SYNERGY PHARMACEUTICALS, INC. Form 10-Q May 10, 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: MARCH 31, 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 64,306,156 as of May 9, 2012.

SYNERGY PHARMACEUTICALS, INC.

(A development stage company)

FORM 10-Q

TABLE OF CONTENTS

		Page
<u>PART I FINANCIAL INFORMATIO</u> N		4
<u>Item 1.</u>	<u>Financial Statements</u>	4
	Condensed Consolidated Balance Sheets as of March 31, 2012 (unaudited) and	
	<u>December 31, 2011</u>	4
	Condensed Consolidated Statements of Operations for the Three Months Ended	
	March 31, 2012 and 2011 (unaudited) and the period November 15, 2005 (Inception)	
	to March 31, 2012 (unaudited)	5
	Condensed Consolidated Statements of Cash Flows for the Three Months Ended	
	March 31, 2012 and 2011 (unaudited) and for the period November 15, 2005	
	(Inception) to March 31, 2012 (unaudited)	6
	Condensed Consolidated Statements of Changes in Stockholders	<u>o</u> d
	November 15, 2005 (Inception) to March 31, 2012 (unaudited)	7
	Notes to Condensed Consolidated Financial Statements (unaudited)	9
<u>Item 2.</u>	Management s Discussion and Analysis of Financial Condition and Results of	
	<u>Operations</u>	17
<u>Item 3.</u>	Quantitative and Qualitative Disclosures About Market Risk	20
<u>Item 4.</u>	Controls and Procedures	20
<u>PART II OTHER INFORMATIO</u> N		20
<u>Item 1.</u>	<u>Legal Proceedings</u>	20
<u>Item 1A.</u>	Risk Factors	20
<u>Item 2.</u>	<u>Properties</u>	20
<u>Item 6.</u>	<u>Exhibits</u>	21
<u>SIGNATURES</u>		22

2

Table of Contents

INTRODUCTORY NOTE

This Report on Form 10-Q for Synergy Pharmaceuticals, Inc. (Synergy or the Company) may contain forward-looking statements. You can identify these statements by forward-looking words such as plan, may, will, expect, intend, anticipate, believe, estimate 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 in our Form 10-K for the year ended December 31, 2011 as filed with the Securities Exchange Commission on March 15, 2012 and other periodic reports filed with the 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 Synergy s actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements.

3

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2012 (unaudited)]	December 31, 2011
ASSETS			
Current Assets:			
Cash and cash equivalents	\$ 6,123,340	\$	13,244,883
Prepaid expenses and other current assets	1,617,526		1,063,402
Total Current Assets	7,740,866		14,308,285
Property and equipment, net	5,279		5,773
Security deposits	14,025		14,025
Due from controlling shareholder	1,819,658		1,541,456
Total Assets	\$ 9,579,828	\$	15,869,539
LIABILITIES AND STOCKHOLDERS EQUITY			
Current Liabilities:			
Accounts payable	\$ 2,084,471	\$	1,415,617
Accrued expenses	965,336		1,331,382
Total Current Liabilities	3,049,807		2,746,999
Derivative financial instruments, at estimated fair value-warrants	3,317,168		3,325,114
Total Liabilities	6,366,975		6,072,113
Stockholders Equity:			
Preferred stock, Authorized 20,000,000 shares, at March 31, 2012 and December 31, 2011,			
none outstanding			
Common stock, par value of \$.0001 authorized 100,000,000 shares, outstanding 54,306,156			
and 54,279,906 shares at March 31, 2012 and December 31, 2011, respectively.	5,432		5,429
Additional paid-in capital	79,839,083		79,401,015
Deficit accumulated during development stage	(76,631,662)		(69,609,018)
Total Stockholders Equity	\$ 3,212,853	\$	9,797,426
Total Liabilities and Stockholder s Equity	\$ 9,579,828	\$	15,869,539

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

SYNERGY PHARMACEUTICALS, INC.

(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Mo Mar 2012	nths Enc ch 31,	November 15, 2005 (inception) to March 31, 2012	
Revenues	\$ 2012	\$	2011 \$	March 31, 2012
G IP				
Costs and Expenses:	5 220 1 40		1.450.106	22.751.204
Research and development	5,338,140		1,478,126	33,751,294
Purchased in-process research and development	. =			28,156,502
General and administrative	1,731,128		1,897,626	21,375,770
Loss from Operations	(7,069,268)		(3,375,752)	(83,283,566)
Interest and investment income	38,678		24,064	316,864
Interest expense			(11,877)	(11,877)
Other Income				856,977
Change in fair value of derivative instruments-warrants	7,946		(338,715)	5,561,761
Total Other Income/(Expense)	46,624		(326,528)	6,723,725
Loss from Continuing Operations	(7,022,644)		(3,702,280)	(76,559,841)
Loss from Discontinued Operations				(71,821)
Net Loss	\$ (7,022,644)	\$	(3,702,280) \$	(76,631,662)
Weighted Average Common Shares Outstanding				
Basic and Diluted (restated for stock split)	54,298,079		46,167,416	
Net Loss per Common Share, Basic and Diluted				
Net Loss per Common Share, Basic and Diluted	\$ (0.13)	\$	(0.08)	
•				

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

SYNERGY PHARMACEUTICALS, INC.

(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

		ree Months d March 31, 2012	Three Months Ended March 31, 2011	Period from November 15, 2005 (Inception) to March 31, 2012
Cash Flows From Operating Activities:				
N 1	Ф	(7,000,644)	Ф (2.702.202)	Φ (Π((01 ((0)
Net loss	\$	(7,022,644)	\$ (3,702,280)	\$ (76,631,662)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation		494	494	7,644
Stock-based compensation expense		438,071	147,460	3,406,720
Purchased in-process research and development				28,156,502
Change in fair value of derivative instruments-warrants		(7,946)	338,715	(5,561,761)
Interest expense on short term notes borrowing			11,877	
Changes in operating assets and liabilities:				
Security deposit				(14,025)
Accounts payable and accrued expenses		302,808	(64,031)	2,326,764
Prepaid expenses and other current assets		(554,124)	263,929	(1,617,526)
Total Adjustments		179,303	698,444	26,704,318
Net Cash Used in Operating Activities		(6,843,341)	(3,003,836)	(49,927,344)
Cash Flows From Investing Activities:				
Net cash paid on Exchange Transaction				(155,326)
Loans from (to) related parties		(278,202)	120,020	(1,819,658)
Additions to property and equipment				(12,195)
Net Cash (Used in)/Provided by Investing Activities		(278,202)	120,020	(1,987,179)
Cash Flows From Financing Activities:				
Capital contribution by shareholders				8,893
Issuance of common stock				2,000
Proceeds from sale of common stock			1,800,000	60,543,164
Proceeds from exercise of warrants				415,309
Proceeds from sale of unregistered common stock to				
founders				18,100
Fees and expenses related to sale of common stock and				
warrants			(185,000)	(2,949,603)
Proceeds from issuance of short term note			500,000	-0.00 - 5.5
Net Cash Provided by Financing Activities			2,115,000	58,037,863
Net (decrease) increase in cash and cash equivalents		(7,121,543)	(768,816)	6,123,340
Cash and cash equivalents at beginning of period		13,244,883	1,707,516	

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

Cash and cash equivalents at end of period	\$ 6,123,340	\$ 938,700	\$ 6,123,340
Supplementary disclosure of cash flow information:			
Cash paid for taxes	\$ 1,000	\$ 5,910	\$ 72,616
Value of warrants classified as derivative liability-net	\$	\$ 1,312,673	\$ 8,878,929
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.

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

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)
P-l P 21 2006	92 540 609	9.254	11.046	(20.219)	(110)
Balance, December 31, 2006	82,540,608	8,254	11,846	(20,218)	(118)
Capital contribution by shareholders			8,893	(20,042)	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	(1, 1)	(,)
Common stock issued via Exchange	(1,222,000)	(,,,,,,	1,122		
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	(31,775,111)	15,970,100
Fees and expenses related to private	11,107,213	1,111	13,700,737		13,770,100
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			-,0,0	(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)
Common stock issued to extend lock-up					
agreements related to unregistered shares	670,933	67	(67)		
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)
				, and a second of	

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT) Cont d

	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders Equity (Deficit)
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 for services rendered	26,250	3	92,660		92,663
Stock based compensation expense			345,408		345,408
Net loss for the period				(7,022,644)	(7,022,644)
Balance, March 31, 2012	54,306,156	\$ 5,432	\$ 79,839,083	\$ (76,631,662)	\$ 3,212,853

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

1	T	na	111	di	tο	А
١,	·	ша	ıu	uı	ıc	u

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. Synergy s 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 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.

Plecanatide

On October 24, 2011 Synergy initiated dosing of patients in its Phase II/III clinical trial of plecanatide to treat CC. 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 using a responder analysis. The trial will also evaluate spontaneous bowel movements and daily constipation symptoms, as well as the impact of plecanatide on disease-specific quality of life measures.

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.

SP-333

Synergy is also developing a second generation GC-C receptor analog, SP-333, which is currently in pre-clinical development for the treatment of gastrointestinal diseases and disorders. 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 predicted 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 and Crohn s disease.

On February 1, 2011 the U.S. Patent and Trademark Office issued U.S. Patent No. 7,879,802, covering Synergy s novel drug candidate SP-333 to treat inflammatory bowel disease. SP-333 is a second-generation GC-C agonist with the potential to treat gastrointestinal diseases such as ulcerative colitis. 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.

2. Basis of Presentation and Going Concern

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.

Table of Contents

On November 29, 2011 the Company filed an amendment to its amended and restated articles of incorporation pursuant to which the Company affected 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, 2011 financial 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 March 31, 2012 and December 31, 2011 have been prepared under the assumption that Synergy will continue as a going concern for the next twelve months. 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 March 31, 2012, Synergy had an accumulated deficit of \$ 76,631,662 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 \$6,843,341for the three months ended March 31, 2012 as compared to net cash used of \$3,003,836 during the three months ended March 31, 2011. As of March 31, 2012 Synergy has \$6,123,340 of cash on hand as compared to \$13,244,833 on hand as of December 31, 2011. During the three months ended March 31, 2012, Synergy incurred a Net Loss of \$7,022,644 as compared to a Net Loss of \$3,702,280 incurred during the three months ended March 31, 2011. To date, Synergy sources of cash have been primarily limited to the sale of common stock, warrants and issuance of notes. There were no financing activities for the three months ended March 31, 2012. As of March 31, 2012 Synergy had working capital of \$4,691,059 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 are \$45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of approximately \$3 million. 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.

Synergy may be required to raise additional capital within the next year 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.

Table of Contents

3. 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 nonowner 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 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.

In December 2011, the FASB issued ASU 2011-12, Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05. ASU 2011-12 defers the specific requirement to present items that are reclassified from accumulated other comprehensive income to net income separately with their respective components of net income and other comprehensive income. ASU 2011-12 did not defer the requirement to report comprehensive income either in a single continuous statement or in two separate but consecutive financial statements. The amendments are effective at the same time as the amendments in ASU 2011-05.

4. 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. Synergy did not issue stock options prior to the quarter ended September 30, 2008.

Table of Contents

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

		Three M Ended M	November 15, 2005 (inception) to	
		2012	2011	March 31, 2012
Employees included in research and development	\$	115,770	\$ 36,749	\$ 742,552
Employees included in general and administrative		93,649	44,618	868,060
Subtotal employee stock based compensation		209,419	81,367	1,610,612
Non-employees included in research and development			8,362	168,096
Non-employees included in general and administrative		228,652	57,731	1,628,012
Subtotal non-employee stock based compensation		228,652	66,093	1,796,108
• •				
Total stock-based compensation expense	\$	438,071	\$ 147,460	\$ 3,406,720

The unrecognized compensation cost related to non-vested stock options outstanding at March 31, 2012, net of expected forfeitures, was \$3,498,455 to be recognized over a weighted-average remaining vesting period of approximately 2.5 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 periods indicated.

	Three Months Ended March 31, 2011	Three Months Ended March 31, 2010
Risk-free interest rate	1.05%-1.50%	(*)
Dividend yield		(*)
Expected volatility	60%	(*)
Expected term (in years)	6 years	(*)

^(*) No stock options granted during this period.

On March 1, 2010, a majority of Synergy s shareholders acting by written consent approved an amendment to the Plan increasing the number of shares reserved under the Plan to 7,500,000 shares, after a retroactive change of a one for two (1:2) reverse stock split effective on November 30, 2011. 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 \$	1.7	7 \$	10,631,388	8.18 years
Granted	772,000	\$ 3.40	4.38 \$	3.54	ļ		
Exercised		\$	\$				

Forfeited		\$	\$			
Balance outstanding,						
March 31, 2012	6,736,039	\$ 0.50	4.38 \$	1.97	\$ 14,107,539	8.06 years
Exercisable at March 31,						
2012	2,076,539	\$ 0.50	4.30 \$	0.75	\$ 6,857,989	6.45 years

5. Income Taxes

During the year ended December 31, 2011 the Company recorded a refundable tax credit 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 the 2010 New York State QETC credit.

Table of Contents

6. Stockholder s Equity

On January 30, 2012 Synergy issued 26,250 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 became 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 shall be 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 of February 16, 2012.

7. 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 \$1,064,136 and \$577,745 as of March 31, 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 these costs when drug compound is delivered and services are performed.

8. 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, 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 during the three months ended March 31, 2012 and March 31, 2011 were:

	ree Months Ended March 31, 2012	-	Three Months Ended March 31, 2011
Estimated fair value of Synergy common stock	\$ 3.51 - \$4.05	\$	4.86 - \$6.26
Expected warrant term	5.0 - 7.0 years		4.0 - 7.0 years
Risk-free interest rate	0.51%-1.33%		1.80% - 2.9%
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 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 and the date of grant or quarterly revaluation.

Table of Contents

As of March 31, 2012, certain of Synergy s outstanding warrants contained a price protection clause which variable exercise price required the Company to use a binomial model to determine fair value. There was no binomial model calculation required as of March 31, 2011. The range of assumptions used to determine the fair value of the warrants at March 31, 2012 was as follows:

	Three months ended,
	March 31, 2012
Estimated fair value of Synergy commonstock	\$ 3.28
Expected warrant term	4.63 years
Risk-free interest rate	1.04%
Expected volatility	60%
Dividend yield	0%

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 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 outstanding warrants which were deemed derivative financial instruments and the associated liability balance for the periods indicated:

				Derivative Instrument
Date		Description	Warrants	Liability
	12/31/2010	Balance	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	938,469 \$	5,139,347
	6/30/2011	Fair value of new warrants issued during the quarter	611,207 \$	2,607,827
		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	1,469,676 \$	7,958,506
		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		1,510,134 \$	3,860,838
		Fair value of new warrants issued during the quarter	1,810,294 \$	3,082,203
		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		2,265,160 \$	3,325,114
	3/31/2012	Change in fair value of warrants during the quarter recognized		
		as other income in the statement of operations		(7,946)
	3/31/2012	Balance	2,265,160 \$	3,317,168

Table of Contents

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 March 31, 2012:

	Quoted Prices						Quoted Prices					
	in						in					
	Active						Active					
	Markets	Significant					Markets	Significant				
	for Identical	Other	Si	ignificant			for Identical	Other	S	Significant		
	Assets and	Observable	Un	observable	Ba	lance as of	Assets and	Observable	Ur	observable	В	Salance as of
	Liabilities	Inputs		Inputs	Dec	cember 31,	Liabilities	Inputs		Inputs		March 31,
Description	(Level 1)	(Level 2)	((Level 3)		2011	(Level 1)	(Level 2)		(Level 3)		2012
Derivative liabilities												
related to Warrants	\$	\$	\$	3,325,114	\$	3,325,114	\$	\$	\$	3,317,168	\$	3,317,168

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, 2012:

	Balance at December 31,	Fair Value of warrants upon	Unrealized (gains) or	Balance as of March 31,	
Description	2011	issuance	losses	2012	
Derivative liabilities related to Warrants	\$ 3,325,114	\$	\$ (7,946) \$	3,317,168	

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.

9. 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 months ended March 31, 2012 and March 31, 2011 the effect of 6,736,039 and 4,199,539, 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, 2012 and March 31, 2011, the effect of 5,597,203 and 1,876,938 outstanding warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive.

10. Related Parties

As of March 31, 2012, Synergy s majority shareholder, Callisto, owns 41.1 % of its outstanding shares. Synergy occupied corporate office space in New York City under a month to month sharing arrangement with Callisto until March 30, 2012. On March 30, 2012 Synergy assumed the Callisto lease and extended this lease through March 31, 2014, at a monthly rate of \$18,833 on a straight line basis. Rent will henceforth be allocated to Callisto based on the square footage of office space occupied by Callisto.

As of March 31, 2012 Synergy had advanced Callisto \$1,819,658 which is Callisto s share of Synergy payments for common operating costs since July 2008. 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 March 31, 2012 and December 31, 2011, the balances due from Callisto Pharmaceuticals, Inc. are comprised of the following amounts:

	March 31, 2012	December 31, 2011
Rent, utilities and property taxes	\$ 98,074 \$	90,166
Insurance and other facilities related overhead	276,298	249,635
Independent accountants and legal fees	581,222	510,331
Financial printer and transfer agent fees	224,199	217,476
Salaries and consulting fees of shared executives	302,268	289,270
Working capital advances, net of repayments	337,597	184,578
Total due from Callisto	\$ 1,819,658 \$	1,541,456

Table of Contents

11. Subsequent Events

During the year ended December 31, 2011Synergy recorded a refundable tax credit 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 the 2010 New York State QETC credit. On April 25, 2012, the Company received \$246,402 for 2010 New York State QETC credit and will expense the difference of \$2.084 in the quarter ended June 30, 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 are \$45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of approximately \$3 million. 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.

16

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

BUSINESS

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.

On October 24, 2011, we initiated dosing of patients in a Phase II/III clinical trial of plecanatide to treat CC. This study is being conducted at 110 sites in the United States and is designed to enroll 880 patients with CC to insure we have 800 evaluable patients at the end of the study. Patients 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 CSBMs using a responder analysis. The trial will also evaluate SBMs and daily constipation symptoms, as well as the impact of plecanatide on disease-specific quality of life measures.

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 are \$45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of approximately \$3 million. 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 May 2, 2012, we issued a press release announcing the appointment of Gail M. Comer, M. D. as Chief Medical Officer, effective May 14, 2012. In this newly created position, Dr. Comer will report directly to President and Chief Executive Officer, Gary S. Jacob, Ph.D., and will be responsible for guiding Synergy s clinical programs, including the ongoing Phase II/III study of plecanatide, the Company s leading drug candidate.

As of April 9, 2012, we have successfully achieved the halfway mark for total enrollment in our ongoing plecanatide Phase II/III clinical trial in chronic idiopathic constipation (CIC) patients. Over 800 patients have been screened at present, resulting in a total of 440 randomized,

Table of Contents

enrolled patients as of April 9, 2012. The trial, designed to enroll 880 patients to achieve 800 evaluable patients, was initiated on October 24, 2011. We anticipate completing enrollment of the trial in the third quarter of this year and reporting top line data in the fourth quarter of 2012.

FINANCIAL OPERATIONS OVERVIEW

From inception through March 31, 2012, we have sustained cumulative net losses of \$76,631,662. From inception through March 31, 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 Commitment*, included in our Annual Report on Form 10-K as of December 31, 2011. There have been changes in our contractual obligations and commitments during the three months ended March 31, 2012 as follows:

Our corporate headquarters totals approximately 4,300 rentable square feet located at 420 Lexington Avenue, New York, and was subject to a lease which has a monthly rate of \$16,414 and expired on March 31, 2012. This facility was provided to us under a space sharing arrangement with Callisto Pharmaceuticals, Inc., our principal stockholder. On March 30, 2012 we assumed the Callisto lease and extended this lease through March 31, 2014, at a monthly rate of \$18,833 on a straight line basis. We also occupy a small laboratory and several offices, totaling approximately 1, 300 square feet, in the Bucks County Biotechnology Center in Doylestown, Pennsylvania under a lease which expired August 31, 2011. On February 1, 2012 we extended this lease through December 31, 2013, at a monthly rate of \$2,254.

In addition during the quarter ended March 31, 2012 we have entered into new drug substance purchase commitments to support our clinical and non-clinical development of plecanatide and SP-333.

The following table is a summary of contractual cash obligations for the periods indicated that existed as of March 31, 2012, and is based on information appearing in the notes to Consolidated Financial Statements included in our Annual Report on Form 10-K as of December 31, 2011, filed with the SEC on March 15, 2012; as well as the notes to Condensed Consolidated Financial Statements included in elsewhere in this Quarterly Report on Form 10-Q.

	Total]	Less than 1 Year	1-2 Years	3-5 Years	More than 5 Years
Operating leases	\$ 472,294	\$	242,950	\$ 229,344	\$	\$
Purchase obligations principally employment and consulting						
services (1)	2,859,140		1,153,865	1,703,275		
Purchase Obligations Major						
Vendors (2)	3,506,589		3,506,589			
Total obligations	\$ 6,838,023	\$	4,903,404	\$ 1,934,619	\$	\$

⁽¹⁾ Represents salary and bonus for remaining term of employment agreements with Gary S. Jacob, CEO, Bernard F Denoyer, Senior Vice President, Finance and consulting fees and bonus for remaining term of consulting agreement with Gabriele M. Cerrone, Chairman.

Table of Contents

(2) Represents amounts that will become due upon future delivery of supplies, drug substance and test results from various suppliers, under open purchase orders as of March 31, 2012.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of March 31, 2012.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2012 AND MARCH 31, 2011

We had no revenues during the three months ended March 31, 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.

For the three months ended March 31, 2012, research and development expenses increased \$3,860,014 or 261% to \$5,338,140 as compared to \$1,478,126 during the three months ended March 31, 2011. This increase in research and development expenses was entirely attributable to continuing the development of our plecanatide product candidate. These expenses included (i) higher program expenses for ongoing plecanatide Phase II/III clinical trial in CIC patients which totaled approximately \$3,249,000, as compared to approximately \$258,000 during the three months ended March 31, 2011, (ii) higher chemistry, manufacturing, and controls (CMC) costs of drug substance and product, which totaled approximately \$1,327,000, as compared to approximately \$900,000 during the three months ended March 31, 2011, (ii) higher compensation and employee benefits of approximately \$469,000, as compared to \$260,000 during the three months ended March 31, 2011, as a result of increased staffing levels required to support our Phase II/III trial which was initiated in October 2011 and (iii) higher scientific and regulatory advisory fees and expenses of approximately \$129,000, as compared to \$56,000 during the three months ended March 31, 2011.

For the three months ended March 31, 2012, general and administrative expenses decreased \$166,498 or 8.8 % to \$1,731,128, as compared to \$1,897,626, during the three months ended March 31, 2012. These decreased expenses were primarily the result of (i) lower compensation and related employee benefits of approximately \$540,000, as compared to \$744,000 during the three months ended March 31, 2011, (ii) lower consultants and financial advisors fees of approximately \$344,000, as compared to \$695,000 during the three months ended March 31, 2011, partially offset by (iii) higher facilities cost of approximately \$301,000 as compared to \$210,000 during the three months ended March 31, 2011 and (ii) higher corporate legal services of approximately \$511,000 for the three months ended March 31, 2012, as compared to \$203,000 for the three months ended March 31, 2011 as a result of increased intellectual property related costs.

Net loss for the three months ended March 31, 2012 was \$7,022,644 of compared to a net loss of \$3,702,280 incurred for the three months ended March 31, 2011. This increase in our net loss of \$3,320,364, or 90 % was a result of higher research and development expenses partially offset by lower general and administrative expenses discussed above. These higher operating costs were partially offset by other income, principally a gain resulting from the change in fair value of our derivative financial instrument liabilities of \$7,946 during the three months ended March 31, 2012, as compared to an expense of \$338,715 recorded during the three months ended March 31, 2011.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2012, we had \$6,123,340 in cash and cash equivalents, compared to \$13,244,883 as of December 31, 2011. Net cash used in operating activities was \$6,843,341 for the three months ended March 31, 2012 as compared to \$3,003,836 during the three months ended March 31, 2011. There were no financing transactions for the three months ended March 31, 2012, and \$2,115,000 was provided by financing activities for the three months ended March 31, 2011. As of March 31, 2012, we had working capital of \$4,691,059, as compared to working capital of \$11,516,286 on 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 are \$45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of approximately \$3 million. 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.

We may be required to raise additional capital within the next year 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.

Table of Contents

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 March 31, 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 may 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 and the FDIC insurance limit on our bank balances. At March 31, 2012, we had \$5,262,000 balances in money market balances.

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 March 31, 2012, our Chief Executive Officer and Principal Financial Officer have concluded that as of March 31, 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 March 31, 2012.

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 2. PROPERTIES.

Our corporate headquarters totals approximately 4,300 rentable square feet located at 420 Lexington Avenue, New York, and was subject to a lease which has a monthly rate of \$16,414 and expired on March 31, 2012. This facility was provided to us under a space sharing arrangement with Callisto Pharmaceuticals, Inc., our principal stockholder. On March 30, 2012 we assumed the Callisto lease and extended this lease through March 31, 2014, at a monthly rate of \$18,833 on a straight line basis. We also occupy a small laboratory and several offices, totaling approximately 1, 300 square feet, in the Bucks County Biotechnology Center in Doylestown, Pennsylvania under a lease which expired August 31, 2011. On February 1, 2012 we extended this lease through December 31, 2013, at a monthly rate of \$2,254.

Table of Contents

ITEM 6	EXHIBITS
(a) Ex	xhibits
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 Sarbanes	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the s-Oxley Act of 2002.
32.2 Sarbanes	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the s-Oxley Act of 2002.
Condens	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2012, filed on March 2, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the sed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statement of Stockholders Equity (Deficit) (iv) the Condensed dated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements tagged as blocks of text.

21

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: May 10, 2012 By: /s/ GARY S. JACOB

Gary S. Jacob

President and Chief Executive Officer

Date: May 10, 2012 By: /s/ BERNARD F. DENOYER

Bernard F. Denoyer Senior Vice President, Finance

22