SYNERGY PHARMACEUTICALS, INC. Form 10-Q August 09, 2011 <u>Table of Contents</u>

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: JUNE 30, 2011

0 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)

420 Lexington Avenue, Suite 1609, New York, New York (Address of principal executive offices) **20-3823853** (I.R.S. Employer Identification No.)

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 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

Non-accelerated filer o (Do not check if a smaller reporting company)

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

The number of the registrant s hares of common stock outstanding was 94,464,708 as of August 8, 2011.

Accelerated filer x

Smaller reporting company o

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

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

SYNERGY PHARMACEUTICALS, INC. (A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2011 (unaudited)	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 503,744	\$ 1,707,516
Prepaid expenses and other current assets	861,399	997,584
Total Current Assets	1,365,143	2,705,100
Property and equipment, net	6,761	7,749
Security deposits	14,025	14,025
Due from controlling shareholder	1,378,473	1,674,087
Total assets	\$ 2,764,402	\$ 4,400,961
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current Liabilities:		
Accounts payable	\$ 2,627,657	\$ 2,961,333
Accrued expenses	2,193,099	2,051,057
Total Current Liabilities	4,820,756	5,012,390
Derivative financial instruments, at estimated fair value-warrants	7,958,506	3,487,959
Total Liabilities	12,779,262	8,500,349
Stockholders Deficit:		
Common stock, par value of \$.0001 authorized 200,000,000 shares, outstanding 94,168,578		
and 92,188,164 shares at June 30, 2011 and December 31, 2010	9,418	9,220
Additional paid-in capital	53,376,493	51,033,374
Deficit accumulated during development stage	(63,400,771)	(55,141,982)
Total Stockholders Deficit	\$ (10,014,860)	\$ (4,099,388)
Total liabilities and stockholder s deficit	\$ 2,764,402	\$ 4,400,961

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 June 30,		Six Months Ended June 30,				November 15, 2005 (inception) to	
	2011		2010	2011		2010		June 30, 2011
Revenues	\$	\$		\$	\$		\$	
Costs and Expenses:								
Research and development	2,354,450		4,395,266	3,832,576		5,579,128		18,826,976
Purchased in-process research and								
development								28,156,502
General and administrative	1,524,402		1,419,019	3,422,028		2,617,302		16,321,028
Loss from Operations	(3,878,852)		(5,814,285)	(7,254,604)		(8,196,430)		(63,304,506)
Interest and investment income	20,003		27,724	44,067		60,964		232,545
Interest expense				(11,877)				(11,877)
Other Income								494,479
Change in fair value of derivative								
instruments-warrants	(697,660)			(1,036,375)				(739,591)
Loss from Continuing Operations	(4,556,509)		(5,786,561)	(8,258,789)		(8,135,466)		(63,328,950)
Loss from discontinued operations								(71,821)
Net Loss	\$ (4,556,509)	\$	(5,786,561)	\$ (8,258,789)	\$	(8,135,466)	\$	(63,400,771)
Weighted Average Common Shares								
Outstanding								
Basic and Diluted	93,285,801		88,462,128	92,812,943		88,442,851		
Net Loss per Common Share, Basic and								
Diluted	\$ (0.05)	\$	(0.07)	\$ (0.09)	\$	(0.9)		
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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			\$	\$ 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)
Palance December 21, 2006	165 001 015	16 500	2 500	(00.010)	(110)
Balance, December 31, 2006 Capital contribution by shareholders	165,081,215	16,508	3,592 8,893	(20,218)	(118) 8,893
			8,893	(20, 0.42)	-)
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	105,001,215	10,500	12,405	(40,201)	(11,200)
founder shares	(149,981,208)	(14,998)	14,998		
Common stock issued via Exchange	(149,901,200)	(14,998)	14,990		
Transaction	45,464,760	4,546	27,274,315		27,278,861
Common stock issued via private	13,101,700	1,510	27,271,313		27,270,001
placement	5,041,667	504	3,024,496		3,025,000
Fees and expenses related to private	5,011,007	501	5,021,190		5,025,000
placements			(73,088)		(73,088)
Stock based compensation expense			379,883		379,883
Net loss for the year			579,005	(31,755,180)	(31,755,180)
The ross for the year				(51,755,100)	(51,755,100)
Balance, December 31, 2008	65,606,434	6,560	30,633,089	(31,795,441)	(1,155,792)
Common stock issued via private		0,000	20,000,000	(01,790,111)	(1,100,172)
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			())		<pre></pre>
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)
-					

Warrants reclassified to derivative liability			(3,784,743)		(3,784,743)
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 and exercise of					
warrants	1,980,414	182	5,461,060		5,461,242
Fees and expenses related to direct					
offering			(395,620)		(395,620)
Exercise of warrants		16	415,293		415,309
Warrants reclassified to derivative					
liability - net			(3,434,172)		(3,434,172)
Stock based compensation expense			296,558		296,558
Net loss for the period				(8,258,789)	(8,258,789)
Balance, June 30, 2011	94,168,578	\$ 9,418	\$ 53,376,493	\$ (63,400,771) \$	(10,014,860)

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)

	F	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010	Period from November 15, 2005 (Inception) to June 30, 2011
Cash Flows From Operating Activities:				
Net loss	\$	(8,258,789)	\$ (8,135,466)	\$ (63,400,771)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation		988	988	6,162
Stock-based compensation expense		296,558	377,405	2,443,161
Purchased in-process research and development				28,156,502
Change in fair value of derivative instruments-warrants		1,036,375		739,591
Changes in operating assets and liabilities:				
Security deposit				(14,025)
Accounts payable and accrued expenses		(191,634)	1,244,640	4,097,713
Prepaid expenses and other current assets		136,185	848,825	(861,399)
Net Cash Used in Operating Activities		(6,980,317)	(5,663,608)	(28,833,066)
Cash Flows From Investing Activities:				
Net cash paid on Exchange Transaction				(155,326)
Repayment from/(loans to) related parties		295,614	(393,085)	(1,378,473)
Additions to property and equipment				(12,195)
Net Cash Provided by/ (Used in) Investing Activities		295,614	(393,085)	(1,545,994)
Cash Flows From Financing Activities:				
Capital contribution by founding shareholders				8,893
Issuance of common stock to founders				2,000
Proceeds from sale of common stock		5,461,242	255,000	31,635,342
Proceeds from exercise of warrants		415,309		415,309
Proceeds from sale of unregistered common stock to founders				18,100
Fees and expenses related to sale of common stock		(395,620)	(25,000)	(1,196,840)
Net Cash Provided by Financing Activities		5,480,931	230,000	30,882,804
Net (decrease) increase in cash and cash equivalents		(1,203,772)	(5,826,693)	503,744
Cash and cash equivalents at beginning of period		1,707,516	7,152,568	
Cash and cash equivalents at end of period	\$	503,744	\$ 1,325,875	\$ 503,744
Supplementary disclosure of cash flow information:				
Cash paid for taxes	\$	8,021	\$ 900	\$ 41,842
Value of warrants classified as derivative liability - net	\$	3,920,500	\$	\$ 7,958,506
Value of common stock issued to induce stockholders to extend				
lock-up agreements	\$		\$	\$ 3,235,040
Cash received in escrow for June 30, 2010 direct registered				
offering	\$		\$ 2,499,000	\$

Accrued finder s fees related to registered direct offering in		
escrow	\$ \$	261,630 \$

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., 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 diseases and disorders. SP-333 is a synthetic analog of uroguanylin, a natriuretic hormone which is normally produced in the body s intestinal tract. Deficiency of this hormone is predicted to be one of the primary reasons for the formation of polyps that can lead to colon cancer, as well as debilitating and difficult-to-treat GI inflammatory disorders such as ulcerative colitis and Crohn s disease.

On February 1, 2011 the U.S. Patent and Trademark Office issued U.S. Patent No. 7,879,802, covering Synergy s novel drug candidate SP-333 to treat inflammatory bowel disease (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 an exchange agreement (the Exchange Transaction). Pawfect acquired the GI drugs (plecanatide and SP-333) and the 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

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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, 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 June 30, 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 June 30, 2011, Synergy had an accumulated deficit of \$63,400,771 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 (e.g. SP-333) into clinical development, seeks regulatory approval and, if FDA approval is received, commercializes products. Because of the numerous risks and uncertainties associated with product development efforts, Synergy is unable to predict the extent of any future losses or when Synergy will become profitable, if at all.

Net cash used in operating activities was \$6,980,317 for the six months ended June 30, 2011. As of June 30, 2011 Synergy has \$503,744 of cash on hand. During the six months ended June 30, 2011 Synergy incurred a net loss of \$8,258,789. To date, Synergy 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 six months ended June 30, 2011 was \$5,480,931. As of June 30, 2011 Synergy had a negative working capital of \$3,435,613.

On July 11, 2011, Synergy entered into a securities purchase agreement with an investor to raise gross proceeds of \$242,750 in a private placement. The Company issued to the investor 80,916 shares of its common stock and warrants to purchase 80,916 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 \$3.25 per share. Synergy also paid a selling agent \$16,993 and issued 6,503 warrants in connection with this transaction.

On July 28, 2011, Synergy entered into a securities purchase agreement with certain investors to raise gross proceeds of \$2,336,472 in a registered direct offering. The Company issued to the investors 667,563 shares of its common stock. The purchase price paid by the investors was \$3.50 for each share of common stock. Selling agent fees and expenses totaled approximately \$287,000 and there were no warrants issued in connection with this transaction.

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.

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 that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 Equity-*Based Payment to Non-Employees* and accordingly the value of the stock compensation to non-employees is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly the fair value of these options is being marked to market quarterly until the measurement date is determined.

ASC Topic 718 requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to Synergy s accumulated deficit position, no excess tax benefits have been recognized. Synergy accounts for common stock, stock options, and warrants granted to employees and non-employees based on the fair market value of the instrument, using the Black-Scholes option pricing model based on assumptions for expected stock price volatility, term of the option, risk-free interest rate and expected dividend yield, at the grant date.

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

	Three Months Ended June 30,			Six M Ended	November 15, 2005 (inception) to	
	2011		2010	2011	2010	June 30, 2011
Employees included in research and development \$	37,157	\$	49,804 \$	73,906	\$ 99,263 \$	593,496
Employees included in general and administrative	45,115		58,994	89,733	117,948	771,219
Non-employees included in research and						
development	8,456		8,455	16,818	16,817	111,464
Non-employees included in general and						
administrative	58,370		71,778	116,101	143,377	966,982
Total stock-based compensation expense \$	149,098	\$	189,031 \$	296,558	\$ 377,405 \$	2,443,161

The unrecognized compensation cost related to non-vested employee stock options outstanding at June 30, 2011, net of expected forfeitures, was \$10,727 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.

	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010
Risk-free interest rate	(*)	2.31-2.71%
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	(289,939)	\$0.25-0.70	\$ 0.52		
Balance outstanding, June 30, 2011	8,314,077	\$0.25-0.95	\$ 0.51 \$	29,887,896	7.91 years
Exercisable at June 30, 2011	2,683,343	\$0.25-0.95	\$ 0.30 \$	10,208,371	7.04 years

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 borrowed and issued a note to the Lender in the principal amount of \$500,000 (the First Note). Synergy had, but never exercised, 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 bore interest at 17% per annum and were payable on April 1, 2011. 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 registered direct offering with a non-U.S. investor which raised gross proceeds of \$1,800,000. 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 upon issuance and marked to market on a quarterly basis.

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 upon issuance and marked to market on a quarterly basis.

From May 17 to May 23, 2011, Synergy entered into securities purchase agreements with certain investors to raise gross proceeds of \$1,199,997 in a registered direct offering. The Company issued to the investors 399,999 shares of its common stock and warrants to purchase 399,999 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 upon issuance and marked to market on a quarterly basis.

On June 3, 2011, a Synergy warrant holder exercised his warrants and purchased a total of 160,000 shares of common stock. Synergy raised gross proceeds of \$415,309 as a result of the warrant exercise. The purchase price paid by the warrant holder was \$2.50 for 98,675 shares and \$2.75 for 61,235 shares. Based upon the Company s analysis of the criteria contained in ASC Topic 815-40, Synergy had determined that the warrants exercised in connection with this transaction were derivative liabilities when issued and the Company had been marking this liability to market at the end of each reporting period. Upon the exercise of these warrants the fair value of the related derivative liability totaling \$486,328 was reclassified to Additional Paid in Capital. (See Note 8 Derivative Financial Instruments)

From June 3 to June 15, 2011, Synergy entered into securities purchase agreements with certain investors to raise gross proceeds of \$1,161,243 in a private placement. The Company issued to the investors 387,081 shares of its common stock and warrants to purchase 387,081 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. In connection with this transaction Synergy entered into a registration rights agreement with each of the investors pursuant to which Synergy agreed to register the shares of common stock and shares of common stock underlying the warrants in a resale registration statement to be filed within 45 days after the final closing of the private placement. 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 private placement must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

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For the six months ended June 30, 2011, Synergy paid \$395,620 in selling agent fees and legal expenses related to the above financing transactions and issued 11,547 warrants to a selling agent which 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 these warrants issued to selling agents were equity instruments upon issuance.

7. Derivative Financial Instruments

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

Based upon the Company s analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that the warrants issued in connection with its registered direct offerings and private placements must be recorded as derivative liabilities. Accordingly 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 model in order to determine the associated derivative instrument liability and change in fair value described above. The range of assumptions used to determine the fair value of the warrants at the end of each period of June 30, 2011 and June 30, 2010 were indicated as follows:

	Six Months Ended S June 30, 2011	ix Months Ended June 30, 2010
Estimated fair value of Synergy common stock	2.56-3.30	2.64
Expected warrant term	5-7 years	5 years
Risk-free interest rate	1.18%-2.5%	1.79%
Expected volatility	90%	90%
Dividend vield		

Estimated fair value of the stock is based on a Black-Scholes based apportionment of the unit price paid for the shares and warrants issued in Synergy s registered direct offerings, which resulting stock prices were deemed to be arms-length negotiated prices. Expected volatility is based on historical volatility of Synergy s common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants.

Certain of Synergy s warrants issued during the six months ended June 30, 2011 contained a price protection clause which variable term required the Company to use a binomial model to determine fair value. The exercise price protection clause is effective on 833,333 warrants in the event of a subsequent equity sale at a price lower than \$3.25 per share of common stock, for a period of two years from date of issuance. Except for this variable exercise price the input assumptions to this methodology were the same as used in our Black Scholes model indicated above.

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
6/30/2011	Fair value of new warrants issued during the quarter	1,220,414	2,607,827
6/30/2011	Exercise of warrants during the quarter	(160,000)	\$ (486,328)
6/30/2011	Change in fair value of warrants during the quarter		\$ 697,660
6/30/2011	Balance of derivative financial instruments liability	2,937,352	\$ 7,958,506

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 June 30, 2011:

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significa Unobserva Inputs (Level 3	able	Balanco Decemb 201	er 31,	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Inobservable Inputs (Level 3)	B	alance as of June 30, 2011
•	(Level I)	(Level 2)	(Level .	"	201	U	(Level I)	(Level 2)	(Level 3)		2011
Derivative liabilities related											
to Warrants	\$	\$	\$ 3,48	7,959	\$ 3,4	87,959	\$	\$	\$ 7,958,506	\$	7,958,506

The following table sets forth a summary of changes in the fair value of the Company s Level 3 liabilities for the six months ended June 30, 2011:

		nce at 1ber 31,	Wai and	Fair Value of rrants Exercised I Reclassified to ditional Paid in	New V	value of Varrants 1 During	Unrealized (gains) or	В	alance as of June 30,
Description)10	110	Capital		Period	losses		2011
Derivative liabilities related									
to Warrants	\$ 3	3,487,959	\$	(486,328) \$	5	3,920,500	\$ 1,036,375	\$	7,958,506

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.

8. Research and Development Expense

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

In accordance with FASB ASC Topic 730-10-55, Research and Development, Synergy recorded prepaid research and development costs of \$574,691 and \$683,182 as of June 30, 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.

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 and six months ended June 30, 2011 the effect of 8,314,077 outstanding stock options and 2,948,899 warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive. For the three and six months ended June 30, 2010 the effect of 8,679,016 outstanding stock options and 648,000 warrants were excluded from the

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calculation of diluted loss per share because the effect was antidilutive. For the three and six months ended June 30, 2009 the effect of 4,080,016 outstanding stock options was excluded from the calculation of diluted loss per share because the effect was antidilutive.

10. Related Parties

As of June 30, 2011, Synergy s majority shareholder, Callisto, owns 47.4 % 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. On July 21, 2011 Callisto extended its lease on Suite 1609 from June 30, 2011, to March 31, 2012; at a monthly rent \$16,414.

As of June 30, 2011 Synergy had advanced Callisto \$ 1,378,473 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 June 30, 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 June 30, 2011 and December 31, 2010, the balances due from Callisto Pharmaceuticals, Inc. are comprised of the following amounts:

	June 30, 2011	December 31, 2010
Rent, utilities and property taxes	\$ 73,936	\$ 61,813
Insurance and other facilities related overhead	176,645	150,836
Independent accountants and legal fees	487,615	417,298
Financial printer and transfer agent fees	170,535	147,171
Salaries and consulting fees of shared executives	255,165	214,311
Working capital advances, net of repayments	214,577	682,658
Total due from Callisto	\$ 1,378,473	\$ 1,674,087

11. Subsequent Events

On July 11, 2011, Synergy entered into a securities purchase agreement with an investor to raise gross proceeds of \$242,750 in a private placement. The Company issued to the investor 80,916 shares of its common stock and warrants to purchase 80,916 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. Synergy also paid a selling agent \$16,993 and issued 9,547 warrants, with the same terms as the investor warrants, in connection with this transaction Synergy entered into a registration rights agreement with the investor pursuant to which Synergy agreed to register the shares of common stock and shares of common stock underlying the warrants in a resale registration statement to be filed within 45 days after the final closing of the private placement. 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 private placement must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

On July 28, 2011, Synergy entered into a securities purchase agreement with certain investors to raise gross proceeds of \$2,336,472 in a registered direct offering. The Company issued to the investors 667,563 shares of its common stock. The purchase price paid by the investors

was \$3.50 for each share of common stock. Selling agent fees and expenses totaled approximately \$287,000 and there were no warrants issued in connection with this transaction.

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 July 28, 2011, we entered into a securities purchase agreement with certain investors to raise gross proceeds of \$2,336,472 in a registered direct offering. We issued to the investors 667,563 shares of our common stock. The purchase price paid by the investors was \$3.50 for each share of common stock. Selling agent fees and expenses totaled approximately \$287,000 and there were no warrants issued in connection with this transaction.

On July 11, 2011, we entered into a securities purchase agreement with an investor to raise gross proceeds of \$242,750 in a private placement. We issued to the investor 80,916 shares of its common stock and warrants to purchase 80,916 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 \$3.25 per share. We also paid a selling agent \$16,993 and issued 9,547 warrants, with the same terms as the investor warrants, in connection with this transaction.

Our corporate headquarters totals approximately 3,800 square feet in suite 1609, located at 420 Lexington Avenue, New York, NY, which lease expired on June 30, 2011. This facility is provided to us under a space sharing arrangement with Callisto Pharmaceuticals, Inc., our controlling stockholder. On July 21, 2011 Callisto extended its lease on Suite 1609 from June 30, 2011, to March 31, 2012; at a monthly rent \$16,414.

FINANCIAL OPERATIONS OVERVIEW

From inception through June 30, 2011, we have sustained cumulative net losses of \$63,400,771. From inception through June 30, 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 June 30, 2011.

On July 21, 2011 Callisto extended its lease on Suite 1609 from June 30, 2011, to March 31, 2012; at a monthly rent of \$16,414

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of June 30, 2011.

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2011 AND 2010

We had no revenues during the three months ended June 30, 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.

Research and development expenses for the three months ended June 30, 2011decreased \$2,040,816 or 46%, to \$2,354,450 from \$4,395,266 for the three months ended June 30, 2010. This decrease was primarily due to lower drug production expenses of approximately \$2,060,000 as a result of lower clinical trial activities during the three months ended June 30, 2011. Our Phase 2a 28 day clinical trial concluded during the third quarter of 2010 and our next Phase 2/3 90 day clinical trial is scheduled to begin during the third quarter of 2011.

General and administrative expenses increased \$105,383 or 7%, to \$1,524,402 for the three months ended June 30, 2011 from \$1,419,019 for the three months ended June 30, 2010. This increase was primarily due to (i) approximately \$167,000 of higher financial advisory expenses related to our private placements and registered direct offerings, offset by (ii) approximately \$53,000 of lower travel and patent legal expenses in the quarter ended June 30, 2011 as compared to the same period last year.

Net loss for the three months ended June 30, 2011 was \$4,556,509 as compared to a net loss of \$5,786,561 incurred for the three months ended June 30, 2010. This decrease in our net loss of \$1,230,052, or 21% was a result of the decreases in operating expenses discussed above, partially

offset by the loss resulting from the change in fair value of derivative instruments-warrants of \$697,660 during the quarter ended June 30, 2011. The Company had no derivative instruments outstanding during the quarter ended June 30, 2010.

SIX MONTHS ENDED JUNE 30, 2011 AND 2010

We had no revenues during the six months ended June 30, 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.

Research and development expenses for the six months ended June 30, 2011 decreased \$1,746,552 or 31%, to \$3,832,576 from \$5,579,128 for the six months ended June 30, 2010. This decrease was primarily due to (i) lower drug production expenses of approximately \$2,200,000 as a result of lower clinical trial activities during the three months ended June 30, 2011. Our Phase 2a 28 day clinical trial concluded during the third quarter of 2010 and our next Phase 2/3 90 day clinical trial is scheduled to begin during the third quarter of 2011; offset by (ii) higher program expenses, including animal studies, analytical testing, and clinical start-up expenses which increased by approximately \$440,000 during the six months ended June 30, 2011 to approximately \$3,200,000.

General and administrative expenses increased \$804,726 or 31%, to \$3,422,028 for the six months ended June 30, 2011 from \$2,617,302 for the six months ended June 30, 2010. This increase was primarily due to (i) \$650,000 of higher financial advisory accounting services related to our private placements and registered direct offerings.

Net loss for the six months ended June 30, 2011 was \$8,258,789 compared to a net loss of \$8,135,466 incurred for the six months ended June 30, 2010. This increase in our net loss of \$123,323, was a result of the decreases in operating expenses discussed above, partially offset by the loss resulting from the change in fair value of derivative instruments-warrants of \$1,036,375 during the six months ended June 30, 2011. The Company had no derivative instruments outstanding during six months ended June 30, 2010.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2011, we had \$503,744 in cash and cash equivalents, compared to \$1,707,516 as of December 31, 2010. Net cash used in operating activities was \$6,980,317 for the six months ended June 30, 2011 as compared to \$5,663,608 during the six months ended June 30, 2010. Net cash provided by financing activities for the six months ended June 30, 2011 was \$5,480,931, as compared to \$230,000 provided during the six months ended June 30, 2011, we had a negative working capital of \$3,455,613 as compared to a negative working capital of \$2,307,290 on December 31, 2010.

On July 28, 2011, we entered into a securities purchase agreement with certain investors to raise gross proceeds of \$2,336,472 in a registered direct offering. We issued to the investors 667,563 shares of our common stock. The purchase price paid by the investors was \$3.50 for each share of common stock. Selling agent fees and expenses totaled approximately \$287,000 and there were no warrants issued in connection with this transaction.

On July 11, 2011, we entered into a securities purchase agreement with a certain investor to raise gross proceeds of \$242,750 in a private placement. We issued to the investor 80,916 shares of our common stock and warrants to purchase 80,916 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 \$3.25 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.

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 June 30, 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 June 30, 2011, we had no balances in money market balances.

ITEM 4. CONTROLS AND PROCEDURES

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of June 30, 2011, our Chief Executive Officer and Principal Financial Officer have concluded that as of June 30, 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.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

There were no changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that could significantly affect internal controls over financial reporting during the quarter ended June 30, 2011.

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.
- 101 Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended June 30,2011, filed on August 9, 2011, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows (iv) the Condensed Consolidated Statement of Stockholders Equity (Deficit) and (v) the Notes to Consolidated Financial Statements tagged as blocks of text.

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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 PHARMACEUTIC. (Registrant)	ALS, INC.
Date: August 9, 2011	By:	/s/ GARY S. JACOB Gary S. Jacob President and Chief Executive Officer
Date: August 9, 2011	By:	/s/ BERNARD F. DENOYER Bernard F. Denoyer Senior Vice President, Finance