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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: SEPTEMBER 30, 2013

☐ **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	**33-0505269**
(State or Other Jurisdiction of Incorporation or Organization)	(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)

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 ☐ (Do not check if a smaller reporting company)	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 90,182,115 as of November 8, 2013.

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SYNERGY PHARMACEUTICALS INC.
(A development stage company)

FORM 10-Q

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

SYNERGY PHARMACEUTICALS INC.
(A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	September 30, 2013 (unaudited)	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 12,064	$ 12,416
Available-for-sale securities	70,041	20,086
Prepaid expenses and other current assets	5,244	1,547
Total Current Assets	87,349	34,049
Property and equipment, net	617	30
Security deposits	94	20
Due from controlling shareholder	—	3,306
Total Assets	$ 88,060	$ 37,405
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 10,275	$ 5,255
Accrued expenses	2,892	2,060
Total Current Liabilities	13,167	7,315
Derivative financial instruments, at estimated fair value-warrants	1,050	5,258
Total Liabilities	14,217	12,573
Stockholders' Equity:		
Preferred stock, Authorized 20,000,000 shares and none outstanding, at September 30, 2013 and December 31, 2012	—	—
Common stock, par value of $.0001 authorized 200,000,000 shares at September 30, 2013		

and 100,000,000 shares at December 31, 2012. Issued and outstanding 90,182,115 and 66,621,832 shares at September 30, 2013 and December 31, 2012, respectively	10	7
Additional paid-in capital	225,159	133,878
Deficit accumulated during development stage	(151,326)	(109,053)
Total Stockholders' Equity	73,843	24,832
Total Liabilities and Stockholders' Equity	$ 88,060	$ 37,405

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

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SYNERGY PHARMACEUTICALS INC.
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		November 15, 2005 (inception) to
	2013	2012	2013	2012	September 30, 2013
Revenues	$ —	$ —	$ —	$ —	$ —
Costs and Expenses:					
Research and development	10,782	8,246	34,181	21,210	91,888
Purchased in-process research and development	—	—	—	—	29,157
General and administrative	2,692	1,843	8,773	5,493	36,358
Loss from Operations	(13,474)	(10,089)	(42,954)	(26,703)	(157,403)
Interest and investment income	14	63	48	150	544
Interest expense	—	—	—	—	(12)
Other income	—		—	256	1,363
Change in fair value of derivative instruments-warrants	(77)	140	633	(1,169)	4,254
Total Other (Expense)/Income	(63)	203	681	(763)	6,149
Loss from Continuing Operations	(13,537)	(9,886)	(42,273)	(27,466)	(151,254)
Loss from discontinued operations	—	—	—	—	(72)
Net Loss	$ (13,537)	$ (9,886)	$ (42,273)	$ (27,466)	$ (151,326)
Weighted Average Common Shares Outstanding Basic and Diluted	90,182,115	65,806,178	83,548,398	60,194,004	
Net Loss per Common Share Basic and Diluted	$ (0.15)	$ (0.15)	$ (0.51)	$ (0.46)	

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

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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	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 (audited)	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	—	—	3,133	—	3,133

Net loss for the period	—	—	—	(42,273)	(42,273)
Balance, September 30, 2013 (unaudited)	90,182,115	$ 10	$ 225,159	$ (151,326)	$ 73,843

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

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SYNERGY PHARMACEUTICALS INC.

(A development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

(In thousands)	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012	Period from November 15, 2005 (Inception) to September 30, 2013
Cash Flows From Operating Activities:			
Net loss	$ (42,273)	$ (27,466)	$ (151,326)
Adjustments to reconcile net loss to net cash (used in) operating activities:			
Depreciation	28	2	38
Loss on disposal of property and equipment	—	2	2
Stock-based compensation expense	3,258	1,345	8,742
Accretion of discount/premium on available-for-sale securities	45	(123)	(41)
Purchased in-process research and development	—	—	28,157
Change in fair value of derivative instruments-warrants	(633)	1,169	(4,254)
Changes in operating assets and liabilities:			
Security deposit	—	(6)	(20)
Accounts payable and accrued expenses	4,575	2,228	11,042
Prepaid expenses and other current assets	(3,697)	(222)	(5,244)
Total Adjustments	3,576	4,395	38,422
Net Cash Used in Operating Activities	(38,697)	(23,071)	(112,904)
Cash Flows From Investing Activities:			
Net liabilities assumed in connection with Exchange Agreement	—	—	(155)
Loans to related parties	(270)	(1,114)	(3,576)
Net purchases of available-for-sale securities	(50,000)	(20,000)	(70,000)
Additions to property and equipment	(615)	—	(657)
Net Cash Used in Investing Activities	(50,885)	(21,114)	(74,388)
Cash Flows From Financing Activities:			
Proceeds from sale of common stock	94,734	51,750	211,168
Fees and expenses related to sale of common stock	(5,623)	—	(12,346)
Proceeds from exercise of stock warrants	—	—	415
Proceeds from exercise of stock options	119	(3,566)	119
Net Cash Provided by Financing Activities	89,230	48,184	199,356
Net (decrease)/ increase in cash and cash equivalents	(352)	3,999	12,064
Cash and cash equivalents at beginning of period	12,416	13,245	—
Cash and cash equivalents at end of period	$ 12,064	$ 17,244	$ 12,064
Supplementary disclosure of cash flow information:			
Cash paid for taxes	$ 37	$ 19	$ 177
Supplementary disclosure of non-cash investing and financing activities:			
Value of warrants classified as derivative liability-net	$ (3,575)	$ 169	$ 5,304
Value of common stock issued to induce stockholders to extend lock-up agreements	$ —	$ —	$ 3,235
Recapitalization of Synergy	$ 4,904	$ —	$ 4,904

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

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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, a guanylate 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 low bowel movement frequency. A majority of these patients additionally report experiencing straining, 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, a second generation GC-C receptor agonist for the treatment of gastrointestinal disorders and diseases, including opioid-induced constipation, or OIC, and the inflammatory bowel disease ulcerative colitis, or UC.

2. Basis of Presentation

These unaudited condensed consolidated financial statements of Synergy include its wholly-owned subsidiaries: (1) Synergy Advanced Pharmaceuticals, Inc. (2) IgX, Ltd (Ireland—inactive) and (3) ContraVir Pharmaceuticals, Inc. 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, 2012 contained in the Company's Annual Report on Form 10-K filed with the SEC on March 18, 2013. All intercompany balances and transactions have been eliminated.

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 September 30, 2013, the amount of cash and cash equivalents was approximately $12.1 million and consists of checking accounts and short-term money market funds held at U.S. commercial banks. As of December 31, 2012, the amount of cash and cash equivalent was approximately $12.4 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 equivalent may exceed federally insured limits.

The Company's marketable securities as of September 30, 2013 consist of approximately $70 million in U.S. Treasury securities with maturities of less than one year and have been classified and accounted for as available-for-sale. Marketable securities as of December 31, 2012 consisted of approximately $20 million in U.S. Treasury securities. 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 September 30, 2013 and 2012, gross unrealized losses were not material. The Company recognized no net realized gains or losses for the three and nine months ended September 30, 2013 and 2012. The Company considers the declines in market value of its marketable securities investment portfolio to be 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 and nine months ended September 30, 2013 and 2012, the Company did not recognize any impairment charges. As of September 30, 2013 and December 31, 2012, the Company did not consider any of its investments to be other-than-temporarily impaired.

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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: (dollars in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30		November 15, 2005 (inception) to
	2013	2012	2013	2012	September 30, 2013
Employees—included in research and development	$ 388	$ 226	$ 942	$ 488	$ 2,544
Employees—included in general and administrative	386	154	1,166	347	2,576
Subtotal employee stock based compensation	774	380	2,108	835	5,120
Non-employees—included in research and development	3	3	140	3	436
Non-employees—included in general and administrative	313	170	1,010	507	3,186
Subtotal non-employee stock based compensation	316	173	1,150	510	3,622
Total stock-based compensation expense	$ 1,090	$ 553	$ 3,258	$ 1,345	$ 8,742

The unrecognized compensation cost related to non-vested stock options outstanding at September 30, 2013, net of expected forfeitures, was approximately $8.3 million to be recognized over a weighted-average remaining vesting period of approximately 1.9 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.

	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Risk-free interest rate	0.41%-2.64%	0.92%-1.50%
Dividend yield	—	—
Expected volatility	60%	60%
Expected term (in years)	6 years	6 years

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

	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, 2012	9,734,268	$ 0.50 — 5.20	$ 2.75	$ 24,482	6.45 years
Granted	2,495,965(a)	$ 0.44 — 20.01	$ 6.45		
Exercised	(61,787)	$ 0.44 — 4.28	$ 1.91		
Forfeited	(887,202)(a)	$ 4.42 — 12.51	$ 5.99		
Balance outstanding, September 30, 2013	11,281,244(a)	$ 0.44-20.01	$ 3.32	$ 18,816	7.2 years

Exercisable at September 30, 2013	3,955,151(a)	$ 0.44-20.01	$ 2.76	$ 9,503	5.8 years

(a) Includes 1,221,316 stock options issued to former Callisto option holders under the terms of Callisto Synergy Merger Agreement dated January 17, 2013, of which 854,763 stock options are vested and 357,202 stock options that expired and were forfeited through September 30, 2013.

7. Income Taxes

During the year ended December 31, 2012 the Company recorded refundable tax credits in prepaid and other current assets for its (i) 2011 New York State QETC credit, totaling $250,000 and (ii) the 2012 New York City Biotechnology Tax Credit totaling $218,000. These credits were recorded as other current assets at December 31, 2012. On July 23, 2013, the Company received $250,000 for the 2011 New York State QETC credit and on September 8, 2013 the Company received the New York City Biotechnology Tax Credit of $218,000. As of September 30, 2013 the Company had no outstanding refundable tax credits.

8. Stockholders' Equity

On April 16, 2013, Synergy closed an underwritten public offering of 16,375,000 shares of its common stock at a price of $5.50 per share. The gross proceeds to the Company from this sale was approximately $90 million, before deducting underwriting discounts and commissions and other offering expenses of approximately $5.5 million paid by the Company.

From January 1, 2013 through September 30, 2013, Synergy sold 758,093 shares of common stock with gross proceeds of approximately $4.7 million, at an average selling price of $6.16 per share, pursuant to a controlled equity sales agreement with a placement agent. Selling expenses totaled approximately $0.1 million.

On November 14, 2011, Synergy entered into a securities purchase agreement with certain accredited investors for the sale of 1,328,941 units in a private placement and on December 1, 2011, Synergy issued 77,750 units to a selling agent related to November and December financing transactions. Each unit consists of one share of common stock and one warrant to purchase one share of Synergy's common stock. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy recorded the above warrants as derivative liabilities upon issuance and they were marked to market on a quarterly basis. The price protection clauses on 1,328,941warrants and 77,750 warrants expired on May 14, 2013 and June 1, 2013 respectively, which removed the condition requiring derivative liability accounting and resulted in a zero value ratchet. Accordingly the warrants were marked to market through the expected expiration dates and the total fair value of approximately $3.6 million was reclassified from derivative liability - warrants to additional paid in capital upon the respective expiration dates.

On October 18, 2012 Synergy entered into a Stock Purchase Agreement with a clinical trial contract research organization (or CRO) whereby the CRO would be compensated for services performed by issuance of shares of Synergy common stock. The agreed fair value of the work performed was $250,000, based on 55,000 shares at a price of $4.55 per share. The closing stock price for Synergy common stock on October 17, 2012 was $4.57 per share. Approximately 50% of the services were completed as of December 31, 2012 and Synergy accrued stock based compensation expense of $125,000 during the quarter ended December 31, 2012. The remaining balance of $125,000 was recorded as stock based compensation expense upon completion of the contract in January 2013 and Synergy issued 55,000 shares to the CRO during the quarter ended March 31, 2013.

On January 17, 2013, the number of authorized shares of common stock increased from 100,000,000 to 200,000,000.

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Synergy - Callisto Merger

On January 17, 2013, Synergy completed its acquisition of Callisto Pharmaceuticals, pursuant to the Merger Agreement. As a result of the Merger, Synergy issued a total of 28,605,379 shares of its common stock to former Callisto stockholders in exchange for their shares of Callisto common stock, in which each outstanding share of Callisto common stock was converted into the right to receive 0.1799 of one share of Synergy common stock (the Exchange Ratio). The 22,294,976 shares of Synergy common stock held by Callisto were canceled. The 28,605,379 new shares of Synergy common stock issued to Callisto shareholders are locked-up for 24 months until January 17, 2014.

In addition, each stock option exercisable for shares of Callisto common stock that was outstanding on January 17, 2013 was assumed by Synergy and converted into a stock option to purchase the number of shares of Synergy's common stock that the holder would have received if such holder had exercised such stock option for shares of Callisto common stock prior to the Merger and exchanged such shares for shares of the Company's common stock in accordance with the Exchange Ratio. Synergy issued 1,221,316 stock options in connection with this exchange. In addition, each outstanding warrant or obligation to issue a warrant to purchase shares of Callisto common stock, whether or not vested, was cancelled.

As Callisto does not meet the input, process and output definition of a business under ASC 805, the merger was not accounted for as a business combination. The merger was accounted for as a recapitalization of Synergy, affected through exchange of Callisto shares for Synergy shares, and the cancellation of its shares held by Callisto. The excess of Synergy shares issued to Callisto shareholders over Synergy shares held by Callisto is the result of a discount associated with the restricted nature of the new Synergy shares received by Callisto shareholders. Therefore, considering this discount, the share exchange has been determined to be equal from a fair value standpoint. Upon the effective date of the Merger, Synergy accounted for the merger by assuming Callisto's net liabilities, of approximately $1.3 million, with a corresponding decrease in additional paid in capital. Synergy's financial statements will not be restated retroactively to reflect the

historical financial position or results of operations of Callisto.

In addition, as of January 17, 2013, Synergy had advanced Callisto approximately $3.6 million, which was Callisto's share of Synergy payments for common operating costs since July 2008. This balance was eliminated upon the recapitalization date, with a corresponding decrease in additional paid in capital.

Net liabilities of Callisto assumed and advances to Callisto eliminated in connection with this recapitalization were as follows:

($ in thousands)	Balance January 17, 2013
Assets	
Cash	$ —
Security deposits	74
Total assets acquired	74
Liabilities	
Accounts payable and other liabilities	(1,400)
Net assumed liabilities	(1,326)
Elimination of amounts due from Callisto	(3,578)
Recapitalization of Synergy	$ (4,904)

9. 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 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 $4.9 million and $0.9 million as of September 30, 2013 and December 31, 2012, respectively, of pre-payments for production of drug substance, analytical testing services and clinical trial monitoring for its drug candidates. In accordance with this guidance, Synergy expenses these costs when drug substance is delivered and/or services are performed.

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10. 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 was:

	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Fair value of Synergy common stock	$ 4.57	$ 4.75
Expected warrant term	1.8 - 4.4 years	2.8 - 5.4 years
Risk-free interest rate	0.33%-1.39%	0.32%-1.33%
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.

On November 14, 2011, Synergy entered into a securities purchase agreement with certain accredited investors for the sale of 1,328,941 units in a private placement and on December 1, 2011, Synergy issued 77,750 units to a selling agent related to November and December financing transactions. Each unit consists of one share of common stock and one warrant to purchase one share of Synergy's common stock. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in

Entity's Own Equity" Synergy recorded the above warrants as derivative liabilities upon issuance and they were marked to market on a quarterly basis. The price protection clauses on 1,328,941 warrants and 77,750 warrants expired on May 14, 2013 and June 1, 2013 respectively, which removed the condition requiring derivative liability accounting, resulting in a zero value ratchet. Accordingly the warrants were marked to market through the expected expiration dates and the total fair value of approximately $3.6 million was reclassified from derivative liability - warrants to additional paid in capital upon the respective expiration dates.

As of September 30, 2013, 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:

	Nine months ended September 30, 2012
Fair value of Synergy common stock	$3.28-$4.50
Expected warrant term	4.4 - 4.6 years
Risk-free interest rate	0.72%-1.03%
Expected volatility	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 end of each reporting period the derivative instruments are marked to market. Expected volatility is based in part on the 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 Synergy's outstanding warrants which were deemed derivative financial instruments and the associated liability balance for the periods indicated:

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Date	Description	Warrants	Derivative Instrument Liability (in thousands)
12/31/2011	Balance	2,265,160	$ 3,325
3/31/2012	Fair value of new warrants issued during the quarter		
3/31/2012	Change in fair value of warrants during the quarter recognized as other income in the statement of operations		(8)
3/31/2012	Balance	2,265,160	3,317
6/30/2012	Fair value of new warrants issued during the quarter	112,500	169
6/30/2012	Change in fair value of warrants during the quarter recognized as other expense in the statement of operations	—	1,317
6/30/2012	Balance	2,377,660	4,803
9/30/2012	Fair value of new warrants issued during the quarter	—	—
9/30/2012	Change in fair value of warrants during the quarter recognized as other income in the statement of operations	—	(140)
9/30/2012	Balance	2,377,660	4,663
12/31/2012	Fair value of new warrants issued during the quarter	—	—
12/31/2012	Reclassification of derivative liability to equity during the quarter	(112,500)	(169)
12/31/2012	Change in fair value of warrants during the quarter recognized as other expense in the statement of operations	—	764
12/31/2012	Balance	2,265,160	5,258
3/31/2013	Change in fair value of warrants during the quarter recognized as other expense in the statement of operations	—	1,093
3/31/2013	Balance	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 recognized as other income in the statement of operations	—	(1,803)
6/30/2013	Balance	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 recognized as other income in the statement of operations	—	77
9/30/2013	Balance	858,469	$ 1,050

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, 2012 and September 30, 2013:

($ in thousands)

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2012	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of September 30, 2013
Derivative liabilities related to Warrants	$ —	$ —	$ 5,258	$ 5,258	$ —	$ —	$ 1,050	$ 1,050

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the nine months ended September 30, 2013:

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Description	Balance at December 31, 2012	Fair value of warrants reclassified to additional paid in capital	(Gain) or loss recognized in earning from Change in Fair Value	Balance as of September 30, 2013
Derivative liabilities related to Warrants	$ 5,258	$ (3,575)	$ (633)	$ 1,050

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, the Company 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 are instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

11. Loss per Share

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 and nine months ended September 30, 2013 the effect of 11,281,244 outstanding stock options and 5,647,203 warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive. For the three and nine months ended September 30, 2012, 7,131,039 outstanding stock options and 5,647,203 warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive.

12. Spin-off of FV-100

On August 17, 2012, Synergy entered into an Asset Purchase Agreement ("Asset Purchase Agreement") with Bristol-Myers Squibb Company ("BMS") and acquired certain assets related to FV-100 ("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. Pursuant to the BMS Purchase Agreement Synergy purchased from BMS certain assets defined as "Acquired Assets" and assumed from BMS certain liabilities defined as "Assumed Liabilities", in each case relating to the business being conducted by BMS as of the date of the BMS Purchase Agreement, consisting of the research, development, product design and related activities of BMS relating solely to FV-100, the valyl ester pro-drug of Cf1743, a bicyclic nucleoside analogue (the "Product").

On May 15, 2013 Synergy formed ContraVir Pharmaceuticals, Inc. (ContraVir), a Delaware corporation, for the purpose of developing the FV-100 Product.

The following agreements were entered into during the period May 15, 2013 (inception of ContraVir) through September 30, 2013:

Contribution Agreement

Synergy and ContraVir entered into a Contribution Agreement (the "Contribution Agreement"), transferring the FV-100 Product to ContraVir, in exchange for the issuance to Synergy of 9,000,000 shares of the ContraVir common stock, par value $0.0001 per share (the "Common Stock"), representing 100% of the outstanding shares of Common Stock as of immediately following such issuance. During the period since August 17, 2012 through June 30, 2013 Synergy made no expenditures related to the research and development of FV-100, thus, the Company determined that the contributed asset did not meet the definition of a business, as defined in ASC 805, "Business

Combinations" and was accounted for under ASC 350, "Intangibles Goodwill and Other" as a contribution of assets. The contribution of this asset was accounted for at Synergy's net book value which was zero. This agreement was amended and restated on August 5, 2013 to clarify certain indemnification provisions.

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"). Pursuant to the Loan Agreement, as of September 30, 2013, Synergy made advances to ContraVir totaling $200,000 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 ContraVir 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

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intellectual property, until the Note is repaid in full. On October 3, 2013, the Board of Directors of Synergy unanimously approved an increase in this lending facility to $1,000,000.

Shared Services Agreement

On July 8, 2013, ContraVir entered into a Shared Services Agreement with Synergy, effective May 16, 2013. Under the Shared Services Agreement, Synergy will provide and/or make available to ContraVir various administrative, financial (including internal audit and payroll functions), legal, insurance, facility, information technology, laboratory, real estate 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 will pay fees to Synergy for the services provided, and those fees will generally be in amounts intended to allow Synergy to recover all of its direct and indirect costs incurred in providing those services. The personnel performing services under the Shared Services Agreement will be employees and/or independent contractors of Synergy and will not be under ContraVir's direction or control. These personnel costs will be based upon the actual 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 shared services provided to ContraVir (e.g. rent).

The shared services agreement will continue in effect until terminated (1) by ContraVir at any time on at least 30 days' prior written notice, (2) by either party if the non-defaulting party shall have failed to perform any of its material obligations under the agreement, provided the non-defaulting party shall have notified the defaulting party in writing and such failure shall have continued for a period of at least 30 days after receipt of such written notice. This agreement was amended and restated on August 5, 2013 to clarify certain indemnification provisions.

On August 8, 2013 ContraVir Pharmaceuticals, Inc. filed an initial Form 10 Registration Statement ("Form 10") with the U.S. Securities and Exchange Commission. The separation contemplates a 100% distribution of the ContraVir shares of common stock, now held by Synergy, to Synergy's stockholders on a pro-rata basis. Completion of the transaction is subject to a number of conditions, including effectiveness of the registration statement filed with the SEC, and other customary conditions. The transaction also remains subject to final approval by the Synergy Board of Directors. Synergy notes that there can be no assurance that any separation transaction will ultimately occur, or, if one does occur, its terms or timing.

As of September 30, 2013 the ContraVir Form 10 has not gone effective, however ContraVir became a public registrant on October 8, 2013 and will be filing a Form 10-Q for the quarter ended September 30, 2013.

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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.

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, 2012 and other periodic reports filed with the United States Securities and Exchange Commission ("SEC"). Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of us, please be advised that our actual financial condition, operating results and business performance may differ materially from that projected or estimated by us in forward-looking 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, an essentially non-systemic 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 symptoms such as hard stool, infrequent bowel movements, and straining, but a majority of these patients also 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. We are also developing SP-333, our second-generation GC-C receptor agonist, for the treatment of GI disorders and diseases, including opioid-induced constipation, or OIC, a common condition affecting patients who receive opioid treatments to relieve pain. OIC is characterized by infrequent and incomplete evacuation of stool, hard stool consistency and straining associated with bowel movements. SP-333 is also being formulated as a potential treatment for the GI inflammatory disease ulcerative colitis, or UC.

Our patented GI drug candidates were discovered and developed in-house by our own scientists. Today there are few available therapies for CIC, IBS-C, and OIC, with diarrhea and nausea being common side effects of such therapies.

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.

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. A pivotal phase 3 program evaluating the safety and efficacy of plecanatide in CIC patients is expected to be initiated in the fourth quarter of 2013.

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In addition to CIC, plecanatide is also being developed to treat IBS-C. IBS 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. IBS is one of the most commonly diagnosed GI illnesses in the United States. 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 profoundly impacts patients' physical, social and working lives. A quarter of patients describe their abdominal pain as constant. IBS is one of the most common reasons for work or school absenteeism, second only to the common cold. Fewer than 1 in 10 patients say they are satisfied with available IBS treatments. Healthcare systems spend billions of dollars annually to diagnose and treat this disorder. In the U.S., the annual cost of IBS treatment is estimated to be as much as $10 billion in direct medical costs (doctor and hospital visits, diagnostic procedures, etc.)

On December 27, 2012, we commenced a Phase2b clinical trial of plecanatide to treat patients with IBS-C. This study is currently being conducted at 70 sites in the U.S., and is planned to enroll 350 patients. To qualify for enrollment, patients must 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 1 to 10) for 3 days in each of the two pre-treatment weeks. Qualified patients are being randomized to receive 0.3, 1, 3 or 9 mg of plecanatide or placebo once daily for 12 weeks, and will be 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. The primary objective of this study is to select doses for the following Phase 3 studies, based on safety and efficacy endpoints including bowel movements, stool consistency, time to first bowel

movement, reduction of abdominal pain, and quality of life measures.

On July 17, 2013, we announced that we had reached the halfway mark for total enrollment in our plecanatide Phase 2b clinical trial in patients with IBS-C. At that point, over 726 patients had been screened, and 204 patients had been enrolled in the study. We indicated that we anticipate completing enrollment in the fourth quarter of 2013 and reporting top line data in the first quarter of 2014.

SP-333

We are developing a second-generation GC-C receptor analog, SP-333, for the treatment of OIC, and for the inflammatory bowel disease, UC. 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 IBD. On December 28, 2012, we successfully completed a Phase 1 placebo-controlled, dose escalating, single-dose study of 70 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 2, 2013 we announced plans to move forward with SP-333 in a phase 2 study for the treatment of OIC. The phase 2 trial is designed as a dose-ranging study to evaluate a 4-week regimen of SP-333, a once daily oral treatment, in adult patients taking opioid analgesics for chronic, non-cancer pain for at least three months.

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 Week 4 of the treatment period.

FV-100

On August 17, 2012, we signed an Asset Purchase Agreement with Bristol-Myers Squibb Company and acquired certain assets related to FV-100, an orally available nucleoside analog, that was currently being developed 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) marketing (FDA) approval and (ii) on achieving the milestone of aggregate net sales equal to or greater than $125 million, as well as a single digit royalty based on net sales. Please refer to Note 12 to our condensed consolidated financial statements, Item 1 of this Report on Form 10-Q, for discussion of spin-off of FV-100, via our newly formed subsidiary, ContraVir Pharmaceuticals, Inc. ("ContraVir").

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On August 8, 2013 ContraVir filed an initial Form 10 Registration Statement ("Form 10") with the U.S. Securities and Exchange Commission. The separation contemplates a 100% distribution of the ContraVir shares of common stock, now held by Synergy, to Synergy's stockholders on a pro-rata basis. Completion of the transaction is subject to a number of conditions, including effectiveness of the registration statement filed with the SEC and other customary conditions. The transaction also remains subject to final approval by the Synergy Board of Directors. Synergy notes that there can be no assurance that any separation transaction will ultimately occur, or, if one does occur, its terms or timing. As of September 30, 2013 the ContraVir Form 10 has not gone effective, however ContraVir became a public registrant on October 8, 2013 and will be filing a Form 10-Q for the quarter ended September 30, 2013.

FINANCIAL OPERATIONS OVERVIEW

From inception through September 30, 2013, we have sustained cumulative net losses of approximately $151 million. From inception through September 30, 2013, 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.

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.

On April 16, 2013, we closed an underwritten public offering of 16,375,000 shares of our common stock at a price of $5.50 per share. The gross proceeds to us from this sale was approximately $90 million, after deducting underwriting discounts and commissions and other offering expenses payable of approximately $5.5 million.

From January 1, 2013 through September 30, 2013, we sold 758,093 shares of common stock with gross proceeds of approximately $4.7 million, at an average selling price of $6.16 per share, pursuant to the June 2012 controlled equity sales agreement with a placement agent. Selling expenses totaled approximately $0.1 million.

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, 2012, filed with the SEC on March 18, 2013. There have been no changes to our critical accounting policies since December 31, 2012.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

For a discussion of our contractual obligations see (i) our Financial Statements and Notes To Consolidated Financial Statements—Note 7. *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, 2012.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2013.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2013 AND 2012

We had no revenues during the three months ended September 30, 2013 and 2012 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 September 30, 2013 (“Current Quarter”) increased approximately $2.5 million or 30%, to approximately $10.8 million from approximately $8.3 million for the three months ended September 30, 2012 (“Prior Year Quarter”). This increase in research and development expenses was largely attributable to the ongoing development of our plecanatide and SP-333 product candidates. The following table sets forth our research and development expenses directly related to our product candidates for the three months ended September 30, 2013 and 2012. These expenses include 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:

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	($ in thousands) Three Months Ended September 30,	
Drug candidates	**2013**	**2012**
Plecanatide	$ 6,693	$ 5,487
SP-333	2,618	969
FV-100	—	1,000
Total direct cost	$ 9,311	$ 7,456

Indirect research and development costs related to in-house staff compensation, facilities, depreciation, stock-based compensation and research and development support services are not directly allocated to specific drug candidates and not included above. Indirect costs were approximately $1.5 million in the Current Quarter, as compared to approximately $0.8 million during the Prior Year Quarter primarily due to higher stock based compensation and scientific advisory costs.

General and administrative expenses increased approximately $0.9 million or 50%, to approximately $2.7 million for the Current Quarter from approximately $1.8 million for the Prior Year Quarter. These increased expenses were primarily the result of (i) higher compensation and related employee benefits of approximately $1.2 million, as compared to $0.7 million during the Prior Year Quarter, which were primarily due to higher stock based compensation expense, (ii) higher corporate legal and accounting services of approximately $0.6 million for the Current Quarter, as compared to $0.3 million for the Prior Year Quarter, primarily as a result of the ongoing class action litigation in connection with the Callisto merger.

Net loss for the Current Quarter was approximately $13.5 million as compared to a net loss of approximately $9.9 million incurred for the Prior Year Quarter. This increase in our net loss of approximately $3.6 million or 36% was a result of the increases in operating expenses discussed above plus the change in fair value of derivative instruments-warrants of approximately $77,000 during the Current Quarter, as compared to a gain of approximately $140,000 during the Prior Year Quarter.

NINE MONTHS ENDED SEPTEMBER 30, 2013 AND 2012

We had no revenues during the nine months ended September 30, 2013 and 2012 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 nine months ended September 30, 2013 (“Current Period”) increased approximately $13

million or 61%, to approximately $34.2 million from approximately $21.2 million for the nine months ended September 30, 2012 ("Prior Year Period"). This increase in research and development expenses was largely attributable to ongoing development of our plecanatide and SP-333 product candidates. The following table sets forth our research and development expenses directly related to our product candidates for the nine months ended September 30, 2013 and 2012. These expenses were primarily external costs associated with chemistry, manufacturing and controls including costs of drug substance and product (CMC), as well as preclinical studies and clinical trial costs, as follows:

	($ in thousands) Nine Months Ended September 30,	
Drug candidates	**2013**	**2012**
Plecanatide	$ 21,545	$ 16,163
SP-333	8,042	1,923
FV-100	—	1,000
Total direct cost	$ 29,587	$ 19,086

Indirect research and development costs related to in-house staff compensation, facilities, depreciation, stock-based compensation and research and development support services are not directly allocated to specific drug candidates. Indirect costs were approximately $4.6 million in the Current Period, as compared to approximately $2.1 million during the Prior Year Period primarily due to higher stock based compensation and scientific advisory costs.

General and administrative expenses increased approximately $3.3 million or 60%, to approximately $8.8 million for the Current Period from approximately $5.5 million for the Prior Year Period. These increased expenses were primarily the result of (i) higher compensation and related employee benefits of approximately $3.5 million, as compared to $1.9 million during the Prior Year Period, which were primarily due to higher stock based compensation expense, (ii) higher facilities cost of approximately $1.5 million in the Current Period as compared to

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approximately $0.9 million during the Prior Year Period, reflecting our recent move into our larger New York City headquarters and (iii) higher corporate legal services of approximately $1.5 million for the Current Period, as compared to $0.9 million for the Prior Year Period, primarily as a result of ongoing class action litigation in connection with the Callisto merger.

Net loss for the Current Period was approximately $42.3 million as compared to a net loss of approximately $27.5 million incurred for the Prior Year Period. This increase in our net loss of approximately $14.8 million or 54% was a result of the increases in operating expenses discussed above, offset by a gain resulting from the change in fair value of derivative instruments-warrants of $0.6 million during the Current Period, as compared to a loss of approximately $1.2 million during the Prior Year Period.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2013, we had approximately $12.1 million in cash and cash equivalents and approximately $70 million in available for sale securities, compared to approximately $12.4 million in cash and cash equivalents and approximately $20.1 million in available for sale securities as of December 31, 2012. Net cash used in operating activities was approximately $38.7 million for the nine months ended September 30, 2013 as compared to approximately $23.1 million during the nine months ended September 30, 2012. Approximately $89 million was provided by financing transactions for the nine months ended September 30, 2013, as compared to $48 million provided by financing activities for the nine months ended September 30, 2012. As of September 30, 2013, we had working capital of approximately $74.2 million, as compared to working capital of $26.7 million on December 31, 2012.

As of September 30, 2013, we had an accumulated deficit of approximately $151 million and expect to incur significant and increasing operating losses for the next several years as the we continue to expand our research, development and clinical trials of plecanatide and SP-333 for the treatment of GI diseases and disorders, acquire or license technologies, advance other product candidates into clinical development, seek regulatory approval and, if FDA approval is received, commercialize 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.

PROPERTIES.

On June 14, 2013, we moved our corporate headquarters and clinical development offices to the 20th floor of 420 Lexington Avenue from the 16th floor, resulting in approximately 50% more space, 6,722 square feet vs. 4,282 in suite 1609. The new lease has a monthly rate of approximately $35,000 and expires March 31, 2019.

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 September 30, 2013, we held approximately $1.7 million in money market accounts and held approximately $70 million in U.S. Treasury securities. We maintained our cash, cash equivalents and available-for-sale securities at one or more large money center financial institutions, 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.

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 September 30, 2013, 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.

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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 September 30, 2013.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On December 22, 2009, we, through our subsidiary, Synergy Advanced Pharmaceuticals, Inc., filed a complaint in the Supreme Court of the State of New York against CapeBio, LLC, CombiMab Inc. and Per Lindell alleging that defendants intentionally breached certain provisions of agreements previously entered into with us. In the complaint we requested that the defendants be permanently restrained and enjoined from breaching such agreements and disgorging all compensation and all profits derived from their claimed misappropriation of plaintiff's intellectual property.

On August 8, 2013 the parties entered into Settlement Agreement and Mutual Release in the Supreme Court of the State of New York and we expect no further legal action in this case.

There have been no other material changes from the legal proceedings disclosed in our Form 10-K for the year ended December 31, 2012.

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2012 and additional risk factors disclosed in our Form 10-Q for the quarter ended March 31, 2013.

ITEM 6. EXHIBITS

(a) Exhibits

31.1 Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.

31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2013, filed on November 12, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statement of Stockholders Equity (iv) the Condensed Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements tagged as blocks of text.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SYNERGY PHARMACEUTICALS INC.
(Registrant)

Date: November 12, 2013

By: /s/ GARY S. JACOB
Gary S. Jacob
President and Chief Executive Officer

Date: November 12, 2013

By: /s/ BERNARD F. DENOYER
Bernard F. Denoyer
Senior Vice President, Finance

EXHIBIT 31.1

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: November 12, 2013

/s/ GARY S. JACOB

Gary S. Jacob

President and Chief Executive Officer

EXHIBIT 31.2

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: November 12, 2013

/s/ BERNARD F. DENOYER
Bernard F. Denoyer
Senior Vice President, Finance

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
SYNERGY PHARMACEUTICALS INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2013
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 September 30, 2013 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: November 12, 2013

/s/ GARY S. JACOB
Gary S. Jacob
President and Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION OF SENIOR VICE PRESIDENT, FINANCE
SYNERGY PHARMACEUTICALS INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2013
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 September 30, 2013 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: November 12, 2013

/s/ BERNARD F. DENOYER
Bernard F. Denoyer
Senior Vice President, Finance