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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

**FOR THE QUARTERLY PERIOD ENDED: MARCH 31, 2010**

**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**

(State or Other Jurisdiction of  
Incorporation or Organization)

**20-3823853**

(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  No

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(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  No

The number of the registrant's shares of common stock outstanding was 88,423,359 as of May 6, 2010.

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**SYNERGY PHARMACEUTICALS, INC.**  
**(A development stage company)**

**FORM 10-Q**

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## 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 in this Report on Form 10-Q 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**

	<u>March 31,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
	<u>(unaudited)</u>	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 3,949,412	\$ 7,152,568
Prepaid expenses and other current assets	1,316,393	1,061,630
Total Current Assets	5,265,805	8,214,198
Property and equipment, net	9,231	9,725
Security deposits	14,025	14,025
Due from majority shareholder	1,150,609	972,552
	<u>\$ 6,439,670</u>	<u>\$ 9,210,500</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 648,481	\$ 1,283,466
Accrued expenses	467,951	443,266
Total Current Liabilities	1,116,432	1,726,732
Stockholders' Equity:		
Common stock, par value of \$.0001 authorized 200,000,000 shares, outstanding 88,423,359 shares at March 31, 2010 and December 31, 2009	8,844	8,844
Preferred stock, Authorized 20,000,000 shares and 0 shares outstanding at March 31, 2010 and December 31, 2009	—	—
Additional paid-in capital	47,583,840	47,395,465
Deficit accumulated during development stage	(42,269,446)	(39,920,541)
Total Stockholders' Equity	5,323,238	7,483,768
	<u>\$ 6,439,670</u>	<u>\$ 9,210,500</u>

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 Months Ended March 31,		November 15, 2005 (inception) to March 31, 2010
	2010	2009	
Revenues	\$ —	\$ —	\$ —
Costs and Expenses:			
Research and development	1,404,284	333,147	7,570,795
Purchased in-process research and development	—	—	28,156,502
General and administrative	977,861	663,512	6,583,484
Loss from Operations	(2,382,145)	(996,659)	(42,310,781)
Interest and investment income	33,240	130	113,156
Loss from Continuing Operations	(2,348,905)	(996,529)	(42,197,625)
Loss from discontinued operations	—	—	(71,821)
Net Loss	\$ (2,348,905)	\$ (996,529)	\$ (42,269,446)
Weighted Average Common Shares Outstanding			
Basic and Diluted	88,423,359	65,742,879	
Net Loss per Common Share			
Basic and Diluted	\$ (0.03)	\$ (0.02)	

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

**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	\$ 15,138	\$ (13,138)	\$ —	\$ 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)	14,998	—	—
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, 2008	5,000,000	500	2,999,500	—	3,000,000
Common stock issued via private placement— August 25, 2008	41,667	4	24,996	—	25,000
Fees and expenses related to private placements	—	—	(73,088)	—	(73,088)
Stock based compensation expense	—	—	379,883	—	379,883
Net loss for the year	—	—	—	(31,755,180)	(31,755,180)
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 issued via private placements	—	—	—	—	—
Fees and expenses related to private placements	—	—	—	—	—
Stock based compensation expense	—	—	188,375	—	188,375
Net loss for the period	—	—	—	(2,348,905)	(2,348,905)
Balance, March 31, 2010	88,423,359	\$ 8,844	\$ 47,583,840	\$ (42,269,446)	\$ 5,323,238

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)

	Three Months Ended March 31, 2010	Three Months Ended March 31, 2009	Period from November 15, 2005 (Inception) to March 31, 2010
<b>Cash Flows From Operating Activities:</b>			
Net loss	\$ (2,348,905)	\$ (996,529)	\$ (42,269,446)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	494	494	3,692
Stock-based compensation expense	188,375	176,496	1,622,820
Purchased in-process research and development	—	—	28,156,502
Changes in operating assets and liabilities:			
Security deposit	—	—	(14,025)
Accounts payable and accrued expenses	(610,300)	410,937	393,389
Prepaid expenses and other current assets	(254,763)	—	(1,316,393)
Total Adjustments	<u>(676,194)</u>	<u>587,927</u>	<u>28,845,985</u>
Net Cash Used in Operating Activities	(3,025,099)	(408,602)	(13,423,461)
<b>Cash Flows From Investing Activities:</b>			
Net cash paid on Exchange Transaction	—	—	(155,326)
Loans to related parties	(178,057)	(7,398)	(1,150,609)
Additions to property and equipment	—	—	(12,195)
Net Cash Used in Investing Activities	(178,057)	(7,398)	(1,318,130)
<b>Cash Flows From Financing Activities:</b>			
Capital contribution by shareholders	—	—	8,893
Issuance of common stock	—	—	2,000
Proceeds of private placement of common stock	—	—	18,995,100
Proceeds from sale of common stock	—	200,000	—
Fees and expenses related to private placements	—	—	(333,090)
Proceeds from sale of unregistered common stock to founders	—	—	18,100
Net Cash Provided by Financing Activities	—	200,000	18,691,003
Net (decrease) increase in cash and cash equivalents	(3,203,156)	(216,000)	3,949,412
Cash and cash equivalents at beginning of period	7,152,568	216,007	—
Cash and cash equivalents at end of period	<u>\$ 3,949,412</u>	<u>\$ 7</u>	<u>\$ 3,949,412</u>
<b>Supplementary disclosure of cash flow information:</b>			
Cash paid for taxes	\$ 10,908	\$ 1,674	\$ 17,829
Cash paid for interest	\$ —	\$ —	\$ —
Cash Received in escrow for private placement of common stock	\$ —	\$ 191,000	\$ —
Value of common stock issued via Exchange Transaction	\$ —	\$ —	\$ 27,278,861

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

**SYNERGY PHARMACEUTICALS, INC.**  
**(A development stage company)**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Business Overview**

Synergy Pharmaceuticals, Inc. ("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 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 SP-304 which showed that SP-304 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 SP-304 in the blood. The data obtained from this trial supported advancing SP-304 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 SP-304 in CC patients.

**2. Basis of Presentation and Going Concern**

On July 14, 2008, Synergy completed the acquisition of Synergy-DE. 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 July 14, 2008 to date. 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.

All intercompany balances and transactions have been eliminated. These unaudited condensed consolidated financial statements include Synergy and its wholly-owned subsidiaries: (1) Synergy-DE, (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 filed with the Securities Exchange Commission ("SEC") on March 15, 2010. Certain items in the prior year's financial statements may have been reclassified to conform to the current year's presentation.

These condensed consolidated financial statements as of March 31, 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 additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate

**SYNERGY PHARMACEUTICALS, INC.**  
**(A development stage company)**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

**2. Basis of Presentation and Going Concern (Continued)**

revenue. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As of March 31, 2010, Synergy had an accumulated deficit of \$ 42,269,446 resulting primarily from acquired in-process research and development valued at \$28,156,502 and expensed upon the acquisition of Synergy on July 14, 2008. 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 SP-304 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 \$3,025,099 for the three months ended March 31, 2010. As of March 31, 2010 Synergy has \$3,949,412 of cash. During the three months ended March 31, 2010, Synergy incurred net losses from continuing operations of \$2,348,905. To date, Synergy's sources of cash have been primarily limited to private placements of common stock. We did not have any financing activities during the three months ended March 31, 2010. As of March 31, 2010 Synergy had working capital of \$4,149,373 as compared to a 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.

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

**SYNERGY PHARMACEUTICALS, INC.**  
**(A development stage company)**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

**3. Recent Accounting Pronouncements (Continued)**

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 provisions of ASU 2010-06 are effective for periods beginning after December 15, 2009. The disclosures relating to Level 3 activity are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years. 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 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.

**SYNERGY PHARMACEUTICALS, INC.**  
(A development stage company)

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(Unaudited)

**4. Accounting for Shared-Based Payments (Continued)**

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

	Three Months Ended March 31,		November 15, 2005 (inception) to March 31, 2010
	2010	2009	
Employees—included in research and development	\$ 49,459	\$ 43,241	\$ 381,530
Employees—included in general and administrative	58,955	56,073	529,849
Non-employees—included in research and development	8,362	8,362	50,824
Non-employees—included in general and administrative	71,599	68,820	660,617
<b>Total stock-based compensation expense</b>	<b>\$ 188,375</b>	<b>\$ 176,496</b>	<b>\$ 1,622,820</b>

The unrecognized compensation cost related to non-vested employee stock options outstanding at March 31, 2010, net of expected forfeitures, was \$821,874, to be recognized over a weighted-average remaining vesting period of approximately 1 year.

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. 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
Balance outstanding, December 31, 2009	4,214,016	\$ 0.25 - 0.95	\$ 0.30	\$ 22,320,436
Granted	3,600,000(1)	0.70	0.70	
Exercised	—	—	—	
Forfeited	—	—	—	
Balance outstanding, March 31, 2010	<u>7,814,016</u>	\$ 0.25 - 0.95	\$ 0.49	\$ 62,230,381
Exercisable at March 31, 2010	<u>1,417,420</u>	\$ 0.25 - 0.95	\$ 0.29	\$ 11,561,594

(1) These will vest and become exercisable only upon a change of control of the company.

**Synergy Restricted Stock Units**

Restricted stock units, which entitle the holder to receive, 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 grant. Subject to a repurchase agreement assumed by Synergy pursuant to the Exchange Transaction, 50% of the units vest after 1 year of continuous service and the remaining 50% vest after 2 years of continuous service from the grant 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 March 31, 2010 there were 874,760 restricted stock units outstanding. These units were originally issued on July 3, 2008 and are included in

**SYNERGY PHARMACEUTICALS, INC.**  
(A development stage company)

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(Unaudited)

**4. Accounting for Shared-Based Payments (Continued)**

shares outstanding. The fair value of the 874,760 restricted stock units on the date of issuance was \$524,856 of which \$32,353 and \$491,065 was recorded as stock-based compensation expense during the three months ended March 31, 2010 and for the period from inception to March 31, 2010, leaving \$33,791 unrecognized as of March 31, 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 March 31, 2010 Synergy's majority shareholder, Callisto, owns approximately 50.4% of its outstanding shares. As of March 31, 2010, the balance due from majority shareholder amounted to \$1,150,609 as compared to \$972,552 as of December 31, 2009 which reflects Callisto's share of Synergy payments for common operating costs. 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.

**6. Research and Development Expense**

In accordance with FASB ASC Topic 730-10-55, Research and Development, Synergy recorded prepaid research and development expense of \$1.3 million and \$1.0 million as of March 31, 2010 and December 31, 2009, respectively, for nonrefundable deposits on production of drug substance of our drug candidate SP-304 and analytical testing services of our drug candidate SP-333. In accordance with this guidance, Synergy expenses these advance payments 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 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, 2010 and March 31, 2009 the effect of 7,814,016 and 4,080,016 outstanding stock options were excluded from the calculation of diluted loss per share because the effect was antidilutive.

## **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 March 19, 2010, we initiated a Phase 2a 14-day repeated-oral-dose, placebo-controlled, dose-escalation trial of SP-304 in CC patients. We expect to obtain meaningful topline data from this trial in 2010, and use that data to establish doses for follow-up Phase 2b clinical trials in CC and IBS-C. Our plan is to begin a Phase 2b 28-day repeated-oral-dose, placebo-controlled trial in SP-304 in CC patients in early 2011 and a Phase 2b 90-day repeated-oral-dose, placebo-controlled trial of SP-304 in IBS-C patients in the second quarter of 2011.

We also plan to initiate a Phase 1 clinical trial of SP-333 in volunteers in the fourth quarter of 2010. We expect to follow this trial in 2011 with a Phase 1b single-dose trial in UC patients to evaluate safety and pharmacokinetics of orally administered SP-333 in UC patients.

### **FINANCIAL OPERATIONS OVERVIEW**

From inception through March 31, 2010, we have sustained cumulative net losses of \$42,269,446, resulting primarily from acquired in-process research and development valued at \$28,156,502 which was expensed upon the acquisition of Synergy on July 14, 2008. From inception through March 31, 2010, 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 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 months ended March 31, 2010.

## OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of March 31, 2010.

## RESULTS OF OPERATIONS

### *THREE MONTHS ENDED MARCH 31, 2010 AND 2009*

As discussed in note 2 of the financial statements, on July 14, 2008, Synergy completed the acquisition of Synergy-DE. The acquisition of Synergy-DE was treated as an asset acquisition, since Synergy-DE was a development stage company and did 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 July 14, 2008 to March 31, 2010. As a result of the acquisition of Synergy-DE on July 14, 2008, we decided to discontinue our 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.

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

Research and development expenses for the three months ended March 31, 2010 increased \$1,071,137 or 321%, to \$1,404,284 from \$333,147 for the three months ended March 31, 2009. This increase was primarily due to higher clinical program expenses, including analytical testing, clinical data monitoring and patient costs, which increased by approximately \$820,000 during the three months ended March 31, 2010 to approximately \$898,000 related to (i) our Phase 2a trial of SP-304 in CC patients which opened for enrollment this quarter, (ii) patent related legal fees increased approximately \$160,000 to approximately \$220,000 for both domestic and international filings and (iii) in-house staff salaries and wages, stock based compensation and employee benefits which increased approximately \$62,000 to \$207,000. Additionally, in accordance with FASB ASC Topic 730-10-55, Research and Development, our prepaid research and development expense increased approximately \$300,000 during the quarter ended March 31, 2010 for nonrefundable deposits on production of drug substance of our drug candidate SP-304 and analytical testing services of our drug candidate SP-333. In accordance with this guidance, Synergy will expense these advance payments when drug compound is delivered and or services are performed.

General and administrative expenses increased \$314,349 or 47%, to \$977,861 for the three months ended March 31, 2010 from \$663,512 for the three months ended March 31, 2009. This increase was

primarily due to (i) approximately \$106,000 of higher financial advisory, legal, audit and travel expenses related to our prospective public offerings, (ii) approximated \$87,000 of increased facilities overhead and (iii) approximately \$40,000 in higher public relations costs. Staff salaries, wages and benefits were unchanged in the quarter ended March 31, 2010 and compared to the same period last year.

Net loss for the three months ended March 31, 2010 increased to \$2,348,905, as compared to a net loss of \$996,529 incurred for the three months ended March 31, 2009 for the reasons discussed above partially offset by higher interest income of \$33,000, on higher cash balances.

## **LIQUIDITY AND CAPITAL RESOURCES**

As of March 31, 2010 we had \$3,949,412 in cash and cash equivalents, compared to \$7,152,568 as of December 31, 2009. Net cash used in operating activities was \$3,025,099 for the three months ended March 31, 2010. As of March 31, 2010 we had working capital of \$4,149,313 as compared to working capital of \$6,487,466 as of December 31, 2009.

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.

Our condensed consolidated financial statements as of March 31, 2010 and December 31, 2009 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the negative outcome of this uncertainty.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk on the fair values of certain assets is related to credit risk associated with securities held in money market accounts and the FDIC insurance limit on our bank balances. At March 31, 2010, we had approximately \$3,200,000 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 March 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.

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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.

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. We have hired a controller who will: (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 will allow for proper segregation of duties within our financial department. We are also considering the use of an independent GAAP advisor. While we expect these remedial actions to be essentially implemented in calendar year 2010, some 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 March 31, 2010, we are in the process of remediating the 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 March 31, 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.





**CERTIFICATIONS**

I, Gary S. Jacob, certify that:

- 1) I have reviewed this report on Form 10-Q of Synergy Pharmaceuticals, Inc.
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2010

/s/ GARY S. JACOB

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Gary S. Jacob  
*President and Chief Executive Officer*

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[EXHIBIT 31.1](#)

[CERTIFICATIONS](#)

**CERTIFICATIONS**

I, Bernard F. Denoyer, certify that:

- 1) I have reviewed this report on Form 10-Q of Synergy Pharmaceuticals, Inc.
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2010

/s/ BERNARD F. DENOYER

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Bernard F. Denoyer  
*Senior Vice President, Finance*

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[CERTIFICATIONS](#)

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EXHIBIT 32.1

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
SYNERGY PHARMACEUTICALS, INC.  
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2010  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I am the Chief Executive Officer of Synergy Pharmaceuticals, Inc., a Florida corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended March 31, 2010 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2010

/s/ GARY S. JACOB

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Gary S. Jacob  
*President and Chief Executive Officer*

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[EXHIBIT 32.1](#)

[CERTIFICATION OF CHIEF EXECUTIVE OFFICER SYNERGY PHARMACEUTICALS, INC. FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2010 PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002](#)

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EXHIBIT 32.2

**CERTIFICATION OF SENIOR VICE PRESIDENT, FINANCE  
SYNERGY PHARMACEUTICALS, INC.  
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2010  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I am the Senior Vice President, Finance of Synergy Pharmaceuticals, Inc., a Florida corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended March 31, 2010 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2010

/s/ BERNARD F. DENOYER

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Bernard F. Denoyer  
*Senior Vice President, Finance*

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[EXHIBIT 32.2](#)

[CERTIFICATION OF SENIOR VICE PRESIDENT, FINANCE SYNERGY PHARMACEUTICALS, INC. FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2010 PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002](#)