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

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: September 30, 2012

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

For the transition period from to

Commission File Number: 333-131722

SYNERGY PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

Delaware	**33-0505269**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
420 Lexington Avenue, Suite 1609, New York, New York	**10170**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

The number of the registrant's shares of common stock outstanding was 66,106,089 as of November 12, 2012.

SYNERGY PHARMACEUTICALS INC.
(A development stage company)

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

SYNERGY PHARMACEUTICALS INC.
(A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2012 (unaudited)	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 17,244,049	$ 13,244,883
Available-for-sale securities	20,123,315	—
Prepaid expenses and other current assets	1,285,246	1,063,402
Total Current Assets	38,652,610	14,308,285
Property and equipment, net	1,970	5,773
Security deposits	19,511	14,025
Due from related party	2,655,594	1,541,456
Total Assets	$ 41,329,685	$ 15,869,539
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	2,505,520	$ 1,415,617
Accrued expenses	2,469,675	1,331,382
Total Current Liabilities	4,975,195	2,746,999
Derivative financial instruments, at estimated fair value-warrants	4,663,395	3,325,114
Total Liabilities	9,638,590	6,072,113
Stockholders' Equity:		
Preferred stock, Authorized 20,000,000 shares, at September 30, 2012 and December 31, 2011, none outstanding	—	—

Common stock, par value of $.0001 authorized 100,000,000 shares, outstanding 65,806,178 and 54,279,906 shares at September 30, 2012 and December 31, 2011, respectively	6,582	5,429
Additional paid-in capital	128,759,910	79,401,015
Deficit accumulated during development stage	(97,075,397)	(69,609,018)
Total Stockholders' Equity	$ 31,691,095	$ 9,797,426
	$ 41,329,685	$ 15,869,539

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 September 30,		Nine Months Ended September 30,		November 15, 2005 (inception) to
	2012	2011	2012	2011	September 30, 2012
Revenues	$ —	$ —	$ —	$ —	$ —
Costs and Expenses:					
Research and development	8,245,620	3,882,803	21,210,028	7,715,379	49,623,182
Purchased in-process research and development	—	—	—	—	28,156,502
General and administrative	1,843,150	1,102,844	5,492,766	4,524,875	25,137,408
Loss from Operations	(10,088,770)	(4,985,647)	(26,702,794)	(12,240,254)	(102,917,092)
Interest and investment income	63,161	20,000	149,955	64,070	428,141
Interest expense	—	—	—	(11,877)	(11,877)
Other income	—	—	255,539	—	1,112,516
Change in fair value of derivative instruments-warrants	140,322	4,382,796	(1,169,079)	3,346,421	4,384,736
Total Other Income/(Expense)	203,483	4,402,796	(763,585)	3,398,614	5,913,516
Loss from Continuing Operations	(9,885,287)	(582,851)	(27,466,379)	(8,841,640)	(97,003,576)
Loss from discontinued operations	—	—	—	—	(71,821)
Net Loss	$ (9,885,287)	$ (582,851)	$ (27,466,379)	$ (8,841,640)	$ (97,075,397)
Weighted Average Common Shares Outstanding					
Basic and Diluted	65,806,178	47,308,946(*)	60,194,004	46,708,403(*)	
Net Loss per Common Share ,					
Basic and Diluted	$ (0.15)	$ (0.01)(*)	$ (0.46)	$ (0.19)(*)	

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

(*) Restated for 1:2 reverse stock split effective November 30, 2011.

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SYNERGY PHARMACEUTICALS INC.
(A development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Deficit Accumulated	Total

	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Accumulated during the Development Stage	Total Stockholders' Equity (Deficit)
Balance at inception, November 15, 2005	—	$ —	$ —	$ —	$ —
Sale of unregistered common stock to founder	75,690,608	7,569	(5,569)	—	2,000
Sale of common stock	6,850,000	685	17,415	—	18,100
Net loss for the year	—	—	—	(16)	(16)
Balance, December 31, 2005	82,540,608	8,254	11,846	(16)	20,084
Net loss for the year	—	—	—	(20,202)	(20,202)
Balance, December 31, 2006	82,540,608	8,254	11,846	(20,218)	(118)
Capital contribution by shareholders	—	—	8,893	—	8,893
Net loss for the year	—	—	—	(20,043)	(20,043)
Balance, December 31, 2007	82,540,608	8,254	20,739	(40,261)	(11,268)
Cancellation of unregistered founder shares	(74,990,604)	(7,499)	7,499	—	—
Common stock issued via Exchange Transaction	22,732,380	2,273	27,276,588	—	27,278,861
Common stock issued via private placement —	2,520,833	252	3,024,748	—	3,025,000
Fees and expenses related to private placements	—	—	(73,088)	—	(73,088)
Stock based compensation expense	—	—	379,883	—	379,883
Net loss for the period	—	—	—	(31,755,180)	(31,755,180)
Balance, December 31, 2008	32,803,217	3,280	30,636,369	(31,795,441)	(1,155,792)
Common stock issued via private placements	11,407,213	1,141	15,968,959	—	15,970,100
Fees and expenses related to private placements	—	—	(260,002)	—	(260,002)
Common Stocks Issued for services rendered	1,250	1	1,499	—	1,500
Stock based compensation expense	—	—	1,053,062	—	1,053,062
Net loss for the period	—	—	—	(8,125,100)	(8,125,100)
Balance, December 31, 2009	44,211,680	4,422	47,399,887	(39,920,541)	7,483,768
Common stock issued via registered direct offering and private placement	1,209,000	121	7,178,879	—	7,179,000
Fees and expenses related to direct offering	—	—	(468,130)	—	(468,130)
Warrants reclassified to derivative liability	—	—	(3,784,743)	—	(3,784,743)
Common stock issued to extend lock-up agreements related to unregistered shares	670,933	67	(67)	—	—
Common stock Issued for services rendered	2,469	—	18,271	—	18,271
Stock based compensation expense	—	—	693,887	—	693,887
Net loss for the period	—	—	—	(15,221,441)	(15,221,441)
Balance, December 31, 2010	46,094,082	4,610	51,037,984	(55,141,982)	(4,099,388)
Common stock issued via registered direct offerings and private placements	7,733,093	773	34,368,291	—	34,369,064
Fees and expenses related to financing transactions — paid in cash	—	—	(2,148,383)	—	(2,148,383)
Fees and expenses related to financing transactions — paid in units of common stock and warrants	77,750	8	(8)	—	—
Warrants classified to derivative liability — net	—	—	(5,094,186)	—	(5,094,186)
Common stock issued to make whole certain unregistered shares	215,981	22	(22)	—	—
Exercise of warrant	80,000	8	415,301	—	415,309
Common stock issued for services rendered	79,000	8	341,287	—	341,295
Stock based compensation expense	—	—	480,751	—	480,751
Net loss for the period	—	—	—	(14,467,036)	(14,467,036)
Balance, December 31, 2011	54,279,906	$ 5,429	$ 79,401,015	$ (69,609,018)	$ 9,797,426
Common stock issued via registered direct offering	11,500,000	1,150	51,748,850	—	51,750,000
Fees and expenses related to financing transactions — paid in cash	—	—	(3,565,835)	—	(3,565,835)
Warrants classified to derivative liability	—	—	(169,203)	—	(169,203)

Common stock issued for services rendered	26,272	3	92,660	—	92,663
Stock based compensation expense	—	—	1,252,423	—	1,252,423
Net loss for the period	—	—	—	(27,466,379)	(27,466,379)
Balance, September 30, 2012 (unaudited)	65,806,178	$ 6,582	$ 128,759,910	$ (97,075,397)	$ 31,691,095

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)

	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Period from November 15, 2005 (Inception) to September 30, 2012
Cash Flows From Operating Activities:			
Net loss	$ (27,466,379)	$ (8,841,640)	$ (97,075,397)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,482	1,482	8,632
Loss on disposal of property and equipment	2,321	—	2,321
Stock-based compensation expense	1,345,086	307,284	4,313,735
Accretion of discount/premium on investment securities	(123,315)	—	(123,315)
Purchased in-process research and development	—	—	28,156,502
Change in fair value of derivative instruments-warrants	1,169,079	(3,346,421)	(4,384,736)
Changes in operating assets and liabilities:			
Security deposit	(5,486)	—	(19,511)
Accounts payable and accrued expenses	2,228,195	1,788,345	4,252,151
Prepaid expenses and other current assets	(221,844)	409,177	(1,285,246)
Total Adjustments	4,395,518	(840,133)	30,920,533
Net Cash Used in Operating Activities	(23,070,861)	(9,681,773)	(66,154,864)
Cash Flows From Investing Activities:			
Net cash paid on Exchange Transaction	—	—	(155,326)
Repayment from/(loans to) related parties	(1,114,138)	246,906	(2,655,594)
Purchases of available-for-sale securities	(20,000,000)	—	(20,000,000)
Additions to property and equipment	—	—	(12,195)
Net Cash (Used in) /Provided by Investing Activities	(21,114,138)	246,906	(22,823,115)
Cash Flows From Financing Activities:			
Capital contribution by shareholders	—	—	8,893
Issuance of common stock	—	—	2,000
Proceeds from sale of common stock	51,750,000	8,040,464	112,293,164
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	(3,565,835)	(661,052)	(6,515,438)
Net Cash Provided by Financing Activities	48,184,165	7,794,721	106,222,028
Net increase (decrease) in cash and cash equivalents	3,999,166	(1,640,146)	17,244,049
Cash and cash equivalents at beginning of period	13,244,883	1,707,516	—
Cash and cash equivalents at end of period	$ 17,244,049	$ 67,370	$ 17,244,049
Supplementary disclosure of cash flow information:			
Cash paid for taxes	$ 18,465	$ 9,104	$ 90,081
Value of warrants classified as derivative liability - net	$ 169,203	$ 4,205,628	$ 9,048,132
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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1. Business Overview

Synergy Pharmaceuticals Inc. ("Synergy" or the "Company") is a biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. Its lead product candidate is plecanatide (formerly called SP-304), a guanylyl cyclase C, or GC-C, receptor agonist, to treat GI disorders, primarily chronic idiopathic constipation, or CC, and constipation-predominant irritable bowel syndrome, or IBS-C. CC and IBS-C are functional gastrointestinal disorders that afflict millions of sufferers worldwide. CC is primarily characterized by constipation symptoms but a majority of these patients report experiencing bloating and abdominal discomfort as among their most bothersome symptoms. IBS-C is characterized by frequent and recurring abdominal pain and/or discomfort associated with chronic constipation. Synergy is also developing SP-333, its second generation GC-C receptor agonist for the treatment of gastrointestinal inflammatory diseases, such as ulcerative colitis, or UC.

On August 23, 2012, Synergy signed an Asset Purchase Agreement with Bristol-Myers Squibb Company and acquired the assets related to FV-100, an orally available nucleoside analogue, currently being developed for the treatment of shingles, a severe, painful skin rash caused by reactivation of the varicella zoster virus — the virus that causes chickenpox. The terms of the Agreement provide for an initial payment of $1 million, subsequent milestone payments covering marketing approval and achieving the milestone of aggregate net sales equal to or greater than $125 million, as well as a single digit royalty based on net sales.

On September 7, 2012, Synergy submitted an Investigational New Drug (IND) application for clinical evaluation of SP-333 to treat inflammatory bowel disease (IBD). On October 19, 2012, Synergy began oral dosing of healthy adult volunteers in a Phase I clinical trial of SP-333 that is designed as a placebo-controlled, dose-escalating, single-dose study, planned to enroll up to 70 volunteers. A multi-dose, dose-escalation trial is planned for early 2013.

On September 14, 2012, Synergy entered into a binding letter of intent (the "LOI") with Ironwood Pharmaceuticals, Inc. ("Ironwood") pursuant to which Synergy and Ironwood agreed to enter into a definitive license agreement giving Synergy an exclusive worldwide license to Ironwood's method of use patents on plecanatide for the treatment of CC and IBS-C. The LOI contemplates a low single digit royalty on net sales and both parties agreed not to challenge each other's patents covering certain GC-C agonists, with the exception that Synergy retains the right to challenge Ironwood's method of use patent on plecanatide.

2. Basis of Presentation and Accounting Policies

These unaudited condensed consolidated financial statements include Synergy and its wholly-owned subsidiaries: (1) Synergy Advanced Pharmaceuticals, Inc. and (2) IgX, Ltd (Ireland—inactive). These unaudited condensed consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission ("SEC") and United States generally accepted accounting principles ("GAAP") for interim reporting. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, which include only normal recurring adjustments, necessary to present fairly Synergy's interim financial information. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2011 contained in the Company's Annual Report on Form 10-K filed with the Securities Exchange Commission ("SEC") on March 15, 2012. Certain items in the prior year's financial statements have been reclassified to conform to the current year's presentation. All intercompany balances and transactions have been eliminated.

Synergy's independent registered public accounting firm has issued a report on Synergy's December 31, 2011financial statements that included an explanatory paragraph referring to its recurring losses from operations and expressing substantial doubt in Synergy's ability to continue as a going concern without additional capital becoming available. These condensed consolidated financial statements as of September 30, 2012 and December 31, 2011 have been prepared under the assumption that Synergy will continue as a going concern. 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,

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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 September 30, 2012, Synergy had an accumulated deficit of $97,075,397 and expects to incur significant and increasing operating losses for the next several years as the Company continues to expand its research and development and 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 $23,070,861 for the nine months ended September 30, 2012, as compared to net cash used of $9,681,773 for the nine months ended September 30, 2011. As of September 30, 2012 Synergy has $17,244,049 of cash and cash equivalents on hand as compared to $13,244,883 of cash and cash equivalents on hand as of December 31, 2011. In addition, on

September 30, 2012 Synergy held $20,123,315 in available-for-sale securities, whereas the Company had no such investments as of December 31, 2011. As of September 30, 2012 Synergy had working capital of $33,677,415 as compared to working capital of $11,561,286 as of December 31, 2011.

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

3. Financial Instruments - Cash, Cash Equivalents and Marketable Securities

All highly liquid investments with maturities of three months or less at the date of purchase are classified as cash equivalents. The Company's marketable securities consist solely of investments in US Treasury Bills and Notes and have been classified and accounted for as available-for-sale. Management determines the appropriate classification of its investments at the time of purchase and reevaluates the available-for-sale designations as of each balance sheet date.

Cash equivalents and marketable securities are carried at amounts that approximate fair value due to their short-term maturities. As of September 30, 2012, gross unrealized losses were not material. The Company recognized no net realized gains or losses during the three and nine month periods ended September 30, 2012. The Company considers the declines in market value of its marketable securities investment portfolio to be temporary in nature. Fair values were determined for each individual security in the investment portfolio. When evaluating the investments for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, and the Company's intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment's amortized cost basis. During the three and nine month periods ended September 30, 2012, the Company did not recognize any impairment charges. As of September 30, 2012, the Company did not consider any of its investments to be other-than-temporarily impaired.

4. Recent Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income* ("ASU 2011-05") which is intended to facilitate the convergence of U.S. GAAP and International Financial Reporting Standards ("IFRS") as well as to increase the transparency of items reported in other comprehensive income. As a result of ASU 2011-05, all non-owner changes in stockholders' equity are required to be presented in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present other comprehensive income in the statement of changes in equity has been eliminated. ASU 2011-05 is effective for fiscal years beginning after December 15, 2011 and should be applied retrospectively. The Company adopted this standard on January 1 2012 and the adoption did not have a material impact on the Company's consolidated financial statements.

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In May 2011, FASB issued ASU No. 2011-04, "Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs." ASU 2011-04 amends Topic 820 to provide common fair value measurement and disclosure requirements in U.S. Generally Accepted Accounting Principles ("U.S. GAAP") and International Financial Reporting Standards. Consequently, the amendments change the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements, as well as providing guidance on how fair value should be applied where its use is already required or permitted by other standards within U.S. GAAP. ASU No. 2011-04 is to be applied prospectively, and early adoption is not permitted. For public entities, the amendments are effective during interim and annual periods beginning after December 15, 2011. The adoption of ASU No. 2011-04 on January 1, 2012 did not have a material impact on the Company's consolidated financial statements.

In December 2011, the FASB issued ASU 2011-11, "Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities." ASU 2011-11 provides for additional disclosures of both gross information and net information about both instruments and transactions eligible for offset in the statement of financial position and instruments and transactions subject to an agreement similar to a master netting arrangement. This scope would include derivatives, sale and repurchase agreements and reverse sale and repurchase agreements, and securities borrowing and securities lending arrangements. The amendments in this Update are effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods, and disclosures required by these amendments should be provided retrospectively for all comparative periods presented. The adoption of ASU No. 2011-11 is not expected to have a material impact on the Company's consolidated financial statements.

5. 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.

	Three Months Ended September 30,		Nine Months Ended September 30		November 15, 2005 (inception) to September 30, 2012
	2012	2011	2012	2011	
Employees—included in research and development	$ 226,191	$ 1,225	$ 488,030	$ 75,131	$ 1,114,800
Employees—included in general and administrative	153,524	1,487	347,264	91,220	1,121,675
Non-employees—included in research and development	2,708	4,832	2,708	21,649	170,804
Non-employees—included in general and administrative	170,365	3,184	507,084	119,284	1,906,456
Total stock-based compensation expense	$ 552,788	$ 10,728	$ 1,345,086	$ 307,284	$ 4,313,735

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The unrecognized compensation cost related to non-vested employee stock options outstanding at September 30, 2012, net of expected forfeitures, was $5,592,253, to be recognized over a weighted-average remaining vesting period of approximately 2.5 years. This unrecognized compensation cost does not include amounts related to 4,364,000 stock options which vest upon a change of control.

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

	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
Risk-free interest rate	0.92%-1.50%	(*)
Dividend yield	—	(*)
Expected volatility	60%	(*)
Expected term (in years)	6 years	(*)

(*) No stock options granted during this period.

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

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2011	5,964,039	$ 0.50 – 4.30	$ 1.77	$ 10,631,388	8.2 years
Granted	2,602,891	$ 3.40 – 4.54	$ 3.93		
Exercised	—	$ —	$ —		
Forfeited	(105,000)	$ 3.40 – 4.38	$ 4.10		
Balance outstanding, September 30, 2012	8,461,930	$ 0.50 – 4.54	$ 2.40	$ 20,107,786	8 years
Exercisable at					

September 30, 2012	2,112,298	$ 0.50 – 4.30	$ 0.80	$ 8,398,667	6 years

6. Income Taxes

During the year ended December 31, 2011 the Company recorded refundable tax credits in prepaid and other current assets for its (i) 2010 New York State QETC credit, totaling $248,486 and (ii) its New York City Biotechnology Tax Credit for the tax year of 2011 totaling $118,437. On April 25, 2012, the Company received $246,402 for 2010 New York State QETC credit and on July 17, 2012, the Company collected $120,812 for 2011 New York City Biotechnology Tax Credit. On June 15, 2012, the Company applied for its 2011 New York State QETC tax credit of $250,000.

7. Stockholder's Equity

On January 29, 2012 Synergy issued 26,272 unregistered shares of common stock to its corporate counsel for professional services rendered. The shares had a fair value on the date of issuance of $3.53 per share and $92,663 was recorded as legal expense during the quarter ended March 31, 2012.

On February 14, 2012, Synergy Pharmaceuticals Inc., (the "Company") entered into an agreement and plan of merger (the "Agreement") with its wholly-owned subsidiary, Synergy Pharmaceuticals Inc., a Delaware corporation ("Synergy-DE") for the purpose of changing the state of incorporation of the Company to Delaware from Florida. Pursuant to the Agreement, the Company merged with and into Synergy-DE with Synergy-DE continuing as the surviving corporation. The directors and officers in office of the Company upon the effective date of the merger shall be the directors and officers of Synergy-DE, all of whom shall hold their directorships and offices until the election and qualification of their respective successors or until their tenure is otherwise terminated in accordance with the by-laws of Synergy-DE. The effective date of the merger was the date on which the Certificate of Merger is filed with the Secretary of State of Delaware and the Secretary of State of Florida. The Certificate of Merger was filed with the Secretary of State of Florida on February 15, 2012 and with the Secretary of State of Delaware on February 16, 2012.

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On May 9, 2012, Synergy closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of $4.50 per share. The gross proceeds from this offering were $45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of $2,952,930. Synergy also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of $4.50 per share to cover over-allotments, if any. On June 6, 2012 the underwriters exercised the over-allotment option resulting in additional gross proceeds of $6,750,000, before deducting underwriting discounts, commissions and other offering expenses of $405,000, bringing total gross proceeds from the offering to $51,750,000.

Synergy Callisto Merger

On July 20, 2012, Synergy entered into an Agreement and Plan of Merger (the "Merger Agreement") with Callisto. Pursuant to the Merger Agreement, following the satisfaction or waiver of each of the applicable conditions set forth in the Merger Agreement, Callisto and Synergy will merge (the "Merger"), whereupon Callisto's separate corporate existence will cease and Synergy will continue as the surviving corporation of the Merger. Callisto is Synergy's largest shareholder and is a development stage biopharmaceutical company.

On July 23, 2012, Synergy paid $207,905 to an investment bank in regards to a fairness opinion, from a financial point of view, of the Synergy shares to be issued to Callisto shareholders, in connection with the merger with Callisto. This transaction has been reflected in our statement of changes in stockholder's equity/(deficit) as a cost of capital for the quarter ended September 30, 2012.

On October 15, 2012, Synergy entered into Amendment No. 1 to the above Agreement and Plan of Merger, dated July 20, 2012 with Callisto Pharmaceuticals, Inc., a Delaware corporation. Pursuant to the Amendment, the parties have agreed to, among other things, (i) increase the exchange ratio from .17 to .1799 and (ii) change the lock-up provision such that each share of Company common stock received in connection with the merger shall be subject to a lock-up beginning on the effective date of the merger and ending on the earlier of (i) twenty-four (24) months after such date, (ii) a Change in Control (as defined in the Merger Agreement), or (iii) written consent of the Company, at the Company's sole discretion, provided the Company's consent shall apply to all shares of the Company's common stock issued pursuant to the merger.

As Callisto does not meet the definition of a business under ASC 805, the merger will not be accounted for as a business combination. The merger is expected to be accounted for as a recapitalization of Synergy, effected through exchange of Callisto shares for Synergy shares, and the cancellation of Synergy shares held by Callisto. The excess of Synergy shares issued to Callisto shareholders over the Synergy shares held by Callisto is the result of a discount associated with the restricted nature of the Synergy shares to be received by Callisto shareholders. Therefore, considering this discount, the share exchange has been determined to be equal from a fair value stand point. Upon the effective date of the Merger, Synergy will account for the merger by assuming Callisto's net liabilities. Synergy's financial statements will reflect the operations of Callisto prospectively and will not be restated retroactively to reflect the historical financial position or results of operations of Callisto.

The consummation of the Merger is subject to various customary closing conditions, including but not limited to, (i) approval by Callisto's and our stockholders, (ii) the Registration Statement on Form S-4 shall have been declared effective by the SEC and (iii) the shares of our common stock to be issued in the Merger shall have been approved for listing on The NASDAQ Capital Market. Upon consummation of the Merger the related party balance due from Callisto, $2,655,594 as of September 30, 2012, will be eliminated.

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 $924,155 and $577,745 as of September 30, 2012 and December 31, 2011, respectively, for nonrefundable pre-payments for production of drug substance, analytical testing services for its drug candidates, and upcoming clinical trial on SP-333. In accordance with this guidance, Synergy expenses deferred research and development costs when drug compound is delivered and services are performed.

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9. Intangible assets

On August 17, 2012, Synergy signed an Asset Purchase Agreement with Bristol-Myers Squibb Company ("BMS") and acquired certain assets related to FV-100, an orally available nucleoside analog, currently being developed for the treatment of shingles, a severe, painful skin rash caused by reactivation of the varicella zoster virus — the virus that causes chickenpox. The terms of the Agreement provide for an initial base payment of $1 million, subsequent milestone payments covering (i) marketing (FDA) approval and (ii) on achieving the milestone of aggregate net sales equal to or greater than $125 million, as well as a single digit royalty based on net sales.

The FV-100 assets acquired from BMS were principally intangible, including (i) the patent portfolio and (ii) all historical research and clinical study protocols, data and results. Both of these intangible assets enable Synergy to continue the clinical development in future trials and ultimately have the freedom to operate ("FTO") should FDA approval be achieved. Synergy believes the intangible assets purchased from BMS are limited exclusively to the future development of FV-100 for the treatment of shingles. ASC Topic 350-30-25-2(c) requires that… the costs of intangibles that are purchased from others for a particular research and development project and that have no alternative future uses (in other research and development projects or otherwise) and therefore no separate economic values are research and development costs at the time the costs are incurred. Accordingly, Synergy has charged the $1,000,000 base payment to research and development expense during the quarter ended September 30, 2012

10. Derivative Financial Instruments

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

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that certain warrants issued in connection with sale of its common stock must be classified as derivative instruments. In accordance with ASC Topic 815-40, the fair value of these warrants is being re-measured at each balance sheet date and any resultant changes in fair value is being recorded in the Company's statement of operations. The Company estimates the fair value of certain warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability and change in fair value described above. The range of assumptions used to determine the fair value of the warrants at each period end during the nine months ended September 30, 2012 and September 30, 2011 was as follows:

	Nine Months Ended September 30,	
	2012	2011
Fair value of Synergy common stock	$4.05 - $4.78	$2.12 - $4.14(*)
Expected warrant term	5-7 years	5-7 years
Risk-free interest rate	0.23%-1.33%	0.69-1.43%
Expected volatility	60%	90%
Dividend yield	—	—

(*) Restated for 1:2 reverse stock split effective November 30, 2011.

Estimated fair value of stock is the closing market price of the Company's common stock on the date of warrant issuance and at the end of each reporting period when the derivative instruments are marked to market. Expected volatility is based on historical volatility of Synergy's common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants and the date of grant or quarterly revaluation.

Certain of Synergy's warrants issued during the nine months ended September 30, 2011 contained a price protection clause which variable term required the Company to use a binomial model to determine fair value. The range of assumptions used to determine the fair value of the warrants at each period end during the nine months ended September 30, 2012 and September 30, 2011 was as follows:

	Nine Months Ended September 30,	
	2012	2011
Estimated fair value of Synergy common stock	$3.28-$4.53	$2.72 - $3.78(*)
Expected warrant term	4.13-4.63 years	6.59 years -7 years
Risk-free interest rate	0.62%-1.04%	1.43%
Expected volatility	60%	90%
Dividend yield	—	—

(*) Restated for 1:2 reverse stock split effective November 30, 2011.

In the Binomial model, the assumption for estimated fair value of the stock during year 2011 was based on a Black-Scholes based apportionment of the unit price paid for the shares and warrants issued in Synergy's most recent registered direct unit offerings, which resulting stock prices were deemed to be arms-length negotiated prices. The assumption for estimated fair value of the stock in year 2012 was based on the closing market price of the Synergy's common stock, as a result of increased trading volume. Expected volatility is based on historical volatility of Synergy's common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants.

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

Date	Description	Warrants	Derivative Instrument Liability
12/31/2010	Balance of derivative financial instruments liability	728,469	$ 3,487,959
3/31/2011	Fair value of new warrants issued during the quarter	210,000	$ 1,312,673
3/31/2011	Change in fair value of warrants during the quarter recognized as other expense in the statement of operations	—	$ 338,715
3/31/2011	Balance of derivative financial instruments liability	938,469	$ 5,139,347
6/30/2011	Fair value of new warrants issued during the quarter	611,207	$ 2,607,827
6/30/2011	Exercise of warrants during the quarter	(80,000)	$ (486,328)
6/30/2011	Change in fair value of warrants during the quarter recognized as other expense in the statement of operations	—	$ 697,660
6/30/2011	Balance of derivative financial instruments liability	1,469,676	$ 7,958,506
9/30/2011	Fair value of new warrants issued during the quarter	40,458	$ 285,128
9/30/2011	Change in fair value of warrants during the quarter recognized as other income in the statement of operations	—	$ (4,382,796)
9/30/2011	Balance of derivative financial instruments liability	1,510,134	$ 3,860,838
12/31/2011	Fair value of new warrants issued during the quarter	1,810,294	$ 3,082,203
12/31/2011	Reclass of derivative liability to equity during the quarter	(1,055,268)	$ (1,707,317)
12/31/2011	Change in fair value of warrants during the quarter recognized as other income in the statement of operations	—	$ (1,910,610)
12/31/2011	Balance of derivative financial instruments liability	2,265,160	$ 3,325,114
3/31/2012	Fair value of new warrants issued during the quarter	—	—
3/31/2012	Change in fair value of warrants during the quarter	—	(7,946)
3/31/2012	Balance of derivative financial instruments liability	2,265,160	$ 3,317,168
6/30/2012	Warrants classified to derivative liability during quarter	112,500	169,202
6/30/2012	Change in fair value of warrants during the quarter	—	1,317,347
6/30/2012	Balance of derivative financial instruments liability	2,377,660	$ 4,803,717
9/30/2012	Fair value of new warrants issued during the quarter	—	—
9/30/2012	Change in fair value of warrants during the quarter	—	(140,322)
9/30/2012	Balance of derivative financial instruments liability	2,377,660	$ 4,663,395

Synergy Fair Value Measurements

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2011 and September 30, 2012:

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, 2011	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 September 30, 2012
Derivative liabilities related to Warrants	$ —	$ —	$ 3,325,114	$ 3,325,114	$ —	$ —	$ 4,663,395	$ 4,663,395

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the nine months ended September 30, 2012:

Description	Balance at December 31, 2011	Fair Value of Warrants classified to derivative liability	Unrealized (gains) or losses	Balance as of September 30, 2012
Derivative liabilities related to Warrants	$ 3,325,114	$ 169,203	$ 1,169,078	$ 4,663,395

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.

11. Related Parties

As of September 30, 2012 Callisto owns 34% of Synergy's outstanding shares.

As of September 30, 2012 Synergy had advanced Callisto $2,655,594 which is Callisto's share of Synergy payments for common operating costs since July 2008 that Callisto was unable to fund. The indebtedness as of December 31, 2011 is evidenced by an unsecured promissory note which bears interest at 6% per annum. Synergy is unable to determine if this balance will be repaid within one year and accordingly Synergy has classified the balance due as a long term asset.

As of September 30, 2012 and December 31, 2011, the balances due from Callisto are comprised of the following amounts:

	September 30, 2012	December 31, 2011
Rent, utilities and property taxes	$ 114,313	$ 90,166
Insurance and other facilities related overhead	311,215	249,635
Independent accountants and legal fees	696,519	510,331
Financial printer and transfer agent fees	268,356	217,476
Salaries and consulting fees	329,660	289,270
Income taxes	297,725	—
Merger fairness opinion	210,000	—
Working capital advances, net of repayments	427,806	184,578
Total due from Callisto	$ 2,655,594	$ 1,541,456

Upon consummation of the Merger the related party balances due from Callisto, $2,655,594 as of September 30, 2012, will be eliminated (See Note 7. Above).

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12. 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 nine months ended September 30, 2012, the effect of 8,461,930 outstanding stock options and 5,647,203 warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive. For the three and nine months ended September 30, 2011, the effect of 8,314,077 outstanding stock options and 3,036,318 warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive.

13. Contingencies

On August 9, 2012, a purported stockholder class action complaint was filed in the Supreme Court for the State of New York, captioned Shona Investments v. Callisto Pharmaceuticals, Inc., et al., Civil Action No. 652783/2012. The complaint names as defendants,

Callisto, each member of the Board of Callisto (the "***Individual Defendants***") and Synergy. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that Synergy aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs' attorneys' fees and costs. Callisto and Synergy believe the plaintiffs' allegations lack merit and will contest them.

On August 31, 2012, a purported stockholder class action complaint was filed in the Court of Chancery of the State of Delaware, captioned Gary Wagner v. Gary S. Jacob, Inc., et al., Case No. 7820-VCP. The complaint names as defendants, Callisto, the Individual Defendants and Synergy. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that Synergy aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs' attorneys' fees and costs. Callisto and Synergy believe the plaintiffs' allegations lack merit and will contest them.

14. Subsequent Events

On October 15, 2012, Synergy entered into Amendment No. 1 to the Agreement and Plan of Merger, dated July 20, 2012 with Callisto Pharmaceuticals, Inc., a Delaware corporation. Pursuant to the Amendment, the parties have agreed to, among other things, (i) increase the exchange ratio from .17 to .1799 and (ii) change the lock-up provision such that each share of Company common stock received in connection with the merger shall be subject to a lock-up beginning on the effective date of the merger and ending on the earlier of(i) twenty-four (24) months after such date, (ii) a Change in Control (as defined in the Merger Agreement), or (iii) written consent of the Company, at the Company's sole discretion, provided the Company's consent shall apply to all shares of the Company's common stock issued pursuant to the merger.

As Callisto does not meet the definition of a business under ASC 805, the merger will not be accounted for as a business combination. The merger is expected to be accounted for as a recapitalization of Synergy, affected through exchange of Callisto shares for Synergy shares, and the cancellation of Synergy shares held by Callisto. The excess of Synergy shares issued to Callisto shareholders over the Synergy shares held by Callisto is the result of a discount associated with the restricted nature of the Synergy shares to be received by Callisto shareholders. Therefore, considering this discount, the share exchange has been determined to be equal from a fair value stand point. Upon the effective date of the Merger, Synergy will account for the merger by assuming Callisto's net liabilities. Synergy's financial statements will reflect the operations of Callisto prospectively and will not be restated retroactively to reflect the historical financial position or results of operations of Callisto.

On June 21, 2012, Synergy entered into a controlled equity sales agreement with a placement agent ("Agent") and agreed that Synergy may issue and sell through the Agent, up to $30,000,000 of common stock of the Company. From October 8, 2012 through October 26, 2012, Synergy sold 299,911 shares of common stock with gross proceeds of $1,423,491, at an average selling price of $4.74 per share. Selling agent fees totalled $42,705 on these sales.

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

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under "Risk Factors" in our Annual Report on Form 10-K as of and for the year ended December 31, 2011 and other periodic reports filed with the United States Securities and Exchange Commission ("SEC"). Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of Synergy, please be advised that Synergy's actual financial condition, operating results and business performance may differ materially from that projected or estimated by Synergy in forward-looking statements.

Overview

We are a biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. Our lead product candidate is plecanatide (formerly called SP-304), a guanylyl cyclase C, or GC-C, receptor agonist, to treat GI disorders, primarily chronic idiopathic constipation, or CC, and constipation-predominant irritable bowel syndrome, or IBS-C. CC and IBS-C are functional gastrointestinal disorders that afflict millions of sufferers worldwide. CC is primarily characterized by constipation symptoms but a majority of these patients report experiencing bloating and abdominal discomfort as among their most bothersome symptoms. IBS-C is characterized by frequent and recurring abdominal pain and/or discomfort associated with chronic constipation. We are also developing SP-333, our second generation GC-C receptor agonist for the treatment of gastrointestinal inflammatory diseases, such

as ulcerative colitis, or UC.

Plecanatide

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

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

On October 24, 2011, we initiated dosing of patients in a Phase II/III clinical trial of plecanatide to treat chronic constipation. This study is being conducted at 113 clinical sites in the United States and was originally designed to enroll 880 patients with CC to be treated with one of three doses of plecanatide (0.3, 1.0 or 3.0 mg) or placebo taken once daily over a period of 12 weeks. The study's primary objective is the measure of complete spontaneous bowel movements, or CSBMs, using a responder analysis. The trial also is designed to evaluate spontaneous bowel movements, or SBMs, and daily constipation symptoms, as well as the impact of plecanatide on disease-specific quality of life measures. On April 9, 2012, we announced that we had reached the halfway mark for total enrollment in the clinical trial, with over 800 screened patients, resulting in a total of 440 randomized enrolled patients at that time. On August 14, 2012, we announced that we achieved our enrollment target of 880 patients and would close enrollment at all sites on August 31, 2012. We completed enrollment with a total of 951 patients enrolled at the 113 clinical sites participating in this study. We anticipate reporting top line data during the first week of January 2013.

On September 14, 2012, we entered into a binding letter of intent (the "LOI") with Ironwood Pharmaceuticals, Inc. ("Ironwood") pursuant to which we and Ironwood agreed to enter into a definitive license agreement giving us an exclusive worldwide license to Ironwood's method of use patents on plecanatide for the treatment of CC and IBS-C. The LOI contemplates a low single digit royalty on net sales and both parties agreed not to challenge each other's patents covering certain GC-C agonists, with the exception that Synergy retains the right to challenge Ironwood's method of use patent on plecanatide.

We are also preparing to initiate a Phase IIb clinical trial of plecanatide for the treatment of IBS-C in patients during the fourth quarter of 2012.

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SP-333

We are also developing a second generation GC-C receptor analog, SP-333, 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 thought 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 UC and Crohn's disease. SP-333 has exhibited potent anti-inflammatory activity in animal studies of colitis, displaying a novel mechanism-of-action that the company believes can provide a new way to treat UC patients with mild to moderate disease.

On September 7, 2012, Synergy submitted an Investigational New Drug (IND) application for clinical evaluation of SP-333 to treat inflammatory bowel disease (IBD). On October 19, 2012, we began oral dosing of healthy adult volunteers in a Phase I clinical trial of SP-333 that is designed as a placebo-controlled, dose-escalating, single-dose study, planned to enroll up to 70 volunteers. A multi-dose, dose-escalation trial is planned for early 2013.

FV-100

On August 17, 2012, Synergy signed an Asset Purchase Agreement with Bristol-Myers Squibb Company ("BMS") and acquired certain assets related to FV-100, an orally available nucleoside analog, currently being developed for the treatment of shingles, a severe, painful skin rash caused by reactivation of the varicella zoster virus — the virus that causes chickenpox. The terms of the Agreement provide for an initial base payment of $1 million, subsequent milestone payments covering (i) marketing (FDA) approval and (ii) on achieving the milestone of aggregate net sales equal to or greater than $125 million, as well as a single digit royalty based on net sales.

Recent Developments

Synergy Callisto Merger

On July 20, 2012, Synergy entered into an Agreement and Plan of Merger (the "Merger Agreement") with Callisto. Pursuant to the Merger Agreement, following the satisfaction or waiver of each of the applicable conditions set forth in the Merger Agreement, Callisto and Synergy will merge (the "Merger"), whereupon Callisto's separate corporate existence will cease and Synergy will continue as the surviving corporation of the Merger. Callisto is Synergy's largest shareholder and is a development stage biopharmaceutical company.

On October 15, 2012, Synergy entered into Amendment No. 1 to the above Agreement and Plan of Merger, dated July 20, 2012 with Callisto Pharmaceuticals, Inc., a Delaware corporation. Pursuant to the Amendment, the parties have agreed to, among other things, (i) increase the exchange ratio from .17 to .1799 and (ii) change the lock-up provision such that each share of Company common stock received in connection with the merger shall be subject to a lock-up beginning on the effective date of the merger and ending on the earlier of

(i) twenty-four (24) months after such date, (ii) a Change in Control (as defined in the Merger Agreement), or (iii) written consent of the Company, at the Company's sole discretion, provided the Company's consent shall apply to all shares of the Company's common stock issued pursuant to the merger.

The consummation of the Merger is subject to various customary closing conditions, including but not limited to, (i) approval by Callisto's and our stockholders, (ii) the Registration Statement on Form S-4 shall have been declared effective by the SEC and (iii) the shares of our common stock to be issued in the Merger shall have been approved for listing on The NASDAQ Capital Market. Upon consummation of the Merger the related party balances due from Callisto, $2,655,594 as of September 30, 2012, will be eliminated.

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Ironwood

On September 14, 2012, we entered into a binding letter of intent (the "LOI") with Ironwood Pharmaceuticals, Inc. ("Ironwood") pursuant to which we and Ironwood agreed to enter into a definitive license agreement giving us an exclusive worldwide license to Ironwood's method of use patents on plecanatide for the treatment of chronic constipation. The LOI contemplates a low single digit royalty on net sales and both parties agreed not to challenge each other's patents covering certain GC-C agonists, with the exception that Synergy retains the right to challenge Ironwood's method of use patent on plecanatide.

FINANCIAL OPERATIONS OVERVIEW

From inception through September 30, 2012, we have sustained cumulative net losses of $97,075,397. From inception through September 30, 2012, we have not generated any revenue from operations and expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products. We do not expect to have such for several years, if at all.

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

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA of our Annual Report on Form 10-K as of and for year ended December 31, 2011, filed with the SEC on March 15, 2012. There have been no changes to our critical accounting policies since December 31, 2011.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

For a discussion of our contractual obligations see (i) our Financial Statements and Notes To Consolidated Financial Statements— Note 7. *Commitments and Contingencies* , and (ii) Item 7 Management Discussion and Analysis of Financial Condition and Results of Operations— *Contractual Obligations and Commitments* , included in our Annual Report on Form 10-K as of December 31, 2011 and changes in contractual obligations and commitments as reported in our Form 10-Q for the three months ended and as of March 31, 2012. There have been no major changes in our contractual obligations and commitments during the three months ended September 30, 2012.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2012.

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RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

We had no revenues during the three months ended September 30, 2012 and 2011 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the three months ended September 30, 2012 ("Current Quarter") increased $4,362,817 or 112 %, to $8,245,620 from $3,882,803 for the three months ended September 30, 2011("Prior Year Quarter"). This increase in research and development expenses was largely attributable to continuing the development of our plecanatide and SP-333 product candidates. The following table sets forth our research and development expenses directly related to our product candidates for the three months ended September 30, 2012 and 2011. These expenses were primarily external costs associated with chemistry, manufacturing and controls

including costs of drug substance and product (CMC), as well as preclinical studies and clinical trial costs, as follows:

	Three Months Ended September 30,	
Drug candidates	**2012**	**2011**
Plecanatide (Phase IIb/III)	$ 5,486,386	$ 3,089,294
SP-333(Phase I)	969,104	—
FV-100 (Pre-clinical)	1,000,000	—
Total direct cost	$ 7,455,490	$ 3,089,294
Total indirect cost	790,130	793,509
Total Research and Development	$ 8,245,620	$ 3,882,803

Indirect research and development costs related to in-house staff compensation, facilities, depreciation, share-based compensation and research and development support services are not directly allocated to specific drug candidates. Indirect cost was $ 790,130 in the Current Quarter, as compared to $793,509 during the Prior Year Quarter due to lower share based compensation.

General and administrative expenses increased $740,306 or 67%, to $1,843,150 for the Current Quarter from $1,102,844 for the three months ended September 30, 2011. These increased expenses were primarily the result of (i) higher compensation and related employee benefits of approximately $686,000 in the Current Quarter as compared to $ 327,000 during the Prior Year Quarter, primary due to higher stock based compensation expenses for employee related stock options granted this quarter, (ii) higher facilities cost of approximately $248,000 in the Current Quarter as compared to $218,000 during the Prior Year Quarter and (iii) higher corporate legal services of approximately $283,000 for the Current Quarter, as compared to $170,000 for the Prior Year Quarter, (iv) higher consultants and financial advisors fees of approximately $483,000 in the Current Quarter, as compared to $145,000 during the Prior Year Quarter related to the merger, partially offset by (v) lower accounting, tax and travel expenses of approximately $143,000 the Current Quarter, as compared to $237,000 during the Prior Year Quarter.

Net loss for the Current Quarter was $9,885,287as compared to a net loss of $582,851 incurred for the Prior Year Quarter. This increase in our net loss of $9,302,436, or 1596% was a result of the increases in operating expenses discussed above, and the gain resulting from the change in fair value of derivative instruments-warrants of $140,322 during the Current Quarter, as compared to a gain of $4,382,796 during the Prior Year Quarter.

NINE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

We had no revenues during the nine months ended September 30, 2012 and 2011 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the nine months ended September 30, 2012 (“Current Period”) increased $13,494,649 or 175%, to $21,210,028 from $7,715,379 for the nine months ended September 30, 2011(“Prior Year Period”). This increase in research and development expenses was largely attributable to continuing the development of our plecanatide and SP-333 product candidates. The following table sets forth our research and development expenses directly related to our product candidates for the nine months ended September 30, 2012 and 2011. These direct expenses were primarily external costs associated with chemistry, manufacturing, controls including drug substance and product (CMC), as well as preclinical studies and clinical trial costs, as follows:

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	Nine Months Ended September 30,	
Drug candidates	**2012**	**2011**
Plecanatide (Phase IIb/III)	$ 16,163,387	$ 6,756,884
SP-333 (Phase I)	1,923,104	—
FV-100 (Pre-clinical)	1,000,000	—
Total direct cost	$ 19,086,491	$ 6,756,884
Total indirect cost	2,123,537	958,495
Total research and development cost	21,210,028	7,715,379

In addition, indirect research and development costs related to in-house staff compensation, facilities, depreciation, share-based compensation and research and development support services are not directly allocated to specific drug candidates were $1,165,042 higher due to (i) higher compensation, employee benefits and stock based compensation expenses of $1,640,000 in the Current Period, as compared to $820,000 during the Prior Year Period, as a result of increased staffing levels required to support the our Phase II/III trial which was initiated in October 2011 and (ii) higher scientific and regulatory advisory fees and expenses of $583,000 in the Current Period, as compared to $179,000 during the Prior Year Period, related to an Investigational New Drug (IND) application for clinical evaluation of SP-333 to treat inflammatory bowel disease (IBD) filed on September 7, 2012, and work on an IND filing for a new clinical study of plecanatide in IBS-C patients.

General and administrative expenses increased $967,891 or 21%, to $5,492,766 for the Current Period from $4,524,875 for the Prior Year Period. These increased expenses were primarily the result of higher legal cost of approximately $973,000 in the Current Period as compared to $464,000 during the Prior Year Period, related to (i) our Form S-3 Shelf Registration filing in June of 2012, (ii) our Merger related Form S-4 Proxy and Registration Statement filed October 25, 2012 and (iii) costs associated with defending against Merger related class action suits filed in New York and Delaware during the Current Period. See Part II, Item 1 Legal Proceedings of this report for details

of these cases.

Net loss for the Current Period was $ 27,466,379 as compared to a net loss of $8,841,640 incurred for the Prior Year Period. This increase in our net loss of $18,624,739, or 211% was a result of the increases in operating expenses discussed above, and loss resulting from the change in fair value of derivative instruments-warrants of $1,169,079 during the Current Period, as compared to a gain of $3,346,421 during the Prior Year Period, due principally to an increase in the stock price of Synergy common from $3.51 as of December 31, 2011 to $4.78 per share on September 30, 2012.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2012 we had $17,244,049 of cash and cash equivalents on hand as compared to $13,244,883 of cash and cash equivalents on hand as of December 31, 2011. In addition, on September 30, 2012 we held $20,123,315 in available-for-sale securities, U.S. Treasury Bills and Notes, whereas we had no such investments as of December 31, 2011. As of September 30, 2012 we had working capital of $33,677,415 as compared to working capital of $11,561,286 as of December 31, 2011.

On May 9, 2012, we closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of $4.50 per share. The gross proceeds from this offering were $45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of $2,952,930. We also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of $4.50 per share to cover over-allotments, if any. On June 6, 2012 the underwriters exercised all of the over-allotment option resulting in additional gross proceeds of $6,750,000, before deducting underwriting discounts, commissions and other offering expenses of $405,000, bringing total gross proceeds from the offering to $51,750,000.

On June 21, 2012, Synergy entered into a controlled equity sales agreement with a placement agent ("Agent") and agreed that Synergy may issue and sell through the Agent, up to $30,000,000 of common stock of the Company. From October 8, 2012 through October 26, 2012, Synergy sold 299,911 shares of common stock with gross proceeds of $1,423,491at an average selling price of $4.74 per share. No sales were initiated prior to this period.

We will be required to raise additional capital to complete the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Recent worldwide economic conditions, as well as domestic and international equity and credit markets, have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult to obtain additional equity or credit financing, when needed. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business.

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.

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Our condensed consolidated financial statements as of September 30, 2012 and December 31, 2011 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our ability to continue as a going concern 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, U.S. Treasury Bills and Notes, and the FDIC insurance limit on our bank balances. As of September 30, 2012, we held approximately $15 million in money market accounts and held approximately $20 million in U.S. Treasury Bills and Notes. We maintained our cash, cash equivalents and available-for-sale securities at one or more financial institutions that are in excess of federally insured limits. We believe our cash, cash equivalents and available-for-sale securities do not contain excessive risk, however we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. Given the current instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits and investments.

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 September 30, 2012, our Chief Executive Officer and Principal Financial Officer have concluded that as of September 30, 2012, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitations, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded there were no changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that could significantly affect internal controls over financial reporting during the quarter ended September 30, 2012.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On August 9, 2012, a purported stockholder class action complaint was filed in the Supreme Court for the State of New York, captioned Shona Investments v. Callisto Pharmaceuticals, Inc., et al., Civil Action No. 652783/2012. The complaint names as defendants, Callisto, each member of the Board of Callisto (the "***Individual Defendants***") and Synergy. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that Synergy aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs' attorneys' fees and costs. Callisto and Synergy believe the plaintiffs' allegations lack merit and will contest them.

On August 31, 2012, a purported stockholder class action complaint was filed in the Court of Chancery of the State of Delaware, captioned Gary Wagner v. Gary S. Jacob, Inc., et al., Case No. 7820-VCP. The complaint names as defendants, Callisto, the Individual Defendants and Synergy. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that Synergy aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs' attorneys' fees and costs. Callisto and Synergy believe the plaintiffs' allegations lack merit and will contest them.

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2011.

ITEM 2. PROPERTIES.

On July 1, 2012 we entered into the First Addendum to Lease Agreement with the Bucks County Biotechnology Center in Doylestown PA wherein we expanded our space from approximately 800 to 1,000 square feet at a monthly rate of approximately $2,200 per month.

On August 28, 2012 we entered into a Lease Modification, Substitution of Space and Extension Agreement with SL Green Graybar Associates. Under the new lease we will be moving our corporate headquarters and clinical development offices into approximately 6,700 square feet on the 20th floor of 420 Lexington Avenue, New York, NY 10170. Previously Synergy leased approximately 4,200 square feet in Suite 1609 at 420 Lexington Avenue. The new lease has a monthly rate of approximately $32,000 expires March 31, 2019. We expect to move in on or about November 30, 2012.

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 Synergy for the quarter ended September 30, 2012, filed on November 13, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated

Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statement of Stockholders Equity (Deficit) (iv) the Condensed Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements tagged as blocks of text.

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* Indicates a management contract or compensatory plan or arrangement.

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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: November 13, 2012 By: /s/ GARY S. JACOB
Gary S. Jacob
President and Chief Executive Officer

Date: November 13, 2012 By: /s/ BERNARD F. DENOYER
Bernard F. Denoyer
Senior Vice President, Finance

EXHIBIT 31.1

CERTIFICATIONS

I, Gary S. Jacob, certify that:

1) I have reviewed this report on Form 10-Q of Synergy Pharmaceuticals Inc.

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2012

/s/ GARY S. JACOB
Gary S. Jacob
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATIONS

I, Bernard F. Denoyer, certify that:

1) I have reviewed this report on Form 10-Q of Synergy Pharmaceuticals Inc.

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2012

/s/ BERNARD F. DENOYER
Bernard F. Denoyer
Senior Vice President, Finance

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
SYNERGY PHARMACEUTICALS INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2012
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I am the Chief Executive Officer of Synergy Pharmaceuticals Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended September 30, 2012 and filed with the Securities and Exchange Commission ("Form 10-Q").

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

Date: November 13, 2012

/s/ GARY S. JACOB
Gary S. Jacob
President and Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION OF SENIOR VICE PRESIDENT, FINANCE
SYNERGY PHARMACEUTICALS INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2012
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I am the Senior Vice President, Finance of Synergy Pharmaceuticals Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended September 30, 2012 and filed with the Securities and Exchange Commission ("Form 10-Q").

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

Date: November 13, 2012

/s/ BERNARD F. DENOYER
Bernard F. Denoyer
Senior Vice President, Finance