

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark One)

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

**FOR THE QUARTERLY PERIOD ENDED: MARCH 31, 2014**

**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: 333-131722

**SYNERGY PHARMACEUTICALS INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

33-0505269

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

420 Lexington Avenue, Suite 2012, New York, New York 10170

(Address of principal executive offices) (Zip Code)

(212) 297-0020

(Registrant's telephone number)

(Former Name, Former Address and Former Fiscal Year, if changed since last report)

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 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  No

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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The number of the registrant's shares of common stock outstanding was 93,699,913 as of May 9, 2014.

---

---

**SYNERGY PHARMACEUTICALS INC.**  
(A development stage company)

**FORM 10-Q**

**TABLE OF CONTENTS**

	<u>Page</u>
<b><u>PART I—FINANCIAL INFORMATION</u></b>	4
<b><u>Item 1.</u></b> <u>Financial Statements</u>	4
<u>Condensed Consolidated Balance Sheets as of March 31, 2014 (unaudited) and December 31, 2013</u>	4
<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2014 and</u>	
<u>2013(unaudited) and the period November 15, 2005 (Inception) to March 31, 2014 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Changes in Stockholders' Equity/(Deficit) for the period November 15,</u>	
<u>2005 (Inception) to March 31, 2014 (period from January 1 to March 31, 2014 is unaudited)</u>	6
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2014 and 2013</u>	
<u>(unaudited) and for the period November 15, 2005 (Inception) to March 31, 2014 (unaudited)</u>	7
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	8
<b><u>Item 2.</u></b> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<b><u>Item 3.</u></b> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	19
<b><u>Item 4.</u></b> <u>Controls and Procedures</u>	19
<b><u>PART II—OTHER INFORMATION</u></b>	19
<b><u>Item 1.</u></b> <u>Legal Proceedings</u>	19
<b><u>Item 6.</u></b> <u>Exhibits</u>	20
<b><u>SIGNATURES</u></b>	

[Table of Contents](#)

**NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q for Synergy Pharmaceuticals Inc. may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such forward-looking statements are characterized by future or conditional verbs such as “may,” “will,” “expect,” “intend,” “anticipate,” “believe,” “estimate” and “continue” or similar words. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. Such statements are only predictions and our actual results may differ materially from those anticipated in these forward-looking statements. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Factors that may cause such differences include, but are not limited to, those discussed under Item 1A. Risk Factors and elsewhere in our Form 10-K for the year ended December 31, 2013, as filed with the Securities and Exchange Commission on March 17, 2014. These factors include the uncertainties associated with product development, the risk that products that appeared promising in early clinical trials do not demonstrate safety and efficacy in larger-scale clinical trials, the risk that we will not obtain approval to market our products, the risks associated with dependence upon key personnel and the need for additional financing. We do not assume any obligation to update forward-looking statements as circumstances change and thus you should not unduly rely on these statements.

[Table of Contents](#)

**PART I—FINANCIAL INFORMATION**

**Item 1.      Financial Statements**

**SYNERGY PHARMACEUTICALS INC.**  
(A development stage company)

**CONDENSED CONSOLIDATED BALANCE SHEETS**

(In thousands, except share amounts)

	<u>March 31, 2014</u> (unaudited)	<u>December 31, 2013</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 20,635	\$ 18,130
Available-for-sale securities	50,003	50,027
Prepaid expenses and other current assets	5,578	3,718
Total Current Assets	76,216	71,875
Property and equipment, net	589	589
Security deposits	94	94
Total Assets	<u>\$ 76,899</u>	<u>\$ 72,558</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 9,931	\$ 13,542
Accrued expenses	2,663	2,134
Total Current Liabilities	12,594	15,676
Derivative financial instruments, at estimated fair value-warrants	1,311	1,534
Total Liabilities	<u>13,905</u>	<u>17,210</u>
Stockholders' Equity:		
Preferred stock, Authorized 20,000,000 shares, at March 31, 2014 and December 31, 2013, none outstanding	—	—
Common stock, par value of \$.0001 authorized 200,000,000 shares at March 31, 2014 and 200,000,000 shares at December 31, 2013. Issued and outstanding 94,064,506 and 90,182,115 shares at March 31, 2014 and December 31, 2013 respectively.	10	10
Additional paid-in capital	250,386	226,515
Deficit accumulated during development stage	<u>(187,402)</u>	<u>(171,177)</u>
Total Stockholders' Equity	<u>62,994</u>	<u>55,348</u>
Total Liabilities and Stockholders' Equity	<u>\$ 76,899</u>	<u>\$ 72,558</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

[Table of Contents](#)

**SYNERGY PHARMACEUTICALS INC.**  
(A development stage company)

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended March 31,		November 15, 2005 (inception) to March 31, 2014
	2014	2013	
Revenues	\$ —	\$ —	\$ —
Costs and Expenses:			
Research and development	13,299	14,344	121,636
Purchased in-process research and development	—	—	29,157
General and administrative	3,178	3,278	42,444
Loss from Operations	<u>(16,477)</u>	<u>(17,622)</u>	<u>(193,237)</u>
Other Income/(Loss)			
Interest and investment income	58	18	613
Other income/(expense)	(29)	—	1,301
Change in fair value of derivative instruments-warrants	223	(1,093)	3,993
Total Other Income/(loss)	<u>252</u>	<u>(1,075)</u>	<u>5,907</u>
Loss from Continuing Operations	(16,225)	(18,697)	(187,330)

Loss from Discontinued Operations	—	—	(72)
Net Loss	\$ (16,225)	\$ (18,697)	\$ (187,402)
<i>Weighted Average Common Shares Outstanding</i>			
Basic and Diluted	92,056,124	72,789,006	
<i>Net Loss per Common Share, Basic and Diluted</i>			
Net Loss per Common Share, Basic and Diluted	\$ (0.18)	\$ (0.26)	

The accompanying notes are an integral part of these condensed consolidated financial statements.

[Table of Contents](#)

**SYNERGY PHARMACEUTICALS INC.**  
(A development stage company)

**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**

(In thousands, except share amounts)

	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Non-Controlling Interest	Total Stockholders' Equity (Deficit)
Balance at inception, November 15, 2005	—	\$ —	\$ —	\$ —	\$ —	\$ —
Sale of unregistered common stock to founder	75,690,608	7	(5)	—	—	2
Sale of common stock	6,850,000	1	17	—	—	18
Net loss for the year	—	—	—	—	—	—
Balance, December 31, 2005	82,540,608	8	12	—	—	20
Net loss for the year	—	—	—	(20)	—	(20)
Balance, December 31, 2006	82,540,608	8	12	(20)	—	—
Capital contribution by shareholders	—	—	9	—	—	9
Net loss for the year	—	—	—	(20)	—	(20)
Balance, December 31, 2007	82,540,608	8	21	(40)	—	(11)
Cancellation of unregistered founder shares	(74,990,604)	(7)	7	—	—	—
Common stock issued via Exchange Transaction	22,732,380	3	27,277	—	—	27,280
Common stock issued via private placement—	2,520,833	—	3,025	—	—	3,025
Fees and expenses related to private placements	—	—	(73)	—	—	(73)
Stock based compensation expense	—	—	380	—	—	380
Net loss for the period	—	—	—	(31,757)	—	(31,757)
Balance, December 31, 2008	32,803,217	4	30,637	(31,797)	—	(1,156)
Common stock issued via private placements	11,407,213	1	15,969	—	—	15,970
Fees and expenses related to private placements	—	—	(260)	—	—	(260)
Common Stocks Issued for services rendered	1,250	—	2	—	—	2
Stock based compensation expense	—	—	1,052	—	—	1,052
Net loss for the period	—	—	—	(8,124)	—	(8,124)
Balance, December 31, 2009	44,211,680	5	47,400	(39,921)	—	7,484
Common stock issued via registered direct offering and private placement	1,209,000	—	7,179	—	—	7,179
Fees and expenses related to direct offering	—	—	(468)	—	—	(468)
Warrants reclassified to derivative liability	—	—	(3,785)	—	—	(3,785)
Common stock issued to extend lock-up	—	—	—	—	—	—

agreements related to unregistered shares	670,933	—	—	—	—	—
Common stock Issued for services rendered	2,469	—	18	—	—	18
Stock based compensation expense	—	—	694	—	—	694
Net loss for the period	—	—	—	(15,221)	—	(15,221)
Balance, December 31, 2010	46,094,082	5	51,038	(55,142)	—	(4,099)
Common stock issued via registered direct offerings and private placements	7,733,093	1	34,368	—	—	34,369
Fees and expenses related to financing transactions — paid in cash	—	—	(2,148)	—	—	(2,148)
Fees and expenses related to financing transactions — paid in units of common stock and warrants	77,750	—	—	—	—	—
Warrants classified to derivative liability - net	—	—	(5,094)	—	—	(5,094)
Common stock issued to make whole certain unregistered shares	215,981	—	—	—	—	—
Exercise of warrant	80,000	—	415	—	—	415
Common stock issued for services rendered	79,000	—	341	—	—	341
Stock based compensation expense	—	—	481	—	—	481
Net loss for the period	—	—	—	(14,467)	—	(14,467)
Balance, December 31, 2011	54,279,906	6	79,401	(69,609)	—	9,798
Common stock issued via registered direct offering	12,315,654	1	55,861	—	—	55,862
Fees and expenses related to financing transactions — paid in cash	—	—	(3,774)	—	—	(3,774)
Common stock issued for services rendered	26,272	—	93	—	—	93
Stock based compensation expense	—	—	2,297	—	—	2,297
Net loss for the period	—	—	—	(39,444)	—	(39,444)
Balance, December 31, 2012	66,621,832	7	133,878	(109,053)	—	24,832
Common stock issued via registered direct offering	17,133,093	2	94,732	—	—	94,734
Fees and expenses related to financing transactions	—	—	(5,623)	—	—	(5,623)
Cancellation of unregistered shares owned by former controlling shareholder (Callisto)	(22,294,976)	(2)	2	—	—	—
Common stock issued to former Callisto shareholders	28,605,379	3	(3)	—	—	—
Fair value of warrants reclassified to additional paid in capital	—	—	3,575	—	—	3,575
Recapitalization of Synergy	—	—	(4,904)	—	—	(4,904)
Common stock issued for services rendered	55,000	—	250	—	—	250
Exercise of stock options	61,787	—	119	—	—	119
Stock based compensation expense	—	—	4,489	—	—	4,489
Net loss for the period	—	—	—	(62,124)	—	(62,124)
Balance, December 31, 2013	90,182,115	10	226,515	(171,177)	—	55,348
Period ended 3/31/2014 is unaudited						
Common stock issued pursuant to a controlled equity “at-the-market” sales agreement	3,872,392	—	22,606	—	—	22,606
Fees and expenses related to controlled equity sales	—	—	(624)	—	—	(624)
Stock based compensation expense	—	—	1,264	—	—	1,264
Exercise of stock options	9,999	—	36	—	—	36
Private placement of ContraVir common stock	—	—	3,224	—	—	3,224
Fees and expenses associated with ContraVir Private Placement	—	—	(15)	—	—	(15)
Fair value of warrants issued in connection with ContraVir private placement	—	—	(880)	—	—	(880)
Noncontrolling interest of ContraVir	—	—	—	—	(1,622)	(1,622)

Distribution of ContraVir common stock to Synergy shareholders	—	—	(1,740)	—	—	(1,740)
Elimination of noncontrolling interest of ContraVir upon distribution	—	—	—	—	1,622	1,622
Net loss for the period	—	—	—	(16,225)	—	(16,225)
Balance, March 31, 2014 (unaudited)	<u>94,064,506</u>	<u>\$ 10</u>	<u>\$ 250,386</u>	<u>\$ (187,402)</u>	<u>\$ —</u>	<u>\$ 62,994</u>

The accompanying notes are an integral part of these consolidated financial statements.

[Table of Contents](#)

**SYNERGY PHARMACEUTICALS INC.**  
(A development stage company)  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Unaudited)  
(In thousands)

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2013	Period from November 15, 2005 (Inception) to March 31, 2014
<b>Cash Flows From Operating Activities:</b>			
Net loss	\$ (16,225)	\$ (18,697)	\$ (187,402)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	28	—	94
Loss on disposal of property and equipment	—	—	2
Stock-based compensation expense	1,264	1,257	11,362
Accretion of discount/premium on investment securities	24	37	(3)
Purchased in-process research and development	—	—	28,157
Change in fair value of derivative instruments-warrants	(223)	1,093	(3,993)
Distribution of non-cash items	84	—	84
Changes in operating assets and liabilities:			
Security deposit	—	—	(20)
Accounts payable and accrued expenses	(3,011)	700	10,540
Prepaid expenses and other current assets	(1,860)	(27)	(5,578)
Total Adjustments	<u>(3,694)</u>	<u>3,060</u>	<u>40,645</u>
Net Cash Used in Operating Activities	(19,919)	(15,637)	(146,757)
<b>Cash Flows From Investing Activities:</b>			
Net cash paid on Exchange Transaction	—	—	(155)
Loans to related parties	—	(270)	(3,576)
Sale/(purchases) of available-for-sale securities	—	8,000	(50,000)
Additions to property and equipment	(28)	(78)	(685)
Repayment on ContraVir loan receivable	455	—	455
Net Cash (Used in)/Provided by Investing Activities	427	7,652	(53,961)
<b>Cash Flows From Financing Activities:</b>			
Issuance of common stock pursuant to controlled equity sales agreement	22,606	4,671	233,774
Issuance of common stock of ContraVir	3,224	—	3,224
Fees and expenses-combined	(639)	(140)	(12,985)
Proceeds from exercise of stock warrants	—	—	415
Proceeds from exercise of stock options	36	105	155
Distribution associated with ContraVir Spinoff	(3,230)	—	(3,230)
Net Cash Provided by Financing Activities	<u>21,997</u>	<u>4,636</u>	<u>221,353</u>
Net increase/(decrease) in cash and cash equivalents	2,505	(3,349)	20,635
Cash and cash equivalents at beginning of period	18,130	12,416	—
Cash and cash equivalents at end of period	<u>\$ 20,635</u>	<u>\$ 9,067</u>	<u>\$ 20,635</u>
<b>Supplementary disclosure of cash flow information:</b>			
Cash paid for taxes	\$ 30	\$ 18	\$ 251
<b>Supplementary disclosure of non-cash investing and financing activities:</b>			
Value of warrants classified as derivative liability-net	\$ 0	\$ —	\$ 5,304
Value of common stock issued to induce stockholders to extend lock-up agreements	\$ —	\$ —	\$ 3,235

The accompanying notes are an integral part of these condensed consolidated financial statements.

[Table of Contents](#)

**SYNERGY PHARMACEUTICALS INC.**  
**(A development stage company)**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Business Overview**

Synergy Pharmaceuticals Inc. (“Synergy” or the “Company”) is a biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. Its lead product candidate is plecanatide (formerly called SP-304), a guanylyl cyclase C, or GC-C, receptor agonist, to treat GI disorders, primarily chronic idiopathic constipation, or CIC, and constipation-predominant irritable bowel syndrome, or IBS-C. CIC and IBS-C are functional gastrointestinal disorders that afflict millions of sufferers worldwide. CIC is primarily characterized by constipation symptoms but a majority of these patients report experiencing bloating and abdominal discomfort as among their most bothersome symptoms. IBS-C is characterized by frequent and recurring abdominal pain and/or discomfort associated with chronic constipation. Synergy is also developing SP-333, its second generation GC-C receptor agonist for the treatment of gastrointestinal inflammatory diseases, such as ulcerative colitis, or UC.

**2. Basis of Presentation**

These unaudited condensed consolidated financial statements include Synergy and its wholly-owned subsidiaries: (1) Synergy Advanced Pharmaceuticals, Inc. and (2) IgX, Ltd (Ireland—inactive). These unaudited condensed consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission (“SEC”) and United States generally accepted accounting principles (“GAAP”) for interim reporting. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, which include only normal recurring adjustments, necessary to present fairly Synergy’s interim financial information. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2013 contained in the Company’s Annual Report on Form 10-K filed with the Securities Exchange Commission (“SEC”) on March 17, 2014. All intercompany balances and transactions have been eliminated.

On February 18, 2014, Synergy completed the distribution of ContraVir common stock (its previous wholly-owned subsidiary), to the Company’s stockholders on a pro rata basis with a stock dividend of .0986 ContraVir shares for each Synergy common stock share held as of the record date of February 6, 2014. Synergy accounted for this distribution according to FASB ASC Topic 505-60, *Spinoffs and reverse spinoffs* by eliminating ContraVir’s net assets of approximately \$1.7 million, with a corresponding decrease in additional paid in capital and eliminating the non-controlling interest of \$1.6 million. The spin-off of ContraVir’s operation had an immaterial effect on Synergy’s financial statements.

**3. Recent Accounting Pronouncements**

There are no recent accounting pronouncements affecting the Company.

**4. Fair Value of Financial Instruments**

Financial instruments consist of cash and cash equivalents, available-for-sale securities, accounts payable, and derivative instruments. These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short term nature, except available-for-sale securities and derivative instruments which are marked to market at the end of each reporting period.

**5. Cash, Cash Equivalents and Marketable Securities**

All highly liquid investments with maturities of three months or less at the date of purchase are classified as cash equivalents. As of March 31, 2014, the amount of cash and cash equivalents was approximately \$20.6 million and consists of checking accounts and short-term money market funds held at U.S. commercial banks. As of December 31, 2013, the amount of cash and cash equivalents was approximately \$18.1 million and consisted of checking accounts and short-term money market funds with U.S. commercial banks. At any point in time, the Company’s balance of cash and cash equivalents may exceed federally insured limits.

The Company’s marketable securities as of March 31, 2014 and December 31, 2013 consist of approximately \$50 million in U.S. Treasury securities with maturities of less than one year and have been classified and accounted for as available-for-sale. Management determines the appropriate classification of its investments at the time of purchase and reevaluates the available-for-sale designations as of each balance sheet date. As of March 31, 2014, gross unrealized losses were not material. The Company recognized no net realized gains or losses for the three months ended March 31, 2014. The Company considers the declines in market value of its marketable securities investment portfolio to be

[Table of Contents](#)

temporary in nature. Fair values were determined for each individual security in the investment portfolio. When evaluating the investments for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, and the Company's intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment's amortized cost basis. During the three months ended March 31, 2014 and the year ended December 31, 2013, the Company did not recognize any impairment charges. As of March 31, 2014 and December 31, 2013, the Company did not consider any of its investments to be other-than-temporarily impaired.

## 6. Accounting for Shared-Based Payments

### Stock Options

ASC Topic 718 "Compensation—Stock Compensation" requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. ASC Topic 718 did not change the way Synergy accounts for non-employee stock-based compensation. Synergy continues to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 "Equity -Based Payment to Non-Employees" and accordingly the value of the stock compensation to non-employees is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly the fair value of these options is being "marked to market" quarterly until the measurement date is determined.

ASC Topic 718 requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to Synergy's accumulated deficit position, no excess tax benefits have been recognized. Synergy accounts for common stock, stock options, and warrants granted to employees and non-employees based on the fair market value of the instrument, using the Black-Scholes option pricing model based on assumptions for expected stock price volatility, term of the option, risk-free interest rate and expected dividend yield, at the grant date.

Synergy adopted the 2008 Equity Compensation Incentive Plan (the "Plan") during the quarter ended September 30, 2008. Stock options granted under the Plan typically vest after three years of continuous service from the grant date and have a contractual term of ten years. On January 17, 2013, Synergy amended its 2008 Equity Compensation Incentive Plan and increased the number of shares of its common stock reserved for issuance under the Plan from 7,500,000 to 15,000,000.

Stock-based compensation has been recognized in operating results as follow:

(\$ in thousands)	Three Months Ended March 31,		November 15, 2005 (inception) to March 31, 2014
	2014	2013	
Employees—including in research and development	\$ 426	\$ 276	\$ 3,346
Employees—including in general and administrative	396	450	3,337
Subtotal employee stock based compensation	822	726	6,683
Non-employees—including in research and development	6	135	448
Non-employees—including in general and administrative	436	396	4,231
Subtotal non-employee stock based compensation	442	531	4,679
Total stock-based compensation expense	\$ 1,264	\$ 1,257	\$ 11,362

The unrecognized compensation cost related to non-vested stock options outstanding at March 31, 2014, net of expected forfeitures, was approximately \$8 million to be recognized over a weighted-average remaining vesting period of approximately 1.5 years. This unrecognized compensation cost does not include amounts related to 4,364,000 shares of stock options which vest upon a change of control.

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the periods indicated.

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2013
Risk-free interest rate	1.94%-2.52%	0.04%-1.87%
Dividend yield	—	—
Expected volatility	60%	60%
Expected term (in years)	6-9.3 years	6 years

A summary of stock option activity and of changes in stock options outstanding under the Plan is presented below:



[Table of Contents](#)

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value (in thousands)	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2013(1)	11,324,049	\$ 0.44-20.01	\$ 3.31	\$ 37,521	6.94 years
Granted	350,000	\$ 5.97	\$ 5.97		
Exercised	(9,999)	\$ 3.40-3.95	\$ 3.58		
Forfeited	(17,990)	\$ 20.01	\$ 20.01		
Balance outstanding, March 31, 2014(1)	11,646,060	\$ 0.44 - 17.79	\$ 3.37	\$ 39,215	6.8 years
Exercisable, at March 31, 2014	5,157,125	\$ 0.44 - 17.79	\$ 2.98	\$ 15,367	5.89 years

(1) Number of shares represented above includes contingent vesting shares upon change of control. The Fair Value at the date of grant was approximately \$28,918,822 determined using the Black-Scholes option valuation model assumptions discussed above. No stock based compensation expense associated with these options was recognized since the grant date.

## 7. Stockholders' Equity

From January 1, 2014 through February 27, 2014, Synergy sold 3,644,143 shares of common stock for gross proceeds of approximately \$21.2 million, at an average selling price of \$5.82 per share. This completed the \$30 million of proposed sales of common stock pursuant to the June 2012 Controlled Equity Offering sales agreement, dated June 21, 2012.

On March 5, 2014, Synergy entered into Amendment No. 1 (the "Amendment") to its Controlled Equity Offering Sales Agreement, dated June 21, 2012 (as amended, the "Agreement"), with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which the Company may offer and sell, from time to time, through Cantor shares of the Company's common stock, par value \$0.0001 per share (the "Shares"), up to an additional aggregate offering price of \$50.0 million. The Company intends to use the net proceeds of this offering to fund its research and development activities, including further clinical development of plecanatide and SP-333, and for working capital and other general corporate purposes, and possible acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated.

Under the Agreement, Cantor may sell the Shares by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on The NASDAQ Global Select Market, on any other existing trading market for the Shares or to or through a market maker. In addition, under the Agreement, Cantor may sell the Shares by any other method permitted by law, including in privately negotiated transactions. Subject to the terms and conditions of the Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The NASDAQ Global Select Market, to sell the Shares from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose).

The Company is not obligated to make any sales of the Shares under the Agreement. The offering of Shares pursuant to the Agreement will terminate upon the earlier of (1) the sale of all of the Shares subject to the Agreement or (2) the termination of the Agreement by Cantor or the Company. The Company will pay Cantor a commission of up to 3.0% of the gross sales price per share sold and has agreed to provide Cantor with customary indemnification and contribution rights.

From March 5, 2014 through March 31, 2014, Synergy sold 228,249 shares of common stock for gross proceeds of \$1.4 million, at an average selling price of \$6.08 per share, under the Amendment. Selling agent fees related to above financings from January 1, 2014 through March 31, 2014 totalled approximately \$0.6 million.

Proceeds from exercise of stock options were \$36,000 from January 1, 2014 through March 31, 2014.

### *ContraVir*

#### *Loan and Security Agreement*

On June 5, 2013, ContraVir entered into a Loan and Security Agreement with Synergy pursuant to which Synergy agreed to lend ContraVir up to five hundred thousand dollars (\$500,000) for working capital purposes (the "Loan Agreement"). Also on June 5, 2013, August 29, 2013, October 18, 2013 and January 9, 2014, pursuant to the Loan Agreement, Synergy made an advance to ContraVir of \$100,000, \$100,000, \$150,000 and \$100,000, respectively, under a promissory note (the "Note"). The Note bears interest at six percent (6%) per annum and such interest shall be paid on the 15th of each of January, March, June and September, beginning September 15, 2013. The Note matures on the earlier of June 10, 2014 or the date that the entire principal amount and interest shall become due and payable by reason of an event of default under the Note or otherwise. In addition, Synergy has the right to demand payment of the unpaid principal amount and all accrued but unpaid interest thereon at any time after August 4, 2013, upon providing us fifteen (15) days prior written notice. In connection with the Loan Agreement ContraVir granted Synergy a security interest in all of its assets, including its intellectual property, until the Note is repaid in full. On November 18, 2013, ContraVir entered into an amendment to the Loan Agreement with Synergy pursuant to which Synergy agreed to increase the aggregate amount available to ContraVir under the Loan Agreement from five hundred thousand dollars (\$500,000) to one million dollars.

[Table of Contents](#)

(\$1,000,000). On March 27, 2014, ContraVir paid \$461,236 to Synergy in full repayment of the advance, including accrued but unpaid interest thereon.

#### Shared Services Agreement

On July 8, 2013, ContraVir entered into a Shared Services Agreement, as amended and restated August 5, 2013, with Synergy, effective May 16, 2013. Under the Shared Services Agreement, Synergy has provided and/or made available to ContraVir various administrative, financial (accounting), insurance, facility, information technology, and other services to be provided by, or on behalf of, Synergy, together with such other services as reasonably requested by ContraVir. In consideration for such services, ContraVir paid fees to Synergy for the services provided, and those fees will generally be in amounts intended to allow the party providing services to recover all of its direct and indirect costs incurred in providing those services. The personnel performing services under the Shared Services Agreement are employees and/or independent contractors of Synergy and are not under our direction or control. These personnel costs are based upon the actual percentages of time spent by Synergy personnel performing services for ContraVir under the Shared Services Agreement. ContraVir will also reimburse Synergy for direct out-of-pocket costs incurred by Synergy for third party services provided to ContraVir. Effective April 1, 2014, Synergy terminated the shared services agreement with ContraVir.

#### Private Placement

On February 4, 2014, ContraVir entered into a securities purchase agreement with accredited investors to sell securities and raise gross proceeds of approximately \$3.2 million in a private placement and incurred expenses of \$15,000 related to this placement. ContraVir sold 9,485,294 units to the investors with each unit consisting of one share of ContraVir's common stock and one warrant to purchase an additional one half share of ContraVir's common stock. The purchase price paid by the investors was \$0.34 for each unit. The 4.7 million warrants expire after six years and are exercisable at \$0.37 per share. Based upon the ContraVir's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" ContraVir recorded approximately \$0.88 million of derivative liability on the warrants issued in connection with this transaction.

#### Spin-off

On February 18, 2014, Synergy completed the distribution of the ContraVir common stock (its previous wholly-owned subsidiary) to Synergy's stockholders on a pro rata basis with a stock dividend of .0986 ContraVir shares for each Synergy common stock share held as of the record date of February 6, 2014.

Synergy accounted for this distribution according to FASB ASC Topic 505-60, *Spinoffs and reverse spinoffs* by eliminating ContraVir's net assets of approximately \$1.7 million, with a corresponding decrease in additional paid in capital and the non-controlling interest of \$1.6 million.

Net assets of ContraVir eliminated in connection with this spin-off was as follows:

(\$ in thousands)	Balance February 18, 2014 (unaudited)
Assets	
Cash	\$ 3,230
Prepaid expense	6
Total assets	3,236
Accounts payable and other liabilities	(107)
Note Payable to Synergy	(455)
Due to Synergy	(54)
Derivative financial instruments, at estimated fair value-warrants	(880)
Total Liabilities	(1,496)
Net assets	\$ 1,740

As a result of the ContraVir distribution, an adjustment was made to the exercise price of all outstanding Synergy warrants in accordance with their terms. Accordingly the exercise price decreased approximately \$0.011 per share on the record date. As of March 31, 2014, there were 5,647,203 warrants outstanding with a weighted average exercise price of \$5.37 per share pre-distribution and \$5.359 per share as adjusted. The spin-off of ContraVir's operation had an immaterial effect on Synergy's financial statements.

## 8. Research and Development Expense

Research and development costs include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, regulatory and

[Table of Contents](#)

scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring, and clinical insurance.

In accordance with FASB ASC Topic 730-10-55, *Research and Development*, Synergy recorded prepaid research and development costs of approximately \$5.1 million and \$3.6 million as of March 31, 2014 and December 31, 2013, respectively, for nonrefundable pre-payments for production of drug substance and analytical testing services for its drug candidates. In accordance with this guidance, Synergy expenses these costs when drug compound is delivered and services are performed.

**9. Derivative Financial Instruments**

*Synergy Derivative Financial Instruments*

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, “Derivatives and Hedging: Contracts in Entity’s Own Equity” (“ASC Topic 815-40”). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity’s own stock, which would qualify as a scope exception under ASC Topic 815-10.

Based upon the Company’s analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that certain warrants issued in connection with sale of its common stock must be classified as derivative instruments. In accordance with ASC Topic 815-40, these warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company’s statement of operations. The Company estimates the fair value of certain warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability and change in fair value described above. The range of assumptions used to determine the fair value of the warrants at each period end were:

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2013
Fair value of Synergy common stock	\$ 5.31	\$ 6.07
Expected warrant term	1.25 — 3.9 years	2.25 — 4.9 years
Risk-free interest rate	0.13%-1.32%	0.31% - 0.77%
Expected volatility	60%	60%
Dividend yield	—	—

Fair value of stock is the closing market price of the Company’s common stock on the date of warrant issuance and at the end of each reporting period when the derivative instruments are marked to market. Expected volatility is a management estimate of future volatility, over the expected warrant term, based on historical volatility of Synergy’s common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants at the date of grant or quarterly revaluation.

As of March 31, 2014, Synergy does not have any outstanding warrants which contained terms that require the use of a binomial model to determine fair value. The range of assumptions in the binomial model used to determine the fair value of certain warrants at the dates indicated was as follows:

	Three months ended March 31, 2013
Fair value of Synergy common stock	\$ 3.28- 6.07
Expected warrant term	3.63 years
Risk-free interest rate	0.36%
Expected volatility	60%
Dividend yield	0%

Fair value of stock is the closing market price of the Company’s common stock on the date of warrant issuance and end of each reporting period the derivative instruments are marked to market. Expected volatility is based on historical volatility of Synergy’s common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants at the date of grant or quarterly revaluation.

The following table sets forth the components of changes in the Synergy’s outstanding warrants which were deemed derivative financial instruments and the associated liability balance for the periods indicated:

[Table of Contents](#)

Date	Description	Warrants	Derivative Instrument Liability (\$ in thousands)
------	-------------	----------	--

12/31/2012	Balance of derivative financial instruments liability	2,265,160	\$	5,258
3/31/2013	Change in fair value of warrants during the quarter	—		1,093
3/31/2013	Balance of derivative financial instruments liability	2,265,160		6,351
6/30/2013	Fair value of new warrants issued during the quarter	—		—
6/30/2013	Reclassification of derivative liability to equity during the quarter	(1,406,691)		(3,575)
6/30/2013	Change in fair value of warrants during the quarter	—		(1,803)
6/30/2013	Balance of derivative financial instruments liability	858,469		973
9/30/2013	Fair value of new warrants issued during the quarter	—		—
9/30/2013	Change in fair value of warrants during the quarter	—		77
9/30/2013	Balance of derivative financial instruments liability	858,469		1,050
12/31/2013	Fair value of new warrants issued during the quarter	—		—
12/31/2013	Change in fair value of warrants during the quarter	—		484
12/31/2013	Balance of derivative financial instruments liability	858,469		1,534
3/31/2014	Fair value of new warrants issued during the quarter	—		—
3/31/2014	Change in fair value of warrants during the quarter	—		(223)
3/31/2014	Balance of derivative financial instruments liability	858,469	\$	1,311

### Synergy Fair Value Measurements

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2013 and March 31, 2014:

(\$ in thousands)

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)			Balance as of December 31, 2013	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)			Balance as of March 31, 2014
	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)			
Derivative liabilities related to Warrants	\$ —	\$ —	\$ 1,534	\$ 1,534	\$ —	\$ —	\$ 1,311	\$ 1,311

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the three months ended March 31, 2014:

Description	Balance at December 31, 2013	Fair Value of warrants upon issuance	(Gain) or loss recognized in earning from Change in Fair Value	Balance as of March 31, 2014
Derivative liabilities related to Warrants	\$ 1,534	\$ —	\$ (223)	\$ 1,311

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, Synergy reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

On January 28, 2014, the Synergy Board of Directors declared a stock dividend of .0986 ContraVir shares for each share of Synergy common stock held as of the record date of February 6, 2014, which was distributed on February 18, 2014. As a result of the distribution, an adjustment was made to the exercise price of all outstanding warrants in accordance with their terms and accordingly the exercise price decreased approximately \$0.011 per share on the record date and was reflected in the fair value calculation of the warrants. As of March 31, 2014 there were 5,647,203 warrants outstanding with a weighted average exercise price of \$5.37 per share pre-Distribution and \$5.359 per share as adjusted.

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, *Earnings per Share*, (“ASC Topic 260”) for all periods presented. In accordance with ASC Topic 260, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares because shares issuable pursuant to the exercise of stock options would be antidilutive. For the three months ended March 31, 2014 and March 31, 2013 the effect of 11,646,060 and 10,449,232, respectively outstanding stock options were excluded from the calculation of diluted loss per share because the effect was antidilutive. For the three months ended March 31, 2014 and March 31, 2013, the effect of 5,647,203 outstanding warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive.

---

[Table of Contents](#)

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and other financial information appearing elsewhere in this quarterly report. In addition to historical information, the following discussion and other parts of this quarterly report contain forward-looking statements. You can identify these statements by forward-looking words such as “plan,” “may,” “will,” “expect,” “intend,” “anticipate,” “believe,” “estimate” and “continue” or similar words. Forward-looking statements include information concerning possible or assumed future business success or financial results. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Accordingly, we do not undertake any obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future and thus you should not unduly rely on these statements.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under “Risk Factors” in our Annual Report on Form 10-K as of and for the year ended December 31, 2013 and other periodic reports filed with the United States Securities and Exchange Commission (“SEC”), on March 17, 2014. Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of the Company, please be advised that the Company’s actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements and thus you should not unduly rely on these statements.

### Business Overview

We are a biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. Our lead product candidate is plecanatide (formerly called SP-304), a guanylyl cyclase C, or GC-C, receptor agonist, to treat GI disorders, primarily chronic idiopathic constipation, or CIC, and constipation-predominant irritable bowel syndrome, or IBS-C. CIC and IBS-C are functional gastrointestinal disorders that afflict millions of sufferers worldwide. CIC is primarily characterized by constipation symptoms but a majority of these patients report experiencing bloating and abdominal discomfort as among their most bothersome symptoms. IBS-C is characterized by frequent and recurring abdominal pain and/or discomfort associated with chronic constipation. Synergy is also developing SP-333, its second generation GC-C receptor agonist for the treatment of gastrointestinal inflammatory diseases, such as ulcerative colitis, or UC.

### Recent Developments

On April 28, 2014, we started our second pivotal phase 3 clinical trial to confirm the safety and efficacy of plecanatide, our lead uroguanylin analog and once-daily oral treatment, in adult patients with chronic idiopathic constipation (CIC). This phase 3 trial is a randomized, double-blind clinical trial to compare a 12-week, dose-ranging regimen of plecanatide (3.0 and 6.0mg) against placebo in adult patients with CIC. The study will be conducted at approximately 180 sites in the United States and will enroll approximately 1350 patients with CIC. The primary endpoint of the study is the proportion of patients who are overall responders for the 12-week treatment period. This study will be running in parallel with the first phase 3 CIC trial that was initiated in November 2013. The phase 3 program will enroll a total of approximately 2700 patients with CIC.

On April 30, 2014 we announced positive top-line results from our phase 2b dose-ranging study assessing plecanatide’s safety and efficacy in 424 patients with IBS-C. The primary objective of this trial was to determine an effective, safe and well tolerated dose for plecanatide phase 3 trials with IBS-C patients. Synergy has achieved that objective. Preliminary analysis of the data indicates that plecanatide demonstrated statistically significant improvement in complete spontaneous bowel movement (CSBM) frequency — the study’s primary endpoint — and was safe and well tolerated. Notably, patients taking the plecanatide 3.0mg dose experienced statistically significant improvement in change from baseline versus placebo in worst abdominal pain and met the FDA overall responder endpoint for IBS-C over the 12-week treatment. An overall responder for the FDA endpoint fulfills both  $\geq 30\%$  reduction in worst abdominal pain and an increase of  $\geq 1$  complete spontaneous bowel movements (CSBMs) from baseline in the same week for at least 50% of the weeks (i.e. 6/12 weeks).

### Plecanatide

Plecanatide is a synthetic analog of uroguanylin, a natural human hormone that regulates ion and fluid transport in the intestine. Orally-administered, plecanatide binds to the same receptors on the inside of the gastrointestinal tract as uroguanylin, and we believe it is capable of restoring the normal balance of fluid, thus restoring the regular function of the intestine in patients suffering from GI disorders such as CIC and IBS-C.

Constipation can be the by-product of other disease states, as well as due to certain drug therapies (e.g., narcotics) or anatomic anomalies. CIC, in contrast, has no identifiable causes. Patients diagnosed with CIC have had symptoms for 6 months or more, and commonly have less than 3 bowel movements a week and often less than one. They suffer from very hard stool and abdominal symptoms such as bloating, discomfort, gas, and a feeling of incomplete evacuation. Over-the-counter medications offer only short-term relief and are not indicated for chronic treatment. The prescription drugs available have significant side effects and are only effective in less than half of patients treated. Plecanatide offers hope for a more effective and tolerable treatment that can relieve the significant burden CIC places on patients' lives.

## [Table of Contents](#)

On January 2, 2013, we announced positive results from our large multicenter clinical trial of our lead investigational drug plecanatide in patients with CIC. On May 15, 2013, at Digestive Disease Week 2013, we presented a late-breaking abstract, the title of which is: "Plecanatide, a Novel Guanylate Cyclase C (GC-C) Receptor Agonist, is Efficacious and Safe in Patients with Chronic Idiopathic Constipation (CIC): Results from a 951-Patient, 12-Week, Multi-Center Trial."

On August 5, 2013, we announced that we had completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) regarding plecanatide for the treatment of CIC. Agreement was reached with the FDA on design, duration, size and primary and secondary efficacy endpoints for pivotal phase 3 studies.

### *Phase 3 Clinical Trial for CIC*

On November 13, 2013, we announced the start of the first of two planned pivotal phase 3 clinical trials to confirm the safety and efficacy of plecanatide in adult patients with CIC. This pivotal phase 3 trial is a randomized, double-blind, clinical trial to compare a 12-week regimen of plecanatide (3.0 and 6.0mg) against placebo in adult patients with CIC. The study will be conducted at approximately 180 sites in the United States and Canada and is expected to enroll approximately 1,350 patients with CIC. The primary endpoint of the study is the proportion of patients who are overall responders for the 12-week treatment period.

### *Phase 2b Clinical Trial for IBS-C*

In addition to CIC, plecanatide is also being developed to treat IBS-C. IBS, which is one of the most commonly diagnosed GI illnesses in the United States, is generally characterized by symptoms of abdominal pain or discomfort such as cramping, bloating, gas, and constipation or diarrhea or both. IBS-C is the subtype of IBS that plecanatide is being developed to treat and is characterized by abdominal pain associated with infrequent bowel movement and hard or lumpy stool. As many as 1 in 6 or up to 50 million adult Americans suffer from IBS. About 13 million of them suffer from the IBS-C subtype.

IBS-C profoundly impacts patients' physical, social and working lives. A quarter of patients describe their abdominal pain as constant. Fewer than 1 in 10 patients say they are satisfied with available IBS-C treatments. Healthcare systems spend billions of dollars annually to diagnose and treat this disorder. In the U.S., the annual cost of IBS-C treatment is estimated to be as much as \$26 billion in direct medical costs (doctor and hospital visits, diagnostic procedures, etc.)

On December 27, 2012, we commenced a Phase 2b clinical trial of plecanatide to treat patients with IBS-C. To qualify for enrollment, patients were required to meet the Rome III criteria for IBS-C as modified for this study. Abdominal pain is a major part of this syndrome and patients need to have pain scores of 3 or more (on a scale of 0 to 10) for 3 days in each of the two pre-treatment weeks to qualify for the trial. Qualified patients were randomized to receive 0.3, 1, 3 or 9 mg of plecanatide or placebo once daily for 12 weeks, and were seen at the clinical site once a month during the study. At the end of treatment, patients are followed for two weeks, and return for an end of study visit. On December 24, 2013, we announced that we had closed patient enrollment and expected to report top line data in the second quarter of 2014.

### **SP-333**

We are developing a second-generation GC-C receptor agonist, SP-333, for the treatment of opioid induced constipation, or OIC, and for ulcerative colitis, or UC, an inflammatory bowel disease. SP-333 is a synthetic analog of uroguanylin, a natriuretic hormone that is normally produced in the body's intestinal tract. Deficiency of this hormone is thought to be one of the primary reasons for the formation of polyps that can lead to colon cancer, as well as debilitating and difficult-to-treat GI inflammatory disorders such as UC and Crohn's disease.

On September 7, 2012, we submitted an Investigational New Drug, or IND, application for clinical evaluation of SP-333 to treat inflammatory bowel disease, or IBD. On December 28, 2012, we successfully completed a Phase 1 placebo-controlled, dose escalating, single-dose study of 71 healthy adult volunteers. On January 28, 2013, we commenced a multiple ascending oral dosing study of healthy volunteers in a Phase 1 trial of SP-333 which was completed during the quarter ended June 30, 2013.

On October 30, 2013 we announced the start of the phase 2 clinical trial to evaluate the safety and efficacy of SP-333 in adult patients with OIC. The multi-center, randomized, double-blind clinical trial will compare a 4-week, dose-ranging regimen of SP-333 (1.0, 3.0 and 6.0mg) against placebo in adult patients taking opioid analgesics for chronic, non-cancer pain for at least three months. The study plans to enroll approximately 260 patients with OIC who have less than 3 spontaneous bowel movements (SBMs) per week and who experience constipation-related symptoms. The primary endpoint of the study is mean change from baseline in the number of SBMs during the 4-week treatment period.

### **FV-100**

On August 17, 2012, we entered into an Asset Purchase Agreement with Bristol-Myers Squibb Company and acquired certain assets related to FV-100, an orally available nucleoside analog, for the treatment of shingles, a severe, painful skin rash caused by reactivation of the varicella zoster virus — the virus that causes chickenpox. The terms of the agreement provide for an initial base payment of \$1 million, subsequent milestone payments covering (i) FDA approval and (ii) aggregate net sales equal to or greater than \$125 million, as well as a single digit royalty based on net sales.

---

[Table of Contents](#)

On May 15, 2013, we formed ContraVir Pharmaceuticals, Inc. (ContraVir), a Delaware corporation, for the purpose of developing the FV-100 asset and entered into a Contribution Agreement with ContraVir transferring the FV-100 Product to ContraVir, in exchange for the issuance to us of 9,000,000 shares of ContraVir common stock, par value \$0.0001 per share, representing 100% of the outstanding shares of common stock as of immediately following such issuance.

*Spin-Off*

On August 8, 2013, ContraVir Pharmaceuticals, Inc. filed an initial Form 10 Registration Statement with the U.S. Securities and Exchange Commission covering the 9,000,000 shares of ContraVir held by us. The separation contemplated a 100% distribution of the ContraVir shares of common stock to our stockholders on a pro-rata basis. On January 28, 2014, our Board of Directors declared a stock dividend of .0986 ContraVir shares for each share of our common stock held as of the record date of February 6, 2014, which was distributed on February 18, 2014.

We accounted for this distribution according to FASB ASC Topic 505-60, *Spinoffs and reverse spinoffs* by eliminating ContraVir's net assets of approximately \$1.7 million as of February 18, 2014, with a corresponding decrease in additional paid in capital. The spin-off of ContraVir's operation had immaterial effect on Synergy's financial statements. As a result of the distribution, an adjustment was made to the exercise price of all outstanding warrants in accordance with their terms and accordingly the exercise price decreased approximately \$0.011 per share on the record date. As of March 31, 2014 there were 5,647,203 warrants outstanding with a weighted average exercise price of \$5.37 per share pre-Distribution and \$5.359 per share as adjusted.

**FINANCIAL OPERATIONS OVERVIEW**

From inception through March 31, 2014, we have sustained cumulative net losses of approximately \$187 million. From inception through March 31, 2014, we have not generated any revenue from operations and expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products. We do not expect to have such for several years, if at all.

On March 5, 2014, we entered into Amendment No. 1 (the "Amendment") to our Controlled Equity Offering Sales Agreement, dated June 21, 2012 (as amended, the "Agreement"), with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which we may offer and sell, from time to time, through Cantor shares of our common stock, par value \$0.0001 per share (the "Shares"), up to an additional aggregate offering price of \$50.0 million. We intend to use the net proceeds of this offering to fund our research and development activities, including further clinical development of plecanatide and SP-333, and for working capital and other general corporate purposes, and possible acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated.

Under the Agreement, Cantor may sell the Shares by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on The NASDAQ Global Select Market, on any other existing trading market for the Shares or to or through a market maker. In addition, under the Agreement, Cantor may sell the Shares by any other method permitted by law, including in privately negotiated transactions. Subject to the terms and conditions of the Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The NASDAQ Global Select Market, to sell the Shares from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose).

We are not obligated to make any sales of the Shares under the Agreement. The offering of Shares pursuant to the Agreement will terminate upon the earlier of (1) the sale of all of the Shares subject to the Agreement or (2) the termination of the Agreement by Cantor or us. We will pay Cantor a commission of up to 3.0% of the gross sales price per share sold and we agreed to provide Cantor with customary indemnification and contribution rights.

From January 1, 2014 through February 27, 2014, we sold 3,644,143 shares of common stock for gross proceeds of approximately \$21.2 million, at an average selling price of \$5.82 per share. These sales completed the \$30.0 million of proposed sales of common stock pursuant to our Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., dated June 21, 2012. For the quarter ended March 31, 2014 we sold an additional 228,249 shares of common stock for gross proceeds of \$1.4 million, at an average selling price of \$6.08 per share, under the Amendment. Aggregate proceeds from these sales during the quarter ended March 31, 2014 were \$22.6 million and selling agent fees related to above financings totalled approximately \$0.6 million.

On February 4, 2014, ContraVir entered into a securities purchase agreement with accredited investors to sell securities and raise gross proceeds of approximately \$3.2 million in a private placement and expenses of \$15,000 related to this placement. ContraVir sold 9,485,294 units to the investors with each unit consisting of one share of ContraVir common stock and one warrant to purchase an additional one half share of ContraVir common stock.

On February 18, 2014, we completed distribution of ContraVir common stock (its previous wholly-owned subsidiary) to our

stockholders on a pro rata basis with a stock dividend of .0986 ContraVir shares to each Synergy common stock share held as of the record date of February 6, 2014. We accounted for this distribution according to FASB ASC Topic 505-60, *Spinoffs and reverse spinoffs* by eliminating ContraVir's net assets of approximately \$1.7 million, with a corresponding decrease in additional paid in capital and eliminating the non-controlling interest of \$1.6 million. The spin-off of ContraVir's operation had immaterial effect on Synergy's financial statements. (footnote 7)

[Table of Contents](#)

Our product development efforts are thus in their early stages and we cannot make estimates of the costs or the time they will take to complete. The risk of completion of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, our ability to raise additional capital, the nature and timing of research and development expenses and competing technologies being developed by organizations with significantly greater resources.

**CRITICAL ACCOUNTING POLICIES**

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA of our Annual Report on Form 10-K as of and for year ended December 31, 2013, filed with the SEC on March 17, 2014. There have been no changes to our critical accounting policies since December 31, 2013.

**CONTRACTUAL OBLIGATIONS AND COMMITMENTS**

For a discussion of our contractual obligations see (i) our Financial Statements and Notes To Consolidated Financial Statements— Note 6. *Commitments and Contingencies* , and (ii) Item 7 Management Discussion and Analysis of Financial Condition and Results of Operations— *Contractual Obligations and Commitment* , included in our Annual Report on Form 10-K as of December 31, 2013.

**OFF-BALANCE SHEET ARRANGEMENTS**

We had no off-balance sheet arrangements as of March 31, 2014.

**RESULTS OF OPERATIONS**

**THREE MONTHS ENDED MARCH 31, 2014 AND 2013**

We had no revenues during the three months ended March 31, 2014 and 2013 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the three months ended March 31, 2014 (“Current Quarter”) decreased approximately \$1 million to approximately \$13.3 million from approximately \$14.3 million for the three months ended March 31, 2013 (“Prior Year Quarter”). This decrease in research and development expenses was primary due to lower drug production and clinical trial activities of approximately \$1 million for SP-333 during the Current Quarter. The following table sets forth our research and development expenses directly related to our product candidates for the three months ended March 31, 2014 and 2013. These expenses were primarily external costs associated with chemistry, manufacturing and controls (CMC), including costs of drug substance and product, as well as preclinical studies and clinical trial costs, as follows:

<b>Drug candidates</b>	<b>(\$ in thousands)</b>	
	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2014</b>	<b>2013</b>
Plecanatide	\$ 8,728	\$ 8,689
SP-333	2,938	3,908
Total direct costs	11,666	12,597
Total indirect costs	1,633	1,747
Total Research and Development	\$ 13,299	\$ 14,344

Indirect research and development costs related to in-house staff compensation, facilities, depreciation, share-based compensation and research and development support services are not directly allocated to specific drug candidates.

General and administrative expenses decreased approximately \$0.1 million, to approximately \$3.2 million for the Current Quarter from approximately \$3.3 million for the Prior Year Quarter. These decreased expenses were primarily the result of lower corporate legal services of approximately \$0.6 million for the Current Quarter, as compared to \$0.7 million for the Prior Year Quarter.

Net loss for the Current Quarter was approximately \$16.2 million as compared to a net loss of approximately \$18.7 million incurred for the Prior Year Quarter. This decrease in our net loss of approximately \$2.5 million or 13% was a result of the decreases in operating expenses discussed above, and a gain resulting from the change in fair value of derivative instruments-warrants of \$0.2 million during the Current Quarter, as compared to a loss on derivative instruments-warrants of approximately \$1.1 during the Prior Year Quarter.



## LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2014, we had approximately \$20.6 million in cash and cash equivalents and approximately \$50 million in available for sale securities, compared to approximately \$18.1 million in cash and cash equivalents and approximately \$50 million in available for sale securities as of December 31, 2013. Net cash used in operating activities was approximately \$20 million for the three months ended March 31,

### [Table of Contents](#)

2014 as compared to approximately \$15.6 million during the three months ended March 31, 2013. Approximately \$ 22 million was provided by financing transactions for the three months ended March 31, 2014, and \$4.6 million for the three months ended March 31, 2013. As of March 31, 2014, we had working capital of approximately \$63.6 million, as compared to working capital of \$56.2 million on December 31, 2013.

As of March 31, 2014, we had an accumulated deficit of approximately \$187.4 million and expects to incur significant and increasing operating losses for the next several years as we continue to expand our research, development and clinical trials of plecanatide and SP-333 for the treatment of GI diseases and disorders, acquires or licenses technologies, advances other product candidates into clinical development, seeks regulatory approval and, if FDA approval is received, commercializes products. Because of the numerous risks and uncertainties associated with product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We may be required to raise additional capital to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. We cannot be certain that additional funding will be available on acceptable terms, or at all. Recently worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain difficult for the foreseeable future. These developments will make it more difficult to obtain additional equity or credit financing, when needed. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize its self on unfavorable terms.

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

Our exposure to market risk on the fair values of certain assets is related to credit risk associated with securities held in money market accounts, U.S. Treasury Bills and Notes, and the FDIC insurance limit on our bank balances. As of March 31, 2014, we held approximately \$20.6 million in checking and money market accounts and held approximately \$50 million in U.S. Treasury securities. We maintained our cash, cash equivalents and available-for-sale securities at one large money center financial institution, however balances are in excess of federally insured limits. We believe our cash, cash equivalents and available-for-sale securities do not contain excessive risk, however we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. Given the current instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits and investments.

### ITEM 4. CONTROLS AND PROCEDURES

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, our Chief Executive Officer and Principal Financial Officer have concluded that as of March 31, 2014, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitations, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

### CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded there were no changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that could significantly affect internal controls over financial reporting during the quarter ended March 31, 2014.



## CERTIFICATIONS

I, Gary S. Jacob, certify that:

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

Date: May 12, 2014

/s/ GARY S. JACOB

Gary S. Jacob

*President, Chairman of Board, and Chief Executive Officer*

---

## CERTIFICATIONS

I, Bernard F. Denoyer, certify that:

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

Date: May 12, 2014

/s/ BERNARD F. DENOYER

Bernard F. Denoyer

Senior Vice President, Finance

---

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
SYNERGY PHARMACEUTICALS INC.  
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2014  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I am the Chief Executive Officer of Synergy Pharmaceuticals Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended March 31, 2014 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2014

/s/ GARY S. JACOB

Gary S. Jacob

*President, Chairman of Board, and Chief Executive Officer*

---

**CERTIFICATION OF SENIOR VICE PRESIDENT, FINANCE  
SYNERGY PHARMACEUTICALS INC.  
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2014  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I am the Senior Vice President, Finance of Synergy Pharmaceuticals Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended March 31, 2014 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2014

/s/ BERNARD F. DENOYER

Bernard F. Denoyer

*Senior Vice President, Finance*

---