SYNERGY PHARMACEUTICALS, INC.
Form 10-Q
May 09, 2013
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: MARCH 31, 2013

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

For the transition period from to

Commission File Number: 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 1609, 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 x No o

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes x No o

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

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

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

The number of the registrant s shares of common stock outstanding was 90,182,090 as of May 8, 2013.

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(A development stage company)

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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)

	March 31, 2013 (unaudited)	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 9,067	$ 12,416
Available-for-sale securities	12,049	20,086
Prepaid expenses and other current assets	1,573	1,547
Total Current Assets	22,689	34,049
Property and equipment, net	108	30
Security deposits	93	20
Due from controlling shareholder		3,306
Total Assets	$ 22,890	$ 37,405
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 5,978	$ 5,255
Accrued expenses	3,312	2,060
Total Current Liabilities	9,290	7,315
Derivative financial instruments, at estimated fair value-warrants	6,351	5,258
Total Liabilities	15,641	12,573
Stockholders Equity:		
Preferred stock, Authorized 20,000,000 shares, at March 31, 2013 and December 31, 2012, none outstanding		
Common stock, par value of $.0001 authorized 200,000,000 shares at March 31, 2013 and 100,000,000 shares at December 31, 2012. Issued and outstanding 73,779,680 and 66,621,832 shares at March 31, 2013 and December 31, 2012, respectively.	8	7
Additional paid-in capital	134,991	133,878
Deficit accumulated during development stage	(127,750)	(109,053)
Total Stockholders Equity	7,249	24,832

Total Liabilities and Stockholders Equity	$ 22,890	$ 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

(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended March 31,		November 15, 2005 (inception) to March 31, 2013
	2013	2012	
Revenues	$	$	$
Costs and Expenses:			
Research and development	14,344	5,338	72,051
Purchased in-process research and development			29,157
General and administrative	3,278	1,732	30,863
Loss from Operations	(17,622)	(7,070)	(132,071)
Interest and investment income	18	39	514
Interest expense			(12)
Other income			1,363
Change in fair value of derivative instruments-warrants	(1,093)	8	2,528
Total Other (Loss)/Income	(1,075)	47	4,393
Loss from Continuing Operations	(18,697)	(7,023)	(127,678)
Loss from Discontinued Operations			(72)
Net Loss	$ (18,697)	$ (7,023)	$ (127,750)
Weighted Average Common Shares Outstanding			
Basic and Diluted	72,789,006	54,298,079	
Net Loss per Common Share, Basic and Diluted			
Net Loss per Common Share, Basic and Diluted	$ (0.26)	$ (0.13)	

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	66,621,832	7	133,878	(109,053)	24,832
Common stock issued via registered direct offering	758,093		4,671		4,671
Fees and expenses related to financing transactions			(140)		(140)
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)		
Recapitalization of Synergy			(4,904)		(4,904)
Common stock issued for services rendered	55,000		250		250
Exercise of stock options	34,352		105		105
Stock based compensation expense			1,132		1,132
Net loss for the period				(18,697)	(18,697)
Balance, March 31, 2013	73,779,680	$ 8	$ 134,991	$ (127,750)	$ 7,249

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)

	Three Months Ended March 31, 2013	Three Months Ended March 31, 2012	Period from November 15, 2005 (Inception) to March 31, 2013
Cash Flows From Operating Activities:			
Net loss	$ (18,697)	$ (7,023)	$ (127,750)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation			10
Loss on disposal of property and equipment			2
Stock-based compensation expense	1,257	438	6,741
Accretion of discount/premium on investment securities	37		(49)
Purchased in-process research and development			28,157
Change in fair value of derivative instruments-warrants	1,093	(8)	(2,528)
Changes in operating assets and liabilities:			
Security deposit			(20)
Accounts payable and accrued expenses	700	303	7,167
Prepaid expenses and other current assets	(27)	(554)	(1,574)
Total Adjustments	3,060	179	37,906
Net Cash Used in Operating Activities	(15,637)	(6,844)	(89,844)
Cash Flows From Investing Activities:			
Loans to related parties	(270)	(278)	(3,731)
Sale/(purchases) of available-for-sale securities	8,000		(12,000)
Additions to property and equipment	(78)		(120)
Net Cash Provided by/(Used in)Investing Activities	7,652	(278)	(15,851)
Cash Flows From Financing Activities:			
Proceeds from sale of common stock	4,671		121,105
Fees and expenses related to sale of common stock	(140)		(6,863)
Proceeds from exercise of stock warrants			415
Proceeds from exercise of stock options	105		105
Net Cash Provided by Financing Activities	4,636		114,762
Net (decrease) increase in cash and cash equivalents	(3,349)	(7,122)	9,067
Cash and cash equivalents at beginning of period	12,416	13,245	
Cash and cash equivalents at end of period	$ 9,067	$ 6,123	$ 9,067
Supplementary disclosure of cash flow information:			
Cash paid for taxes	$ 18	$ 1	$ 158
Supplementary disclosure of non-cash investing and financing activities:			
Value of warrants classified as derivative liability-net	$	$	$ 8,879

Value of common stock issued to induce stockholders to extend lock-up agreements	$	$	$ 3,235
Recapitalization of Synergy	$ 4,904	$	$ 4,904
Cancellation of unregistered shares owned by former controlling shareholder			
Common stock issued to Callisto			

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

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Business Overview

Synergy 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 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 constipation symptoms but a majority of these patients 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 inflammatory bowel diseases, such as ulcerative colitis, or UC.

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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, 2012 contained in the Company s Annual Report on Form 10-K filed with the Securities Exchange Commission (SEC) on March 18, 2013. All intercompany balances and transactions have been eliminated.

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3. Recent Accounting Pronouncements

There are no recent accounting pronouncements affecting the Company.

4. 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, 2013, the amount of cash and cash equivalents was approximately $9.1 million and consists of checking accounts, 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 March 31, 2013 consist of approximately $12.0 million in U.S. Treasury securities 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. Cash equivalents and marketable securities are carried at amounts that approximate fair value due to their short-term maturities. As of March 31, 2013, gross unrealized losses were not material. The Company recognized no net realized gains or losses for the three months ended March 31, 2013. 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 months ended March 31, 2013, the Company did not recognize any impairment charges. As of March 31, 2013 and December 31, 2012, the Company did not consider any of its investments to be other-than-temporarily impaired. The Company s marketable securities as of December 31, 2012 consisted of approximately $20.1 million in U.S. Treasury securities.

5. 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:

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($ in thousands)	Three Months Ended March 31, 2013	2012	November 15, 2005 (inception) to March 31, 2012
Employees included in research and development	$ 276	$ 116	$ 1,877
Employees included in general and administrative	450	94	1,859
Subtotal employee stock based compensation	726	210	3,736
Non-employees included in research and development	135	0	432
Non-employees included in general and administrative	396	228	2,573
Subtotal non-employee stock based compensation	531	228	3,005
Total stock-based compensation expense	$ 1,257	$ 438	$ 6,741

The unrecognized compensation cost related to non-vested stock options outstanding at March 31, 2013, net of expected forfeitures, was approximately $8.3 million to be recognized over a weighted-average remaining vesting period of approximately 2.4 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, 2013	Three Months Ended March 31, 2012
Risk-free interest rate	0.04%-1.87%	1.05%-1.50%
Dividend yield		
Expected volatility	60%	60%
Expected term (in years)	6 years	6 years

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	1,249,316(a)	$ 0.44-20.01	$ 8.29		
Exercised	(34,352)	$ 0.50 4.28	$ 3.04		
Forfeited	(500,000)	$ 4.42	$ 4.42		
Balance outstanding, March 31, 2013	10,449,232(a)	$ 0.44-20.01	$ 3.33	$ 32,466	7.1 years
Exercisable at March 31, 2013	3,917,662(a)	$ 0.44-20.01	$ 3.09	$ 14,136	5.3 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 1,010,026 stock options are vested as of March 31, 2013. (Note 7)

6. 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) its New York City Biotechnology Tax Credit for the tax year of 2012 totaling $250,000. These credits have been recorded as other current assets at December 31, 2012 and March 31, 2013.

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7. Stockholder s Equity

From January 1, 2013 through March 31, 2013, Synergy sold 758,093 shares of common stock with gross proceeds of approximately $4.67 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 $140,000.

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 and represented approximately 25% of the total contract. The agreed number of shares was 55,000 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 share based compensation expense of $125,000 during the quarter ended December 31, 2012. The remaining balance of $125,000 was recorded as share based compensation expense upon completion of the contact in January 2013 and Synergy issued 55,000 shares to the CRO during the quarter ended March 31, 2013.

On January 15, 2013, the number of authorized shares of common stock increased from 100,000,000 to 200,000,000.

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.

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, effected 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 stand point. 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)

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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 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 $0.7 million and $0.9 million as of March 31, 2013 and December 31, 2012, 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, 2013	Three Months Ended March 31, 2012
Fair value of Synergy common stock	$ 6.07	$ 4.05
Expected warrant term	5.0-7.0 years	5.0 - 7.0 years
Risk-free interest rate	0.31% - 0.77%	0.51% - 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.

As of March 31, 2013, certain of Synergy s outstanding warrants contained a price protection clause which variable exercise price requires the Company to use a binomial model to determine fair value. The range of assumptions used to determine the fair value of the warrants at the dates indicated were as follows:

	Three months ended, March 31, 2013	Three months ended, March 31, 2012
Fair value of Synergy common stock	$ 6.07	$ 3.28
Expected warrant term	3.63 years	4.63 years
Risk-free interest rate	0.36%	1.04%
Expected volatility	60%	60%
Dividend yield	0%	0%

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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:

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	Reclass 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

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, 2012 and March 31, 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 March 31, 2013
Derivative liabilities related to Warrants	$	$	$ 5,258	$ 5,258	$	$	$ 6,351	$ 6,351

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, 2013:

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Description	Balance at December 31, 2012	Fair Value of warrants upon issuance	(Gain) or loss recognized in earning from Change in Fair Value	Balance as of March 31, 2012
Derivative liabilities related to Warrants	$ 5,258	$	$ 1,093	$ 6,351

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

10. 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 months ended March 31, 2013 and March 31, 2012 the effect of 10,449,232 and 6,736,039, 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, 2013 and March 31, 2012, the effect of 5,647,203 and 5,597,203 outstanding warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive.

11. Subsequent Event

On April 16, 2013, Synergy closed a public offering of 16,375,000 shares of its common stock at a price of $5.50 per share, less underwriting discounts and commissions. The net proceeds to the Company from this sale was approximately $84.4 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. The Company has also granted the underwriters a 30-day option to purchase up to an additional 2,456,250 shares of its common stock to cover over-allotments, if any. As of May 8, 2013 this option had not been exercised. The following table sets forth the pro-forma effect on the financial position of the Company had the transaction taken place on March 31, 2013:

($000 s except share amounts)	March 31, 2013 As Reported	Effect of April 16, 2013 Public Offering	March 31, 2013 Pro-forma
Cash, cash equivalents and available for sale securities	$ 21,116	$ 84,444	$ 105,560
Total Assets	22,890	84,444	107,334
Common Stock	8	2	10
Additional paid-in-capital	134,991	84,442	219,433
	(127,750)		(127,750)

Deficit accumulated during development stage			
Total stockholder s equity	7,249	84,444	91,693
Total liabilities and stockholder s equity	$ 22,890	$ 84,444	$ 107,334
Common Shares Outstanding	73,779,680	16,375,000	90,154,680

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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 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.

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 guanylylcyclase 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. We are also developing SP-333, our second generation GC-C receptor agonist for the treatment of gastrointestinal inflammatory diseases, such as 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 and IBS-C, with diarrhea and nausea being common side effects of such therapies.

Plecanatide

Plecanatide, our lead investigational drug, is a member of a new class of non-systemic drugs, referred to as guanylate cyclase C (GC-C) agonists. 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.

There are a multitude of causes of constipation including other disease states and certain drug therapies (e.g., narcotics). CIC has no identifiable causes such as these diseases or drugs or physical anomalies. Patients 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 March 15, 2013, we announced that the study results from this multicenter-trial would be featured in a late-breaking oral presentation session at Digestive Disease Week 2013 in Orlando, Florida on Tuesday, May 21, at 10:00 am. On April 3, 2013, Digestive Disease Week 2013 released the 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.

IBS is characterized by symptoms of abdominal pain or discomfort such as cramping, bloating, gas, and constipation or diarrhea or both. IBS-C is the subtype 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.

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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. alone, 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. We expect this study will be conducted at 70 sites in the U.S. and that 350 patients will be enrolled. 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 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. We expect this trial will be reported during the first quarter of 2014.

Plecanatide is covered by a U.S. patent issued on May 9, 2006 with respect to composition of matter that expires on March 25, 2023, subject to possible patent term extension, and a U.S. patent issued on September 21, 2010 with respect to composition of matter that expires on June 9, 2022, subject to possible patent term extension. We have filed patent applications to broaden our patent estate covering GC-C receptor agonists.

SP-333

We are developing a second generation GC-C receptor analog, SP-333, for the treatment of inflammatory bowel diseases, or IBD. SP-333 is a synthetic analog of uroguanylin, a natriuretic hormone which 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 ulcerative colitis, or UC and Crohn s disease.

More than 500,000 Americans are afflicted with UC, a type of IBD that causes chronic inflammation of the colon. Along with Crohn s disease, the other major form of IBD, UC is painful and debilitating, and can lead to other serious and life-threatening complications such as increased incidence of colon cancer. There is currently no medical cure for UC. A considerable medical need exists for the control and treatment of UC. SP-333 has exhibited potent anti-inflammatory activity in animal studies of colitis, displaying a novel mechanism-of-action that Synergy believes might provide a new way to treat UC patients with mild to moderate 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.

On February 1, 2011 the U.S. Patent and Trademark Office issued U.S. Patent No. 7,879,802 to us, covering our novel drug candidate SP-333 to treat IBD. The patent entitled Agonists of Guanylate Cyclase Useful for the Treatment of Gastrointestinal Disorders, Inflammation, Cancer and Other Disorders specifically claims composition of matter of SP-333 and use in the treatment of human diseases.

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, 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. As of March 31, 2013, no milestones have been achieved.

RECENT DEVELOPMENTS

On January 17, 2013, we completed our acquisition of Callisto Pharmaceuticals, pursuant to the Merger Agreement. As a result of the Merger, we issued a total of 28,605,379 shares of our 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 our common stock (the Exchange Ratio). The 22,294,976 shares of our common stock held by Callisto were canceled. In addition, each stock option exercisable for shares of Callisto common stock that was outstanding on January 17, 2013 was assumed by us and converted into a stock option to purchase the number of shares of our 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 our common stock in accordance with the Exchange Ratio. Accordingly, we issued 1,221,316 stock options in connection with this exchange.

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FINANCIAL OPERATIONS OVERVIEW

From inception through March 31, 2013, we have sustained cumulative net losses of approximately $127.8 million. From inception through March 31, 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.

On April 16, 2013, we closed a public offering of 16,375,000 shares of our common stock at a price of $5.50 per share, less underwriting discounts and commissions. The net proceeds to the Company from this sale was approximately $84.4 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. We have also granted the underwriters a 30-day option to purchase up to an additional 2,456,250 shares of its common stock to cover over-allotments, if any. As of May 8, 2013 this option had not been exercised.

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, 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 March 31, 2013.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2013 AND 2012

We had no revenues during the three months ended March 31, 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 March 31, 2013 (Current Quarter) increased approximately $9 million or 169 %, to approximately $14.3 million from approximately $5.3 million for the three months ended March 31, 2012 (Prior Year Quarter). This increase in research and development expenses was largely attributable to continuing the 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 March 31, 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) Three Months Ended March 31,	
Drug candidates	**2013**	**2012**
Plecanatide	$ 8,689	$ 4,739
SP-333	3,908	
Total direct costs	$ 12,597	$ 4,739
Total indirect costs	1,747	599
Total Research and Development	$ 14,344	$ 5,338

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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. Indirect costs were approximately $1.7 million in the Current Quarter, as compared to approximately $0.6 million during the Prior Year Quarter primarily due to higher share based compensation and scientific advisory costs.

General and administrative expenses increased approximately $1.6 million or 95%, to approximately $3.3 million for the Current Quarter from approximately $1.7 million for the Prior Year Quarter. These increased expenses were primarily the result of (i) higher compensation and related employee benefits of approximately $1.3 million, as compared to $0.5 million during the Prior Year Quarter, which were primarily due to higher stock based compensation expense, (ii) higher facilities cost of approximately $0.4 million in the Current Quarter as compared to approximately $0.3 million during the Prior Year Quarter and (iii) higher corporate legal services of approximately $0.7 million for the Current Quarter, as compared to $0.4 million for the Prior Year Quarter, as a result of ongoing class action litigation in connection with the merger, and (iv) higher consulting in public relations and advisory fees of approximately $0.6 million in the Current Quarter, as compared to $0.3 million during the Prior Year Quarter.

Net loss for the Current Quarter was approximately $18.7 million as compared to a net loss of approximately $7 million incurred for the Prior Year Quarter. This increase in our net loss of approximately $11.7 million or 167% was a result of the increases in operating expenses discussed above, and a loss resulting from the change in fair value of derivative instruments-warrants of $1.1 million during the Current Quarter, as compared to a gain of approximately $8,000 during the Prior Year Quarter.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2013, we had approximately $9.1 million in cash and cash equivalents and approximately $12.1 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 $15.6 million for the three months ended March 31, 2013 as compared to approximately $6.8 million during the three months ended March 31, 2012. Approximately $4.6 million was provided by financing transactions for the three months ended March 31, 2013, and there was no financing activity for the three months ended March 31, 2012. As of March 31, 2013, we had working capital of approximately $13.4 million, as compared to working capital of $26.7 million on December 31, 2012.

The following table sets forth the pro-forma effect on the financial position of the Company had the April 16, 2013 public offering transaction discussed above taken place on March 31, 2013:

($000 s except share amounts)	**March 31, 2013 As Reported**	**Effect of April 16, 2013 Public Offering**	**March 31, 2013 Pro-forma**
Cash, cash equivalents and available for sale securities	$ 21,116	$ 84,444	$ 105,560
Total Assets	22,890	84,444	107,334
Common Stock	8	2	10
Additional paid-in-capital	134,991	84,442	219,433

Retained earnings (deficit)	(127,750)		(127,750)
Total stockholder s equity	7,249	84,444	91,693
Total liabilities and stockholder s equity	$ 22,890	$ 84,444	$ 107,334
Common Shares Outstanding	73,779,680	16,375,000	90,154,680

As of March 31, 2013, Synergy had an accumulated deficit of approximately $127.8 million and expects to incur significant and increasing operating losses for the next several years as the Company continues to expand its 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, Synergy is unable to predict the extent of any future losses or when Synergy will become profitable, if at all.

Synergy s independent registered public accounting firm has issued a report on Synergy s December 31, 2012 financial statements that included an explanatory paragraph referring to its projected future losses along with recurring losses from operations and expressing substantial doubt in Synergy s ability to continue as a going concern without additional capital becoming available. These condensed consolidated financial statements as of December 31, 2012 have been prepared under the assumption that Synergy will continue as a going concern. Synergy s ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The condensed consolidated financial statements as of December 31, 2012 do not include any adjustments that might result from the outcome of this uncertainty.

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Synergy 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. Synergy 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 Synergy raises additional funds by issuing equity securities, Synergy s stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Synergy s 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 Synergy 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, 2013, we held approximately $8.4 million in money market accounts and held approximately $12.1 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. 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, 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.

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, 2013.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

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ITEM 1A. RISK FACTORS

There have been no other material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2012, except the following:

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of clinical trial participants and employees. Similarly, our business partners and third party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information, including our data being breached at our business partners or third-party providers, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

Our clinical activities involve the handling of hazardous materials, and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our clinical activities involve the controlled storage, use and disposal of hazardous materials. We are subject to federal, state, city and local environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, storage, handling and disposal of these hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or if we fail to comply with such laws or regulations, local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations or impose sanctions, such as fines, and we could be liable for any resulting damages or liabilities. We do not currently maintain hazardous materials insurance coverage.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure protection of such rights.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. We will only be able to protect our product candidates from unauthorized making, using, selling and offering to sell or importation by third parties to the extent that we have rights under valid and enforceable patents or trade secrets that cover these activities.

As of May 8, 2013, we have six issued United States patents related to guanylate cyclase agonists. Two of these patents cover the composition-of-matter of plecanatide and were issued on May 8, 2006 and September 21, 2010; they will expire in 2023 and 2022, respectively.

The patent that issued on May 9, 2006 has claims directed to the species of plecanatide, whereas the patent that issued on September 21, 2010 has claims directed to a genus of peptides that are identical in length to plecanatide and is inclusive of plecanatide. A third patent covers the composition-of-matter of SP-333 issued on February 1, 2011 and expires in 2028. A fourth patent granted October 11, 2011 covers composition-of-matter of analogs related to plecanatide and SP-333 and will expire in 2028. A fifth patent granted February 14, 2012 covers a method of treating inflammatory bowel disease using plecanatide and will expire in 2022. A sixth patent granted June 26, 2012 covers addition composition-of-matter related to plecanatide and SP-333 and will expire in 2029. In addition, we have four granted foreign patents which cover composition-of-matter of plecanatide and expire in 2022. These foreign patents cover Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Sweden, Turkey, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyz Republic, Moldova, Russian Federation, Tajikistan, Turkmenistan, Canada and Japan. We also have a granted foreign patent that covers composition of matter related to SP-333 that expires in 2028. This patent covers Switzerland, Germany, Denmark, Spain, France, United Kingdom, Ireland, Italy, and Netherlands.

Additionally, as of May 8, 2013, we have 11 pending United States patent applications and 47 pending foreign patent applications covering plecanatide and SP-333 and various derivatives and analogs. In April 2010, two parties filed an opposition to our granted patent with the European Patent Office. An opposition hearing was held December 14, 2011, which resulted in the European Patent Office issuing the following statement: Account being taken of the amendments made by the patent proprietor during the opposition proceedings, the patent and the invention to which it relates are found to meet the requirements of the European Patent Convention (Art.101(3)(a)EPC). In particular, the composition-of-matter claim covering plecanatide was upheld.

On September 14, 2012 we entered into a binding Letter of Intent, or LOI, with Ironwood pursuant to which we and Ironwood agreed to enter into a definitive license agreement giving us an exclusive worldwide license to Ironwood s method of use patents on plecanatide. The LOI contemplates a low single digit royalty on net sales of plecanatide and both parties agreed not to challenge each other s patents covering certain GC-C agonists, except that we retain the right to challenge Ironwood s method of use patents on plecanatide.

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As of May 8, 2013, we exclusively license three issued United States patents related to FV-100. One of these patents covers the composition-of-matter of FV-100 and was issued on December 11, 2012 and will expire in 2028. The other two cover the precursor and close analogs of FV-100 and were issued on October 26, 2010 and June 3, 2003 and will both expire in 2018. In addition we exclusively license 36 granted foreign patents which cover composition-of-matter of FV-100 and expire in 2027. These foreign patents cover Australia, Austria, Belgium, Bulgaria, China, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, New Zealand, Pakistan, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, and the Russian Federation. We exclusively license 7 foreign patent applications that cover composition-of-matter of FV-100 in Brazil, Canada, India, Israel, Japan, Korea, and Taiwan. We also exclusively license 44 additional foreign patents and 2 foreign patent applications that cover the precursor and close analogs of FV-100.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The biotechnology patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our issued patents or in third-party patents.

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 March 31, 2013, filed on May 9, 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 (Deficit) (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: May 9, 2013	By:	/s/ GARY S. JACOB Gary S. Jacob *President and Chief Executive Officer*
Date: May 9, 2013	By:	/s/ BERNARD F. DENOYER Bernard F. Denoyer *Senior Vice President, Finance*