SYNERGY PHARMACEUTICALS, INC. Form 10-Q August 09, 2010

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: JUNE 30, 2010

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)

Florida

20-3823853

(State or Other Jurisdiction of Incorporation or Organization)

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

420 Lexington Avenue, Suite 1609, New York, New York (Address of principal executive offices)

10170

(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 \circ 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 o 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 ý

Non-accelerated filer o

Smaller reporting company o

(Do not check if a smaller reporting company)

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

The number of the registrant's shares of common stock outstanding was 90,133,226 as of August 6, 2010.

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

FORM 10-Q

TABLE OF CONTENTS

DADTI EINAN	CIAL INFORMATION	Page
		3
Item 1.	<u>Financial Statements</u>	<u>3</u>
	Condensed Consolidated Balance Sheets as of June 30, 2010 (unaudited) and December 31, 2009	
	Condensed Consolidated Statements of Operations for the Three Months and Six Months Ended June 30, 2010 and	<u>3</u>
	2009 (unaudited) and the period November 15, 2005 (Inception) to June 30, 2010 (unaudited)	<u>4</u>
	Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period November 15, 2005 (Inception) to June 30, 2010 (unaudited)	<u>5</u>
	Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2010 and 2009 (unaudited) and for the period November 15, 2005 (Inception) to June 30, 2010 (unaudited)	<u>6</u>
	Notes to Condensed Consolidated Financial Statements (unaudited)	
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	7
Itom 2	Quantitative and Qualitative Disalogues About Moulest Disk	<u>16</u>
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	<u>19</u>
<u>Item 4.</u>	Controls and Procedures	<u>19</u>
PART II OTHE	ER INFORMATION	
Item 1.	Legal Proceedings	<u>21</u>
		<u>21</u>
Item 1A.	Risk Factors	<u>21</u>
Item 6.	<u>Exhibits</u>	<u>21</u>
<u>SIGNATURES</u>		21
	1	<u>22</u>

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 "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 for the year ended December 31, 2009 and other periodic filings with the Securities Exchange Commission. 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.

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

		June 30, 2010	E	December 31, 2009
A COPPEC	((unaudited)		
ASSETS				
Current Assets:	\$	1 225 975	\$	7 152 569
Cash and cash equivalents Cash in escrow	Ф	1,325,875 2,499,000	Ф	7,152,568
Prepaid expenses and other current		2,499,000		
assets		212,805		1,061,630
assets		212,003		1,001,030
T 1 1 C 1 A 1		4.027.690		0.214.100
Total Current Assets		4,037,680		8,214,198
Property and equipment, net		8,737		9,725
Security deposits Due from majority shareholder		14,025 1,365,637		14,025 972,552
Due from majority snareholder		1,303,037		912,332
	\$	5,426,079	\$	9,210,500
				, ,
LIABILITIES AND				
STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts payable	\$	2,294,915	\$	1,283,466
Accrued expenses		938,087		443,266
Total Current Liabilities		3,233,002		1,726,732
Derivative financial instruments, at				
estimated fair value-warrants		1,045,214		
Stockholders' Equity:				
Common stock, par value of \$.0001 authorized 200,000,000 shares, outstanding 89,071,359 and				
88,423,359 shares at June 30, 2010				
and December 31, 2009		8,909		8,844
Preferred stock, Authorized				
20,000,000 shares and 0 shares				
outstanding at June 30, 2010 and				
December 31, 2009				
Additional paid-in capital		49,194,961		47,395,465
Deficit accumulated during				
development stage		(48,056,007)		(39,920,541)
Total Stockholders' Equity		1,147,863		7,483,768
	\$	5,426,079	\$	9,210,500

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	
		2010	2009		2010		2009	(inception) to June 30, 2010
Revenues	\$	\$		\$		\$	\$	
Costs and Expenses:								
Research and development(1)		4,395,266	1,100,142		5,579,128		1,374,501	11,014,920
Purchased in-process research and development								28,156,502
General and administrative(1)		1,419,019	874,406		2,617,302		1,596,707	8,953,644
Loss from Operations		(5,814,285)	(1,974,548)		(8,196,430)		(2,971,208)	(48,125,066)
Interest and investment income		27,724	14		60,964		145	140,880
Loss from Continuing Operations		(5,786,561)	(1,974,534)		(8,135,466)		(2,971,063)	(47,984,186)
Loss from discontinued operations								(71,821)
Net Loss	\$	(5,786,561) \$	(1,974,534)	\$	(8,135,466)	\$	(2,971,063) \$	6 (48,056,007)
Weighted Average Common Shares Outstanding								
Basic and Diluted		88,462,128	67,360,288		88,442,851		66,550,834	
Net Loss per Common Share, Basic and Diluted	\$	(0.07) \$	(0.03)	\$	(0.10)	\$	(0.04)	

(1) Patent costs reclassified. See Note 2.

SYNERGY PHARMACEUTICALS, INC.

(A development stage company)

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

(Unaudited)

	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	151,381,215) \$	\$ 2,000
Sale of common stock	13,700,000	1,370	16,730		18,100
Net loss for the year				(16)	(16)
Balance, December 31, 2005	165,081,215	16,508	3,592	(16)	20,084
Net loss for the year		·	·	(20,202)	(20,202)
Balance, December 31, 2006	165,081,215	16,508	3,592	(20,218)	(118)
Capital contribution by shareholders			8,893		8,893
Net loss for the year				(20,043)	(20,043)
•					
Balance, December 31, 2007	165,081,215	16,508	12,485	(40,261)	(11,268)
Cancellation of unregistered founder shares	(149,981,208)	(14,998)		(10,201)	(11,200)
Common stock issued via Exchange Transaction	45,464,760	4,546	27,274,315		27,278,861
Common stock issued via private placement July 14,	13, 10 1,700	1,5 10	27,27 1,313		27,270,001
2008	5,000,000	500	2,999,500		3,000,000
Common stock issued via private	2,000,000	200	2,>>>,000		2,000,000
placement August 25, 2008	41,667	4	24,996		25,000
Fees and expenses related to private placements	11,007	•	(73,088))	(73,088)
Stock based compensation expense			379,883	,	379,883
Net loss for the year			277,002	(31,755,180)	
1 CO 1000 ToT the your				(81,788,188)	(51,755,155)
Balance, December 31, 2008	65,606,434	6,560	30,633,089	(31,795,441)	(1,155,792)
Common stock issued via private placements	22,814,425	2,282	15,967,818		15,970,100
Fees and expenses related to private placements			(260,002))	(260,002)
Common Stocks Issued for services rendered	2,500	2	1,498		1,500
Stock based compensation expense			1,053,062		1,053,062
Net loss for the year				(8,125,100)	(8,125,100)
•					
Balance, December 31, 2009	88,423,359	8,844	47,395,465	(39,920,541)	7,483,768
Common stock and warrants issued via registered					
direct offering	648,000	65	2,753,935		2,754,000
Warrants issued in connection with registered direct					
offering classified as derivative liability			(1,045,214))	(1,045,214)
Fees and expenses related to direct offering			(286,630))	(286,630)
Stock based compensation expense			377,405		377,405
Net loss for the period				(8,135,466)	(8,135,466)
Balance, June 30, 2010	89,071,359	\$ 8,909	\$ 49,194,961	\$ (48,056,007)	\$ 1,147,863

${\bf SYNERGY\ PHARMACEUTICALS,\ INC.}$

(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

Adjustments to reconcile net loss to net cash used in operating activities: Depreciation 988 988 Stock-based compensation expense 377,405 354,286 1. Purchased in-process research and development 28. Changes in operating assets and liabilities: Security deposit Accounts payable and accrued expenses 1,244,640 1,008,106 2.	4,186 ,811,850 ,156,502 (14,025) ,248,329 (212,805) ,994,037
Adjustments to reconcile net loss to net cash used in operating activities: Depreciation 988 988 Stock-based compensation expense 377,405 354,286 1. Purchased in-process research and development 28. Changes in operating assets and liabilities: Security deposit Accounts payable and accrued expenses 1,244,640 1,008,106 2.	4,186 ,811,850 ,156,502 (14,025) ,248,329 (212,805)
activities: Depreciation 988 988 Stock-based compensation expense 377,405 354,286 1. Purchased in-process research and development 28. Changes in operating assets and liabilities: Security deposit Accounts payable and accrued expenses 1,244,640 1,008,106 2.	,811,850 ,156,502 (14,025) ,248,329 (212,805)
Stock-based compensation expense 377,405 354,286 1. Purchased in-process research and development 28. Changes in operating assets and liabilities: Security deposit Accounts payable and accrued expenses 1,244,640 1,008,106 2.	,811,850 ,156,502 (14,025) ,248,329 (212,805)
Purchased in-process research and development Changes in operating assets and liabilities: Security deposit Accounts payable and accrued expenses 1,244,640 1,008,106 28,000 1,008,106	(14,025) (2,248,329) (212,805)
Changes in operating assets and liabilities: Security deposit Accounts payable and accrued expenses 1,244,640 1,008,106 2	(14,025) 2,248,329 (212,805)
Security deposit Accounts payable and accrued expenses 1,244,640 1,008,106 2.	(212,805)
Security deposit Accounts payable and accrued expenses 1,244,640 1,008,106 2.	(212,805)
Accounts payable and accrued expenses 1,244,640 1,008,106 2,	(212,805)
	(212,805)
	,994,037
Total Adjustments 2,471,858 1,363,380 31.	
	,061,970)
Cash Flows From Investing Activities:	
	(155,326)
	,365,637)
Additions to property and equipment	(12,195)
	,533,158)
Cash Flows From Financing Activities:	
Capital contribution by shareholders	8,893
Issuance of common stock	2,000
1 1	,250,100
	(358,090)
Proceeds from sale of unregistered common stock to founders	18,100
Net Cash Provided by Financing Activities 230,000 4,980,573 18,	,921,003
Net (decrease) increase in cash and cash equivalents (5,826,693) 3,243,930 1,	,325,875
Cash and cash equivalents at beginning of period 7,152,568 216,007	, ,
Cash and cash equivalents at end of period \$ 1,325,875 \$ 3,459,937 \$ 1.	,325,875
Supplementary disclosure of cash flow information:	
Cash paid for taxes \$ 900 \$ 1,874 \$	3,406
Cash paid for interest \$ \$	
	,278,861
Supplementary disclosure of non-cash financing activities:	
•••	,499,000
Accrued finder's fees related to direct registered offering 261,630	261,630

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Business Overview

Synergy Pharmaceuticals, Inc., incorporated in Florida on November 15, 2005, ("Synergy") is a biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. Synergy's lead drug candidate is plecanatide (previously designated 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 recurrent abdominal pain and/or discomfort associated with chronic constipation.

In December 2008, Synergy completed a Phase 1 clinical trial of plecanatide which showed that plecanatide was well tolerated at all doses studied (0.1 mg to 48.6 mg) and exhibited gastrointestinal pharmacodynamic activity in healthy volunteers with no detectable systemic absorption of plecanatide in the blood. The data obtained from this trial supported advancing plecanatide for further clinical studies in patients with CC and IBS-C. On March 19, 2010, we announced the initiation of a Phase 2a 14-day repeated-oral-dose, placebo-controlled, dose-escalation trial of plecanatide in CC patients. The Company expects to obtain meaningful topline data from this by trial late summer of 2010, and use those data to establish doses for follow-up Phase 2b clinical trials in CC and IBS-C. Synergy plans to open a 24-day repeated-oral-dose trial of plecanatide in CC patients in the autumn of 2010, and a 90-day trial of plecanatide in IBS-C patients in the second quarter of 2011.

2. Basis of Presentation and Going Concern

These unaudited condensed consolidated financial statements include Synergy and its wholly-owned subsidiaries: (1) Synergy Pharmaceuticals, Inc. (Delaware), (2) Synergy Advanced Pharmaceuticals, Inc. and (3) 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, 2009 contained in the Company's Annual Report on Form 10-K, as well as other periodic reports, filed with the Securities Exchange Commission. Certain items in the prior year's financial statements have been reclassified to conform to the current year's presentation. Specifically, legal cost associated with patent applications and maintenance have been classified as general and administrative expense, where previously these costs were classified as research and development expense in our statement of operations. All intercompany balances and transactions have been eliminated. The results of operations for the six months ended June 30, 2010 are not necessarily indicative of the results of operations to be expected for the full year ended December 31, 2010.

These condensed consolidated financial statements as of June 30, 2010 and December 31, 2009 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

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

2. Basis of Presentation and Going Concern (Continued)

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, 2010, Synergy had an accumulated deficit of \$48,056,007. Synergy expects to incur significant and increasing operating losses for the next several years as Synergy 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 \$5,663,608 for the six months ended June 30, 2010. As of June 30, 2010 Synergy has \$1,325,875 of cash. During the six months ended June 30, 2010, Synergy incurred net losses from continuing operations of \$8,135,466. To date, Synergy's sources of cash have been primarily limited to the sale of common stock and warrants.

On June 30, 2010, Synergy entered into securities purchase agreements to sell securities to non-U.S. investors and raised gross proceeds of approximately \$2,754,000 in a registered direct offering. Synergy sold 648,000 units at \$4.25 per share to investors. Each unit consists of one share of Synergy's common stock and one warrant to purchase one additional share of Synergy's common stock. The warrants expire after five years and are exercisable at \$4.50 per share. The offering was made pursuant to a shelf registration statement on Form S-3 (the base prospectus effective December 10, 2009), as supplemented by a prospectus supplement filed with the Securities and Exchange Commission on June 23, 2010. As of June 30, 2010, Synergy had received proceeds of \$255,000, less legal fees of \$25,000 associated with this offering. The remaining \$2,499,000 was held in escrow and received by Synergy on July 2 and July 8, 2010. In July 2010, the Company paid an aggregate \$261,630 to selling agents in connection with this placement, of which the entire amount was accrued as of and for the period ended June 30, 2010. As of June 30, 2010 Synergy had working capital of \$804,678 compared to working capital of \$6,487,466 as of December 31, 2009.

Synergy will be required to raise additional capital during the current year to complete 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. 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.

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

2. Basis of Presentation and Going Concern (Continued)

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.

3. Recent Accounting Pronouncements

In April 2010, the FASB issued ASU 2010-13, "Compensation Stock Compensation (Topic 718) Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in Which the Underlying Equity Security Trades." ASU 2010-13 provides amendments to Topic 718 to clarify that an employee share-based payment award with an exercise price denominated in the currency of a market in which a substantial portion of the entity's equity securities trades should not be considered to contain a condition that is not a market, performance, or service condition. Therefore, an entity would not classify such an award as a liability if it otherwise qualifies as equity. The amendments in ASU 2010-13 are effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2010. Synergy expects the adoption of this standard will not have a material effect on its results of operation or its financial position.

In February 2010, the FASB issued ASU 2010-09, "Subsequent Events (Topic 855) Amendments to Certain Recognition and Disclosure Requirements." ASU 2010-09 requires an entity that is an SEC filer to evaluate subsequent events through the date that the financial statements are issued and removes the requirement that an SEC filer disclose the date through which subsequent events have been evaluated. ASC 2010-09 was effective upon issuance. The adoption of this standard had no effect on its results of operation or its financial position.

In January 2010, the FASB issued Accounting Standards Update ("ASU") 2010-06, "Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements" ("ASU 2010-06"). ASU 2010-06 includes new disclosure requirements related to fair value measurements, including transfers in and out of Levels 1 and 2 and information about purchases, sales, issuances and settlements for Level 3 fair value measurements. This update also clarifies existing disclosure requirements relating to levels of disaggregation and disclosures of inputs and valuation techniques. The adoption of ASU 2010-06 did not have a material impact on the Company's financial statements.

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.

Synergy adopted the 2008 Equity Compensation Incentive Plan (the "Plan") on July 3, 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 periodically issues stock options to employees and non-employees and has adopted ASC Topic 718 for employee awards on July 3, 2008. The Company

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for Shared-Based Payments (Continued)

accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 Equity-Based Payment to Non-Employees whereas the value of the stock compensation 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.

Stock-based compensation expense, including all options and restricted stock units, has been recognized in operating results as follow:

	Three I Ended (Six M Ended (November 15, 2005 (inception) to June 30, 2010
Employees included in research and	2010	2005	_010		, 4110 00, 2010
development	\$ 49,804	\$ 43,055	\$ 99,263	\$ 86,296	\$ 431,334
Employees included in general and					
administrative	58,994	56,695	117,948	112,769	588,842
Non-employees included in research and					
development	8,455	8,455	16,817	16,817	59,279
Non-employees included in general and					
administrative	71,778	69,585	143,377	138,404	732,395
Total stock-based compensation expense	\$ 189,031	\$ 177,790	\$ 377,405	\$ 354,286	\$ 1,811,850

The estimated fair value of each Synergy stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions:

Six months ended March 31,

	2010	2009
Risk free interest rate	2.31 to 2.71%	No awards
Dividend yield	n/a	No awards
Expected volatility	90%	No awards
Expected term	6 years	No awards

Risk-free interest rate Based upon observed US Treasury yield curve interest rates for Treasury instruments with maturities which correspond to the expected term of Synergy's employee stock options at the date of grant.

Dividend yield Synergy has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future.

Expected volatility Based on the historical volatility of similar publicly traded stocks in Synergy's industry segment with comparable market capitalization and stage of development.

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for Shared-Based Payments (Continued)

Expected term Synergy has had no stock options exercised since inception. The expected option term represents the period that stock-based awards are expected to be outstanding based on the simplified method provided in Staff Accounting Bulletin ("SAB") No. 107, Share-Based Payment, ("SAB No. 107"), which averages an award's weighted-average vesting period and expected term for "plain vanilla" share options. Under SAB No. 107, options are considered to be "plain vanilla" if they have the following basic characteristics: (i) granted "at-the-money"; (ii) exercisability is conditioned upon service through the vesting date; (iii) termination of service prior to vesting results in forfeiture; (iv) limited exercise period following termination of service; and (v) options are non-transferable and non-hedgeable.

In December 2007, the SEC issued SAB No. 110, *Share-Based Payment*, ("SAB No. 110"). SAB No. 110 was effective January 1, 2008 and expresses the views of the Staff of the SEC with respect to extending the use of the simplified method, as discussed in SAB No. 107, in developing an estimate of the expected term of "plain vanilla" share options in accordance with ASC Topic 718. The Company will continue to use the simplified method until it has the historical data necessary to provide a reasonable estimate of expected life in accordance with SAB No. 107, as amended by SAB No. 110. For the expected term, the Company has "plain-vanilla" stock options, and therefore used a simple average of the vesting period and the contractual term for options granted subsequent to January 1, 2006 as permitted by SAB No. 107.

Forfeitures ASC Topic 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Synergy's estimated future unvested option forfeitures is based on the historical experience of its majority shareholder, Callisto.

The unrecognized compensation cost related to non-vested stock options outstanding at June 30, 2010, net of expected forfeitures, was \$631,405, to be recognized over the next three quarters.

On March 1, 2010, a majority of our shareholders acting by written consent approved an amendment to the Plan increasing the number of shares reserved under the Plan to 15,000,000 shares.

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for Shared-Based Payments (Continued)

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

	Number of Options		xercise Price Per Share	Exerci	d Average se Price Share		Intrinsic Value
Balance							
outstanding,							
December 31,							
2009	4,214,016	\$	0.25 - 0.95	\$	0.30	\$	22,320,436
Granted	4,465,000(1)	0.70		0.70		
Exercised							
Forfeited							
Balance							
outstanding,							
June 30, 2010	8,679,016	\$	0.25 - 0.95	\$	0.51	\$	63,987,092
,	, ,			•			, ,
Exercisable at							
	1 417 420	\$	0.25 - 0.95	\$	0.29	\$	10 752 665
June 30, 2010	1,417,420	Φ	0.23 - 0.93	Ф	0.29	Φ	10,753,665

(1)

These stock options will vest and become exercisable only upon a change of control of the company. Because of this contingent vesting the Company did not record any stock based compensation expense on these stock options during the six months ended June 30, 2010. The weighted average fair value of these stock options at the date of grant was \$6.77 per share as calculated by the Black-Scholes model, using the assumptions noted in the table above.

Synergy Restricted Stock Units

Restricted stock units, which entitle the holder to earn, at the end of a vesting term, a specified number of shares of Synergy common stock are accounted for as stock based compensation in accordance with ASC Topic 718 in the same manner as stock options using fair value at the date of issuance. Restricted stock units are subject to a repurchase agreement, assumed by Synergy pursuant to the Exchange Transaction, whereby 50% of the units vest after 1 year of continuous service and the remaining 50% vest after 2 years of continuous service from the issuance date. The fair value at the date of issuance is being expensed ratably by month over the 2 year service period since July 2008. As of June 30, 2010 there were 874,760 restricted stock units outstanding. These units were originally issued on July 3, 2008 and are included in shares outstanding. The fair value of the 874,760 restricted stock units on the date of issuance was \$524,856 of which \$31,275, \$63,628 and \$523,779 was recorded as stock-based compensation expense during the three and six months ended June 30, 2010 and for the period from inception to June 30, 2010, leaving \$1,077 unrecognized as of June 30, 2010, to be expensed in the quarter ended September 30, 2010.

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 tax benefits have been recognized in the cash flow statement.

5. Stockholder's Equity

As of June 30, 2010 Synergy's majority shareholder, Callisto, owns 50.1% of its outstanding shares. As of June 30, 2010, the balance due from its majority shareholder amounted to \$1,365,637 as

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

5. Stockholder's Equity (Continued)

compared to \$972,552 as of December 31, 2009. This increase reflects Callisto's share of Synergy payments for shared operating costs as well as accrued interest income of \$20,048 and \$36,824 during the three and six months ended June 30, 2010, respectively. Common operating expenses paid by Synergy and charged to Callisto Pharmaceuticals include: (i) rent, utilities and property taxes on shared corporate office space, (ii) insurance and other facilities related overhead, (iii) independent accountants' annual audits and quarterly reviews, (iv) financial printer and transfer agent fees and expenses and (v) salaries and consulting fees of certain shared executives. 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 it as a long term asset.

On June 30, 2010, Synergy entered into securities purchase agreements to sell securities to non-U.S. investors and raise gross proceeds of approximately \$2,754,000 in a registered direct offering. Synergy sold 648,000 units at \$4.25 per share to investors. Each unit consists of one share of Synergy's common stock and one warrant to purchase one additional share of Synergy common stock. The warrants expire after five years and are exercisable at \$4.50 per share. In accordance with ASC 815-40, "Derivatives and Hedging Contracts in Entity's Own Equity" the warrants have been classified as a derivative liability. (See Note 8 below)

The offering was made pursuant to a shelf registration statement on Form S-3 (the base prospectus effective December 10, 2009), as supplemented by a prospectus supplement filed with the Securities and Exchange Commission on June 23, 2010. As of June 30, 2010, Synergy had received proceeds of \$255,000, less legal fees of \$25,000 associated with this offering, and the remaining \$2,499,000 was held in escrow account and received by Synergy on July 2 and July 8, 2010. In July 2010, the Company paid an aggregate \$261,630 to selling agents in connection with this placement, of which the entire amount was accrued as of and for the period ended June 30, 2010.

6. 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 deferred research and development costs of \$176,260 and \$1.0 million as of June 30, 2010 and December 31, 2009, respectively, for nonrefundable pre-payments for production of plecanatide drug substance and analytical testing services of our drug candidate SP-333. In accordance with this guidance, Synergy expenses deferred research and development costs when drug compound is delivered and services are performed.

7. 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

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

7. Loss Per Share (Continued)

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, 2010 the effect of 8,679,016 outstanding stock options and 648,000 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, 2009 the effect of 4,080,016 outstanding stock options was excluded from the calculation of diluted loss per share because the effect was antidilutive.

8. Derivative Financial Instruments

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that the warrants, issued in connection with the issuance of the June 30, 2010 registered direct offering, must be recorded as derivative liabilities with a charge to additional paid in capital. In accordance with ASC Topic 815-40, the warrants will be re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value will be recorded as non-cash valuation adjustments within other income (expense) in the Company's statement of operations. The Company estimates the fair value of the warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability described above. The assumptions used to determine the fair value of the warrants as of June 30, 2010 were:

	June	30, 2010
Estimated fair value of stock	\$	2.64
Expected warrant term		5 years
Risk-free interest rate		1.79%
Expected volatility		90%
Dividend yield		0%

Estimated fair value of the stock is based on an apportionment of the \$4.25 unit price paid for the shares and warrants issued June 30, 2010 in the Company's registered direct offering, which was an arms-length negotiated price.

Expected volatility is based on historical volatility of the Company's majority shareholder'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 consistent with the expected term of the warrants.

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

9. 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 June 30, 2010:

	Quoted Prices			
	in Active	Significant		
	Markets for	Other	Significant	Balance
	Identical Assets	Observable	Unobservable	as of
	and Liabilities	Inputs	Inputs	June 30,
Description	(Level 1)	(Level 2)	(Level 3)	2010
Derivative liabilities related to Warrants	\$	\$	\$ 1,045,214	\$ 1,045,214

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, 2010:

Description	Balance at December 31, 2009	Unrealized gains or losses	Balance as of June 30, 2010
Derivative liabilities related to Warrants	\$	\$	\$ 1,045,214

The unrealized gains or losses on the derivative liabilities will be classified in other income or expense as a change in 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. Subsequent Events

On July 13, 2010 Synergy issued 1,061,867 shares of its common stock as consideration for an agreement by certain holders of the Company's common stock to extend their lock-up of such shares from August 15, 2010 to January 15, 2011 or enter into a lock-up agreement until such date, as the case may be. This issuance was approved by the Company's Board of Directors on June 22, 2010 and represents 5% of the shares of previously issued common stock currently subject to a lock-up agreement or being requested to lock-up, as the case maybe. The fair value of the common stock issued to accomplish this lock-up extension totaled \$2,798,020, based on the estimated fair value of the shares issued in connection with the June 30, 2010 registered direct offering. (See Note 8) This amount will be charged to additional paid in capital as a cost of facilitating the registered direct offering discussed above.

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 "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, 2009 and other periodic reports filed with the United States Securities and Exchange Commission ("SEC"). Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of the Company, please be advised that the Company's actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements.

RECENT DEVELOPMENTS

On June 30, 2010, we entered into securities purchase agreements to sell securities to non-U.S. investors and raised gross proceeds of approximately \$2,754,000 in a registered direct offering. We sold 648,000 units at \$4.25 per share to investors. Each unit consists of one share of our common stock and one warrant to purchase one additional share of our common stock. The warrants expire after five years and are exercisable at \$4.50 per share. The offering was made pursuant to a shelf registration statement on Form S-3 (the base prospectus effective December 10, 2009), as supplemented by a prospectus supplement filed with the Securities and Exchange Commission on June 23, 2010. As of June 30, 2010, we had received proceeds of \$255,000, less legal fees of \$25,000 associated with this offering. The remaining \$2,499,000 was held in escrow and received from escrow on July 2 and July 8, 2010. In July 2010, the Company paid an aggregate \$261,630 to selling agents in connection with this placement, of which the entire amount was accrued as of and for the period ended June 30, 2010.

On March 19, 2010, we initiated a Phase 2a 14-day repeated-oral-dose, placebo-controlled, dose-escalation trial of plecanatide (previously designated SP-304) in CC patients. We expect to obtain meaningful topline data from this by trial late summer of 2010, and use those data to establish doses for follow-up Phase 2b clinical trials in CC and IBS-C. We plan to open a 24-day repeated-oral-dose trial of plecanatide in CC patients in the autumn of 2010, and a 90-day trial of plecanatide in IBS-C patients in the second quarter of 2011.

An Investigational New Drug application ("IND") for SP-333 is planned for the fourth quarter of 2010 and we plan to open the first human trial of SP-333 in volunteers in early 2011.

FINANCIAL OPERATIONS OVERVIEW

From inception through June 30, 2010, we have sustained cumulative net losses of \$48,056,007. From inception through June 30, 2010, we have not generated any revenue from operations and expect

Table of Contents

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 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 years ended December 31, 2009, filed with the SEC on March 15, 2010. There have been no changes to our critical accounting policies since December 31, 2009.

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, 2009. There have been no changes in our contractual obligations and commitments during the three and six months ended June 30, 2010.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of June 30, 2010.

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2010 AND 2009

We had no revenues during the three months ended June 30, 2010 and 2009 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all. Certain reclasses have been made in prior periods to conform to current year presentation. (See Note 2)

Research and development expenses for the three months ended June 30, 2010 increased \$3,295,124 or 300%, to \$4,395,266 from \$1,100,142 for the three months ended June 30, 2009. This increase was primarily due to (i) higher program expenses, including animal studies, analytical testing, clinical data monitoring and patient costs, which increased by approximately \$1,821,000 during the three months ended June 30, 2010 to approximately \$1,862,000 related to our continuing Phase 2a trial of plecanatide in CC patients which began March 19, 2010, (ii) drug production increased approximately \$1,300,000 to approximately \$2,200,000 in support of ongoing and planned clinical trials, (iii) scientific advisors fees and expenses increased approximately \$55,000 to approximately \$93,000 and (iv) staff compensation cost increased approximately \$100,000 to \$223,259 as we hired additional product development personnel.

Table of Contents

General and administrative expenses increased \$544,613 or 62%, to \$1,419,019 for the three months ended June 30, 2010 from \$874,406 for the three months ended June 30, 2009. This increase was primarily due to (i) approximately \$180,000 of higher financial advisory and travel expenses related to our public offerings, (ii) approximately \$94,000 of higher patent legal expenses and (iii) approximately \$180,000 of increased facilities overhead. Staff salaries, wages and benefits were unchanged in the quarter ended June 30, 2010 as compared to the same period last year.

Net loss for the three months ended June 30, 2010 was \$5,786,561 compared to a net loss of \$1,974,534 incurred for the three months ended June 30, 2009. This increase in our net loss of \$3,812,027, or 193% was a result of the increases in operating expenses discussed above.

SIX MONTHS ENDED JUNE 30, 2010 AND 2009

We had no revenues during the six months ended June 30, 2010 and 2009 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all. Certain reclasses have been made in prior periods to conform to current year presentation. (See Note 2)

Research and development expenses for the six months ended June 30, 2010 increased \$4,204,627 or 306%, to \$5,579,128 from \$1,374,501 for the six months ended June 30, 2009. This increase was primarily due to (i) higher program expenses, including animal studies, analytical testing, clinical data monitoring and patient costs, which increased by approximately \$2,660,000 during the six months ended June 30, 2010 to approximately \$2,760,000 related to our Phase 2a clinical trial of plecanatide in CC patients which began March 19, 2010, (ii) drug production increased approximately \$1,300,000 to approximately \$2,200,000 in support of ongoing and planned clinical trials, (iv) scientific advisors fees and expenses increased approximately \$75,000 to approximately \$172,000 and (v) staff compensation cost increased approximately \$164,000 to approximately \$430,000 as we hired additional product development personnel.

General and administrative expenses increased \$1,020,595 or 64%, to \$2,617,302 for the six months ended June 30, 2010 from \$1,596,707 for the six months ended June 30, 2009. This increase was primarily due to (i) approximately \$515,000 of higher financial advisory accounting services, and travel expenses related to our public offerings, (ii) approximately \$220,000 of increased facilities overhead and ((iii) approximately \$286,000 of higher patent legal expense.

Net loss for the six months ended June 30, 2010 was \$8,135,466 compared to a net loss of \$2,971,063 incurred for the six months ended June 30, 2009. This increase in our net loss of \$5,164,403, or 174% was a result of the increases in operating expenses discussed above partially offset by approximately \$61,000 of higher interest income on higher cash balances.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2010 we had \$1,325,875 in cash and cash equivalents, compared to \$7,152,568 as of December 31, 2009. Net cash used in operating activities was \$5,663,608 for the six months ended June 30, 2010. As of June 30, 2010 we had working capital of \$804,678 as compared to working capital of \$6,487,466 as of December 31, 2009.

On June 30, 2010, we entered into securities purchase agreements to sell securities to non-U.S. investors and raise gross proceeds of approximately \$2,754,000 in a registered direct offering. We sold 648,000 units at \$4.25 per share to investors. Each unit consisted of one share of our common stock and one warrant to purchase one additional share of common stock. The warrants expire after five years and are exercisable at \$4.50 per share. The offering was made pursuant to a shelf registration statement on Form S-3 (the base prospectus effective December 10, 2009), as supplemented by a prospectus supplement filed with the Securities and Exchange Commission on June 23, 2010. As of

Table of Contents

June 30, 2010, we had received proceeds of \$255,000, less legal fees of \$25,000 associated with this placement which was included in our cash and cash equivalents. The remaining \$2,499,000 was held in escrow and received by us on July 2, 2010 and July 8, 2010. In July 2010, we also paid an aggregate \$261,630 to selling agents in connection with this offering.

We will 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. 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.

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.

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 June 30, 2010, we had approximately \$630,000 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 June 31, 2010, our Chief Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were not 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.

In connection with the preparation of our annual financial statements, our management performed an assessment of the effectiveness of internal control over financial reporting as of December 31, 2009. Management's assessment included an evaluation of the design of our internal control over financial reporting and the operational effectiveness of those controls. Based on this evaluation, management determined that, as of December 31, 2009, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management's assessment were (i) a lack of sufficient internal accounting expertise to provide reasonable assurance that our financial statements and notes thereto, are prepared in accordance with generally accepted accounting principles (GAAP) and (ii) a lack of segregation of duties to ensure adequate review of financial statement preparation. In light of these material weaknesses, management concluded that, as of December 31, 2009, we did not maintain effective internal control over financial reporting. As defined by Regulation S-X, Rule 1-02(a)(4), a material weakness is a deficiency or a combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Table of Contents

Management, in coordination with the input, oversight and support of our Audit Committee, has identified the following measures to strengthen our internal control over financial reporting and to address the material weaknesses described above. During the quarter ended December 31, 2009 we hired a controller to: (i) prepare annual and quarterly consolidated financial statements, (ii) prepare annual and quarterly account reconciliations and (iii) prepare annual and quarterly journal entries. This hire allows for better segregation of duties within our financial department. During the quarter ended June 30, 2010 we also retained a GAAP advisor to assist management with accounting and reporting matters. While these remedial actions have been implemented, they may not be in place for a sufficient period of time to help us certify that material weaknesses have been fully remediated as of the end of calendar year 2010. We will continue to develop our remediation plans and implement additional measures during calendar year 2010 and possibly into calendar year 2011.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the relationship between the benefit of desired controls and procedures and the cost of implementing new controls and procedures.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As of June 30, 2010, we are in the process of remediating certain material weakness which existed at December 31, 2009. If the remedial measures described above are insufficient to address any of the identified material weaknesses or are not implemented effectively, or additional deficiencies arise in the future, material misstatements in our interim or annual financial statements may occur in the future. We are currently working to improve and simplify our internal processes and implement enhanced controls, as discussed above, to address the material weaknesses in our internal control over financial reporting and to remedy the ineffectiveness of our disclosure controls and procedures. A key element of our remediation effort is the ability to recruit and retain qualified individuals to support our remediation efforts. While our Audit Committee and Board of Directors have been supportive of our efforts by supporting the hiring of a controller in our finance department as well as funding efforts to improve our financial reporting system, improvement in internal control will be hampered if we can not recruit and retain more qualified professionals.

Other than described above, 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, 2010.

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, 2009.

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, 2009.

ITEM 6. EXHIBITS

- (a) Exhibits
- 31.1 Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
- 31.2 Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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 I (Registrant)	PHARMACEUTICALS, INC.
Date: August 9, 2010	Ву:	/s/ GARY S. JACOB
		Gary S. Jacob President and Chief Executive Officer
Date: August 9, 2010	Ву:	/s/ BERNARD F. DENOYER
	22	Bernard F. Denoyer Senior Vice President, Finance