SYNERGY PHARMACEUTICALS, INC.
Form 10-Q
August 09, 2012
Table of Contents

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: JUNE 30, 2012

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 65,806,178 as of August 8, 2012.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

FORM 10-Q

TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2012 (unaudited)	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 27,426,900	$ 13,244,883
Available-for-sales securities	16,149,789	
Prepaid expenses and other current assets	1,408,719	1,063,402
Total Current Assets	44,985,408	14,308,285
Property and equipment, net	2,464	5,773
Available-for-sale securities long term	4,010,787	
Security deposits	19,511	14,025
Due from related party	1,936,609	1,541,456
Total Assets	$ 50,954,779	$ 15,869,539
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 1,154,469	$ 1,415,617
Accrued expenses	3,765,094	1,331,382
Total Current Liabilities	4,919,563	2,746,999
Derivative financial instruments, at estimated fair value-warrants	4,803,717	3,325,114
Total Liabilities	9,723,280	6,072,113
Stockholders Equity:		
Preferred stock, Authorized 20,000,000 shares, at June 30, 2012 and December 31, 2011, none outstanding		
Common stock, par value of $.0001 authorized 100,000,000 shares, outstanding 65,806,178 and 54,279,906 shares at June 30, 2012 and December 31, 2011, respectively	6,582	5,429
Additional paid-in capital	128,415,027	79,401,015
Deficit accumulated during development stage	(87,190,110)	(69,609,018)
Total Stockholders Equity	$ 41,231,499	$ 9,797,426
	$ 50,954,779	$ 15,869,539

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		November 15, 2005 (inception) to
	2012	2011	2012	2011	June 30, 2012
Revenues	$	$	$	$	$
Costs and Expenses:					
Research and development	7,626,268	2,354,450	12,964,408	3,832,576	41,377,562
Purchased in-process research and development					28,156,502
General and administrative	1,918,488	1,524,402	3,649,616	3,422,028	23,294,258
Loss from Operations	(9,544,756)	(3,878,852)	(16,614,024)	(7,254,604)	(92,828,322)
Interest and investment income	48,116	20,003	86,794	44,067	364,980
Interest expense				(11,877)	(11,877)
Other income	255,539		255,539		1,112,516
Change in fair value of derivative instruments-warrants	(1,317,347)	(697,660)	(1,309,401)	(1,036,375)	4,244,414
Total Other Income/(Expense)	(1,013,692)	(677,657)	(967,068)	(1,004,185)	5,710,033
Loss from Continuing Operations	(10,558,448)	(4,556,509)	(17,581,092)	(8,258,789)	(87,118,289)
Loss from discontinued operations					(71,821)
Net Loss	$ (10,558,448)	$ (4,556,509)	$ (17,581,092)	$ (8,258,789)	$ (87,190,110)
Weighted Average Common Shares Outstanding					
Basic and Diluted	60,416,068	46,642,901(*)	57,357,081	46,406,472(*)	
Net Loss per Common Share,					
Basic and Diluted	$ (0.17)	$ (0.10)(*)	$ (0.31)	$ (0.18)(*)	

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

(*) Restated for 1:2 reverse stock split effective November 30, 2011.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)

	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	7,569	(5,569)		2,000
Sale of common stock	6,850,000	685	17,415		18,100
Net loss for the year				(16)	(16)
Balance, December 31, 2005	82,540,608	8,254	11,846	(16)	20,084
Net loss for the year				(20,202)	(20,202)
Balance, December 31, 2006	82,540,608	8,254	11,846	(20,218)	(118)
Capital contribution by shareholders			8,893		8,893
Net loss for the year				(20,043)	(20,043)
Balance, December 31, 2007	82,540,608	8,254	20,739	(40,261)	(11,268)
Cancellation of unregistered founder shares	(74,990,604)	(7,499)	7,499		
Common stock issued via Exchange Transaction	22,732,380	2,273	27,276,588		27,278,861
Common stock issued via private placement	2,520,833	252	3,024,748		3,025,000
Fees and expenses related to private placements			(73,088)		(73,088)
Stock based compensation expense			379,883		379,883
Net loss for the period				(31,755,180)	(31,755,180)
Balance, December 31, 2008	32,803,217	3,280	30,636,369	(31,795,441)	(1,155,792)
Common stock issued via private placements	11,407,213	1,141	15,968,959		15,970,100
Fees and expenses related to private placements			(260,002)		(260,002)
Common Stocks Issued for services rendered	1,250	1	1,499		1,500
Stock based compensation expense			1,053,062		1,053,062
Net loss for the period				(8,125,100)	(8,125,100)
Balance, December 31, 2009	44,211,680	4,422	47,399,887	(39,920,541)	7,483,768
Common stock issued via registered direct offering and private placement	1,209,000	121	7,178,879		7,179,000
Fees and expenses related to direct offering			(468,130)		(468,130)
Warrants reclassified to derivative liability			(3,784,743)		(3,784,743)
	670,933	67	(67)		

Common stock issued to extend lock-up agreements related to unregistered shares					
Common stock Issued for services rendered	2,469		18,271		18,271
Stock based compensation expense			693,887		693,887
Net loss for the period				(15,221,441)	(15,221,441)
Balance, December 31, 2010	46,094,082	4,610	51,037,984	(55,141,982)	(4,099,388)
Common stock issued via registered direct offerings and private placements	7,733,093	773	34,368,291		34,369,064
Fees and expenses related to financing transactions paid in cash			(2,148,383)		(2,148,383)
Fees and expenses related to financing transactions paid in units of common stock and warrants	77,750	8	(8)		
Warrants classified to derivative liability - net			(5,094,186)		(5,094,186)
Common stock issued to make whole certain unregistered shares	215,981	22	(22)		
Exercise of warrant	80,000	8	415,301		415,309
Common stock issued for services rendered	79,000	8	341,287		341,295
Stock based compensation expense			480,751		480,751
Net loss for the period				(14,467,036)	(14,467,036)
Balance, December 31, 2011	54,279,906	$ 5,429	$ 79,401,015	$ (69,609,018)	$ 9,797,426
Common stock issued via registered direct offering	11,500,000	1,150	51,748,850		51,750,000
Fees and expenses related to financing transactions paid in cash			(3,357,930)		(3,357,930)
Warrants classified to derivative liability			(169,203)		(169,203)
Common stock issued for services rendered	26,272	3	92,660		92,663
Stock based compensation expense			699,635		699,635
Net loss for the period				(17,581,092)	(17,581,092)
Balance, June 30, 2012 (unaudited)	65,806,178	$ 6,582	$ 128,415,027	$ (87,190,110)	$ 41,231,499

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.

(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six Months Ended June 30, 2012	Six Months Ended June 30, 2011	Period from November 15, 2005 (Inception) to June 30, 2012
Cash Flows From Operating Activities:			
Net loss	$ (17,581,092)	$ (8,258,789)	$ (87,190,110)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	988	988	8,138
Loss on disposal of property and equipment	2,321		2,321
Stock-based compensation expense	792,298	296,558	3,760,947
Accretion of discount/premium on investment securities	(160,576)		(160,576)
Purchased in-process research and development			28,156,502
Change in fair value of derivative instruments-warrants	1,309,401	1,036,375	(4,244,414)
Changes in operating assets and liabilities:			
Security deposit	(5,486)		(19,511)
Accounts payable and accrued expenses	2,172,563	(191,634)	4,196,519
Prepaid expenses and other current assets	(345,317)	136,185	(1,408,719)
Total Adjustments	3,766,192	1,278,472	30,291,207
Net Cash Used in Operating Activities	(13,814,900)	(6,980,317)	(56,898,903)
Cash Flows From Investing Activities:			
Net cash paid on Exchange Transaction			(155,326)
Repayment from/(loans to) related parties	(395,153)	295,614	(1,936,609)
Purchases of available-for-sale securities	(20,000,000)		(20,000,000)
Additions to property and equipment			(12,195)
Net Cash (Used in) /Provided by Investing Activities	(20,395,153)	295,614	(22,104,130)
Cash Flows From Financing Activities:			
Capital contribution by shareholders			8,893
Issuance of common stock			2,000
Proceeds from sale of common stock	51,750,000	5,461,242	112,293,164
Proceeds from exercise of warrants		415,309	415,309
Proceeds from sale of unregistered common stock to founders			18,100
Fees and expenses related to sale of common stock	(3,357,930)	(395,620)	(6,307,533)
Net Cash Provided by Financing Activities	48,392,070	5,480,931	106,429,933
Net increase (decrease) in cash and cash equivalents	14,182,017	(1,203,772)	27,426,900
Cash and cash equivalents at beginning of period	13,244,883	1,707,516	
Cash and cash equivalents at end of period	$ 27,426,900	$ 503,744	$ 27,426,900
Supplementary disclosure of cash flow information:			
Cash paid for taxes	$ 11,948	$ 8,021	$ 83,564

Value of warrants classified as derivative liability - net	$ 169,203	$ 3,920,500	$ 9,048,132
Value of common stock issued to induce stockholders to extend lock-up agreements	$	$	$ 3,235,040

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Business Overview

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

2. Basis of Presentation and Accounting Policies

On July 14, 2008, Pawfect Foods Inc. (Pawfect), a Florida corporation incorporated on November 15, 2005, acquired 100% of the common stock of Synergy Pharmaceuticals, Inc., a Delaware corporation incorporated on September 11, 1992, and its wholly-owned subsidiary, Synergy Advanced Pharmaceuticals, Inc., (collectively Synergy-DE), under the terms of an Exchange Agreement among Pawfect, Callisto Pharmaceuticals, Inc. (Callisto), Synergy-DE, and certain other holders of Synergy-DE common stock (Exchange Transaction).

Synergy acquired the GI drugs and related technology in connection with the Exchange Transaction. On July 21, 2008, Pawfect amended its articles of incorporation to effect the actions necessary to complete the transactions contemplated by the Exchange Transaction and changed its name to Synergy Pharmaceuticals, Inc. The acquisition of Synergy-DE was treated as an asset acquisition, since Synergy-DE is a development stage company and does not have the necessary inputs and outputs to meet the definition of a business. The results of operations of Synergy-DE are included in the accompanying consolidated financial statements from the date of acquisition. As a result of the acquisition of Synergy-DE on July 14, 2008, the Company decided to discontinue its pet food business and accordingly, amounts in the consolidated statements of operations and related notes for all historical periods have been restated to reflect these operations as discontinued.

On November 29, 2011 the Company filed an amendment to its amended and restated articles of incorporation pursuant to which the Company effected a one for two (1:2) reverse stock split on its authorized, issued and outstanding shares of Common Stock, effective on November 30, 2011. All share and per share information has been adjusted to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented, (e.g. inception November 15, 2005).

On February 14, 2012, Synergy Pharmaceuticals, Inc., (the Company) entered into an agreement and plan of merger (the Agreement) with its wholly-owned subsidiary, Synergy Pharmaceuticals Inc., a Delaware corporation (Synergy-DE) for the purpose of changing the state of incorporation of the Company to Delaware from Florida. Pursuant to the Agreement, the Company merged with and into Synergy-DE with Synergy-DE continuing as the surviving corporation.

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, 2011 contained in the Company s Annual Report on Form 10-K filed with the Securities Exchange Commission (SEC) on March 15, 2012. Certain items in the prior year s financial statements have been reclassified to conform to the current year s presentation. All intercompany balances and transactions have been eliminated.

Synergy s independent registered public accounting firm has issued a report on Synergy s December 31, 2011financial statements that included an explanatory paragraph referring to its 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 June 30, 2012 and December 31, 2011 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 do not include any adjustments that might result from the outcome of this uncertainty.

As of June 30, 2012, Synergy had an accumulated deficit of $87,190,110 and expects to incur significant and increasing operating losses for the next several years as the Company expands its research and development, continues clinical trials of plecanatide for the treatment of GI 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.

Net cash used in operating activities was $13,814,900 for the six months ended June 30, 2012, as compared to net cash used of $6,980,317 for the six months ended June 30, 2011. As of June 30, 2012 Synergy has $27,426,900 of cash and cash equivalents on hand as compared to $13,244,883 of cash and cash equivalents on hand as of December 31, 2011. In addition, on June 30, 2012 Synergy held $20,160,576 in available-for-sale securities, whereas the Company had no such investments as of December 31, 2011. As of June 30, 2012 Synergy had working capital of $40,065,845 as compared to working capital of $11,561,286 as of December 31, 2011.

On May 9, 2012, Synergy closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of $4.50 per share. The gross proceeds from this offering were $45 million, before deducting underwriting discounts and commissions and other offering

Table of Contents

expenses of $2,952,930. Synergy also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of $4.50 per share to cover over-allotments, if any. On June 6, 2012 the underwriters exercised all of the over-allotment option resulting in additional gross proceeds of $6,750,000, before deducting underwriting discounts, commissions and other offering expenses of $405,000, bringing total gross proceeds from the offering to $51,750,000.

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 business. If Synergy is unable to raise additional capital when required or on acceptable terms, Synergy may have to (i) significantly 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 ourselves on unfavorable terms.

3. Financial Instruments - 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. The Company s marketable securities consist solely of investments in US Treasury Bills and Notes 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.

The Company classifies its marketable debt securities as either short-term or long-term based on each instrument s underlying contractual maturity date. Marketable debt securities with maturities of 12 months or less are classified as short-term and marketable debt securities with maturities greater than 12 months are classified as long-term. The Company may sell certain of its marketable securities prior to their stated maturities for strategic reasons including, but not limited to, anticipation of credit deterioration and duration management. The Company recognized no net realized gains or losses during the three and six month periods ended June 30, 2012. The maturities of the Company s long-term marketable securities range from one year to two years.

Cash equivalents and accounts payable are carried at amounts that approximate fair value due to their short-term maturities. As of June 30, 2012, gross unrealized losses were not material. The Company recognized no net realized gains or losses during the three and six month periods ended June 30, 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 six month periods ended June 30, 2012, the Company did not recognize any impairment charges. As of June 30, 2012, the Company did not consider any of its investments to be other-than-temporarily impaired.

4. Recent Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income* (ASU 2011-05) which is intended to facilitate the convergence of U.S. GAAP and International Financial Reporting Standards (IFRS) as well as to increase the transparency of items reported in other comprehensive income. As a result of ASU 2011-05, all non-owner changes in stockholders equity are required to be presented in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present other comprehensive income in the statement of changes in equity has been eliminated. ASU 2011-05 is effective for fiscal years beginning after December 15, 2011 and should be applied retrospectively. The Company adopted this standard on January 1 2012 and the adoption did not have a material impact on the Company s consolidated financial statements.

In May 2011, FASB issued ASU No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs. ASU 2011-04 amends Topic 820 to provide common fair value measurement and disclosure requirements in U.S. Generally Accepted Accounting Principles (U.S. GAAP) and International Financial Reporting Standards. Consequently, the amendments change the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements, as well as providing guidance on how fair value should be applied where its use is already required or permitted by other standards within U.S. GAAP. ASU No. 2011-04 is to be applied prospectively, and early adoption is not permitted. For public entities, the amendments are effective during interim and annual periods beginning after

Table of Contents

December 15, 2011. The adoption of ASU No. 2011-04 on January 1, 2012 did not have a material impact on the Company s consolidated financial statements.

In December 2011, the FASB issued ASU 2011-11, Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities. ASU 2011-11 provides for additional disclosures of both gross information and net information about both instruments and transactions eligible for offset in the statement of financial position and instruments and transactions subject to an agreement similar to a master netting arrangement. This scope would include derivatives, sale and repurchase agreements and reverse sale and repurchase agreements, and securities borrowing and securities lending arrangements. The amendments in this Update are effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods, and disclosures required by these amendments should be provided retrospectively for all comparative periods presented. The adoption of ASU No. 2011-11 is not expected to have a material impact on the Company s consolidated financial statements.

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.

	Three Months Ended June 30,	Six Months Ended June 30	November 15, 2005 (inception) to

	2012	2011	2012	2011	June 30, 2012
Employees included in research and development	$ 146,071	$ 37,157	$ 261,840	$ 73,906	$ 888,622
Employees included in general and administrative	100,091	45,115	193,740	89,733	968,150
Non-employees included in research and development		8,456		16,818	168,096
Non-employees included in general and administrative	108,065	58,370	336,718	116,101	1,736,079
Total stock-based compensation expense	$ 354,227	$ 149,098	$ 792,298	$ 296,558	$ 3,760,947

Table of Contents

The unrecognized compensation cost related to non-vested employee stock options outstanding at June 30, 2012, net of expected forfeitures, was $4,038,235, to be recognized over a weighted-average remaining vesting period of 2.9 years. This unrecognized compensation cost does not include amounts related to 4,364,000 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 following periods indicated.

	Six Months Ended June 30, 2012	Six Months Ended June 30, 2011
Risk-free interest rate	0.97%-1.50%	(*)
Dividend yield		(*)
Expected volatility	60%	(*)
Expected term (in years)	6 years	(*)

(*) No stock options granted during this period.

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	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2011	5,964,039	$ 0.50	4.30	$ 1.77	$ 10,631,388	8.2 years
Granted	1,272,000	$ 3.40	4.42	$ 3.89		
Exercised		$		$		
Forfeited	(105,000)	$ 3.40	4.38	$ 4.10		
Balance outstanding, June 30, 2012	7,131,039	$ 0.50	4.42	$ 2.11	$ 18,830,516	7.9 years
Exercisable at June 30, 2012	2,076,539	$ 0.50	4.30	$ 0.75	$ 8,306,391	6.2 years

6. Income Taxes

During the year ended December 31, 2011 the Company recorded refundable tax credits in prepaid and other current assets for its (i) 2010 New York State QETC credit, totaling $248,486 and (ii) its New York City Biotechnology Tax Credit for the tax year of 2011 totaling $118,437. On April 25, 2012, the Company received $246,402 for 2010 New York State QETC credit and on July 17, 2012, the Company collected $120,812 for 2011 New York City Biotechnology Tax Credit.

In addition, on June 15, 2012, the Company applied for its 2011 New York State QETC tax credit of $250,000 which is recorded as other income in the statement of operations for the quarter ended June 30, 2012.

7. Stockholder s Equity

On January 29, 2012 Synergy issued 26,272 unregistered shares of common stock to its corporate counsel for professional services rendered. The shares had a fair value on the date of issuance of $3.53 per share and $92,663 was recorded as legal expense during the quarter ended March 31, 2012.

On February 14, 2012, Synergy Pharmaceuticals, Inc., (the Company) entered into an agreement and plan of merger (the Agreement) with its wholly-owned subsidiary, Synergy Pharmaceuticals Inc., a Delaware corporation (Synergy-DE) for the purpose of changing the state of incorporation of the Company to Delaware from Florida. Pursuant to the Agreement, the Company merged with and into Synergy-DE with Synergy-DE continuing as the surviving corporation. The directors and officers in office of the Company upon the effective date of the merger shall be the directors and officers of Synergy-DE, all of whom shall hold their directorships and offices until the election and qualification of their respective successors or until their tenure is otherwise terminated in accordance with the by-laws of Synergy-DE. The effective date of the merger was the date on which the Certificate of Merger is filed with the Secretary of State of Delaware and the Secretary of State of Florida. The Certificate of Merger was filed with the Secretary of State of Florida on February 15, 2012 and with the Secretary of State of Delaware on February 16, 2012.

On May 9, 2012, Synergy closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of $4.50 per share. The gross proceeds from this offering were $45 million, before deducting underwriting discounts and commissions and other estimated

Table of Contents

offering expenses of $2,952,930. Synergy also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of $4.50 per share to cover over-allotments, if any. On June 6, 2012 the underwriters exercised the over-allotment option resulting in additional gross proceeds of $6,750,000, before deducting underwriting discounts, commissions and other offering expenses of $405,000, bringing total gross proceeds from the offering to $51,750,000.

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, insurance and FDA consultants.

In accordance with FASB ASC Topic 730-10-55, Research and Development, Synergy recorded prepaid research and development costs of $897,806 and $577,745 as of June 30, 2012 and December 31, 2011, 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 deferred research and development costs when drug compound is delivered and services are performed.

9. 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.

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, the fair value of these warrants is being re-measured at each balance sheet date 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 during the six months ended June 30, 2012 and June 30, 2011 were

	Six Months Ended June 30,	
	2012	2011
Estimated fair value of Synergy common stock	$4.05 - $4.75	$2.56 - $3.30
Expected warrant term	2.4 5.7 years	5-7 years
Risk-free interest rate	0.32% - 1.33%	1.2% - 2.5%
Expected volatility	60%	90%
Dividend yield		

Estimated 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 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 and the date of grant or quarterly revaluation.

Certain of Synergy s warrants issued during the six months ended June 30, 2012 and June 30, 2011 contained a price protection clause which variable term required 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 each period end during the six months ended June 30, 2012 and June 30, 2011 was as follows:

Table of Contents

	Six Months Ended June 30,	
	2012	2011
Estimated fair value of Synergy common stock	$3.28 - $4.50	$1.89
Expected warrant term	4.4 4.6 years	7 years
Risk-free interest rate	0.72% - 1.03%	2.64%
Expected volatility	60%	90%
Dividend yield		

In the Binomial model, the assumption for estimated fair value of the stock is based on a Black-Scholes based apportionment of the unit price paid for the shares and warrants issued in Synergy s most recent registered direct unit offerings, which resulting stock prices were deemed to be arms-length negotiated prices. 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.

The following table sets forth the components of changes in the Synergy s derivative financial instruments liability balance for the periods indicated:

Date	Description	Warrants		Derivative Instrument Liability
12/31/2010	Balance of derivative financial instruments liability	728,469	$	3,487,959
3/31/2011	Fair value of new warrants issued during the quarter	210,000	$	1,312,673
3/31/2011	Change in fair value of warrants during the quarter recognized as other expense in the statement of operations		$	338,715
3/31/2011	Balance of derivative financial instruments liability	938,469	$	5,139,347
6/30/2011	Fair value of new warrants issued during the quarter	611,207	$	2,607,827
6/30/2011	Exercise of warrants during the quarter	(80,000)	$	(486,328)
6/30/2011	Change in fair value of warrants during the quarter recognized as other expense in the statement of operations		$	697,660
6/30/2011	Balance of derivative financial instruments liability	1,469,676	$	7,958,506
9/30/2011	Fair value of new warrants issued during the quarter	40,458	$	285,128
9/30/2011	Change in fair value of warrants during the quarter recognized as other income in the statement of operations		$	(4,382,796)
9/30/2011	Balance of derivative financial instruments liability	1,510,134	$	3,860,838
12/31/2011	Fair value of new warrants issued during the quarter	1,810,294	$	3,082,203
12/31/2011	Reclass of derivative liability to equity during the quarter	(1,055,268)	$	(1,707,317)
12/31/2011	Change in fair value of warrants during the quarter recognized as other income in the statement of operations		$	(1,910,610)
12/31/2011	Balance of derivative financial instruments liability	2,265,160	$	3,325,114
3/31/2012	Fair value of new warrants issued during the quarter			
3/31/2012	Change in fair value of warrants during the quarter			(7,946)
3/31/2012	Balance of derivative financial instruments liability	2,265,160	$	3,317,168
6/30/2012	Fair value of new warrants issued during the quarter	112,500		169,202
6/30/2012	Change in fair value of warrants during the quarter			1,317,347
6/30/2012	Balance of derivative financial instruments liability	2,377,660	$	4,803,717

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, 2011 and June 30, 2012:

Table of Contents

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, 2011	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 June 30, 2012
Derivative liabilities related to Warrants	$	$	$ 3,325,114	$ 3,325,114	$	$	$ 4,803,717	$ 4,803,717

The following table sets forth a summary of changes in the fair value of the Company s Level 3 liabilities for the six months ended June 30, 2012:

Description	Balance at December 31, 2011	Fair Value of warrants upon issuance	Unrealized (gains) or losses	Balance as of June 30, 2012
Derivative liabilities related to Warrants	$ 3,325,114	$ 169,202	$ 1,309,401	$ 4,803,717

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 have been antidilutive.

For the three and six months ended June 30, 2012 the effect of 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. For the three and six months ended June 30, 2011 the effect of 4,157,029 outstanding stock options and 1,469,676 warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive.

11. Related Parties

As of June 30, 2012 Callisto owns 34% of Synergy s outstanding shares.

As of June 30, 2012 Synergy had advanced Callisto $1,936,609 which is Callisto s share of Synergy payments for common operating costs since July 2008 that Callisto was unable to fund. The indebtedness as of December 31, 2011 is evidenced by an unsecured promissory note which bears interest at 6% per annum. Due to the uncertainty surrounding Callisto s ability to raise capital Synergy is unable to determine when this balance will be repaid and accordingly Synergy has classified the balance due as a long term asset.

As of June 30, 2012 and December 31, 2011, the balances due from Callisto are comprised of the following amounts:

	June 30, 2012	December 31, 2011
Rent, utilities and property taxes	$ 145,481	$ 90,166
Insurance and other facilities related overhead	277,309	249,635
Independent accountants and legal fees	611,222	510,331
Financial printer and transfer agent fees	227,190	217,476
Salaries and consulting fees of shared executives	317,739	289,270
Working capital advances, net of repayments	357,668	184,578
Total due from Callisto	$ 1,936,609	$ 1,541,456

Table of Contents

12. Subsequent Events

On July 17, 2012, Synergy collected its 2011 New York City Biotechnology Tax Credit of $120,812.

On July 20, 2012, Synergy entered into an Agreement and Plan of Merger (the Merger Agreement) with Callisto. Pursuant to the Merger Agreement, following the satisfaction or waiver of each of the applicable conditions set forth in the Merger Agreement, Callisto and Synergy will merge (the Merger), whereupon Callisto s separate corporate existence will cease and Synergy will continue as the surviving corporation of the Merger. Callisto is Synergy s largest shareholder and is a development stage biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal disorders and diseases.

As a result of the Merger, each outstanding share of Callisto common stock will be converted into the right to receive 0.17 of one share of Synergy common stock (the Exchange Ratio) as set forth in the Merger Agreement and the 22,295,000 shares of Synergy held by Callisto will be canceled. Under the terms of the Merger Agreement at closing, Synergy will issue, and Callisto stockholders will receive in a tax-free exchange, shares of Synergy common stock such that Callisto stockholders will own approximately 38.3 percent of the combined company on a pro forma basis and Synergy stockholders will own approximately 61.7 percent. Each share of Synergy Common Stock received in connection with the Merger shall be subject to a lock-up beginning on the effective date of the Merger and ending on the earlier of (i) eighteen (18) months after such date or (ii) a Change in Control (as defined in the Merger Agreement).

The consummation of the Merger is subject to various customary closing conditions, including but not limited to, (i) approval by Callisto s and Synergy s stockholders, (ii) the Registration Statement on Form S-4 shall have been declared effective by the SEC and (iii) the shares of Synergy common stock to be issued in the Merger shall have been approved for listing on The NASDAQ Capital Market. Upon consummation of the Merger the related party balances due from Callisto, $1,936,609 as of June 30, 2012, (See Note 11) will be eliminated in consolidation. Callisto s common stock currently trades on the Over the Counter Bulletin Board under the symbol CLSP.OB , and Callisto s recent filings with the SEC are available at http://www.sec.gov.

Table of Contents

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

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

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, 2011 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 Synergy, please be advised that Synergy s actual financial condition, operating results and business performance may differ materially from that projected or estimated by Synergy in forward-looking statements.

Overview

We are a biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. Our lead product candidate is plecanatide (formerly called SP-304), a guanylyl cyclase C, or GC-C, receptor agonist, to treat GI disorders, primarily chronic constipation, or CC, and constipation-predominant- irritable bowel syndrome, or IBS-C. CC and IBS-C are functional gastrointestinal disorders that afflict millions of sufferers worldwide. CC 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.

Plecanatide

We are currently developing plecanatide, a synthetic hexadecapeptide designed to mimic the actions of the GI hormone uroguanylin, for the treatment of CC and IBS-C. Plecanatide is an agonist of GC-C receptor.

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.

On October 24, 2011, we initiated dosing of patients in a Phase II/III clinical trial of plecanatide to treat chronic constipation. This study is being conducted at 110 sites in the United States and is designed to enroll 880 patients with CC who will be treated with one of three doses of plecanatide (0.3, 1.0 or 3.0 mg) or placebo taken once daily over a period of 12 weeks. The study s primary objective is the measure of complete spontaneous bowel movements, or CSBMs, using a responder analysis. The trial will also cover spontaneous bowel movements, or SBMs, and daily constipation symptoms, as well as the impact of plecanatide on disease-specific quality of life measures. On April 9, 2012, we announced that we have reached the halfway mark for total enrollment in the clinical trial with over 800 patients screened, resulting in a total of 440 randomized enrolled patients to date. We anticipate completing enrollment in the third quarter of 2012 and reporting top line data in the fourth quarter of 2012.

We are also preparing to initiate a Phase IIb clinical trial of plecanatide for the treatment of IBS-C in patients during 2012.

SP-333

We are also developing a second generation GC-C receptor analog, SP-333, which is currently in pre-clinical development for the treatment of gastrointestinal inflammatory diseases. 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 UC and Crohn s disease. We plan to submit an Investigational New Drug application, or IND, to the U.S. Food and Drug Administration, or FDA, and intend to initiate a Phase 1 clinical trial of SP-333 in volunteers during the second half of 2012. The study is planned to be conducted at 40 U.S. sites and enroll over 300 patients.

Table of Contents

Recent Developments

On May 9, 2012, we closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of $4.50 per share. The gross proceeds from this offering were $45 million, before deducting underwriting discounts and commissions and other offering expenses of $2,952,930. We also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of $4.50 per share to cover over-allotments, if any. On June 6, 2012 the underwriters exercised of the over-allotment option resulting in additional gross proceeds of $6,750,000, before deducting underwriting discounts, commissions and other offering expenses of $405,000, bringing total gross proceeds from the offering to $51,750,000 and net proceeds of $48,387,070.

On July 20, 2012, we entered into an Agreement and Plan of Merger (the Merger Agreement) with Callisto Pharmaceuticals, Inc. (Callisto). Pursuant to the Merger Agreement, following the satisfaction or waiver of each of the applicable conditions set forth in the Merger Agreement, Callisto and we will merge (the Merger), whereupon Callisto s separate corporate existence will cease and we will continue as the surviving corporation of the Merger. Callisto is our largest shareholder and is a development stage biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal disorders and diseases.

As a result of the Merger, each outstanding share of Callisto common stock will be converted into the right to receive 0.17 of one share of our common stock (the Exchange Ratio) as set forth in the Merger Agreement and the 22,295,000 shares of ours held by Callisto will be canceled. Under the terms of the Merger Agreement at closing, we will issue, and Callisto stockholders will receive in a tax-free exchange, shares of our common stock such that Callisto stockholders will own approximately 38.3 percent of the combined company on a pro forma basis and our stockholders will own approximately 61.7 percent. Each share of Synergy Common Stock received in connection with the Merger shall be subject to a lock-up beginning on the effective date of the Merger and ending on the earlier of (i) eighteen (18) months after such date or (ii) a Change in Control (as defined in the Merger Agreement).

The consummation of the Merger is subject to various customary closing conditions, including but not limited to, (i) approval by Callisto s and our stockholders, (ii) the Registration Statement on Form S-4 shall have been declared effective by the SEC and (iii) the shares of our common stock to be issued in the Merger shall have been approved for listing on The NASDAQ Capital Market. Upon consummation of the Merger the related party balances due from Callisto, $1,936,609 as of June 30, 2012, will be eliminated in consolidation. Callisto s common stock currently trades on the Over the Counter Bulletin Board under the symbol CLSP.OB , and Callisto s recent filings with the SEC are available at http://www.sec.gov.

FINANCIAL OPERATIONS OVERVIEW

From inception through June 30, 2012, we have sustained cumulative net losses of $87,190,110. From inception through June 30, 2012, 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.

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, 2011, filed with the SEC on March 15, 2012. There have been no changes to our critical accounting policies since December 31, 2011.

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 Commitments*, included in our Annual Report on Form 10-K as of December 31, 2011 and changes in contractual obligations and commitments as reported in our Form 10-Q for the three months ended and as of March 31, 2012. There have been no changes in our contractual obligations and commitments during the three months ended June 30, 2012.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of June 30, 2012.

Table of Contents

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2012 AND 2011

We had no revenues during the three months ended June 30, 2012 and 2011 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 June 30, 2012 (Current Quarter) increased $5,271,818 or 224%, to $7,626,268 from $2,354,450 for the three months ended June 30, 2011(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 June 30, 2012 and 2011. These expenses were primarily external costs associated with chemistry, manufacturing, controls including costs of drug substance and product (CMC), as well as preclinical studies and clinical trial costs, as follows:

	Three Months Ended June 30,	
Drug candidates	**2012**	**2011**
Plecanatide	$ 6,044,000	$ 2,019,000
SP-333	848,000	
Total direct cost	$ 6,892,000	$ 2,019,000

In addition, 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. These indirect costs increased approximately $400,000 due to higher compensation, employee benefits, and scientific, regulatory advisory fees of $ 735,000 in the Current Quarter, as compared to $335,000 during the Prior Year Quarter.

General and administrative expenses increased $394,086 or 26%, to $1,918,488 for the Current Quarter from $1,524,402 for the three months ended June 30, 2011. These increased expenses were primarily the result of (i) higher compensation and related employee benefits of approximately $624,000 in the Current Quarter as compared to $430,000 during the Prior Year Quarter, (ii) higher facilities cost of approximately $305,000 in the Current Quarter as compared to $187,000 during the Prior Year Quarter and (iii) higher corporate legal services of approximately $246,000 for the Current Quarter, as compared to $153,000 for the Prior Year Quarter, as a result increased intellectual property related costs.

Net loss for the Current Quarter was $10,588,448 as compared to a net loss of $4,556,509 incurred for the Prior Year Quarter. This increase in our net loss of $6,031,939, or 132% was a result of the increases in operating expenses discussed above, and the loss resulting from the change in fair value of derivative instruments-warrants of $1,317,347 during the Current Quarter, as compared to $697,660 during the Prior Year Quarter.

SIX MONTHS ENDED JUNE 30, 2012 AND 2011

We had no revenues during the six months ended June 30, 2012 and 2011 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 six months ended June 30, 2012 (Current Period) increased $9,131,832 or 238%, to $12,964,408 from $3,832,576 for the six months ended June 30, 2011(Prior Year Period). 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 six months ended June 30, 2012 and 2011. These direct expenses were primarily external costs associated with chemistry, manufacturing, controls including drug substance and product (CMC), as well as preclinical studies and clinical trial costs, as follows:

	Six Months Ended June 30,	
Drug candidates	**2012**	**2011**
Plecanatide	$ 10,677,000	$ 3,180,000
SP-333	954,000	
Total direct cost	$ 11,631,000	$ 3,180,000

In addition, 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 were $681,000 higher due

Table of Contents

to (i) higher compensation and employee benefits of $963,000 in the Current Period, as compared to $549,000 during the Prior Year Period, as a result of increased staffing levels required to support the our Phase II/III trial which was initiated in October 2011 and (ii) higher scientific and regulatory advisory fees and expenses of $370,000 in the Current Period, as compared to $103,000 during the Prior Year Period, as we are now planning the IND filings for two new clinical studies.

General and administrative expenses increased $227,588 or 6%, to $3,649,616 for the Current Period from $3,422,028 for the Prior Year Period. These increased expenses were primarily the result of higher facilities cost of approximately $605,000 in the Current Period as compared to $397,000 during the Prior Year Period.

Net loss for the Current Period was $ 17,581,092 as compared to a net loss of $8,258,789 incurred for the Prior Year Period. This increase in our net loss of $9,322,303, or 113% was a result of the increases in operating expenses discussed above, and losses resulting from the change in fair value of derivative instruments-warrants of $1,309,401 during the Current Period, as compared to $1,036,375 during the Prior Year Period.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2012 we had $27,426,900 of cash and cash equivalents on hand as compared to $13,244,883 of cash and cash equivalents on hand as of December 31, 2011. In addition, on June 30, 2012 we held $20,160,576 in available-for-sale securities, US Treasury Bills and Notes, whereas we had no such investments as of December 31, 2011. As of June 30, 2012 we had working capital of $40,065,845 as compared to working capital of $11,561,286 as of December 31, 2011.

On May 9, 2012, we closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of $4.50 per share. The gross proceeds from this offering were $45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of $2,952,930. We also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of $4.50 per share to cover over-allotments, if any. On June 6, 2012 the underwriters exercised all of the over-allotment option resulting in additional gross proceeds of $6,750,000, before deducting underwriting discounts, commissions and other offering expenses of $405,000, bringing total gross proceeds from the offering to $51,750,000.

We will be required to raise additional capital to complete the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Recent worldwide economic conditions, as well as domestic and international equity and credit markets, have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult to obtain additional equity or credit financing, when needed. We cannot be certain that additional funding will be available on acceptable terms, or at all. 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 business.

If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly 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 ourselves on unfavorable terms.

Our condensed consolidated financial statements as of June 30, 2012 and December 31, 2011 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the negative outcome of this uncertainty.

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 June 30, 2012, we held approximately $27 million in money market accounts and held approximately $20 million in US Treasury Bills and Notes. We maintained our cash, cash equivalents and available-for-sale securities at one or more financial institutions that 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.

Table of Contents

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, as of June 30, 2012, our Chief Executive Officer and Principal Financial Officer have concluded that as of June 30, 2012, 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 June 30, 2012.

Table of Contents

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, 2011.

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, 2011.

ITEM 6. EXHIBITS

(a) Exhibits

10.1	Amended and Restated Executive Employment Agreement dated as of June 25, 2012 between Synergy Pharmaceuticals, Inc. and Kunwar Shailubhai*
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 Synergy for the quarter ended June 30, 2012, filed on August 9, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (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.

* Indicates a management contract or compensatory plan or arrangement.

Table of Contents

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: August 9, 2012	By:	/s/ GARY S. JACOB Gary S. Jacob *President and Chief Executive Officer*
Date: August 9, 2012	By:	/s/ BERNARD F. DENOYER Bernard F. Denoyer *Senior Vice President, Finance*