SYNERGY PHARMACEUTICALS, INC.
Form 10-Q
May 10, 2011
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: MARCH 31, 2011

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	**10170**
(Address of principal executive offices)	(Zip Code)

(212) 297-0020
(Registrant s telephone number)

(Former Name, Former Address and Former Fiscal Year, if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes 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 x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The number of the registrant s shares of common stock outstanding was 93,221,498 as of May 9, 2011.

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

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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 cont similar words. Forward-looking statements include information concerning possible or assumed future business success or financial results. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Accordingly, we do not undertake any obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth in our Form 10-K for the year ended December 31, 2010 as filed with the Securities Exchange Commission on March 16, 2011. 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.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2011 (unaudited)	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 938,700	$ 1,707,516
Prepaid expenses and other current assets	733,655	997,584
Total Current Assets	1,672,355	2,705,100
Property and equipment, net	7,255	7,749
Security deposits	14,025	14,025
Due from controlling shareholder	1,554,067	1,674,087
Total assets	$ 3,247,702	$ 4,400,961
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current Liabilities:		
Accounts payable	$ 2,614,688	$ 2,961,333
Accrued expenses	2,333,671	2,051,057
Notes Payable	511,877	
Total Current Liabilities	5,460,236	5,012,390
Derivative financial instruments, at estimated fair value-warrants	5,139,347	3,487,959
Total Liabilities	10,599,583	8,500,349
Stockholders Deficit:		
Common stock, par value of $.0001 authorized 200,000,000 shares, outstanding 92,788,164 and 92,188,164 shares at March 31, 2011 and December 31, 2010	9,280	9,220
Additional paid-in capital	51,483,101	51,033,374
Deficit accumulated during development stage	(58,844,262)	(55,141,982)
Total Stockholders Deficit	$ (7,351,881)	$ (4,099,388)
Total liabilities and stockholder s deficit	$ 3,247,702	$ 4,400,961

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

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SYNERGY PHARMACEUTICALS, INC
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31,		November 15, 2005 (inception) to March 31, 2011
	2011	2010	
Revenues	$	$	$
Costs and Expenses:			
Research and development	1,478,126	1,183,862	16,472,526
Purchased in-process research and development			28,156,502
General and administrative	1,897,626	1,198,283	14,796,626
Loss from Operations	(3,375,752)	(2,382,145)	(59,425,654)
Interest and investment income	24,064	33,240	212,542
Interest expense	(11,877)		(11,877)
Other Income			494,479
Change in fair value of derivative instruments-warrants	(338,715)		(41,931)
Loss from Continuing Operations	(3,702,280)	(2,348,905)	(58,772,441)
Loss from discontinued operations			(71,821)
Net Loss	$ (3,702,280)	$ (2,348,905)	$ (58,844,262)
Weighted Average Common Shares Outstanding			
Basic and Diluted	92,334,831	88,423,359	
Net Loss per Common Share			
Basic and Diluted	$ (0.04)	$ (0.03)	

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

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF 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	5,041,667	504	3,024,496		3,025,000
Fees and expenses related to private placements			(73,088)		(73,088)
Stock based compensation expense			379,883		379,883
Net loss for the 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 registered direct offering and private placement	2,418,000	242	7,178,758		7,179,000
Fees and expenses related to direct offering			(468,130)		(468,130)
			(3,784,743)		(3,784,743)

Warrants reclassified to derivative liability					
Common stock issued to extend lock-up agreements	1,341,867	134	(134)		
Common stock Issued for services rendered	4,938		18,271		18,271
Stock based compensation expense			693,887		693,887
Net loss for the period				(15,221,441)	(15,221,441)
Balance, December 31, 2010	92,188,164	9,220	51,033,374	(55,141,982)	(4,099,388)
Common stock issued via registered direct offering	600,000	60	1,799,940		1,800,000
Fees and expenses related to direct offering			(185,000)		(185,000)
Warrants reclassified to derivative liability			(1,312,673)		(1,312,673)
Stock based compensation expense			147,460		147,460
Net loss for the period				(3,702,280)	(3,702,280)
Balance, March 31, 2011	92,788,164	$ 9,280	$ 51,483,101	$ (58,844,262)	$ (7,351,881)

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

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SYNERGY PHARMACEUTICALS, INC.

(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31, 2011	Three Months Ended March 31, 2010	Period from November 15, 2005 (Inception) to March 31, 2011
Cash Flows From Operating Activities:			
Net loss	$ (3,702,280)	$ (2,348,905)	$ (58,844,262)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	494	494	5,668
Stock-based compensation expense	147,460	188,375	2,294,063
Purchased in-process research and development			28,156,502
Change in fair value of derivative instruments-warrants	338,715		41,931
Interest expense on short term notes borrowing	11,877		11,877
Changes in operating assets and liabilities:			
Security deposit			(14,025)
Accounts payable and accrued expenses	(64,031)	(610,300)	4,225,316
Prepaid expenses and other current assets	263,929	(254,763)	(733,655)
Net Cash Used in Operating Activities	(3,003,836)	(3,025,099)	(24,856,585)
Cash Flows From Investing Activities:			
Net cash paid on Exchange Transaction			(155,326)
Repayment of/(loans to) related parties	120,020	(178,057)	(1,554,067)
Additions to property and equipment			(12,195)
Net Cash Provided by/ (Used in) Investing Activities	120,020	(178,057)	(1,721,588)
Cash Flows From Financing Activities:			
Capital contribution by shareholders			8,893
Issuance of common stock			2,000
Proceeds from sale of common stock and warrants	1,800,000		27,974,100
Proceeds from sale of unregistered common stockto founders			18,100
Fees and expenses related to sale of common stock and warrants	(185,000)		(986,220)
Proceeds from issuance of short term note	500,000		500,000
Net Cash Provided by Financing Activities	2,115,000		27,516,873
Net (decrease) increase in cash and cash equivalents	(768,816)	(3,203,156)	938,700
Cash and cash equivalents at beginning of period	1,707,516	7,152,568	
Cash and cash equivalents at end of period	$ 938,700	$ 3,949,412	$ 938,700
Supplementary disclosure of cash flow information:			
Cash paid for taxes	$ 5,910	$ 10,908	$ 39,732
Value of common stock issued via Exchange Transaction	$	$	$ 27,278,861
Value of warrants classified as derivative liability	$ 1,312,673	$	$ 5,097,416
Value of common stock issued to induce stockholders to extend lock-up agreements	$	$	$ 3,235,040

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

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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 or the Company) is a biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. Our lead product candidate is plecanatide, 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 infrequent and uncomfortable bowel movements but a majority of these patients also report bloating and abdominal discomfort among their most bothersome symptoms. IBS-C is characterized by frequent and recurring abdominal pain and/or discomfort associated with chronic constipation. Synergy is also developing SP-333, our second generation GC-C receptor agonist for the treatment of gastrointestinal inflammatory diseases, such as ulcerative colitis, or UC.

Plecanatide

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

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

SP-333

We are also developing a second generation GC-C receptor analog, SP-333, which is currently in pre-clinical development for the treatment of gastrointestinal inflammatory diseases. SP-333 is a synthetic analog of uroguanylin, a natriuretic hormone which is normally produced in the body s intestinal tract. Deficiency of this hormone is predicted to be one of the primary reasons for the formation of polyps that can lead to colon cancer, as well as debilitating and difficult-to-treat GI inflammatory disorders such as ulcerative colitis and Crohn s disease.

On February 1, 2011 the U.S. Patent and Trademark Office issued U.S. Patent No. 7,879,802, covering Synergy s novel drug candidate SP-333 to treat inflammatory bowel disease (IBD). SP-333 is a second-generation guanylate cyclase C (GC-C) agonist with the potential to treat gastrointestinal diseases such as ulcerative colitis. The patent entitled Agonists of Guanylate Cyclase Useful for the Treatment of Gastrointestinal Disorders, Inflammation, Cancer and Other Disorders specifically claims composition of matter of SP-333 and use in the treatment of human diseases.

2. Basis of Presentation and Going Concern

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

Synergy acquired the GI drugs and related technology in connection with the Exchange Transaction. On July 21, 2008, Pawfect amended its articles of incorporation to effect the actions necessary to complete the transactions contemplated by the Exchange Transaction and changed its name to Synergy Pharmaceuticals, Inc. (Synergy or the Company).

The acquisition of Synergy-DE was treated as an asset acquisition, since Synergy-DE is a development stage company and does not have the necessary inputs and outputs to meet the definition of a business. The results of operations of Synergy-DE are included in the accompanying consolidated financial statements from the date of acquisition. As a result of the acquisition of Synergy-DE on July 14, 2008, the Company decided to discontinue its pet food business and accordingly, amounts in the consolidated statements of operations and related notes for all historical periods have been restated to reflect these operations as discontinued.

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

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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, 2010 contained in the Company s Annual Report on Form 10-K filed with the Securities Exchange Commission (SEC) on March 16, 2011. Certain items in the prior year s financial statements have been reclassified to conform to the current year s presentation. All intercompany balances and transactions have been eliminated.

These condensed consolidated financial statements as of March 31, 2011 and December 31, 2010 have been prepared under the assumption that Synergy will continue as a going concern for the next twelve months. Synergy s ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As of March 31, 2011, Synergy had an accumulated deficit of $58,844,262 and expects to incur significant and increasing operating losses for the next several years as the Company expands its research and development, continues clinical trials of plecanatide for the treatment of GI disorders, acquires or licenses technologies, advances other product candidates into clinical development, seeks regulatory approval and, if FDA approval is received, commercializes products. Because of the numerous risks and uncertainties associated with product development efforts, Synergy is unable to predict the extent of any future losses or when Synergy will become profitable, if at all.

Net cash used in operating activities was $3,003,836 for the three months ended March 31, 2011. As of March 31, 2011 Synergy has $938,700 of cash on hand. During the three months ended March 31, 2011, Synergy incurred net losses from continuing operations of $3,702,280. To date, Synergy s sources of cash have been primarily limited to the sale of common stock and issuance of notes. Net cash provided by financing activities for the three months ended March 31, 2011 was $2,115,000. As of March 31, 2011 Synergy had a negative working capital of $3,787,881.

Recently worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain difficult for the foreseeable future. These developments will make it more difficult to obtain additional equity or credit financing, when needed. Synergy has accordingly taken steps to conserve cash which include extending payment terms to our suppliers as well as substantial management and staff salary cuts and deferrals. These actions may not be sufficient to allow the Company time to raise additional capital.

Synergy will be required to raise additional capital within the next year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Synergy cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Synergy raises additional funds by issuing equity securities, Synergy s stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Synergy s ability to conduct business. If Synergy is unable to raise additional capital when required or on acceptable terms, Synergy may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that Synergy would otherwise seek to develop or commercialize ourselves on unfavorable terms.

3. 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. The adoption of this standard did not have a material effect on the Company s results of operations or its financial position.

4. Accounting for Shared-Based Payments

Stock Options

ASC Topic 718 *Compensation Stock Compensation* requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award.

ASC Topic 718 did not change the way Synergy accounts for non-employee stock-based compensation. Synergy continues to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if

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that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 *Equity-Based Payment to Non-Employees* 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. Accordingly the fair value of these options is being marked to market quarterly until the measurement date is determined.

ASC Topic 718 requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to Synergy s accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

Synergy accounts for common stock, stock options, and warrants granted to employees and non-employees based on the fair market value of the instrument, using the Black-Scholes option pricing model based on assumptions for expected stock price volatility, term of the option, risk-free interest rate and expected dividend yield, at the grant date.

Synergy adopted the 2008 Equity Compensation Incentive Plan (the Plan) during the quarter ended September 30, 2008. Stock options granted under the Plan typically vest after three years of continuous service from the grant date and have a contractual term of ten years. Synergy did not issue stock options prior to the quarter ended September 30, 2008. Stock-based compensation expense related to Synergy options and restricted stock units have been recognized in operating results as follow:

	Three Months Ended March 31,		November 15, 2005 (inception) to
	2011	2010	March 31, 2011
Employees included in research and development	$ 36,749	$ 49,459	$ 556,339
Employees included in general and administrative	44,618	58,955	726,099
Non-employees included in research and development	8,362	8,362	103,009
Non-employees included in general and administrative	57,731	71,599	908,616
Total stock-based compensation expense	$ 147,460	$ 188,375	$ 2,294,063

The unrecognized compensation cost related to non-vested employee stock options outstanding at March 31, 2011, net of expected forfeitures, was $159,826 to be recognized over a weighted-average remaining vesting period of approximately three months. This unrecognized compensation cost does not include amounts related to stock options which vest upon change of control.

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the following periods indicated.

	Three Months Ended March 31, 2011	Three Months Ended March 31, 2010
Risk-free interest rate	(*)	2.71%
Dividend yield	(*)	

Expected volatility	(*)	90%
Expected term (in years)	(*)	6.0 yrs

(*) No stock options granted during this period.

On March 1, 2010, a majority of Synergy s shareholders acting by written consent approved an amendment to the Plan increasing the number of shares reserved under the Plan to 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	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2010	8,604,016	$ 0.25 - 0.95	$ 0.51	$ 25,763,002	8.4 years
Granted					
Exercised					
Forfeited	(214,939)	$ 0.25-0.70	$ 0.46		
Balance outstanding, March 31, 2011	8,389,077	$ 0.25 - 0.95	$ 0.51	$ 27,961,736	8.2 years
Exercisable at March 31, 2011	2,683,343	$ 0.25 - 0.95	$ 0.30	$ 9,510,701	7.3 years

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5. Notes Payable

On February 8, 2011, Synergy entered into a loan agreement (the Agreement) with an investor (the Lender), pursuant to which the Lender agreed to lend an aggregate $950,000 to Synergy. Simultaneously with the execution and delivery of the Agreement, Synergy issued a note to the Lender in the principal amount of $500,000 (the First Note). Synergy had the option to issue an additional note to the Lender in the principal amount of $450,000 beginning February 21, 2011 (the Second Note and with the First Note, the Notes). The Notes bear interest at 17% per annum and are payable on April 1, 2011. As of March 31, 2011 Synergy had not borrowed under the Second Note. The First Note principal and interest totaling $511,877 was paid when due on April 1, 2011 and the loan agreement was terminated.

6. Stockholder s Equity

On March 4, 2011, Synergy closed a financing with a non-U.S. investor which raised gross proceeds of $1,800,000 less a total of $185,000 for offering expenses in connection with this registered direct offering. Synergy issued to the investor 600,000 shares of its common stock and warrants to purchase 420,000 shares of common stock. The purchase price paid by the investor was $3.00 for each unit. The warrants expire after seven years and are exercisable at $3.10 per share. 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 this registered direct offering must be recorded as derivative liabilities with a charge to additional paid in capital.

7. Research and Development Expense

Research and development costs include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, regulatory and scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring, insurance and FDA consultants.

In accordance with FASB ASC Topic 730-10-55, Research and Development, Synergy recorded prepaid research and development costs of $407,445 and $683,182 as of March 31, 2011 and December 31, 2010, respectively, for nonrefundable pre-payments for production of plecanatide drug substance and analytical testing services of our drug candidate plecanatide and SP-333. In accordance with this guidance, Synergy expenses prepaid research and development costs when drug compound is delivered and services are performed.

8. Derivative Financial Instruments

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, Derivatives and Hedging: Contracts in Entity s Own Equity (ASC Topic 815-40). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity s own stock, which would qualify as a scope exception under ASC Topic 815-10.

Synergy Derivative Financial Instruments

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 its registered direct offerings must be recorded as derivative liabilities. In accordance with ASC Topic 815-40, the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company s statement of operations.

The Company estimates the fair value of the warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability and change in fair value described above. Synergy did not have derivative instruments outstanding during the quarter ended March 31, 2010. The range of assumptions used to determine the fair value of the warrants at the end of and during each period indicated were:

	Three Months Ended March 31, 2011	**Three Months Ended March 31, 2010**
Estimated fair value of Synergy common stock	$2.43 - $3.13	(*)
Expected warrant term	4,25 - 7.0 years	(*)
Risk-free interest rate	1.80% - 2.9%	(*)
Expected volatility	90%	(*)
Dividend yield		(*)

(*) No derivative instruments issued or outstanding during the quarter ended March 31, 2010. See table below

Estimated fair value of the stock is based on an apportionment of the unit price paid for the shares and warrants issued in Synergy s registered direct offerings, which were deemed to be arms-length negotiated prices. Expected volatility is based on historical volatility of the

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Synergy s common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants.

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

Date	Description	Warrants		Derivative Instrument Liability
12/31/2009	Balance of derivative financial instruments liability		$	
6/30/2010	Fair value of new warrants issued during the quarter	648,000	$	1,045,214
9/30/2010	Fair value of new warrants issued during the quarter	103,703	$	163,905
9/30/2010	Change in fair value of warrants during the quarter		$	(110,937)
9/30/2010	Balance of derivative financial instruments liability	751,703	$	1,098,182
12/31/2010	Fair value of new warrants issued during the quarter	705,235	$	2,575,624
12/31/2010	Change in fair value of warrants during the quarter		$	(185,847)
12/31/2010	Balance of derivative financial instruments liability	1,456,938	$	3,487,959
3/31/2011	Fair value of new warrants issued during the quarter	420,000	$	1,312,673
3/31/2011	Change in fair value of warrants during the quarter		$	338,715
3/31/2011	Balance of derivative financial instruments liability	1,876,938	$	5,139,347

Synergy Fair Value Measurements

The following table presents the Company s liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2010 and March 31, 2011:

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2010	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of March 31, 2011
Derivative liabilities related to Warrants	$	$	$ 3,487,959	$ 3,487,959	$	$	$ 5,139,347	$ 5,139,347

The following table sets forth a summary of changes in the fair value of the Company s Level 3 liabilities for the three months ended March 31, 2011:

Description	Balance at December 31, 2010	Fair Value of warrants upon issuance	Unrealized (gains) or losses	Balance as of March 31, 2011
Derivative liabilities related to Warrants	$ 3,487,959	$ 1,312,673	$ 338,715	$ 5,139,347

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities in the Company s statement of operations. A financial instrument s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

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9. Loss Per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, *Earnings per Share* , (ASC Topic 260) for all periods presented. In accordance with ASC Topic 260, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares because shares issuable pursuant to the exercise of stock options would have been antidilutive. For the three months ended March 31, 2011 and March 31, 2010 the effect of 8,389,077 and 7,814,016, respectively outstanding stock options were excluded from the calculation of diluted loss per share because the effect was antidilutive. For the three months ended March 31, 2011 the effect of 1,876,938 outstanding warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive. There were no such warrants issued as of March 31, 2010.

10. Related Parties

As of March 31, 2011, Synergy s majority shareholder, Callisto, owns 48.1% of its outstanding shares. Synergy occupies corporate office space in New York City under a month to month sharing arrangement with Callisto. Rent is allocated from Callisto monthly based on the square footage of office space occupied by Synergy.

As of March 31, 2011 Synergy had advanced Callisto $1,554,067 which is Callisto s share of Synergy payments for common operating costs since July 2008. The indebtedness as of December 31, 2010 is evidenced by an unsecured promissory note which bears interest at 6% per annum. Despite a small reduction in the balance due from Callisto during the quarter ended March 31, 2011, Synergy is unable to determine when this balance will be repaid and accordingly Synergy has classified the balance due as a long term asset.

As of March 31, 2011 and December 31, 2010, the balances due from Callisto Pharmaceuticals, Inc. are comprised of the following amounts:

	March 31, 2011	December 31, 2010
Rent, utilities and property taxes	$ 68,993	$ 61,813
Insurance and other facilities related overhead	172,913	150,836
Independent accountants and legal fees	472,728	417,298
Financial printer and transfer agent fees	153,352	147,171
Salaries and consulting fees of shared executives	233,936	214,311
Working capital advances, net of repayments	452,145	682,658
Total due from Callisto	$ 1,554,067	$ 1,674,087

11. Subsequent Events

On April 1, 2011 Synergy repaid the First Note principal and interest totaling $511,877 and the Agreement discussed in Note 5 above was terminated.

On May 2, 2011, Synergy entered into a securities purchase agreement with certain investors to raise gross proceeds of $1,300,002 in a registered direct offering. The Company issued to the investors 433,334 shares of its common stock and warrants to purchase 433,334 shares of common stock. The purchase price paid by the investors was $3.00 for each unit. The warrants expire after seven years and are exercisable at $3.25 per share. 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 this registered direct offering must be recorded as derivative liabilities with a charge to additional paid in capital.

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and other financial information appearing elsewhere in this quarterly report. In addition to historical information, the following discussion and other parts of this quarterly report contain forward-looking statements. You can identify these statements by forward-looking words such as 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, 2010 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 May 2, 2011, we entered into a securities purchase agreement with certain investors to raise gross proceeds of $1,300,002 in a registered direct offering. We issued to the investors 433,334 shares of its common stock and warrants to purchase 433,334 shares of common stock. The purchase price paid by the investors was $3.00 each unit. The warrants expire after seven years and are exercisable at $3.25 per share.

On March 4, 2011, we closed a financing with a non-U.S. investor which raised gross proceeds of $1,800,000 less a total of $185,000 for offering expenses in connection with this registered direct offering. We issued to the investor 600,000 shares of our common stock and warrants to purchase 420,000 shares of common stock. The purchase price paid by the investor was $3.00 for each unit. The warrants expire after seven years and are exercisable at $3.10 per share.

FINANCIAL OPERATIONS OVERVIEW

From inception through March 31, 2011, we have sustained cumulative net losses of $58,844,262. From inception through March 31, 2011, we have not generated any revenue from operations and expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products. We do not expect to have such for several years, if at all.

Our product development efforts are thus in their early stages and we cannot make estimates of the costs or the time they will take to complete. The risk of completion of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, our ability to raise additional capital, the nature and timing of research and development expenses and competing technologies being developed by organizations with significantly greater resources.

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA of our Annual Report on Form 10-K as of and for year ended December 31, 2010, filed with the SEC on March 16, 2011. There have been no changes to our critical accounting policies since December 31, 2010.

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, 2010. There have been no changes in our contractual obligations and commitments during the three months ended March 31, 2011.

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OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of March 31, 2011.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2011 AND MARCH 31, 2010

We had no revenues during the three months ended March 31, 2011 and 2010 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

For the three months ended March 31, 2011, research and development expenses increased $294,264 or 25% to $1,478,126 as compared to $1,183,862 during the three months ended March 31, 2010. This increase in research and development expenses was entirely attributable to continuing the development of our plecanatide product candidate. These expenses included (i) program expenses including animal studies, analytical testing, clinical data monitoring and patient costs of approximately $1,161,000, as compared to $896,000 during the three months ended March 31, 2010, (ii) in-house staff salaries and wages, stock based compensation and employee benefits of approximately $260,000, as compared to $206,000 during the three months ended March 31, 2010 as we hired additional product development personnel, partially offset by (iii) lower scientific and regulatory advisory fees and expenses of approximately $56,000, as compared to $79,000 during the three months ended March 31, 2010.

For the three months ended March 31, 2011, general and administrative expenses increased $699,343 or 58% to $1,897,626, as compared to $1,198,283 during the three months ended March 31, 2011. These expenses primarily include (i) higher facilities cost of approximately $209,000 as compared to $180,000 during the three months ended March 31, 2010, (ii) higher consultants and financial advisors fees of approximately $695,000, as compared to $223,000 during the three months ended March 31, 2010 , (iii) salaries and wages, stock based compensation and related employee benefits of approximately $745,000, as compared to $355,000 during the three months ended March 31, 2010, partially offset by (iv) accounting, corporate legal and tax services of approximately $203,000 for the three months ended March 31, 2011, as compared to $385,000 for the three months ended March 31, 2010.

Net loss for the three months ended March 31, 2011 was $3,702,280 compared to a net loss of $2,348,905 incurred for the three months ended March 31, 2010. This increase in our net loss of $1,353,375, or 58% was a result of the increases in research and development expenses and general and administrative expenses discussed above and losses resulting from the change in fair value of our derivative liability of $338,715.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2011, we had $938,700 in cash and cash equivalents, compared to $1,707,516 as of December 31, 2010. Net cash used in operating activities was $3,003,836 for the three months ended March 31, 2011 as compared to $3,025,099 during the three months ended March 31, 2010. Net cash provided by investing activities for the three months ended March 31, 2011 was $120,020, as compared to net cash used during the three months ended March 31, 2011 of $178,057. Net cash provided by financing activities for the three months ended March 31, 2011 was $2,115,000, as compared to none provided during the three months ended March 31, 2011.

As of March 31, 2011, we had a negative working capital of $3,787,881, as compared to a negative working capital of $2,307,290 on December 31, 2010.

On February 8, 2011, we entered into a loan agreement (the Agreement) with an investor (the Lender), pursuant to which the Lender agreed to lend an aggregate $950,000 to us. Simultaneously with the execution and delivery of the Agreement, we issued a note to the Lender in the principal amount of $500,000 (the First Note) which was payable on April 1, 2011 and accrued interest at 17% per annum. The First Note principal and interest totaling $511,877 was paid when due on April 1, 2011.

On March 4, 2011, we closed a financing with a non-U.S. investor which raised gross proceeds of $1,800,000 less a total of $185,000 for offering expenses in connection with this registered direct offering. We issued to the investor 600,000 shares of our common stock and warrants to purchase 420,000 shares of common stock. The purchase price paid by the investor was $3.00 for each unit. The warrants expire after seven years and are exercisable at $3.10 per share.

On May 2, 2011, we entered into a securities purchase agreement with certain investors to raise gross proceeds of $1,300,002 in a registered direct offering. We issued to the investors 433,334 shares of its common stock and warrants to purchase 433,334 shares of common stock. The purchase price paid by the investors was $3.00 for each unit. The warrants expire after seven years and are exercisable at $3.25 per share.

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.

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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, 2011 and December 31, 2010 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, 2011, we had no balances in money market balances.

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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, 2011, our Chief Executive Officer and Principal Financial Officer have concluded that as of March 31, 2011, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission s rules and forms.

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, 2010. 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, 2010, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management s assessment were (i) an effective whistle-blower program or other comparable mechanism and (ii) an ongoing program to manage identified fraud risks. As of December 31, 2010, 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.

During the quarter ended March 31, 2011, management, in coordination with the input, oversight and support of our Audit Committee, implemented the following internal controls to remediate our material weaknesses in our internal control over financial reporting:

a) Enforced and monitored our existing whistle-blower policy by ensuring every new employee signs a statement acknowledging and understanding our whistle-blower policy.

b) Reconfirmed on an annual basis with each employee his/her understanding of our whistle-blower policy.

c) Had the Chairman of our Audit Committee in conjunction with our outside counsel monitor any whistle-blower reports on a quarterly basis.

d) Provide a direct channel of communication to the Chairman of our Audit Committee for any whistle-blowers to utilize.

e) Had our Audit Committee periodically review management s assessment of fraud risk and controls designed to mitigate them.

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

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, 2011.

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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, 2010.

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, 2010.

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.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SYNERGY PHARMACEUTICALS, INC.
(Registrant)

Date: May 10, 2011	By:	/s/ GARY S. JACOB Gary S. Jacob *President and Chief Executive Officer*
Date: May 10, 2011	By:	/s/ BERNARD F. DENOYER Bernard F. Denoyer *Senior Vice President, Finance*