FDA-approved MS treatment, including Copaxone®, Avonex®, Betaseron®, Extavia®, Rebif®, Gilenya®, Aubagio® and Tecfidera®. Each patient will be dosed and monitored for one year after being enrolled. The primary endpoint in this clinical trial being run under an investigator-initiated IND application is expected to be improvement in PASAT cognitive testing scores versus matching placebo. We and a private foundation pledged to equally support this new clinical trial, and we will also provide Trimesta drug supply. The trial also received contributions from several other supporters. Patient recruitment and enrollment into this trial is ongoing.

Pathogen-Specific Therapy 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. 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.

Intrexon Collaboration: Monoclonal Antibodies for Infectious Diseases

In August 2012, we entered into a worldwide exclusive channel collaboration with Intrexon through which we intend to develop a series of mAb therapies for the treatment of certain infectious diseases not adequately addressed by existing therapies. To date, we have initiated development of mAb therapies for the treatment of Pertussis and *Acinetobacter* infections. These programs may 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.*

*mAbLogix™ and LEAP® are trademarks of Intrexon Corporation.

Pertussis – SYN-005:

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, because while it 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, exposure of individuals whose immunity has diminished over time.

According to the World Health Organization there are 50 million cases of whooping cough and *B. pertussis* infection that are estimated to cause 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.

Pertussis: Intrexon Collaboration and The University of Texas at Austin Agreement

In December 2012, we initiated mAb development for the treatment of Pertussis focusing on toxin neutralization pursuant to our August 2012 collaboration with Intrexon. Unlike antibiotics, we are developing a therapy comprising a combination of two mAbs, SYN-005, to target and neutralize the pertussis toxin as a prophylaxis for high-risk newborns and in order to reduce the mortality rate in infected infants.

To further the development of this potential therapy for pertussis, we have entered into an agreement with The University of Texas at 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.

Pertussis: Preclinical and Clinical Development

Working with our collaborator, Intrexon, and our academic collaborator, The University of Texas at Austin, we established a combination of two humanized antibodies, SYN-005, designed to neutralize pertussis toxin, a major cause of pertussis-mediated infant morbidity and mortality. Benchtop studies demonstrated high affinity binding to the toxin, as well as potent neutralization of the toxin. In addition, the antibodies 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.

In April 2014, and again in September 2014, we received positive preclinical research findings for SYN-005, our proprietary mAb combination therapy for treating Pertussis (whooping cough), in three non-human primate studies (n = 19). In the latter two Pertussis studies in particular, SYN-005 rapidly blunted the rise in white blood cell count that is characteristic of the disease and accelerated its return to baseline.

In addition, during September 2014 we received U.S. Orphan Drug designation from the FDA for SYN-005 for the treatment of Pertussis.

We intend to seek non-dilutive funding to support additional preclinical and clinical development of SYN-005 for the prophylaxis and treatment of Pertussis, including the anticipated filing of an IND application, and the anticipated initiation of a Phase 1 clinical trial.

In April 2015, preclinical efficacy data that support advancing SYN-005 toward the clinic 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.

Pertussis: Intellectual Property

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

PKU – SYN-200:

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 carefully controlled diet.

PKU: Intrexon Collaboration

In August 2015, we initiated the SYN-200 discovery and the development program for development and commercialization of novel biotherapeutics for the treatment of patients with PKU pursuant to our August 2015 collaboration with Intrexon. This program is in the discovery stage.

Acinetobacter Infections – SYN-001:

Acinetobacter baumanii is a difficult to treat pathogen due to its rapid and well-established development of resistance to most antibiotics, making it a multidrug-resistant pathogen. In addition, as a biofilm-forming pathogen, *Acinetobacter baumanii* has the ability to survive up to twice as long as non-biofilm-forming pathogens. In the U.S., *Acinetobacter baumanii* has been reported to be the cause of up to 2.6% of hospital acquired infections, 1.3% of bloodstream infections and 7.0% of ICU respiratory tract infections, and more than half of the *Acinetobacter baumanii* isolates are multidrug-resistant. According to published articles, mortality rates associated with *Acinetobacter* infections as high as 43.0% are reported in hospitals and ICU settings. While *Acinetobacter baumanii* is a well-documented pathogen in the hospital setting, this pathogen also poses an increasing danger to wounded servicemen and women in military treatment centers and to those treated in trauma centers following natural disasters.

A treatment for *Acinetobacter* infections represents a billion dollar market opportunity.

Acinetobacter: Intrexon Collaboration

In September 2012, we initiated the SYN-001 mAb discovery and development program for *Acinetobacter* infections pursuant to our August 2012 collaboration with Intrexon. This program is in the discovery stage and the generation of a panel of antibodies is ongoing.

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 in the Management's Discussion and Analysis of Financial Condition and Results of Operations section in our 2014 Form 10-K.

Results of Operations

Three Months Ended June 30, 2015 and 2014

General and Administrative Expenses

General and administrative expenses increased by 22% to $2.2 million for the three months ended June 30, 2015, from $1.8 million for the three months ended June 30, 2014. This increase is primarily the result of increased employee costs and legal fees, offset by a decrease in stock-based compensation expense. The charge relating to stock-based compensation expense was $335,000 for the three months ended June 30, 2015, compared to $645,000 for the three months ended June 30, 2014.

Research and Development Expenses

Research and development expenses increased by 165% to $7.5 million for the three months ended June 30, 2015, from $2.8 million for the three months ended June 30, 2014. This increase is primarily the result of increased program costs associated with expanded clinical development programs, manufacturing and research activities within our microbiome-focused pipeline, including our *C. difficile,* IBS-C and Pertussis programs. Research and development expenses also include a charge relating to non-cash stock-based compensation expense of $252,000 for the three months ended June 30, 2015, compared to $210,000 for the three months ended June 30, 2014.

Other Income (Expense)

Other expense was $3.9 million for the three months ended June 30, 2015, compared to other income of $95,000 for the three months ended June 30, 2014. Other expense for the three months ended June 30, 2015 is primarily due to non-cash expense of $3.9 million from the change in fair value of warrants. The increase in the fair value of the warrants was due to the increase in our stock price at the end of the previous quarter. There was no non-cash expense relating to fair value of warrants for the three months ended June 30, 2014.

Net Loss

Our net loss was $13.6 million, or $0.19 per common share for the three months ended June 30, 2015, compared to a net loss of $4.6 million, or $0.08 per common share for the three months ended June 30, 2014.

Six Months Ended June 30, 2015 and 2014

General and Administrative Expenses

General and administrative expenses increased to $3.9 million for the six months ended June 30, 2015, from $2.9 million for the six months ended June 30, 2014. This increase of 34% is primarily the result of increased employee costs, legal fees, and audit fees related to the additional procedures required under the accelerated filer status. The charge relating to stock-based compensation expense was $915,000 for the six months ended June 30, 2015, compared to $899,000 for the six months ended June 30, 2014.

Research and Development Expenses

Research and development expenses increased to $14.0 million for the six months ended June 30, 2015, from $5.6 million for the six months ended June 30, 2014. This increase of 152% 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 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 $498,000 for the six months ended June, 2015, compared to $318,000 for the six months ended June 30, 2014.

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Other Income (Expense)

Other expense was $8.0 million for the six months ended June 30, 2015, compared to other income of $96,000 for the six months ended June 30, 2014. Other expense for the six months ended June 30, 2015 is primarily due to non-cash expense of $8.0 million from the change in fair value of warrants. There was no non-cash expense relating to fair value of warrants for the six months ended June 30, 2014.

Net Loss

Our net loss was $26.0 million, or $0.36 per common share for the six months ended June 30, 2015, compared to a net loss of $8.4 million, or $0.14 per common share for the six months ended June 30, 2014.

Liquidity and Capital Resources

We have financed our operations since inception primarily through proceeds from equity financings, corporate partnering license fees, laboratory revenues and miscellaneous equipment sales.

Our cash totaled $4.8 million as of June 30, 2015, a decrease of $12.8 million from December 31, 2014. During the six months ended June 30, 2015, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $26.0 million for the six months ended June 30, 2015.

On July 21, 2015, we completed a public offering of 15.3 million shares of common stock, including the fully exercised over-allotment option by the underwriters covering 2.0 million shares, at an offering price of $3.00 per share. The total gross proceeds of the offering, including the exercise in full of the over-allotment option, were approximately $46.0 million. Net proceeds to us, after deducting the underwriters' discount and other estimated expenses, were approximately $42.6 million.

Our continued operations 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 and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. 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 $127.0 million through June 30, 2015. With the exception of the quarter ended June 30, 2010, we have incurred negative cash flow from operations since we started our business. 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.

However, 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. 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

As of June 30, 2015, our cash and cash equivalents consisted primarily of money market securities. 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.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures

Pursuant to Rule 13a-15(b) under the Securities Exchange Act of 1934 ("Exchange Act"), the Company carried out an evaluation, with the participation of the Company's management, including the Company's Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of the Company's disclosure controls and procedures (as defined under Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, the Company's CEO and CFO concluded that the Company's disclosure controls and procedures are effective as of June 30, 2015 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 CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

(b) Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our fiscal quarter ended June 30, 2015, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

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,” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which was filed with the Securities and Exchange Commission on March 16, 2015. There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2014, other than as set forth below.

RISKS RELATING TO OUR BUSINESS

We will need to raise additional capital to operate our business.

With the exception of the three months ended June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. 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. As of June 30, 2015, our accumulated deficit totaled approximately $127.0 million on a consolidated basis. 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. If our current cash, cash equivalents and short-term investments are not sufficient to sustain our operations, 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.

We may not be able to retain rights licensed to us by others to commercialize key products and may not be able to establish or maintain the relationships we need to develop, manufacture, and market our products.

In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders/licensors for our products. We have an exclusive license agreement with the Regents of the University of California relating to our Trimesta technology, and an exclusive license agreement with CSMC relating to our IBS-C program. Each of these agreements requires us or our sublicensee to use our best efforts to commercialize each of the technologies as well as meet certain diligence requirements and timelines in order to keep the license agreement in effect. In the event we or our sublicensee are not able to meet our diligence requirements, we may not be able to retain the rights granted under our agreements or renegotiate our arrangement with these institutions on reasonable terms, or at all. Furthermore, we currently have very limited product development capabilities, and limited marketing or sales capabilities. For us to research, develop, and test our product candidates, we would need to contract with outside researchers, in most cases those parties that did the original research and from whom we have licensed the technologies. Our ECC agreements with Intrexon provide that Intrexon may terminate an agreement if we do not perform certain specified requirements, including developing therapies considered superior. Our agreement with The University of Texas allows the University to terminate its agreement if we fail to comply with the terms of the agreement. Our agreement with Prev provides Prev with the right to the return of the assets if we do not perform certain requirements. Our agreement with CSMC allows CSMC to terminate its agreement if we fail to comply with the terms of the agreement.

We can give no assurances that any of our issued patents licensed to us or any of our other patent applications will provide us with significant proprietary protection or be of commercial benefit to us. Furthermore, the issuance of a patent is not conclusive as to its validity or enforceability, nor does the issuance of a patent provide the patent holder with freedom to operate without infringing the patent rights of others.

We will incur additional expenses in connection with our ECC agreements with Intrexon and our agreements with Prev and CSMC.

Pursuant to our ECC agreements with Intrexon, we are responsible for future research and development expenses of product candidates developed under our collaboration, the effect of which has and will continue to increase the level of our overall research and development expenses going forward. Our agreements with Prev and CSMC require that we initiate certain studies and file or have accepted an NDA within a certain amount of time, each of which are costly and will require additional expenditures. Although all manufacturing, preclinical studies and human clinical trials are expensive and difficult to design and implement, costs associated with the manufacturing, research and development of biologic product candidates are generally greater in comparison to small molecule product candidates. We have added additional personnel to support our ECC agreements with Intrexon, and research and development of our candidates, SYN-004 and SYN-010. In addition, we have commenced manufacturing of SYN-004 material to support our planned preclinical and clinical studies which will require us to incur additional expenses.

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Because our biologic programs are relatively new, we have only recently assumed development responsibility and costs associated with such programs. In addition, because development activities in collaboration with Intrexon are determined pursuant to joint steering committees comprised of Intrexon and ourselves and we have limited experience, future development costs associated with this program may be difficult to anticipate and exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaborations due to our own working capital constraints, we may be forced to delay our activities. If we are unable to obtain additional financing on terms acceptable to us or at all, we may be forced to seek licensing partners or discontinue development.

Developments by competitors may render our products or technologies obsolete or non-competitive.

Companies that currently sell or are developing proprietary products for the prevention and treatment of *C. difficile* infection include: Actelion, Merck & Co., Merus, Pfizer and Sanofi. Companies that currently sell or are developing proprietary products for IBS-C include: Ironwood Pharmaceuticals, Inc./Forest Laboratories, Synergy Pharmaceuticals, and Takeda. Companies that currently sell or are developing proprietary products for Pertussis include: GlaxoSmithKline Pharmaceuticals, Mitsubishi and Sanofi. Companies that currently sell or are developing both generic and proprietary products to treat multiple sclerosis include: AB Science, AbbVie Inc., Acordia Therapeutics, Bayer Health Care, Biogen Idec, F. Hoffman-La Roche Ltd., Merck & Co., Neuron Biotech, Opexa Therapeutics, Inc., Pfizer Inc., Novartis AG, Receptos, Inc., Sanofi, and Teva Pharmaceuticals. Companies that sell or are developing products for the treatment of PKU include: BioMarin Pharmaceutical Inc., Codexis, Inc. and Synlogic, Inc. Many of our competitors have significant financial and human resources. The infectious disease market is highly competitive with many generic and proprietary intravenous and oral formulations available to physicians and their patients. For our monoclonal antibodies, we currently do not expect to be able to deliver our infectious disease candidates via the oral route and may thus be limited to the in-patient and/or acute treatment setting. In addition, academic research centers may develop technologies that compete with our Trimesta, SYN-004, SYN-010, SYN-005 and SYN-200 technologies. Should clinicians or regulatory authorities view alternative therapeutic regiments as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid, hospitals and private insurers.

We may fail to retain or recruit necessary personnel, and we may be unable to secure the services of consultants.

As of August 7, 2015, we employed approximately 24 individuals, 20 of whom are full-time employees. We have also engaged clinical consultants to advise us on our clinical programs and regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. We have been and will be required to retain additional consultants and employees in order to fulfill our obligations under the ECC agreements with Intrexon, our development obligations under our agreement with Prev and our agreement with CSMC. Our future performance will depend in part on our ability to successfully integrate newly hired officers into our management team and our ability

to develop an effective working relationship among senior management.

Certain of our directors, scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies that might be developing competitive products to ours. Other than corporate opportunities, none of our directors are obligated under any agreement or understanding with us to make any additional products or technologies available to us. Similarly, we can give no assurances, and we do not expect and stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by any of our directors or affiliates in the future would be made available to us other than corporate opportunities. We can give no assurances that any such other companies will not have interests that are in conflict with our interests.

Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives. There is intense competition for qualified personnel in the drug and biologic development areas, and we may not be able to attract and retain the qualified personnel we would need to develop our business.

We rely on independent organizations, advisors, and consultants to perform certain services for us, including handling substantially all aspects of regulatory approval, clinical management, manufacturing, marketing, and sales. We expect that this will continue to be the case. Such services may not always be available to us on a timely basis when we need them.

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.

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 fiscal years, as outlined in the NYSE MKT Exchange Company Guide. At June 30, 2015, we had a stockholders' deficit of $13.7 million. 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 due to our lack of 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.

Our principal stockholder has the ability to influence the vote on matters submitted to our stockholders and subsequent sales by such stockholder could adversely affect the market for our stock.

Through Intrexon and NRM VII Holdings I, LLC, Randal J. Kirk indirectly, beneficially owns approximately 12.3 million shares of our common stock as of December 31, 2014. Upon the closing of the ECC agreement that we entered into with Intrexon on August 10, 2015, such stock ownership will increase by an additional 937,500 share of common stock. As a result, he will be able to exert influence over issues submitted to our stockholders, including the election of our Board of Directors and the vote on issues. The sale of a number of shares by our principal stockholder could have an adverse effect on the market for our stock and our share price.

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

On April 15, 2015, we issued 442,478 shares of our common stock to Prev ABR, LLC in connection with an asset purchase agreement that we executed on November 8, 2012 (the "Asset Purchase Agreement") with Prev ABR, LLC upon the attainment of certain milestones in connection with the Asset Purchase Agreement. At the time of issuance, the shares of common stock had not been registered under the Securities Act of 1933, as amended, and therefore could not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. For these issuances, we relied on the exemption from federal registration under Section 4(a)(2) of the Securities Act, based on our belief that the offer and issuance of such shares of common stock did not involve a public offering as the purchaser of the common stock and its beneficial owners are "accredited investors" as defined under Section 501 promulgated under the Securities Act and no general solicitation had been involved in the offering. On April 20, 2015, a registration statement registering the shares of common stock was declared effective by the Securities and Exchange Commission.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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 Section 1350 of the Sarbanes-Oxley Act of 2002 *
32.2	Certification of Principal Financial Officer pursuant to Section 1350 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.

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.

SYNTHETIC
BIOLOGICS, INC.

By: /s/ Jeffrey Riley
Jeffrey Riley
President and Chief
Executive Officer
(Principal Executive
Officer)
Date: August 10,
2015

By: /s/ Steven A.
Shallcross
Steven A. Shallcross
Chief Financial
Officer
(Principal Financial
Officer)
Date: August 10,
2015

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