INGRAM MICRO INC
Form 10-Q
November 01, 2011

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended October 1, 2011

OR

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

For the transition period from _____ to _____

Commission file number: 1-12203

Ingram Micro Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**62-1644402**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1600 E. St. Andrew Place, Santa Ana, California 92705-4926

(Address, including zip code, of principal executive offices)

(714) 566-1000

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes þ No o

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes þ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 þ	Accelerated Filer o	Non-Accelerated Filer o (Do not check if a smaller reporting company)	Smaller Reporting Company o

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

The Registrant had 153,401,199 shares of Class A Common Stock, par value $0.01 per share, outstanding at October 1, 2011.

INGRAM MICRO INC.
INDEX

Table of Contents

Part I. Financial Information

Item 1. Financial Statements

INGRAM MICRO INC.
CONSOLIDATED BALANCE SHEET
(In 000s, except par value)
(Unaudited)

	October 1, 2011	January 1, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,002,290	$ 1,155,551
Trade accounts receivable (less allowances of $66,205 and $75,794)	3,735,526	4,138,629
Inventory	3,101,838	2,914,525
Other current assets	318,385	381,383
Total current assets	8,158,039	8,590,088
Property and equipment, net	304,824	247,395
Intangible assets, net	76,678	81,992
Other assets	127,862	164,557
Total assets	$ 8,667,403	$ 9,084,032
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,459,300	$ 4,593,694
Accrued expenses	425,169	536,218
Short-term debt and current maturities of long-term debt	122,950	105,274
Total current liabilities	5,007,419	5,235,186
Long-term debt, less current maturities	316,531	531,127
Other liabilities	77,557	76,537
Total liabilities	5,401,507	5,842,850
Commitments and contingencies (Note 13)		
Stockholders equity:		
Preferred Stock, $0.01 par value, 25,000 shares authorized; no shares issued and outstanding		
Class A Common Stock, $0.01 par value, 500,000 shares authorized; 184,888 and 182,458 shares issued and 153,401 and 158,745 shares outstanding in 2011 and 2010, respectively	1,849	1,825
Class B Common Stock, $0.01 par value, 135,000 shares authorized; no shares issued and outstanding		
Additional paid-in capital	1,306,399	1,259,406
Treasury stock, 31,487 and 23,713 shares in 2011 and 2010, respectively	(529,491)	(388,817)

Retained earnings	2,340,045	2,200,755
Accumulated other comprehensive income	147,094	168,013
Total stockholders equity	3,265,896	3,241,182
Total liabilities and stockholders equity	$ 8,667,403	$ 9,084,032

See accompanying notes to these consolidated financial statements.

Table of Contents

INGRAM MICRO INC.
CONSOLIDATED STATEMENT OF INCOME
(In 000s, except per share data)
(Unaudited)

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	October 1, 2011	October 2, 2010	October 1, 2011	October 2, 2010
Net sales	$ 8,903,020	$ 8,453,835	$ 26,375,757	$ 24,706,117
Cost of sales	8,462,300	8,000,310	25,021,733	23,373,677
Gross profit	440,720	453,525	1,354,024	1,332,440
Operating expenses:				
Selling, general and administrative	354,185	346,614	1,070,556	1,015,622
Reorganization costs (credits)	1,156		887	(358)
	355,341	346,614	1,071,443	1,015,264
Income from operations	85,379	106,911	282,581	317,176
Other expense (income):				
Interest income	(1,432)	(1,334)	(4,056)	(3,447)
Interest expense	13,048	11,545	40,561	25,015
Net foreign currency exchange loss (gain)	(1,348)	4,899	(1,313)	6,576
Loss from settlement of interest rate swap and senior unsecured term loan	5,624		5,624	
Other	2,393	3,239	9,444	8,515
	18,285	18,349	50,260	36,659
Income before income taxes	67,094	88,562	232,321	280,517
Provision for income taxes	43,768	23,573	92,954	77,473
Net income	$ 23,326	$ 64,989	$ 139,367	$ 203,044
Basic earnings per share	$ 0.15	$ 0.41	$ 0.88	$ 1.26
Diluted earnings per share	$ 0.15	$ 0.41	$ 0.86	$ 1.23

See accompanying notes to these consolidated financial statements.

Table of Contents

INGRAM MICRO INC.
CONSOLIDATED STATEMENT OF CASH FLOWS
(In 000s)
(Unaudited)

	Thirty-nine Weeks Ended	
	October 1, 2011	October 2, 2010
Cash flows from operating activities:		
Net income	$ 139,367	$ 203,044
Adjustments to reconcile net income to cash provided by operating activities:		
Depreciation and amortization	42,947	47,626
Stock-based compensation	25,068	18,214
Excess tax benefit from stock-based compensation	(3,029)	(1,226)
Loss from settlement of interest rate swap and senior unsecured term loan	5,624	
Gain on sale of land and building		(2,380)
Noncash charges for interest	1,418	415
Deferred income taxes	27,072	(333)
Changes in operating assets and liabilities, net of effects of acquisitions:		
Trade accounts receivable	424,147	262,286
Inventory	(174,742)	(379,105)
Other current assets	81,642	11,179
Accounts payable	(117,761)	(174,293)
Increase (decrease) in book overdrafts	(44,574)	32,827
Accrued expenses	(148,848)	36,764
Cash provided by operating activities	258,331	55,018
Cash flows from investing activities:		
Purchases of property and equipment	(90,907)	(45,421)
Sale of (investment in) marketable trading securities	(1,261)	956
Proceeds from sale of land and building		3,924
Acquisitions, net of cash acquired	(2,106)	(8,329)
Cash used by investing activities	(94,274)	(48,870)
Cash flows from financing activities:		
Proceeds from exercise of stock options	41,854	13,240
Repurchase of Class A Common Stock	(150,905)	(152,285)
Excess tax benefit from stock-based compensation	3,029	1,226
Proceeds from issuance of senior unsecured notes, net of issuance costs		297,152
Settlement of senior unsecured term loan	(239,752)	(9,375)
Net proceeds from revolving credit facilities	41,659	40,275
Cash provided (used) by financing activities	(304,115)	190,233

Effect of exchange rate changes on cash and cash equivalents	(13,203)	3,936
Increase (decrease) in cash and cash equivalents	(153,261)	200,317
Cash and cash equivalents, beginning of period	1,155,551	910,936
Cash and cash equivalents, end of period	$ 1,002,290	$ 1,111,253

See accompanying notes to these consolidated financial statements.

Table of Contents

INGRAM MICRO INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In 000s, except per share data)
(Unaudited)

Note 1 Organization and Basis of Presentation

Ingram Micro Inc. and its subsidiaries are primarily engaged in the distribution of information technology (IT) products and supply chain solutions worldwide. Ingram Micro Inc. and its subsidiaries operate in North America; Europe, Middle East and Africa (EMEA); Asia-Pacific; and Latin America.

The consolidated financial statements include the accounts of Ingram Micro Inc. and its subsidiaries. Unless the context otherwise requires, the use of the terms Ingram Micro, we, us and our in these notes to the consolidated financial statements refers to Ingram Micro Inc. and its subsidiaries. These consolidated financial statements have been prepared by us, without audit, pursuant to the rules and regulations of the United States Securities and Exchange Commission (the SEC). In the opinion of management, the accompanying unaudited consolidated financial statements contain all material adjustments (consisting of only normal, recurring adjustments) necessary to fairly state our consolidated financial position as of October 1, 2011, our consolidated results of operations for the thirteen and thirty-nine weeks ended October 1, 2011 and October 2, 2010 and our consolidated cash flows for the thirty-nine weeks ended October 1, 2011 and October 2, 2010. All significant intercompany accounts and transactions have been eliminated in consolidation. As permitted under the applicable rules and regulations of the SEC, these consolidated financial statements do not include all disclosures and footnotes normally included with annual consolidated financial statements and, accordingly, should be read in conjunction with the consolidated financial statements and the notes thereto, included in our Annual Report on Form 10-K filed with the SEC for the year ended January 1, 2011. The consolidated results of operations for the thirteen and thirty-nine weeks ended October 1, 2011 may not be indicative of the consolidated results of operations that can be expected for the full year.

Book Overdrafts

Book overdrafts of $472,533 and $517,107 as of October 1, 2011 and January 1, 2011, respectively, represent checks issued on disbursement bank accounts but not yet paid by such banks. These amounts are classified as accounts payable in our consolidated balance sheet. We typically fund these overdrafts through normal collections of funds or transfers from other bank balances at other financial institutions. Under the terms of our facilities with the banks, the respective financial institutions are not legally obligated to honor the book overdraft balances as of October 1, 2011 and January 1, 2011, or any balance on any given date.

Trade Accounts Receivable Factoring Programs

We have an uncommitted factoring program in North America under which trade accounts receivable of one of our larger customers may be sold, without recourse, to a financial institution. The program s total amount of receivables that may be factored at any one point in time cannot exceed $150,000. We also have an uncommitted factoring program in EMEA under which trade accounts receivable of another of our large customers may be sold, without recourse, to a financial institution. The program s total amount of receivables that may be factored at any one point in time cannot exceed 40,000, or approximately $54,000, at October 1, 2011. Available capacity under these programs is dependent on the amount of trade accounts receivable already sold to and held by the financial institutions, the level of our trade accounts receivable eligible to be sold into these programs and the financial institutions willingness to purchase such receivables. At October 1, 2011 and January 1, 2011, we had a total of $169,873 and $112,484, respectively, of trade accounts receivable sold to and held by the financial institutions under these programs. Factoring fees in the amount of $666 and $596 for the thirteen weeks ended October 1, 2011 and October 2, 2010, respectively, and $2,239 and $596 for the thirty-nine weeks ended October 1, 2011 and October 2, 2010, respectively, related to the sale of trade accounts receivable under both facilities are included in other in the other expense (income) section of our consolidated statement of income.

Note 2 Share Repurchases

In October 2010, our Board of Directors authorized a new three-year, $400,000 share repurchase program, following the completion of our previous share repurchase programs in the second quarter of 2010. Under the program, we may repurchase shares in the open market and through privately negotiated transactions. Our repurchases

will be funded with available borrowing capacity and cash. The timing and amount of specific repurchase transactions will depend upon market conditions, corporate considerations and applicable legal and regulatory requirements. We account for repurchased shares of common stock as treasury stock. Treasury shares

Table of Contents

INGRAM MICRO INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In 000s, except per share data)
(Unaudited)

are recorded at cost and are included as a component of stockholders equity in our consolidated balance sheet. We have also issued shares of common stock out of our cumulative balance of treasury shares. Such shares are issued to certain of our associates upon the vesting of their equity awards under the Ingram Micro Inc. 2011 Equity Incentive Plan (see Note 4). Our stock repurchase and issuance activity for the thirty-nine weeks ended October 1, 2011 and October 2, 2010 are summarized in the table below.

	Shares Repurchased	Weighted Average-Price Per Share	Net Amount Repurchased
Cumulative balance at January 1, 2011	23,713	$ 16.40	$ 388,817
Repurchase of Class A Common Stock	8,312	18.15	150,905
Issuance of Class A Common Stock	(538)	19.01	(10,231)
Cumulative balance at October 1, 2011	31,487	16.82	$ 529,491
Cumulative balance at January 2, 2010	15,095	$ 16.11	$ 243,219
Repurchase of Class A Common Stock	8,960	16.99	152,285
Issuance of Class A Common Stock	(226)	19.67	(4,446)
Cumulative balance at October 2, 2010	23,829	16.41	$ 391,058

Note 3 Earnings Per Share

We report a dual presentation of Basic Earnings per Share (Basic EPS) and Diluted Earnings per Share (Diluted EPS). Basic EPS excludes dilution and is computed by dividing net income by the weighted average number of common shares outstanding during the reported period. Diluted EPS uses the treasury stock method or the if-converted method, where applicable, to compute the potential dilution that could occur if stock-based awards and other commitments to issue common stock were exercised.

The computation of Basic EPS and Diluted EPS is as follows:

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	October 1, 2011	October 2, 2010	October 1, 2011	October 2, 2010
Net income	$ 23,326	$ 64,989	$ 139,367	$ 203,044
Weighted average shares	153,759	156,774	157,883	161,431
Basic EPS	$ 0.15	$ 0.41	$ 0.88	$ 1.26

Weighted average shares, including the dilutive effect of stock-based awards (3,008 and 2,782 for the thirteen weeks ended October 1, 2011 and October 2, 2010, respectively, and 3,660 and 3,192 for the thirty-nine weeks ended October 1, 2011 and October 2, 2010, respectively)	156,767	159,556	161,543	164,623
Diluted EPS	$ 0.15	$ 0.41	$ 0.86	$ 1.23

There were approximately 4,452 and 7,525 stock-based awards for the thirteen weeks ended October 1, 2011 and October 2, 2010, respectively, and 2,304 and 5,654 stock-based awards for the thirty-nine weeks ended October 1, 2011 and October 2, 2010, respectively, that were not included in the computation of Diluted EPS because the exercise price was greater than the average market price of the Class A Common Stock during the respective periods, thereby resulting in an antidilutive effect.

Table of Contents

INGRAM MICRO INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In 000s, except per share data)
(Unaudited)

Note 4 Stock-Based Compensation

During the second quarter of 2011, our stockholders approved the Ingram Micro Inc. 2011 Incentive Plan (the 2011 Incentive Plan), which constitutes an amendment and restatement of the Ingram Micro Inc. Amended and Restated 2003 Equity Incentive Plan and a consolidation with the Ingram Micro Inc. 2008 Executive Incentive Plan. The 2011 Incentive Plan increased the number of shares that we may issue by 13,500, for the granting of stock-based incentive awards including incentive stock options, non-qualified stock options, restricted stock, restricted stock units and stock appreciation rights, among others, to key employees and members of our Board of Directors. We have granted time- and/or performance-vested restricted stock and/or restricted stock units, in addition to stock options, to key employees and members of our Board of Directors. In 2011 and 2010, a portion of the performance-vested restricted stock units granted to management is based on the performance measurement of profit before tax, with the remainder based on earnings per share growth and return on invested capital versus preset targets.

No stock options were granted during the thirteen weeks ended October 1, 2011 or October 2, 2010, while restricted stock and restricted stock units granted were 16 for both periods. Stock options granted during the thirty-nine weeks ended October 1, 2011 and October 2, 2010 were 39 and 48, respectively, and restricted stock and restricted stock units granted were 1,775 and 1,817, respectively. As of October 1, 2011, approximately 15,600 shares were available for grant under the 2011 Incentive Plan, taking into account granted options, time-vested restricted stock units/awards and performance-vested restricted stock units assuming maximum achievement. Stock-based compensation expense for the thirteen weeks ended October 1, 2011 and October 2, 2010 was $9,080 and $7,149, respectively, and the related income tax benefit was approximately $2,200 and $1,700, respectively. Stock-based compensation expense for the thirty-nine weeks ended October 1, 2011 and October 2, 2010 was $25,068 and $18,214, respectively, and the related income tax benefit was approximately $6,700 and $5,200, respectively.

During the thirteen weeks ended October 1, 2011 and October 2, 2010, a total of 184 and 83 stock options, respectively, were exercised, and 11 and 12 restricted stock and restricted stock units vested, respectively. For the thirty-nine weeks ended October 1, 2011 and October 2, 2010, a total of 2,195 and 884 stock options, respectively, were exercised, and 1,099 and 744 restricted stock and restricted stock units vested, respectively. During the thirty-nine weeks ended October 1, 2011 and October 2, 2010, the Board of Directors determined that the performance measures for certain performance-based grants were not met, resulting in the cancellation of approximately 772 and 492 shares, respectively.

Note 5 Comprehensive Income (Loss)

Comprehensive income (loss) consists of the following:

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	October 1, 2011	October 2, 2010	October 1, 2011	October 2, 2010
Net income	$ 23,326	$ 64,989	$ 139,367	$ 203,044
Changes in foreign currency translation adjustments and other	(116,432)	116,638	(20,919)	1,357
Comprehensive income (loss)	$ (93,106)	$ 181,627	$ 118,448	$ 204,401

Accumulated other comprehensive income included in stockholders equity consisted primarily of foreign currency translation adjustments, fair value adjustments to our interest rate swap agreement, which we settled in September 2011 (see Note 10), and foreign currency forward contracts designated as cash flow hedges.

8

Table of Contents

INGRAM MICRO INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In 000s, except per share data)
(Unaudited)

Note 6 Derivative Financial Instruments

The notional amounts and fair values of derivative instruments in our consolidated balance sheet were as follows:

	Notional Amounts (1)		Fair Values	
	October 1, 2011	January 1, 2011	October 1, 2011	January 1, 2011
Derivatives designated as hedging instruments recorded in:				
Other current assets				
Foreign exchange contracts	$ 5,827	$	$ 154	$
Accrued expenses				
Foreign exchange contracts	5,525	71,253	(210)	(5,078)
Long-term debt				
Interest rate contract		184,375		(9,252)
	11,352	255,628	(56)	(14,330)
Derivatives not receiving hedge accounting treatment recorded in:				
Other current assets				
Foreign exchange contracts	376,629	347,108	13,818	585
Accrued expenses				
Foreign exchange contracts	489,311	726,187	3,474	(11,428)
	865,940	1,073,295	17,292	(10,843)
Total	$ 877,292	$ 1,328,923	$ 17,236	$ (25,173)
		-	$ -	

See accompanying notes to unaudited consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

(Unaudited)

1. Organization and Nature of Operations and Basis of Presentation

Description of Business

Synthetic Biologics, Inc. (the "Company" or "Synthetic Biologics") is a biotechnology company focused on the development of novel anti-infective biologic and drug candidates targeting specific pathogens that cause serious infections and diseases. The Company is developing an oral biologic to protect the gastrointestinal (GI) microflora from the effects of intravenous (IV) antibiotics for the prevention of *C. diff* infection, an oral treatment to reduce the impact of methane producing organisms on constipation-predominant irritable bowel syndrome (C-IBS), a series of monoclonal antibodies for the treatment of Pertussis and *Acinetobacter* infections, and a biologic targeted at the prevention and treatment of a root cause of a subset of IBS. In addition, the Company is developing an oral estriol drug for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS.

Therapeutic Area	Product Candidate	Status
Relapsing-remitting MS	Trimesta (oral estriol)	Patient follow-up is complete in the Phase II trial and topline results were reported in April 2014. The lead principal investigator from University of California, Los Angeles (UCLA) is scheduled to present additional Phase II clinical outcome data, including more detailed results on improvements in cognitive and disability measures at the ACTRIMS-ECTRIMS Joint Meeting in September 2014
Cognitive dysfunction in MS	Trimesta (oral estriol)	Patient enrollment underway in Phase II clinical trial
C. difficile infection prevention	SYN-004 (oral enzyme)	SYN-004, second generation candidate in preclinical studies; Intend to initiate Phase Ia and Ib clinical trials during 2nd half of 2014
Constipation-predominant irritable bowel syndrome	SYN-010	Planning for *in vivo* studies underway; Intend to initiate Phase II clinical trial during 2nd half of 2014; Collaboration with

(C-IBS)	(oral compound)	Cedars-Sinai Medical Center
Pertussis	SYN-005 (monoclonal antibody)	Positive preclinical research findings reported in April 2014; Collaborations with Intrexon and The University of Texas at Austin
Acinetobacter infection	SYN-001 (monoclonal antibody)	Discovery; Collaboration with Intrexon
IBS	SYN-007 (biologic)	Discovery; We are still evaluating the option; Collaboration with Intrexon

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, 2013 ("2013 Form 10-K") as filed with the SEC. The interim results for the three and six months ended June 30, 2014, 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.

Change in Filing Status

On June 30, 2014, the Company exceeded the $75.0 million public float threshold to trigger accelerated filer status with the SEC. Consequently the Company is no longer a Smaller Reporting Company (SRC) and the Company's auditors must provide an auditor attestation on our internal controls to be included in the Company's Form 10-K for the year ending December 31, 2014. Such Form 10-K will continue to provide scaled SRC-level disclosures; the larger reporting company disclosures will commence in the Company's Form 10-Q for the three months ended March 31, 2015.

2. Management's Plan

The Company has incurred an accumulated deficit of $89.7 million through June 30, 2014. 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 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 $7.8 million and $11.0 million as of June 30, 2014 and December 31, 2013, respectively, that are measured using Level 1 inputs.

4. Selected Balance Sheet Information

Prepaid expenses and other current assets (in thousands)

	June 30, 2014	December 31, 2013
Intrexon prepaid research and development expenses	$ 1,133	$ 1,361
Prepaid insurance	114	177
Prepaid credit cards	90	-
Prepaid expenses	52	53
Total	$ 1,389	$ 1,591

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.

Property and equipment (in thousands)

	June 30, 2014	December 31, 2013
Computer and office equipment	$ 66	$ 45
Software	11	11
	77	56
Less accumulated depreciation	(26)	(19)
Total	$ 51	$ 37

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, 2014, there were 682,449 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, 2014, 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. The exercise price of stock options under the 2010 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of June 30, 2014, there were 4,220,000 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, 2014 and 2013 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Exercise price	$2.52 - $2.91	-	$2.52 - $2.91	$1.74
Expected dividends	0 %	-	0 %	0 %
Expected volatility	106% - 150%	-	106% - 150%	148 %
Risk free interest rate	1.73% - 2.73%	-	1.57% - 2.73%	0.77 %
Expected life of option	5 years – 10 years	-	5 years – 10 years	5 years
Expected forfeitures	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, 2014, the Company granted 1,732,500 options to employees, Board members and consultants having an approximate fair value of $4.1 million based upon the Black-Scholes option pricing model. During the same period in 2013, the Company granted 117,500 options to employees and consultants having an approximate fair value of $185,000 based upon the Black-Scholes option pricing model.

A summary of stock option activities as of June 30, 2014, and for the year ended December 31, 2013, is as follows:

Weighted

	Options	Weighted Average Exercise Price	Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance - December 31, 2012	4,453,746	$ 1.78	6.43 years	$1,308,000
Granted	222,500	$ 1.69		
Exercised	(291,666)	$ 0.79		
Forfeited	(475,000)	$ 2.30		
Balance - December 31, 2013	3,909,580	$ 1.78	5.59 years	$785,000
Granted	1,732,500	$ 2.63		
Exercised	(6,583)	$ 0.58		
Forfeited	(304,391)	$ 1.93		
Balance – June 30, 2014 - outstanding	5,331,106	$ 2.05	6.26 years	$920,000
Balance – June 30, 2014 - exercisable	3,340,280	$ 1.77	5.36 years	$919,000
Grant date fair value of options granted – June 30, 2014		$ 4,088,000		
Weighted average grant date fair value – June 30, 2014		$ 2.36		
Grant date fair value of options granted – December 31, 2013		$ 350,000		
Weighted average grant date fair value – December 31, 2013		$ 1.57		

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, 2014 and 2013 was $855,000 and $407,000, respectively and $1,217,000 and $864,000 for the six month periods ended June 30, 2014 and 2013, respectively.

As of June 30, 2014, total unrecognized stock-based compensation expense related to stock options was $4.5 million, which is expected to be expensed through April 2017.

6. Stock Purchase Warrants

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, 2014 were 316,522.

On March 15, 2012, the Company entered into a consulting agreement for a financial communications program, for a period of twelve months that began on February 20, 2012. As compensation for such program, the consultant is paid a monthly fee and will be issued a performance warrant exercisable for 250,000 shares of the Company’s common stock based on achievement of certain stock price milestones. Upon initiation of the program, 50,000 of the performance warrants vested. The performance warrant is exercisable for a period of two years from the date of issuance for an exercise price equal to the price ($2.20 per share) of the Company’s common stock on the date of execution (March 15, 2012). In March 2013, the performance warrants’ vesting period was extended to March 14, 2014. All other provisions of the performance warrants remain unchanged. These warrants expired unexercised on March 14, 2014.

On December 20, 2011, the Company entered into a consulting agreement for financial advisory services, for a period of twelve months. As compensation for such services, the consultant was paid a monthly fee and on February 2, 2012, was issued warrants exercisable for 100,000 shares of the Company’s common stock. The warrant is exercisable upon issuance for a period of five years from the date of issue at an exercise price equal to the price ($1.14 per share) of the Company’s common stock on the date of issue. As of June 30, 2014, all of these warrants have been exercised.

A summary of warrant activity for the Company for the six months ended June 30, 2014 and for the year ended December 31, 2013 is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2012	1,632,501	$ 1.99
Granted	-	-
Exercised	-	-
Forfeited	-	-
Balance at December 31, 2013	1,632,501	1.99
Granted	-	-
Exercised	(232,619)	1.47
Forfeited	(454,896)	1.88
Balance at June 30, 2014	944,986	$ 2.16

Stock-based compensation expense included in general and administrative expenses relating to warrants issued to consultants was $0 and $22,000 for the three months ended June 30, 2014 and 2013, respectively, and $0 and $22,000 for the six months ended June 30, 2014 and 2013, respectively.

A summary of all outstanding and exercisable warrants as of June 30, 2014 is as follows:

Exercise Price	Warrants Outstanding	Warrants Exercisable	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
$ 1.60	316,522	316,522	3.32 years	$ 38,000
$ 2.22	517,257	517,257	2.41 years	$ -
$ 3.30	61,207	61,207	0.92 years	$ -
$ 3.75	50,000	50,000	1.63 years	$ -
$ 2.58	944,986	944,986	2.58 years	$ 38,000

7. Stockholders' Equity

During the six months ended June 30, 2014, the Company issued 6,583 shares of common stock, in connection with the exercise of stock options, for proceeds of approximately $4,000. The Company also issued 232,619 shares of common stock, in connection with cashless warrant exercises for the six months ended June 30, 2014.

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, 2014 and 2013, 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, 2014 were 5,331,106 and 944,986, respectively, and for the six months ended June 30, 2013 were 3,866,136 and 1,632,501, respectively.

9. Recent Accounting Pronouncements and Developments

In May 2014, the Financial Accounting Standards Board issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosure pertaining to revenue recognition in both the interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. The Company is currently assessing the method of adoption and the expected impact the new standard has on its financial position and results of operations.

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, 2013, found in our Annual Report on Form 10-K for the year ended December 31, 2013. 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 for the year ended December 31, 2013.

Overview

We are a biotechnology company focused on the development of novel anti-infective biologic and drug candidates targeting specific pathogens that cause serious infections and diseases. We are developing an oral biologic to protect the gastrointestinal (GI) microflora from the effects of intravenous (IV) antibiotics for the prevention of *Clostridium difficile (C. diff)* infection, an oral treatment to reduce the impact of methane producing organisms on constipation-predominant irritable bowel syndrome (C-IBS), a series of monoclonal antibodies (mAbs) for the treatment of Pertussis and *Acinetobacter* infections, and a biologic targeted at the prevention and treatment of a root cause of a subset of IBS. In addition, we have two legacy programs. We are also developing an oral estriol drug for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS.

Product Pipeline:

Summary of Pathogen-Specific Anti-Infective Biologic and Drug Programs:

- ***C. diff* infections:** We are in preclinical development of a novel second-generation oral enzyme drug candidate, SYN-004, for co-administration with commonly used IV antibiotics intended to prevent the development of and severe effects from *C. diff* infections (CDI). CDIs are a leading cause of hospital acquired infections (HAIs), that generally occur secondary to treatment with IV antibiotics. Designed to be given orally to protect the gut while

certain IV beta-lactam antibiotics (penicillins and cephalosporins) fight the primary infection, SYN-004 is believed to have a similar profile to its first-generation predecessor, which demonstrated protection of the gut flora (microbiome) during treatment with certain penicillins, with the potential to act against 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. Approximately 14.4 million patients are administered "SYN-004 target" IV beta-lactam antibiotics annually, representing an estimated target market for SYN-004 of 117.6 million beta-lactam doses purchased by U.S. hospitals. The addressable market for SYN-004 is significant. Currently there are no approved treatments designed to protect the microbiome from the damaging effects of IV antibiotics. This worldwide opportunity could represent a multi-billion dollar market.* We remain on schedule to file an Investigational New Drug (IND) application for SYN-004, and intend to initiate Phase Ia and Ib clinical studies in the fourth quarter of 2014. Preliminary Phase I topline data is expected by year-end 2014, and a Phase II efficacy study of SYN-004 is planned to begin in the first half of 2015. Clinical drug manufacturing of SYN-004 in accordance with GMP guidelines has commenced.

* 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-IBS: 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 for acute and chronic diseases. 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 gastrointestinal (GI) microorganisms. Methane produced by these organisms is perceived as the underlying cause of bloating, pain and constipation associated with C-IBS, and may contribute to the pathology of other diseases. Initially we are focusing on the development of SYN-010, an oral treatment being designed to reduce the impact of methane producing organisms on C-IBS. *In vitro* and preclinical animal model studies were initiated in June 2014. We plan to initiate a Phase II dose-discovery and proof-of-mechanism clinical trial during the second half of 2014 under an Investigational New Drug application (IND). Topline data from this Phase II trial are expected in mid-2015.

- **Pertussis:** In April 2014, we received positive preclinical research findings for SYN-005, our proprietary monoclonal antibody (mAb) combination therapy for treating Pertussis (whooping cough), in two non-human primate studies (n=15). In December 2012, in collaboration with Intrexon Corporation (NYSE: XON) (Intrexon), we initiated development of a mAb therapy for the treatment of Pertussis infections, more commonly known as whooping cough. We are developing a mAb therapy, SYN-005, designed to target and neutralize the pertussis toxin, in order to reduce the mortality rate in infants. To further the development of this potential therapy for Pertussis, we 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. According to the World Health Organization, each year, *B. pertussis* infection causes an estimated 300,000 deaths worldwide, primarily among young, unvaccinated infants. Based on positive non-human primate and murine model findings, we intend to file an IND application to support a Phase I clinical trial expected to initiate during the first half of 2015. Topline data is expected to be available within approximately 90 days of the start of the trial. This is expected to be followed by the initiation of a Phase II trial in the second half of 2015. In addition, we have submitted an Orphan Drug designation request for SYN-005 for the treatment of Pertussis.

***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 is ongoing.

IBS: In December 2013, in collaboration with Intrexon, and partially utilizing the intellectual property optioned from CSMC, we announced an intent to develop biologic approaches targeted at the prevention, and acute and chronic treatment of a subset of IBS pathologies specifically caused by auto-antibodies. This program is in the early discovery stage, and we are still evaluating the option.

Summary of Multiple Sclerosis Program:

Relapsing-Remitting MS: Patient follow-up is complete in the Phase II, double-blinded, placebo-controlled Trimesta trial which randomized 158 women with relapsing-remitting MS at 16 sites across the U.S. Positive Phase II topline efficacy and safety results were presented in April 2014 by lead principal investigator, Dr. Rhonda Voskuhl of the University of California, Los Angeles (UCLA) David Geffen School of Medicine at the 66th American Academy of Neurology Annual Meeting. The UCLA-led Phase II study was designed to show statistical significance at 12 months for the MS relapse rate reduction in patients treated with Trimesta plus Copaxone ® compared to patients given placebo plus Copaxone ®. The trial was only powered to trend toward statistical significance at the 24-month time point. According to the protocol, the results of topline data demonstrate that Trimesta met the pre-specified goal of the study with rapid onset of activity observed for Trimesta plus Copaxone ® compared to placebo plus Copaxone ®. The Trimesta study also demonstrated a clinically significant near-normalization of cognitive scores at 12 months of therapy in women taking Trimesta plus Copaxone®. The cognition outcome is of high importance for MS specialists and patients and we believe it is the result of oral estriol's unique neuroprotective effect. In addition, adjunctive oral Trimesta plus injectable standard of care Copaxone® was generally safe and well tolerated by women in the study. This investigator-initiated clinical trial is 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 current MS therapies are estimated at $14.1 billion. We are engaging with the neurology community and potential strategic partners, as we determine next steps for Trimesta. In addition, Dr. Voskuhl is scheduled to present additional Phase II 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 in September 2014.

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Cognitive Dysfunction: Trimesta is also being developed for the treatment of cognitive dysfunction in female MS patients. This 12-month randomized, double-blind, placebo-controlled Phase II clinical trial is being conducted at four sites in the United States, including UCLA. 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 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.

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Recent Developments

On December 11, 2013, we completed a firm commitment underwritten public offering of 13,225,000 shares of our common stock at a closing price of $1.00 per share for gross proceeds of $13.2 million. We paid direct offering costs of $1.0 million.

On December 5, 2013, through our newly formed, majority owned subsidiary, Synthetic Biomics, Inc. (“SYN Biomics”), we entered into a worldwide exclusive license agreement (the “CSMC License Agreement”), and an option agreement (the “CSMC Option Agreement”), which was extended until December xx, 2014, with CSMC for the right to develop, manufacture, use, and sell products for the human and veterinary therapeutic and prophylactic treatments for acute and chronic diseases. An investigational team lead by Mark Pimentel, M.D. at CSMC has discovered that these products may reduce gas production by certain GI microorganisms. Methane produced by these organisms is perceived as an underlying cause of bloating, pain and constipation associated with C-IBS, and may contribute to the pathology of obesity and type 2 diabetes. The portfolio of intellectual property licensed to SYN Biomics under the License Agreement includes nine issued U.S. patents, one issued European patent validated in 18 countries, one issued European patent validated in three countries, two issued Australian patents, and one issued Japanese patent as well as 13 pending U.S. and international patent applications for most fields of use and modalities (subject to certain agreed-upon exceptions); two pending U.S. patent applications are optioned to SYN Biomics under the Option Agreement.” In collaboration with Intrexon, and partially utilizing the intellectual property optioned from CSMC, we announced an intent to develop biologic approaches targeted at the prevention, and acute and chronic treatment of a subset of IBS pathologies specifically caused by autoantibodies.

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. As of June 30, 2010, we emerged from the development stage after entering into a sublicense agreement with Meda AB and receiving an up-front payment of $2.5 million. We consider this sublicense agreement to be an indication that we commenced our principal operations. Meda AB has informed us that due to the decision of the European Medicines Agency (EMA) to limit the use of flupirtine for long-term pill and systemic use, it has decided to postpone the planned fibromyalgia clinical trials in the U.S.

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 $89.7 million through June 30, 2014. 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

Pathogen-Specific Anti-Infective Biologic and Drug Programs

We are a biotechnology company focused on the development of novel anti-infective biologic and drug candidates targeting specific pathogens that cause serious infections and other diseases. 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. We are developing an oral biologic to protect the gastrointestinal microflora from the effects of certain IV beta-lactam antibiotics for the prevention of CDI, an oral treatment to reduce the impact of methane producing organisms on C-IBS, a series of monoclonal antibodies for the treatment of Pertussis and *Acinetobacter* infections, and a biologic targeted at the prevention and treatment of a root cause of a subset of IBS.

Several of our programs are focused on protecting the microbiome, or our gut flora, which is home to millions of bacteria, 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 is compromised.

***C. difficile*:**

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 diarrhea antibiotic-associated diarrhea (AAD), and in the most serious cases, pseudomembranous colitis (erosion of the lower GI tract) that can lead to death. The Centers for Disease Control and Prevention (CDC) identified *C. diff* 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, and it is estimated that 1.1 million patients are infected with *C. diff* annually in the U.S.*, and it has been reported that 30,000 patients die with a *C. diff* infection each year. CDI has surpassed methicillin-resistant staphylococcus aureus (MRSA) as the most frequent infection acquired in the hospital. 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 other inanimate objects. There is currently no vaccine or approved product for the prevention of *C. diff* infection.

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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 referred to as SYN-004), Phase I and Phase II clinical data for P1A, manufacturing processes and data, and a portfolio of issued and pending U.S. and international patents intended to support an IND and Biologics License Application (BLA) with the FDA. Utilizing this portfolio of assets, we intend to develop a proprietary 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. Approximately 14.4 million patients are administered "SYN-004 target" IV beta-lactam antibiotics annually, representing an estimated target market for SYN-004 of 117.6 million beta-lactam doses purchased by U.S. hospitals. The addressable market is significant and currently there are no approved treatments designed to protect the microbiome from the damaging effects of IV antibiotics. This worldwide opportunity could represent a multi-billion dollar market.*

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C. difficile: Oral Enzyme Background

We acquired a series of oral beta-lactamase enzymes. 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 I study. In addition, two Phase II clinical studies demonstrated that P1A had the ability to preserve GI microflora in hospitalized patients treated with intravenous 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 (formerly P3A), 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, it is anticipated that certain preclinical data collected on P1A may be 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 expected to provide expertise and guidance on each aspect of the *C. diff* clinical program.

In August 2014, we announced an agreement with Evonik for GMP manufacturing of the Company's proprietary oral beta-lactamase enzyme, SYN-004, for use in the planned clinical trials. Evonik plans to formulate and encapsulate enterically coated SYN-004 for oral delivery using material generated by our API manufacturer FUJIFILM Diosynth Biotechnologies UK Limited.

We remain on schedule to file an Investigational New Drug (IND) application for SYN-004, and intend to initiate Phase Ia and Ib clinical studies in the fourth quarter of 2014. Preliminary Phase I topline data is expected by year-end 2014, and a Phase II efficacy study of SYN-004 is planned to begin in the first half of 2015.

C-IBS:

Irritable Bowel Syndrome (IBS) is a functional GI disorder characterized by gas, abdominal pain, bloating and diarrhea or constipation, or alternating episodes of both. According to reports published by The International Foundation for Functional Gastrointestinal Disorders (IFFGD), IBS affects an estimated 10 to 15 percent of the population, or as many as 40 million Americans. 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: C-IBS (constipation predominant), D-IBS (diarrhea predominant), M-IBS (mixed diarrhea and constipation) and A-IBS (alternating diarrhea and constipation).

It has been reported that one-third of all IBS patients have C-IBS. Current FDA-approved therapies for the treatment of C-IBS include AMITIZA® (lubiprostone) and LINZESS ® (linaclotide). Prescription and over-the-counter laxatives are also used by C-IBS patients for symptomatic relief. According to GlobalData, sales of approved drugs to treat C-IBS in seven major markets are projected to reach $1.3 billion by 2018.

C-IBS: 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 and optioned from CSMC a portfolio of intellectual property comprised of several U.S. and international patents and pending patent applications for various fields of use, including C-IBS, 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 organisms is perceived as the underlying cause of bloating, pain and constipation associated with C-IBS, 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 C-IBS.

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: 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.

C-IBS: Methane Producing Organisms Background

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

C-IBS: Preclinical and Clinical Development

Ongoing efforts led by Dr. Pimentel include 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 intestinal microflora. Initially we will focus on the development of an oral treatment to reduce the impact of methane producing organisms on C-IBS.

In April 2014, we formed a CAB to support development of SYN-010, an oral treatment being designed to reduce the impact of methane producing organisms on C-IBS. We also announced that gastroenterologist and lead investigator for the C-IBS program, Dr. Mark Pimentel of CSMC, will Chair the CAB.

In vitro and preclinical animal model studies were initiated in June 2014. We plan to initiate a Phase II dose-discovery and proof of mechanism clinical trial during the second half of 2014 under an IND. Topline data from this Phase II trial is expected in mid-2015.

Monoclonal Antibodies:

Monoclonal Antibodies for Infectious Diseases

Acting as the body's army, 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 (“Second ECC”) 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. Utilizing Intrexon’s comprehensive suite of proprietary technologies, including the mAbLogix™ platform for rapid discovery of fully human mAbs and the LEAP ™ cell processing station, our initial efforts will target three infectious disease indications.*** We also have the option to target an additional five infectious disease indications under this collaboration. To date, we have initiated development of a mAb therapy for the treatment of Pertussis and *Acinetobacter* infections.

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

Pertussis:

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 a less effective 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, as well as asymptomatic carriers.

According to the World Health Organization there are 50 million cases of whooping cough and *B. pertussis* infection that causes an estimated 300,000 deaths each year worldwide, primarily among young, 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 mAb therapy, SYN-005, to target and neutralize the pertussis toxin, in order to reduce the mortality rate in 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 Assistant 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 have established a combination of two humanized antibodies 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, we received positive preclinical research findings for SYN-005, our proprietary mAb combination therapy for treating Pertussis (whooping cough), in two non-human primate studies (n=15). In the second pertussis study in particular, SYN-005 was associated with favorable decreases in white blood cell counts within two days and the achievement of nearly normal levels within one week of treatment with SYN-005.

Based on positive non-human primate and murine model findings, we have filed an additional patent application around pertussis antibodies, intend to move into cGMP manufacturing of SYN-005, and intend to file an IND application to support a Phase I clinical trial expected to initiate during the first half of 2015. Topline data is expected to be available within approximately 90 days of the start of the trial. This is expected to be followed by the initiation of a Phase II trial in the second half of 2015. In addition, we have submitted an Orphan Drug designation request for SYN-005 for the treatment of Pertussis.

Acinetobacter Infections:

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 August 2012, we initiated a mAb discovery and development program for *Acinetobacter* infections pursuant to our August 2012 collaboration with Intrexon. Discovery efforts for the development of a mAb are currently underway.

IBS:

Existing IBS therapies, which are primarily focused on supportive care, are unlikely to address the treatment needs of the patient population with auto-antibodies, an underlying immune-specific pathology. Through our collaboration with Intrexon, we intend to address the unmet medical need in these patients with personalized medicine and target the root causes of a subset of IBS-associated pathologies.

IBS: Intrexon Collaboration

In December 2013, in collaboration with Intrexon, and partially utilizing the intellectual property optioned from CSMC, we announced an intent to develop biologic approaches targeted at the prevention, and acute and chronic treatment of a subset of IBS pathologies specifically caused by auto-antibodies.

We intend to utilize intellectual property optioned from CSMC. According to an increasing body of recent work conducted by CSMC, a subset of IBS cases appear to be causally initiated by one or more encounters with acute infectious gastroenteritis, such as the foodborne illness, *Campylobacter jejuni*. CSMC has identified a novel autoimmune target for this subset of IBS cases because of the development of cross-reacting antibodies between a bacterial toxin and a protein important for controlling GI motility. This program is in the discovery stage, and we are still evaluating the option.

Multiple Sclerosis Program

Relapsing-Remitting MS:

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 National Multiple Sclerosis Society (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 were estimated at $14.1 billion in 2012.

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 of pregnancy on MS.

Rhonda Voskuhl, M.D., Director, UCLA MS program, UCLA Department of Neurology, has found that plasma levels of estriol achieved during pregnancy have potent immunomodulatory effects. Dr. Voskuhl further postulated and tested in a pilot clinical study that oral doses of estriol may have a therapeutic benefit when administered to non-pregnant female MS patients by, in essence, mimicking the spontaneous reduction in relapse rates seen in MS patients during pregnancy.

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 oral 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 magnetic resonance imaging (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.

Patient follow-up is complete in the Phase II, double-blinded, placebo-controlled trial randomized 158 women with relapsing-remitting MS at 16 sites across the U.S. The study evaluated Trimesta as an oral, once-daily dose of 8 mg per day plus Copaxone ® in women with relapsing-remitting MS, aged 18-50 years. Positive topline efficacy and safety results were presented in April 2014 by lead principal investigator, Dr. Rhonda Voskuhl of UCLA David Geffen School of Medicine at the 66th American Academy of Neurology Annual Meeting. The UCLA-led Phase II study was designed to show statistical significance at 12 months for the MS relapse rate reduction in patients treated with Trimesta plus Copaxone ® compared to patients given placebo plus Copaxone ®. The trial was only powered to trend toward statistical significance at the 24-month time point. According to the protocol, the results of topline data demonstrate that Trimesta met the pre-specified goal of the study with rapid onset of activity observed for Trimesta plus Copaxone ® compared to placebo plus Copaxone ®. Dr. Voskuhl and her team anticipated an approximately 29% reduction in MS relapse rate, per the study protocol. A statistically significant 47% decrease in relapse rate was observed at 12 months of therapy (p-value = 0.03 / powered for significance level of 0.05), as well as a clear trend toward a 32% reduction at 24 months (p-value = 0.15 / powered for significance level of 0.10), which far surpassed the investigator's expectations. The Trimesta study also demonstrated a clinically significant near-normalization of cognitive scores at 12 months of therapy in women taking Trimesta plus Copaxone ®. This outcome is of high importance for MS specialists and patients and we believe it is the result of oral estriol's unique neuroprotective effect. In addition, adjunctive oral Trimesta plus injectable standard of care Copaxone® was generally safe and well tolerated by women in the study.

By demonstrating the therapeutic potential and safety of Trimesta in the Phase II exploratory trial, we achieved a key goal of the Trimesta program, which is providing further support to enable us to attract a strategic partner to accelerate development of this innovative therapy for MS. We are engaging with the neurology community and potential strategic partners, as we determine next steps for Trimesta.

In addition, Dr. Voskuhl is scheduled to present additional Phase II 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 in September 2014.

This investigator-initiated clinical trial is 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.

Relapsing-Remitting MS: Patents

In March 2014, we announced that the U.S. Patent & Trademark Office 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 (oral estriol), in conjunction with a gestagen for the treatment of multiple sclerosis (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®).

In April 2013, we announced that the U.S. Patent & Trademark Office 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 (oral estriol), in combination with glatiramer acetate injection (Copaxone®). According to Teva Pharmaceutical Industries Ltd.'s Form 20-F for the year ended December 31, 2013, filed with the SEC on February 10, 2014. Copaxone® is the number one selling drug for multiple sclerosis with approximately $4.3 billion in global annual sales. Currently marketed exclusively by Teva Pharmaceutical Industries Ltd., Copaxone ® is expected to face generic competition in the U.S., as certain patent terms began to expire in May 2014.

Through our wholly owned subsidiary, we hold the exclusive worldwide license to issued U.S. Patents 8,658,627, 8,372,826 and 6,936,599 and pending patents for multiple sclerosis and other autoimmune diseases covering the uses of our drug candidate, Trimesta.

Cognitive Dysfunction in MS:

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 (oral estriol) drug candidate is also being developed for the treatment of cognitive dysfunction in female MS patients. This randomized, double-blind, placebo-controlled Phase II 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. Dr. Voskuhl 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 have 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.

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 MD&A section in our Annual Report on Form 10-K for the year ended December 31, 2013.

Recent Accounting Pronouncements and Developments

In May 2014, the Financial Accounting Standards Board issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosure pertaining to revenue recognition in both the interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. We are currently assessing the method of adoption and the expected impact the new standard has on its financial position and results of operations.

Results of Operations

Three Months Ended June 30, 2014 and 2013

General and Administrative Expenses

General and administrative expenses increased by 44% to $1.8 million for the three months ended June 30, 2014, from $1.3 million for the three months ended June 30, 2013. This increase is primarily the result of supplemental compensation granted by our Board of Directors to our executive officers and increased stock-based compensation expense. The charge relating to stock-based compensation expense was $645,000 for the three months ended June 30, 2014, compared to $298,000 for the three months ended June 30, 2013.

Research and Development Expenses

Research and development expenses increased by 136% to $2.8 million for the three months ended June 30, 2014, from $1.2 million for the three months ended June 30, 2013. This increase is primarily the result of increased program costs associated with expanded research, development and manufacturing activities in our anti-infective pipeline, including our *C. diff,* C-IBS and Pertussis programs. Research and development expenses also include a charge

relating to non-cash stock-based compensation expense of $210,000 for the three months ended June, 2014, compared to $109,000 for the three months ended June 30, 2013.

Other Income (Expense)

Other income was $95,000 for the three months ended June 30, 2014, compared to other expense of $36,000 for the three months ended June 30, 2013.

Net Loss

Our net loss was $4.6 million, or $0.08 per common share for the three months ended June 30, 2014, compared to a net loss of $2.5 million, or $0.06 per common share for the three months ended June 30, 2013.

Six Months Ended June 30, 2014 and 2013

General and Administrative Expenses

General and administrative expenses increased to $2.9 million for the six months ended June 30, 2014, from $2.4 million for the six months ended June 30, 2013. This increase of 23% is primarily the result of supplemental compensation granted by our Board of Directors to our executive officers and increased stock-based compensation expense. The charge relating to stock-based compensation expense was $899,000 for the six months ended June 30, 2014, compared to $652,000 for the six months ended June 30, 2013.

Research and Development Expenses

Research and development expenses increased to $5.6 million for the six months ended June 30, 2014, from $2.3 million for the six months ended June 30, 2013. This increase of 139% is primarily the result of increased program costs associated with expanded research, development and manufacturing activities in our anti-infective pipeline, including our *C. diff,* C-IBS and Pertussis programs. Research and development expenses also include a charge relating to non-cash stock-based compensation expense of $318,000 for the six months ended June, 2014, compared to $212,000 for the six months ended June 30, 2013.

Other Income (Expense)

Other income was $96,000 for the six months ended June 30, 2014, compared to other expense of $24,000 for the six months ended June 30, 2013.

Net Loss

Our net loss was $8.4 million, or $0.14 per common share for the six months ended June 30, 2014, compared to a net loss of $4.7 million, or $0.11 per common share for the six months ended June 30, 2013.

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 $7.8 million as of June 30, 2014, a decrease of $6.8 million from December 31, 2013. During the six months ended June 30, 2014, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $8.4 million for the six months ended June 30, 2014.

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 $89.7 million through June 30, 2014. 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, substantial amounts 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 involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

20

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.

Synthetic Biologics, Inc. is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

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, 2014 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, 2014, 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, 2013, which was filed with the Securities and Exchange Commission on March 31, 2014. There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2013, 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, 2014, our accumulated deficit totaled approximately $89.7 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 financing and such 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 cannot determine if or when we may generate any additional revenue from our sublicense with Meda AB due to recent developments in Europe.

On May 6, 2010, we entered into a sublicense agreement with Meda AB whereby we were given the right to receive certain milestone payments totaling $17.5 million (including an upfront payment of $2.5 million that was received in 2010), plus certain royalties on our flupirtine program. The successful achievement of the various milestones set forth in the sublicense agreement is not within our control and we are dependent upon Meda AB for achievement of such milestones. Meda AB has recently informed us that due to the decision of the European Medicines Agency (EMA) to limit the use of flupirtine for long-term pill and systemic use, it has postponed its planned fibromyalgia clinical trials in the U.S. Therefore, there can be no assurance given that the various milestones set forth in the sublicense agreement will be achieved by Meda AB, or that Meda AB will develop flupirtine for fibromyalgia in the U.S., Canada or Japan so that we could receive any additional milestone payments or royalties on sales in connection with the sublicense agreement. If the clinical trials do not recommence, we will not receive any additional milestone or royalty payments from the sublicense agreement with Meda AB.

RISKS RELATING TO OUR STOCK

We are substantially controlled by our current officers, directors and principal stockholder.

Currently, our directors, executive officers, and principal stockholder beneficially own a substantial number of shares of our common stock. As a result, they will be able to exert substantial influence over the election of our Board of Directors and the vote on issues submitted to our stockholders. Our executive officers and directors beneficially owned approximately 2.0 million shares of our common stock, including stock options exercisable within 60 days of August 1, 2014. Through Intrexon Corporation and NRM VII Holdings I, LLC, Randal J. Kirk indirectly, beneficially owns approximately 12.3 million shares of our common stock. Because our common stock has from time to time been “thinly traded”, the sale of a substantial number of shares by our executive officers, directors and principal stockholder would 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

None.

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 *

EX-101.INS XBRL Instance Document *

EX-101.SCH XBRL Taxonomy Extension Schema *

EX-101.CAL XBRL Taxonomy Extension Calculation Linkbase *

EX-101.DEF XBRL Taxonomy Extension Definition Linkbase *

EX-101.LAB XBRL Taxonomy Extension Label Linkbase *

EX-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 14, 2014

By: /s/ C. Evan Ballantyne
C. Evan Ballantyne
Chief Financial Officer
(Principal Financial Officer)
Date: August 14, 2014

GLOSSARY

Term	Definition
Adverse Event	Any adverse change in health or “side-effect” that occurs in a person participating in a clinical trial, from the time they consent to joining the trial until a pre-specified period of time after their treatment has been completed.
BLA - Biologics License Application	An application in the U.S. through which biologic sponsors formally propose that the FDA approve a new biologic for sale and marketing.
Clinical Study/Trial	A research study that is conducted to find out if a treatment or procedure is safe and/or effective in humans.
Controlled Clinical Trial	A clinical study that compares patients receiving a specific treatment to patients receiving an alternate treatment for the condition of interest. The alternate treatment may be another active treatment, standard of care for the condition and/or a placebo (inactive) treatment.
Double-blinded Study/Trial	Both the participant and the researcher are unaware of who is receiving the active treatment or the placebo.
FDA - Food & Drug Administration	The U.S. government agency that ensures that medicines, medical devices, prescription medical foods and radiation-emitting consumer products are safe and effective. Authorized by Congress to enforce the Federal Food, Drug, and Cosmetic Act and several other public health laws, the agency monitors the manufacture, import, transport, storage, and sale of $1 trillion worth of goods annually.
GMP - Good Manufacturing Practice	Regulations that require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are consistently produced, pure, and stable. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors.
Monoclonal Antibodies (mAbs)	Acting as the body's army, 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.
IND - Investigational New Drug	An application in the U.S. submitted to the FDA for a new drug or biologic that, if allowed, will be used in a clinical trial.
IRB - Institutional Review Board	A committee designated to formally approve, monitor, and review biomedical research at an institution involving human studies. Institutional Review Boards aim to protect the rights and welfare of the research subjects.
NDA - New Drug Application	An application in the U.S. through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing.

Open-label Clinical Study/Trial	A trial in which both the treating physician and the patient know they are receiving the experimental treatment.
Phase I Clinical Trial	A Phase I trial represents an initial study in a small group of patients to primarily test for safety.
Phase II Clinical Trial	A Phase II trial represents a study in a larger number of patients to assess the safety and efficacy of a product.
Phase III Clinical Trial	Phase III trials are initiated to establish safety and efficacy in an expanded patient population and at multiple clinical trial sites and are generally larger than trials in earlier phases of development.

Placebo	An inactive pill or liquid. Many studies compare an active drug to a placebo to determine whether any changes seen during the study can be attributed to the active drug.
Principal Investigator	This is the study director who is ultimately responsible for the conduct of the study.
Prospective Clinical Study/Trial	A clinical study/trial in which participants are identified and then followed throughout the study going forward in time.
Protocol	A clinical study/trial's plan - includes the schedule of tests, requirements for participation, procedures, and medications.
Randomized Study/Trial	Participants in a study are assigned by chance to either one or more of the active treatment group(s) or the placebo group.
Single-blinded Study/Trial	One party, either the participant or the researcher, does not know if the participant is taking the active treatment or the placebo.
Study/Trial Coordinator	Staff member who is often the primary contact for research participants and coordinates their care and evaluations throughout the study.