SYNERGY PHARMACEUTICALS, INC.
Form 10-Q
November 09, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: September 30, 2016

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

For the transition period from to

Commission File Number: 001-35268

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 2012, New York, New York 10170
(Address of principal executive offices) (Zip Code)

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

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

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

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

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

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

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

The number of the registrant's shares of common stock outstanding was 179,953,607 as of November 7, 2016.

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SYNERGY PHARMACEUTICALS INC.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q for Synergy Pharmaceuticals Inc. may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such forward-looking statements are characterized by future or conditional verbs such as “may,” “will,” “expect,” “plan” “intend,” “anticipate,” believe,” “estimate” and “continue” or similar words. 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. Such statements are only predictions and our actual results may differ materially from those anticipated in these forward-looking statements. We do not assume any obligation to update forward-looking statements as circumstances change and thus you should not unduly rely on these statements, which speak only as of the date of this Quarterly Report on Form 10-Q.

We believe that it is important to communicate future expectations to readers. However, there may be events in the future that we are not able to accurately predict or control. Risk factors that may cause such differences between predicted and actual results include, but are not limited to, those discussed in our Form 10-K for the year ended December 31, 2015 and other periodic reports filed with the Securities and Exchange Commission.

These risk factors include the uncertainties associated with product development, the risk that products that appeared promising in early clinical trials do not demonstrate safety and efficacy in larger-scale clinical trials, the risk that we will not obtain approval to market our products, the risks associated with dependence upon key personnel and the need for additional financing.

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PART I—FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

SYNERGY PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share amounts)

	September 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 109,090	$ 61,653
Available-for-sale securities	—	50,097
Prepaid expenses and other current assets	1,744	3,305
Total Current Assets	110,834	115,055
Property and equipment, net	635	531
Security deposits	343	343
Total Assets	$ 111,812	$ 115,929
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current Liabilities:		
Accounts payable	$ 15,801	$ 13,263
Accrued expenses	5,242	4,328
Interest payable on senior convertible notes	2,474	1,988
Total Current Liabilities	23,517	19,579
Senior convertible notes, net	76,070	151,241
Derivative financial instruments, at estimated fair value-warrants	171	322
Total Liabilities	99,758	171,142
Commitments and contingencies		
Stockholders’ Equity/(Deficit):		
Preferred stock, Authorized 20,000,000 shares and none outstanding, at September 30, 2016 and December 31, 2015	—	—
Common stock, par value of $.0001, 350,000,000 shares authorized at September 30, 2016 and December 31, 2015. Issued and outstanding 179,836,107 shares and 113,694,606 shares at September 30, 2016 and December 31, 2015, respectively.	18	11
Additional paid-in capital	535,161	329,161
Accumulated deficit	(523,125)	(384,385)
Total Stockholders’ Equity/(Deficit)	12,054	(55,213)
Total Liabilities and Stockholders’ Equity	$ 111,812	$ 115,929

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

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SYNERGY PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues	$—	$ —	$—	$ —
Costs and Expenses:				
Research and development	24,610	20,424	72,396	58,147
Selling, general and administrative	13,872	2,728	30,497	14,727
Loss from Operations	(38,482)	(23,152)	(102,893)	(72,874)
Other Loss				
Interest and investment expense, net	(1,674)	(4,291)	(10,383)	(13,815)
Debt conversion expense	—	—	(25,615)	—
Change in fair value of derivative instruments-warrants	(87)	1,446	151	(364)
Total Other Loss	(1,761)	(2,845)	(35,847)	(14,179)
Net Loss	$(40,243)	$ (25,997)	$(138,740)	$ (87,053)
Weighted Average Common Shares Outstanding				
Basic and Diluted	179,786,580	111,328,339	155,410,353	102,838,814
Net Loss per Common Share, Basic and Diluted				
Net Loss per Common Share, Basic and Diluted	$(0.22)	$ (0.23)	$(0.89)	$ (0.85)

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

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SYNERGY PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY/(DEFICIT)
(Unaudited)
(In thousands, except share amounts)

	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Deficit Accumulated	Total Stockholders' Equity/(Deficit)
December 31, 2015	113,694,606	$ 11	$329,161	$(384,385)	$ (55,213)
Notes conversions including shares issued for accrued interest	26,532,731	3	82,271	—	82,274
Debt conversion expense	9,593,751	1	25,614	—	25,615
Transaction fees on Note conversions	—	—	(434)	—	(434)
Common stock issued in connection with exercise of stock options	66,685	—	213	—	213
Common stock issued in registered direct offering	29,948,334	3	89,842	—	89,845
Stock based compensation expense	—	—	8,494	—	8,494
Net loss for the period	—	—	—	(138,740)	(138,740)
Balance, September 30, 2016	179,836,107	$ 18	$535,161	$(523,125)	$ 12,054

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

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SYNERGY PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Cash Flows From Operating Activities:		
Net loss	$(138,740)	$(87,053)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	193	103
Amortization of deferred debt costs	4,658	4,060
Stock-based compensation expense	8,494	7,724
Value of common stock issued for patent license	—	71
Accretion of discount/premium on available for sale securities	—	(97)
Change in fair value of derivative instruments—warrants	(151)	364
Common stock issued for interest on Notes	2,445	—
Debt conversion expense	25,615	—
Changes in operating assets and liabilities:		
Security deposit	—	(56)
Accounts payable and accrued expenses	3,452	(1,042)
Prepaid expenses and other current assets	1,561	2,781
Accrued interest expense on senior convertible notes	486	2,470
Total Adjustments	46,753	16,378
Net Cash used in Operating Activities	(91,987)	(70,675)
Cash Flows From Investing Activities:		
Net sales (purchases) of available-for-sale securities	50,097	(50,188)
Additions to property and equipment	(297)	(50)
Net Cash provided by (used in) Investing Activities	49,800	(50,238)
Cash Flows From Financing Activities:		
Proceeds of sale of common stock	89,845	14,672
Fees and expenses — note conversions	(434)	—
Fees and expenses — sale of common stock	—	(404)
Proceeds from exercise of warrants	—	1,012
Proceeds from exercise of stock options	213	1,079
Net Cash provided by Financing Activities	89,624	16,359
Net increase (decrease) in cash and cash equivalents	47,437	(104,554)
Cash and cash equivalents at beginning of period	61,653	146,470
Cash and cash equivalents at end of period	$109,090	$41,916
Supplementary disclosure of cash flow information:		
Cash paid for interest on senior convertible notes	$2,969	$7,416
Cash paid for taxes	$45	$258
Supplementary disclosure of non-cash investing and financing activities:		
Conversion of senior convertible notes to Synergy Common Stock	$82,274	$40,989

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

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SYNERGY PHARMACEUTICALS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Business Overview

Synergy Pharmaceuticals Inc. ("the Company" or "Synergy") is a biopharmaceutical company focused on the development and commercialization of novel gastrointestinal (GI) therapies. The Company has pioneered discovery, research and development efforts around analogs of uroguanylin, a naturally occurring human GI peptide, for the treatment of GI diseases and disorders. Synergy discovered, is developing and controls 100% worldwide rights to its proprietary uroguanylin analog platform that includes two lead product candidates - plecanatide and dolcanatide. Plecanatide is Synergy's first uroguanylin analog currently being evaluated for use as a once-daily tablet for chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). Dolcanatide is Synergy's second uroguanylin analog currently being explored for ulcerative colitis.

Net cash used in operating activities was approximately $92.0 million for the nine months ended September 30, 2016. As of September 30, 2016, Synergy had approximately $109.1 million of cash and cash equivalents. During the nine months ended September 30, 2016, Synergy incurred losses from operations of $102.9 million. As of September 30, 2016, Synergy had working capital of approximately $87.3 million.

On May 5, 2016, Synergy announced that it had entered into definitive agreements with certain institutional investors to sell 29,948,334 shares of common stock at a price of $3.00 per share. The shares were offered and sold directly to institutional investors by the Company in a registered direct offering conducted without an underwriter or placement agent. The gross proceeds from the offering were approximately $89.8 million. The offering closed on May 6, 2016.

2. Basis of Presentation

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, 2015 contained in the Company’s Annual Report on Form 10-K filed with the SEC on February 25, 2016. All intercompany balances and transactions have been eliminated.

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

Synergy's consolidated financial statements as of December 31, 2015 and its unaudited condensed consolidated financial statements as of September 30, 2016 have been prepared under the assumption that the Company will continue as a going concern for the next twelve months. Synergy's independent registered public accounting firm has issued a report as of December 31, 2015 that includes an explanatory paragraph referring to the Company's recurring and continuing losses from operations and expressing substantial doubt in the Company's ability to continue as a going concern without additional capital becoming available. 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, reduce expenditures, and, ultimately, to generate revenue. Synergy's consolidated financial statements as of December 31, 2015 and its unaudited condensed consolidated financial statements as of September 30, 2016 do not include any adjustments that might result from the unfavorable outcome of this uncertainty.

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3. Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, “Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting” (“ASU 2016-09”). The standard is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact, classification on the statement of cash flows and forfeitures. ASU 2016-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is permitted. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU 2016-02 “Leases (Topic 842)” (“ASU 2016-02”). The FASB issued ASU 2016-02 to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under ASU 2016-02, a lessee will recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-to-use asset representing its right to use the underlying asset for the lease term. The amendments of this ASU are effective for reporting periods beginning after December 15, 2018, with early adoption permitted. An entity will be required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Management is currently assessing the impact the adoption of ASU 2016-02 will have on its consolidated financial statements and disclosures.

4. Cash, Cash Equivalents and Available-for-sale Securities

All highly liquid investments with maturities of three months or less at the date of purchase are classified as cash equivalents. As of September 30, 2016 and December 31, 2015, the amount of cash and cash equivalents was $109.1 million and $61.7 million, respectively and consists of checking accounts and short-term U.S. Treasury money market mutual funds. Checking accounts are held at U.S. commercial banks, and balances were in excess of the FDIC insurance limit.

The Company had no available-for-sale securities as of September 30, 2016 and $50.1 million of available-for-sale securities as of December 31, 2015. 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.

5. Senior Convertible Notes

On November 3, 2014, Synergy closed a private offering of $200 million aggregate principal amount of 7.50% Convertible Senior Notes due 2019, (the "Notes"), including the full exercise of the over-allotment option granted to the initial purchasers to purchase an additional $25 million aggregate principal amount of the Notes, interest payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2015. The net proceeds from the offering were $187.3 million after deducting the initial purchasers’ discounts and offering expenses.

The Notes are unsecured. Interest expense, not including amortization of deferred debt costs, for the three and nine months ended September 30, 2016 was $1.5 million and $5.9 million, respectively. Interest expense not including amortization of deferred debt costs for the three and nine months ended September 30, 2015 was $2.7 million and $9.9 million, respectively. Accrued interest payable was $2.5 million and $2.0 million as of September 30, 2016 and December 31, 2015 respectively.

The Notes will mature on November 1, 2019, unless earlier purchased or converted. The Notes are convertible, at any time, into shares of Synergy’s common stock at an initial conversion rate of 321.5434 shares per $1,000 principal amount of notes, which is equivalent to the original conversion price of $3.11 per share. Subsequent to the exchange

described below, the principal balance of the Notes at September 30, 2016 was $79.2 million as compared to $159.0 million at December 31, 2015.

Debt costs associated with the sale of the Notes of $12.7 million have been deferred and are being recognized as expense over the expected term of the Notes, calculated using the effective interest rate method. Amortization expense, including amortization associated with reduction of the principal due to the conversion and exchanges of the debentures on a prorated basis for three and nine months ended September 30, 2016 was $0.3 million and $4.7 million, respectively, and for the three and nine months ended September 30, 2015 was $1.5 million and $4.1 million, respectively. The remaining deferred debt costs have been presented as a reduction of the Notes in accordance with the newly adopted Accounting Standards Update (“ASU”) No. 2015-3 “Simplifying the Presentation of Debt Issuance Costs”.

On March 18, 2016 Synergy entered into an agreement (the "Exchange") for the exchange of $79.8 million in aggregate principal amount of the Notes, representing approximately 50% of the outstanding aggregate principal amount of Notes, for 35.3 million shares of Synergy's common stock, with a total of 25.6 million shares representing the conversion price of $3.11

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pursuant to the existing terms of the Notes. Synergy also issued approximately 872,000 shares at the five day average share price of $2.81 in payment of accrued and unpaid interest of $2.4 million on Notes accepted in the Exchanges, from the applicable last interest payment date to, but not including, March 28, 2016. The amortization of deferred debt costs was accelerated consistent with the 50% reduction of aggregate principal amount this transaction represented, and resulted in additional interest expense of approximately $3.6 million. GAAP requires that such conversions be treated as induced conversions with an expense recognized equal to the fair value of the 9.6 million shares transferred in the transaction in excess of the fair value of the securities issuable pursuant to the original conversion terms, with such fair value being measured as of the date the inducement offer is accepted by the convertible debt holder. Accordingly, the Company recognized a debt conversion expense of $25.6 million for the nine months ended September 30, 2016.

A summary of quarterly activity and balances associated with the Notes and related deferred debt costs is presented below ($ in thousands):

	Notes Balance	Deferred Debt Costs	Notes, net of Deferred Debt Costs
Balance at issuance November 1, 2014	$ 200,000	$12,747	$ 187,253
Less: amortization two months ended December 31, 2014		(411)	411
Balance December 31, 2014	200,000	12,336	187,664
Less: amortization three months ended March 31, 2015		(617)	617
Balance March 31, 2015	200,000	11,719	188,281
Less: amortization three months ended June 30, 2015 [1]		(1,899)	1,899
Conversions	(22,213)	—	(22,213)
Balance June 30, 2015	177,787	9,820	167,967
Less: amortization three months ended September 30, 2015 [1]		(1,544)	1,544
Conversions	(18,776)	—	(18,776)
Balance, September 30, 2015	159,011	8,276	150,735
Less: amortization three months ended December 31, 2015		(506)	506
Balance December 31, 2015	159,011	7,770	151,241
Less: amortization three months ended March 31, 2016 [1]		(4,153)	4,153
Conversions	(79,829)	—	(79,829)
Balance, March 31, 2016	79,182	3,617	75,565
Less: amortization three months ended June 30, 2016		(253)	253
Balance, June 30, 2016	79,182	3,364	75,818
Less: amortization three months ended September 30, 2016		(252)	252
Balance, September 30, 2016	$ 79,182	$3,112	$ 76,070

(1) Includes accelerated amortization of deferred debt costs attributable to conversions and exchanges

6. Accounting for Share-based Payments

Stock Options

ASC Topic 718 “Compensation—Stock Compensation” requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. Synergy accounts for shares of common stock, stock options and warrants issued to 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.

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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. On June 8, 2015, Synergy amended its 2008 Equity Compensation Incentive Plan and increased the number of shares of its common stock reserved for issuance under the Plan from 15,000,000 to 30,000,000.

Stock-based compensation has been recognized in operating results as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2016	2015	2016	2015
Included in research and development	961	592	2,555	1,702
Included in general and administrative	3,624	(661)	5,939	6,022
Total stock-based compensation expense	$4,585	$(69)	$8,494	$7,724

The unrecognized compensation cost related to non-vested stock options outstanding at September 30, 2016, net of expected forfeitures, was approximately $18.8 million to be recognized over a weighted-average remaining vesting period of approximately 1.3 years. This unrecognized compensation cost does not include amounts related to 2,159,500 shares of stock options which vest and will be measured 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 periods indicated.

	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Risk-free interest rate	1.13%-1.74%	1.46%-2.02%
Dividend yield	—	—
Expected volatility	50 %	57%-80%
Expected term (in years)	6 years	6 years

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 (in thousands)	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2015 (1)	20,953,375	$0.44-9.12	$ 3.86	$ 42,438	7.15 years
Granted	6,403,000	$2.93-5.63	3.75	—	
Exercised	(66,685)	$2.94-4.61	3.18	—	
Forfeited	(551,760)	$2.98-9.12	5.99	—	
Balance outstanding, September 30, 2016 (1)	26,737,930	$0.44-9.12	$ 3.78	$ —	7.18 years
Exercisable, at September 30, 2016	11,470,357	$0.44-9.12	$ 3.84	$ 23,281	6.02 years

(1) Number of options represented above includes 2,159,500 options vesting upon a change of control, granted between November 20, 2009 and June 22, 2010. The fair value at the date of grant was approximately $28.6 million. Because the probability of a change of control transaction is not predictable no stock based compensation expense

associated with these options has been recognized since the grant date.

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7. Stockholders' Equity/(Deficit)

On March 18, 2016, Synergy entered into an exchange agreement for the exchange of $79.8 million in aggregate principal amount of the Notes, representing approximately 50% of the outstanding aggregate principal amount of Notes, for 35.3 million shares of Synergy's common stock, with a total of 25.6 million shares representing the conversion price of $3.11 pursuant to the existing terms of the Notes. Synergy also issued approximately 872,000 shares at the five day average share price of $2.81 in payment of accrued and unpaid interest of $2.4 million on Notes accepted in the Exchanges. In addition, Synergy issued 9.6 million shares of common stock as an inducement for Note holders to convert.

On May 5, 2016, Synergy announced that it had entered into definitive agreements with certain institutional investors to sell 29,948,334 shares of common stock at a price of $3.00 per share. The shares were offered and sold directly to institutional investors by the company in a registered direct offering conducted without an underwriter or placement agent. The gross proceeds from the offering were approximately $89.8 million. The offering closed on May 6, 2016.

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, regulatory and scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring, and clinical insurance.

In accordance with FASB ASC Topic 730-10-55, Research and Development, Synergy recorded prepaid research and development costs of approximately $1.4 million as of September 30, 2016 and $3.1 million as of December 31, 2015, for nonrefundable advances for production of drug substance and analytical testing services for its drug candidates. In accordance with this guidance, Synergy expenses these costs when drug compound is delivered and services are performed.

The Company will record inventory, manufactured for sale of a product candidate, when the product candidate is considered to have a high likelihood of regulatory approval and the related costs are expected to be recoverable through sales. In determining whether or not to record such inventories, the Company evaluates, among other factors, information regarding the product candidate's safety and efficacy, the status of regulatory submissions and communications with regulatory authorities and the outlook for commercial sales. As of September 30, 2016, all costs associated with batches of inventory, manufactured for sale of a product candidates, had not met the inventory capitalization criteria and have been charged to research and development expense as incurred.

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9. Derivative Financial Instruments

Synergy 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, these warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value are 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 was:

	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Fair value of Synergy common stock	$ 5.51	$ 5.30
Expected warrant term	1.4	0.01—2.4 years
Risk-free interest rate	0.68 %	0.00%—0.78%
Expected volatility	40 %	80 %
Dividend yield	—	—

Fair value of stock is the closing market price of the Company's common stock at the end of each reporting period when the derivative instruments are marked to market. Expected volatility is a management estimate of future volatility, over the expected warrant term, 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 at the date quarterly revaluation.

The following table sets forth the components of changes in the Synergy's outstanding warrants which were deemed derivative financial instruments and the associated liability balance for the periods indicated:

Date	Description	Warrants	Derivative Instrument Liability (in thousands)
12/31/2015	Balance of derivative financial instruments liability	210,000	$ 322
3/31/2016	Change in fair value of warrants during the 3 months ended March 31, 2016		(260)
6/30/2016	Change in fair value of warrants during the 3 months ended June 30, 2016		$ 22
9/30/2016	Change in fair value of warrants during the 3 months ended September 30, 2016		$ 87
9/30/2016	Balance of derivative financial instruments liability	210,000	$ 171

10. Fair Value Measurements

Financial instruments consist of cash and cash equivalents, available-for-sale securities, accounts payable and derivative instruments. These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short term nature, except for available-for-sale securities and derivative instruments which are marked to market at the end of each reporting period.

The value of Senior Convertible Notes is stated at its carrying value at September 30, 2016. The Company believes it could obtain borrowings at September 30, 2016 at comparable interest rates as the November 2014 Notes, therefore, the carrying value approximates fair value.

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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, 2015 and September 30, 2016:

($ in thousands)

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, 2015	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, 2016
Derivative liabilities related to Warrants	$ —	$ —	$ 322	$ 322	$ —	$ —	$ 171	$ 171

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, 2016:

($ in thousands)

Description	Balance as of December 31, 2015	(Gain) or loss recognized in earning from Change in Fair Value	Expiration of warrants	Balance as of September 30, 2016
Derivative liabilities related to Warrants	$ 322	$ (151)	$ —	$ 171

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, Synergy 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. 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 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 and warrants would be antidilutive.

The following table sets forth potential common shares issuable upon the exercise of outstanding options, the exercise of warrants, and the conversion of the Senior Convertible Notes, all of which have been excluded from the computation of diluted weighted average shares outstanding as they would be anti-dilutive, including the impact on dilutive net loss per share of in-the-money warrants as per ASC 260-10-45-35 through ASC 260-10-45-37:

	Nine Months	Nine Months

	Ended September 30, 2016	Ended September 30, 2015
Stock Options	26,737,930	19,767,956
Warrants	4,726,822	5,068,823
Senior Convertible Notes	25,460,450	51,128,939
Total shares issuable upon exercise or conversion	56,925,202	75,965,718

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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" "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 and thus you should not unduly rely on these statements.

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, 2015 and other periodic reports filed with the United States Securities and Exchange Commission ("SEC"). Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of the Company, please be advised that the Company's actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements and thus you should not unduly rely on these statements.

Business Overview

Synergy Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of novel gastrointestinal (GI) therapies. We have pioneered discovery, research and development efforts around analogs of uroguanylin, a naturally occurring human GI peptide, for the treatment of GI diseases and disorders. We discovered, are developing and control 100% worldwide rights to our proprietary uroguanylin analog platform that includes two lead product candidates - plecanatide and dolcanatide.

Plecanatide

Plecanatide is our first uroguanylin analog currently being evaluated for use as a once-daily tablet for chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). Plecanatide is a peptide made up of 16 amino acids and, with the exception of a single amino acid substitution, it is identical to uroguanylin. Plecanatide is the first investigational drug designed to replicate the function of uroguanylin, a naturally occurring and endogenous human GI peptide which acts in a pH-dependent manner targeting guanylate cyclase-C (GC-C) receptors primarily in the proximal small intestine. Plecanatide stimulates fluid secretion and promotes stool consistency necessary to support normal bowel function.

The plecanatide new drug application (NDA) in CIC is currently under review by the Food and Drug Administration (FDA) and the FDA Prescription Drug User Fee Act (PDUFA) target action date is January 29, 2017. In addition, patient enrollment has been completed in the two double-blind placebo-controlled phase 3 clinical trials with plecanatide in IBS-C. Top-line data from both trials are expected by the end of this year. Pending approval in the CIC indication, we plan to file a New Drug Application Supplement with Clinical Data (sNDA) for plecanatide in IBS-C in the first quarter of 2017.

Dolcanatide

Dolcanatide is our second uroguanylin analog currently being explored for ulcerative colitis. Dolcanatide is designed to replicate the activity of uroguanylin with enhanced resistance to standard digestive breakdown by proteases in the intestine. In January 2016, we announced positive proof-of-concept with dolcanatide in a phase 1b trial evaluating 28 patients with mild-to-moderate ulcerative colitis. We are planning to meet with regulatory agencies to discuss phase 2 clinical development plans for dolcanatide in mild-to-moderate ulcerative colitis. In November 2014, we reported successful proof-of-concept with dolcanatide in a double-blind, placebo-controlled phase 2 trial in 289 patients with OIC, demonstrating the utility of our uroguanylin analog platform in OIC.

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Recent Developments

Plecanatide CIC Development Update

The plecanatide new drug application (NDA) in chronic idiopathic constipation (CIC) is currently under review by the Food and Drug Administration (FDA) and the Prescription Drug User Fee Act (PDUFA) target action date is January 29, 2017. Plecanatide is the first investigational therapy designed to replicate the activity of uroguanylin, a naturally occurring human GI peptide, by working locally primarily in the proximal small intestine to stimulate digestive fluid movement and support regular bowel function.

- The late-cycle review meeting with the FDA was completed and no significant issues were identified. The FDA previously informed us that there are no plans at this time for an advisory committee meeting in connection with the review of the plecanatide NDA in CIC. The plecanatide NDA in CIC is supported by two double-blind, placebo-controlled phase 3 trials and one long-term open-label safety study. Over 3,500 patients have been exposed to plecanatide in the CIC clinical development program.

- Two posters were presented on the plecanatide CIC clinical data at the American College of Gastroenterology (ACG) annual scientific meeting in October 2016.
- Safety and Tolerability of Plecanatide in Patients with Chronic Idiopathic Constipation: Long-term Evidence from an Open-Label Study
  - Data presented from the long-term open-label safety study showed plecanatide was associated with low adverse events and low discontinuation rates in patients with CIC who received plecanatide (3 mg or 6 mg) once-daily for up to 72 weeks. The most common adverse events were diarrhea (7.1%) and urinary tract infection (2.2%). The remainder of adverse events occurred in less than 2% of patients treated with plecanatide. Adverse events leading to discontinuation occurred in 5.3% of patients treated with plecanatide, with discontinuation due to diarrhea occurring in 3.1% of patients. In addition, this study asked patients about level of treatment satisfaction and desire to continue treatment. The median score for treatment satisfaction was 4.0 (4=quite satisfied) and for continuation of treatment was 4.0 (4=quite likely).
- Efficacy and Safety of Plecanatide in the Treatment of Chronic Idiopathic Constipation (CIC): Pooled Results from Two Phase 3 Studies
  - Pooled results from two previously reported double-blind placebo-controlled phase 3 CIC trials confirmed patients treated with plecanatide showed a significantly greater response rate of durable overall complete spontaneous bowel movements compared to placebo (20.5% in 3 mg and 19.8% in 6mg dose groups compared to11.5% in placebo; $p<0.001$ for both doses). This is the primary endpoint defined by the FDA for regulatory approval in CIC. This integrated analysis also showed consistent safety data with adverse event rates similar across plecanatide-treatment groups and placebo (30.6% in 3 mg and 31.1% in 6 mg dose groups compared to 28.7% in placebo). Diarrhea was the most common adverse event (4.6% in 3 mg and 5.1% in 6 mg compared to 1.3% in placebo). Discontinuation rates were low across all treatment groups (4.1% in 3.0 mg and 4.5% in 6.0 mg dose groups compared to 2.2% in placebo).

Plecanatide IBS-C Development Update

- Patient enrollment has been completed in the two double-blind, placebo-controlled phase 3 clinical trials with plecanatide in IBS-C patients. Top-line data in both trials are expected by the end of this year. The primary endpoint in both trials is the percentage of patients who are Overall Responders during the 12-week treatment period. An Overall Responder, as defined by the FDA, is a patient who is a weekly responder (i.e. meets both a 30% abdominal pain intensity reduction and stool frequency increase criteria in the same week) for at least 6 of the 12 treatment weeks. Plecanatide previously met this endpoint in a phase 2b trial with 424 IBS-C patients that was completed in 2014.

- The IBS-C pre-NDA meeting with the FDA was completed in September 2016. Pending approval of plecanatide in the CIC indication, we plan to file a New Drug Application Supplement with Clinical Data (sNDA) for plecanatide in IBS-C in the first quarter of 2017 and expect a 10-month review period from submission.

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Commercial Planning & Launch Preparation Update

Product Readiness

Key Highlights

- Met all technical operations timelines to-date and remain on-track to complete all activities by the anticipated launch of plecanatide in early 2017.
- Established a robust supply chain and actively producing commercial product.
- Continuing to build trade and sample stock for launch in early 2017.
- Implemented 3PL distribution network.
- Established strong Quality Management Systems.

Market/Brand Readiness

Key Highlights

- Generated substantial customer insights through qualitative and quantitative market research that will include more than 2,700 HCPs and more than 5,000 patients/consumers by the end of 2016.
- Conducted multiple productive advisory boards with national and regional GI Key Opinion Leaders and payers.
- Finalized plecanatide brand vision, brand positioning, value proposition, core marketing strategies and launch tactics; our message platform and a creative campaign will be completed and ready by year-end.
- Initiated pre-launch multimedia and digital campaigns to drive company awareness and disease education, focusing on current unmet medical needs of patients with CIC.
- Developed a compliant, value maximizing, and cost-effective promotional mix to reach the broadest universe of prescribers.
- Market Access team has conducted meetings with all key commercial and public payers, representing approximately 230 million covered lives in the U.S.

Organizational Readiness

Key Highlights

- National and regional market access teams have been active and in the field introducing Synergy Pharmaceuticals to payers since January 2016.
- Medical education efforts initiated in March 2016 and included strong corporate presence and key data presentations at Digestive Disease Week and ACG.
- Hired regional sales leaders averaging more than 10 years of GI experience who are driving important pre-launch initiatives and who will support an effective hybrid sales infrastructure that will be deployed at launch.
- Initiated a partnership with Publicis Touchpoint Solutions, Inc. to implement a cost-effective, flexible hybrid sales force, leveraging highly experienced sales representatives who will be fully dedicated to supporting the launch and adoption of plecanatide.
- Established a focused and efficient sales force strategy, combined with a comprehensive multi-channel approach, to reach the key prescribers and influencers at launch.
- Implemented all critical IT and compliance systems.

BIND Collaboration Update

- BIND initiated Chapter 11 bankruptcy protection on May 1, 2016 and conducted a sale of assets, pursuant to Section 363 of the Bankruptcy Code, during an auction held on July 25 and 26, 2016. Pfizer Inc. (NYSE: PFE) prevailed at a Section 363 auction on August 2, 2016 to purchase substantially all of BIND's assets. The collaboration was reviewed and a joint decision was made to not proceed with any further early research activities. As previously stated, this early

research collaboration did not and will not have a material financial impact on Synergy Pharmaceuticals.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2016 AND SEPTEMBER 30, 2015

We had no revenues during the three months ended September 30, 2016 and three corresponding months in 2015 because we do not have any commercial biopharmaceutical products.

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Research and development expenses for the three months ended September 30, 2016 ("Current Year Quarter") increased approximately $4.2 million or 20.6%, to approximately $24.6 million from approximately $20.4 million for the three months ended September 30, 2015 ("Prior Year Quarter"). This increase in research and development expenses was due primarily to greater spending on IBS-C studies, additional Technical Operations headcount and consulting services, and plecanatide API and drug product costs of validation batches manufactured in preparation for our anticipated commercial launch.

The following table sets forth our research and development expenses directly related to our product candidates, as well as indirect costs, for the three months ended September 30, 2016 and 2015. Direct expenses include external costs associated with chemistry, manufacturing and controls including costs of drug substance and product formulation, as well as preclinical studies and clinical trial costs.

	($ in thousands) Three Months Ended September 30,	
	2016	2015
Plecanatide	$20,533	$16,360
Dolcanatide	379	1,805
Total direct costs	20,912	18,165
Total indirect costs	3,698	2,259
Total Research and Development	$24,610	$20,424

Indirect research and development costs which are comprised of in-house staff compensation, facilities, depreciation, stock-based compensation and research and development support services, are not directly allocated to specific drug candidates. Indirect costs were approximately $3.7 million in the Current Year, as compared to approximately $2.3 million during the Prior Year representing an increase of approximately $1.4 million which was primarily due to higher stock based compensation and employee compensation expenses. The increase in employee compensation reflects the cost of building a Technical Operations function fully prepared for the anticipated commercial launch of plecanatide during first quarter 2017.

Selling, general and administrative expenses increased approximately $11.2 million or 414.8%, to $13.9 million for the Current Quarter from approximately $2.7 million for the Prior Quarter. These increased expenses primarily reflect the cost of building a Commercial Organization prepared to launch plecanatide during the first quarter of 2017. These costs include approximately a $5.1 million increase in commercial preparedness and planning expenses, a $4.3 million increase in stock compensation expense, and a $1.3 million increase in employee compensation and benefits costs.

Net loss for the Current Year Quarter was $40.2 million as compared to a net loss of a $26.0 million for the Prior Year Quarter. In addition to the operating items discussed above, this increase in our net loss of $14.2 million or 54.6% was a result of a $1.5 million increase in the fair value of our derivative instruments, partially offset by approximately a $1.2 million decrease in the amortization of our deferred debt costs and $1.2 million decrease in interest expense, both related to the conversion of our convertible debt.

NINE MONTHS ENDED SEPTEMBER 30, 2016 AND SEPTEMBER 30, 2015

We had no revenues during the nine months ended September 30, 2016 and nine corresponding months in 2015 because we do not have any commercial biopharmaceutical products.

Research and development expenses for the nine months ended September 30, 2016 ("Current Year Period") increased approximately $14.3 million or 24.6%, to approximately $72.4 million from approximately $58.1 million for the nine

months ended September 30, 2015 (“Prior Year Period”). This increase in research and development expenses was due primarily to greater spending on IBS-C studies, expenses related to filing our CIC NDA in January 2016, additional compensation, consulting services, and plecanatide API and drug product manufacturing costs for validation batches prepared in anticipation of our commercial launch of plecanatide for CIC during the first quarter of 2017. The increase in compensation reflects the cost of building a Technical Operations function fully prepared for the anticipated commercial launch of plecanatide during first quarter 2017.

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The following table sets forth our research and development expenses directly related to our product candidates, as well as indirect costs, for the nine months ended September 30, 2016 and 2015. Direct expenses include external costs associated with chemistry, manufacturing and controls including costs of drug substance and product formulation, as well as preclinical studies and clinical trial costs.

	($ in thousands) Nine Months Ended September 30,	
	2016	2015
Plecanatide	$60,079	$46,920
Dolcanatide	1,295	4,153
Total direct costs	61,374	51,073
Total indirect costs	11,022	7,074
Total Research and Development	$72,396	$58,147

Indirect research and development costs are comprised of in-house staff compensation, facilities, depreciation, stock-based compensation and research and development support services which are not directly allocated to specific drug candidates. Indirect costs were approximately $11.0 million in the Current Year Period, as compared to approximately $7.1 million during the Prior Year Period representing an increase of approximately $3.9 million which were primarily due to an increase in employee compensation of $1.8 million, higher stock based compensation of $0.9 million and $1.0 million increase in consulting services related to systems and packaging design. The increase in compensation reflects the cost of building a Technical Operations function fully prepared for the anticipated commercial launch of plecanatide during first quarter 2017.

Selling, general and administrative expenses increased approximately $15.8 million or 107.5%, to $30.5 million for the Current Year Period from approximately $14.7 million for the Prior Year Period. These increased expenses primarily reflect the cost of building a Commercial Organization prepared to launch plecanatide during first quarter 2017. These costs included approximately a $10.6 million increase in commercial preparedness and planning expenses, a $1.2 million increase in consulting, and a $2.8 million increase in compensation and benefit costs.

As of September 30, 2016 we had 61 full-time employees compared to 44 full-time employees at December 31, 2015.

Net loss for the Current Year Period was $138.7 million compared to a net loss of $87.1 million for the Prior Year Period. In addition to the operating items discussed above, this increase in our net loss of $51.6 million or 59.2% was primarily a result of debt conversion expense of approximately $25.6 million resulting from our March 2016 convertible notes exchange and an increase in the amortization of our deferred debt costs of $0.6 million, partially offset by a decrease of approximately $4.0 million in interest expense related to our convertible notes and a decrease of $0.6 million in the fair value of our derivative instruments.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2016, we had approximately $109.1 million in cash and cash equivalents, compared to approximately $111.8 million in cash, cash equivalents and available for sale securities as of December 31, 2015. Net cash used in operating activities was $92.0 million for the nine months ended September 30, 2016 and $70.7 million for the nine months ended September 30, 2015. As of September 30, 2016 we had working capital of $87.3 million, as compared to working capital of $95.5 million on December 31, 2015.

On May 5, 2016 we announced that we had entered into definitive agreements with certain institutional investors to sell 29,948,334 shares of common stock at a price of $3.00 per share. The shares were offered and sold directly to

institutional investors by us in a registered direct offering conducted without an underwriter or placement agent. The gross proceeds from the offering were approximately $89.8 million. The offering closed on May 6, 2016.

On March 28, 2016, we announced the closing of separate, privately-negotiated exchanges with eligible holders of approximately 50% of our outstanding 7.50% Convertible Senior Notes (“Notes”) due 2019. At the closing, and in satisfaction of the consideration for $79.8 million in aggregate principal amount of the Notes, we issued 35.3 million shares of our common stock (the “Shares”). We also issued approximately 872,000 Shares in payment of accrued and unpaid interest on Notes accepted in the Exchanges from the applicable last interest payment date to, but not including, March 28, 2016. A total of 25.6 million shares carried a conversion price of $3.11 pursuant to the existing terms of the Notes. $79.2 million of the Notes remain outstanding as of September 30, 2016.

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Notwithstanding our May 2016 sale of common stock, we will 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. We 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 may make it more difficult to obtain additional equity or credit financing, when needed. 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 (i) conduct, 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.

Our consolidated financial statements as of December 31, 2015 and our unaudited condensed consolidated financial statements as of September 30, 2016 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our independent registered public accounting firm has issued a report as of December 31, 2015 that includes an explanatory paragraph referring to our recurring and continuing losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Our consolidated financial statements as of December 31, 2015 and our unaudited condensed consolidated financial statements as of September 30, 2016 do not include any adjustments that might result from the outcome of this uncertainty.

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, 2015, filed with the SEC on February 25, 2016. There have been no other changes to our critical accounting policies since December 31, 2015.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2016.

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 bank checking accounts and securities held in money market mutual funds. As of September 30, 2016, we held $109.1 million in checking and U.S. Treasury based mutual funds. Our cash and cash equivalents balances 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.

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, our Chief

Executive Officer and Principal Financial Officer have concluded that as of September 30, 2016, 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

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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 Chief 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 Chief 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, 2016.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

There have been no material changes from the legal proceedings disclosed in our Form 10-K for the year ended December 31, 2015, filed on February 25, 2016.

ITEM 1a. RISK FACTORS

There have been no material changes in our risk factors since the filing on February 25, 2016 of our Form 10-K for the year ended December 31, 2015.

ITEM 2. PROPERTIES

There have been no material changes in our properties since the filing on February 25, 2016 of our Form 10-K for the year ended December 31, 2015.

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ITEM 6. EXHIBITS

(a) Exhibits

31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2016, filed on November 9, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (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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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 9, 2016 By: /s/ GARY S. JACOB
Gary S. Jacob
President, Chairman of Board, and Chief Executive Officer

Date: November 9, 2016 By: /s/ BERNARD F. DENOYER
Bernard F. Denoyer
Senior Vice President, Finance and Principal Financial Officer

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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 9, 2016 /s/ GARY S. JACOB
Gary S. Jacob
President, Chairman of Board, and Chief Executive Officer

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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 9, 2016 /s/ BERNARD F. DENOYER
Bernard F. Denoyer
Senior Vice President, Finance and Principal Financial Officer

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EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
SYNERGY PHARMACEUTICALS INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2016
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, 2016 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 9, 2016 /s/ GARY S. JACOB
Gary S. Jacob
President, Chairman of Board, and Chief Executive Officer

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EXHIBIT 32.2

CERTIFICATION OF SENIOR VICE PRESIDENT, FINANCE
SYNERGY PHARMACEUTICALS INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2016
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, 2016 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 9, 2016 /s/ BERNARD F. DENOYER
Bernard F. Denoyer
Senior Vice President, Finance and Principal Financial Officer