Table of Contents

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, 2015

☐ **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 ☒ 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 113,673,273 as of November 4, 2015.

Table of Contents

SYNERGY PHARMACEUTICALS INC.

FORM 10-Q

TABLE OF CONTENTS

		Page
PART I—FINANCIAL INFORMATION		
Item 1.	Financial Statements	
	Condensed Consolidated Balance Sheets as of September 30, 2015 (unaudited) and December 31, 2014	4
	Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2015 and 2014 (unaudited)	5
	Condensed Consolidated Statement of Changes in Stockholders' Deficit for the Nine Months Ended September 30, 2015 (unaudited)	6
	Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2015 and 2014 (unaudited)	7
	Notes to Condensed Consolidated Financial Statements (unaudited)	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	16
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 4.	Controls and Procedures	22
PART II—OTHER INFORMATION		
Item 1.	Legal Proceedings	22
Item 2.	Properties	22
Item 6.	Exhibits	23
SIGNATURES		24

Table of Contents

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, 2014 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.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 41,916	$ 146,470
Available-for-sale securities	100,085	49,897
Prepaid expenses and other current assets	1,147	3,836

Total Current Assets	143,148	200,203
Property and equipment, net	590	642
Security deposits	219	163
Total Assets	$ 143,957	$ 201,008
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 11,612	$ 13,869
Accrued expenses	3,177	1,962
Interest payable on Senior Convertible Debentures	4,969	2,500
Total Current Liabilities	19,758	18,331
Senior Convertible Notes, net of deferred financing costs of $8,276 and $12,336 as of September 30, 2015 and December 31, 2014, respectively	150,735	187,664
Derivative financial instruments, at estimated fair value-warrants	533	172
Total Liabilities	171,026	206,167
Commitments and contingencies	—	—
Stockholders' Deficit:		
Preferred stock, Authorized 20,000,000 shares and none outstanding, at September 30, 2015 and December 31, 2014	—	—
Common stock, par value of $.0001, 350,000,000 shares and 200,000,000 shares authorized at September 30, 2015 and December 31, 2014, respectively. Issued and outstanding 113,673,273 shares and 96,609,764 shares at September 30, 2015 and December 31, 2014, respectively.	11	10
Additional paid-in capital	326,858	261,716
Accumulated deficit	(353,938)	(266,885)
Total Stockholders' Deficit	(27,069)	(5,159)
Total Liabilities and Stockholders' Deficit	$ 143,957	$ 201,008

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

Table of Contents

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,	
	2015	2014	2015	2014
Revenues	$ —	$ —	$ —	$ —
Costs and Expenses:				
Research and development	20,424	20,946	58,147	58,724
Selling, General and administrative	2,728	2,506	14,727	7,963
Loss from Operations	(23,152)	(23,452)	(72,874)	(66,687)
Other Income/(Loss)				
Interest and investment income/(expense), net (includes interest expense of $2,747 and $9,885 on Senior Convertible Debentures and $1,544 and $4,060 in amortization of deferred financing costs for the three and nine months ended September 30, 2015)	(4,291)	19	(13,815)	47
State R&D tax credits	—	—	—	83
Change in fair value of derivative instruments-warrants	1,446	425	(364)	1,404
Total Other Income/(Loss)	(2,845)	444	(14,179)	1,534
Net Loss	$ (25,997)	$ (23,008)	$ (87,053)	$ (65,153)
Net Loss per Common Share, Basic and Diluted				
Net Loss per Common Share, Basic and Diluted	$ (0.23)	$ (0.24)	$ (0.85)	$ (0.70)
Weighted Average Common Shares Outstanding				
Basic and Diluted	111,328,339	94,738,048	102,838,814	93,631,115

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

Table of Contents

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

	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Deficit Accumulated	Total Stockholders' Deficit
Balance, December 31, 2014	96,609,764	$ 10	$ 261,716	$ (266,885)	$ (5,159)
Common stock issued pursuant to a controlled equity "at-the-market" sales agreement	3,435,998	—	14,672	—	14,672
Fees and expenses related to controlled equity sales	—	—	(404)	—	(404)
Common stock issued in connection with exercise of stock options	248,387	—	1,079	—	1,079
Common stock issued in connection with exercise of warrants	189,412	—	1,012	—	1,012
Shares issued in connection with conversion of Senior Convertible Debentures	13,179,712	1	40,988	—	40,989
Stock based compensation expense	—		7,724	—	7,724
Stock issued in exchange for certain intellectual property	10,000	—	71	—	71
Net loss for the period	—	—	—	(87,053)	(87,053)
Balance September 30, 2015	113,673,273	$ 11	$ 326,858	$ (353,938)	$ (27,069)

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

Table of Contents

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

	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
Cash Flows From Operating Activities:		
Net loss	$ (87,053)	$ (65,153)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	103	86
Amortization of deferred financing costs	4,060	—
Stock-based compensation expense	7,724	3,187
Value of common stock issued for patent license	71	—
Accretion of discount/premium on available for sale securities	(97)	28
Change in fair value of derivative instruments—warrants	364	(1,404)
Changes in operating assets and liabilities:		
Security deposit	(56)	(69)
Accounts payable and accrued expenses	(1,042)	3,086
Prepaid expenses and other current assets	2,781	(394)
Accrued interest expense on Senior Convertible Debentures	2,470	—
Total Adjustments	16,378	4,520
Net Cash used in Operating Activities	(70,675)	(60,633)
Cash Flows From Investing Activities:		
Net purchases of available-for-sale securities	(50,188)	30,000
Additions to property and equipment	(50)	(104)
Repayment on ContraVir loan receivable	—	455
Net Cash (used in) / provided by Investing Activities	(50,238)	30,351
Cash Flows From Financing Activities:		
Proceeds of sale of common stock	14,672	25,612
Proceeds of sale of common stock — ContraVir	—	3,224
Fees and expenses — sale of common stock	(404)	(721)

Proceeds from exercise of warrants	1,012	—
Proceeds from exercise of stock options	1,079	36
Distribution associated with ContraVir Spinoff	—	(3,230)
Net Cash provided by Financing Activities	16,359	24,921
Net decrease in cash and cash equivalents	(104,554)	(5,361)
Cash and cash equivalents at beginning of period	146,470	18,130
Cash and cash equivalents at end of period	$ 41,916	$ 12,769
Supplementary disclosure of cash flow information:		
Cash paid for interest on Senior Convertible Debentures	$ 7,416	$ —
Cash paid for taxes	$ 258	$ 55
Supplementary disclosure of non-cash investing and financing activities:		
Distribution of net assets of ContraVir	$ —	$ 84
Conversion of Senior Convertible Debentures to Synergy Common Stock	$ 40,989	$ —

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

Table of Contents

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. Our proprietary GI platform includes two fully-owned, late-stage clinical assets - plecanatide and dolcanatide. We designed both plecanatide and dolcanatide to be pharmacologically superior versions of the naturally occurring human GI peptide, uroguanylin, which is an important regulator for digestive fluid movement and gut health. Plecanatide is our first novel uroguanylin analog being developed for chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). Taken as a tablet once-a-day, plecanatide is designed to mimic the natural role of uroguanylin by working locally in the upper GI tract to activate and regulate fluid movement required for normal bowel function. In the summer of 2015, we announced positive phase 3 data from two plecanatide clinical trials for CIC. We intend to file our first new drug application (NDA) with plecanatide in the CIC indication in January 2016. Plecanatide is also being evaluated in two ongoing pivotal phase 3 clinical trials for IBS-C. We intend to file our second NDA with plecanatide in the IBS-C indication by year-end 2016. Dolcanatide is our second novel uroguanylin analog currently being evaluated in a phase 1b exploratory study for the treatment of ulcerative colitis. Dolcanatide is designed to have enhanced resistance to proteolysis in intestinal fluid relative to uroguanylin and yet still retain the same physiologic characteristics as natural uroguanylin. In November 2014, we announced positive data with dolcanatide from a phase 2 clinical trial for opioid-induced constipation (OIC).

2. Basis of Presentation

These unaudited condensed consolidated financial statements include Synergy and its wholly-owned subsidiaries: (1) Synergy Advanced Pharmaceuticals, Inc., (2) ContraVir Pharmaceuticals, Inc. (through February 18, 2014) and (3) IgX, Ltd (Ireland—inactive). These unaudited condensed consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission ("SEC") and United States generally accepted accounting principles ("GAAP") for interim reporting. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, which include only normal recurring adjustments, necessary to present fairly Synergy's interim financial information. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2014 contained in the Company's Annual Report on Form 10-K filed with the SEC on March 16, 2015. All intercompany balances and transactions have been eliminated.

3. Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2015-03 *Simplifying the Presentation of Debt Issuance Costs*, which changes the presentation of debt issuance costs in the financial statements. Under the standard, debt issuance costs are presented in the balance sheet as a direct deduction from the related debt liability rather than as an asset. In addition amortization of debt issuance costs are to be combined with interest expense in the statement of operations. The guidance is effective for annual and interim reporting periods beginning after December 15, 2015. The Company adopted this guidance during the quarter ended June 30, 2015. (See Note 6)

In August 2014, the Financial Accounting Standards Board (''FASB") issued Accounting Standards Update ("ASU") 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): *Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern* , which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Company's financial statements.

4. Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, marketable 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 marketable securities and derivative instruments which are marked to market at the end of each reporting period.

Table of Contents

The value of Senior Convertible Notes is stated at its carrying value at September 30, 2015. The Company believes it could obtain borrowings at September 30, 2015 at comparable interest rates as the November 2014 Notes, therefore, the carrying value approximates fair value.

5. 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, 2015 and December 31, 2014, the amount of cash and cash equivalents was $41.9 million and $146.5 million, respectively and consists of checking accounts and short-term 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's available-for-sale securities as of September 30, 2015 and December 31, 2014 consist of $100.1 million and $49.9 million, respectively. 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. As of September 30, 2015, there were no unrealized losses on available-for-sale securities.

The following tables summarize the available-for-sale securities held at September 30, 2015 and December 31, 2014 (in millions):

	Fair Value
September 30, 2015	
U.S. Treasury securities	$ 50.0
U.S. government sponsored entity securities	50.1
Total	$ 100.1

	Fair Value
December 31, 2014	
U.S. Treasury securities	$ 49.9
U.S. government sponsored entity securities	—
Total	$ 49.9

Table of Contents

6. 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 (including the full exercise of the over-allotment option granted to the initial purchasers to purchase an additional $25 million aggregate principal amount of 7.50% Convertible Senior Notes due 2019, (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 financing costs for three and nine months ended September 30, 2015 was $2.7 million and $9.9 million, respectively. There was no such expense in the three and nine months ended September 30, 2014. On May 1, 2015 Synergy made its first semiannual interest payment of $7.4 million. Accrued interest payable was $5.0 million and $2.5 million as of September 30, 2015 and December 31, 2014 respectively. A summary of quarterly activity is listed below (dollars in thousands):

Interest payable on Senior Convertible Debenture at 1/1/2015	$ 2,500
Accrued interest expense during the 3 months ended March 31, 2015	3,750
Interest Payable on Senior Convertible Debenture at March 31, 2015	6,250
Accrued interest expense during the 3 months ended June 30, 2015	3,388
Interest Payment on Senior Convertible Debenture at May 1, 2015	(7,416)
Interest payable on Senior Convertible Debenture as of June 30, 2015	2,222
Accrued interest expense during the 3 months ended	

September 30, 2015	2,747
Interest payable on Senior Convertible Debenture as of September 30, 2015	$ 4,969

Table of Contents

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 an initial conversion price of $3.11 per share. During the three months ended September 30, 2015, $18.8 million aggregate principal amount of the Notes was converted into 6.0 million shares of Synergy common stock. During the nine months ended September 30, 2015, $41.0 million aggregate principal amount of the Notes was converted into 13.2 million shares of Synergy common stock. This brings the principal balance of the Notes to $159.0 million at September 30, 2015 as compared to $200.0 million at December 31, 2014. All conversions were noteholder initiated with no inducement or solicitation on the part of the Company. Transaction costs associated with 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 of the debentures on a prorated basis for three and nine months ended September 30, 2015 were $1.5 million and $4.1 million, respectively. There were no such expenses in the three and nine months ended September 30, 2014. The remaining transaction costs have been presented as a reduction of the Notes in accordance with the newly adopted Accounting Standards Update ("ASU") No. 2015-03 "*Simplifying the Presentation of Debt Issuance Costs"*. A summary of quarterly activity and balances associated with the Notes and related deferred transaction costs is presented below ($ in thousands):

	Notes Balance	Transactions Costs	Notes, net of Transaction 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	—	(1,544)	1,544
Conversions	(18,776)	—	(18,776)
Balance September 30, 2015	$ 159,011	$ 8,276	$ 150,735

(1) Includes accelerated amortization of deferred financing costs attributable to conversions

7. Accounting for Shared-Based Payments

Stock Options

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

Table of Contents

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.

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:

($ in thousands)	Three Months Ended September 30, 2015	Three Months Ended September 30, 2014	Nine Months Ended September 30 2015	Nine Months Ended September 30 2014
Employees—included in research and development	592	522	1,702	1,391
Employees—included in general and administrative	(661)	400	6,022	1,796
Total stock-based compensation expense (income)	$ (69)	$ 922	$ 7,724	$ 3,187

The unrecognized compensation cost related to non-vested stock options outstanding at September 30, 2015, net of expected forfeitures, was approximately $16.5 million to be recognized over a weighted-average remaining vesting period of approximately 2.25 years. This unrecognized compensation cost does not include amounts related to 4,364,000 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, 2015	Nine Months Ended September 30, 2014
Risk-free interest rate	1.46%-2.02%	1.78%-1.98%
Dividend yield	—	—
Expected volatility	57%-80%	60%
Expected term (in years)	6 years	6 years

Table of Contents

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, 2014(1)	16,567,020	$ 0.44-17.79	$ 3.20	$ 8,949	7.29 years
Granted	3,706,112	3.33-9.33	6.70	—	
Exercised	(248,387)	3.40-6.28	4.34	—	
Forfeited	(256,789)	3.33-9.45	6.93	—	
Balance outstanding, September 30, 2015(1)	19,767,956	$ 0.44-9.12	$ 3.74	$ 36,270	7.22 years
Exercisable, at September 30, 2015	7,560,758	$ 0.44-9.12	$ 3.19	$ 16,387	5.61 years

(1) Number of options represented above includes 4,364,000 options vesting upon a change of control, granted during the years ended December 31, 2009 and 2010, at an exercise price of $0.70 per share. 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.

8. Stockholders' Deficit

On March 5, 2014, Synergy entered into Amendment No. 1 (the "Amendment") to its Controlled Equity Offering Sales ("ATM") Agreement, dated June 21, 2012 (as amended, the "Agreement"), with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which the Company may offer and sell, from time to time, through Cantor shares of the Company's common stock, par value $0.0001 per share (the "Shares"), up to an additional aggregate offering price of $50.0 million. The Company will pay Cantor a selling agent fee of up to 3.0% of the gross sales price per share sold and has agreed to provide Cantor with customary indemnification and contribution rights. As of July 10, 2015, the Form S-3 registration statement related to the Agreement expired, effectively terminating the Company's ATM program.

From January 1, 2015 through September 30, 2015, Synergy sold 3,435,998 shares of common stock, pursuant to the Agreement with Cantor, yielding gross proceeds of $14.7 million, at an average selling price of $4.27 per share. Selling agent fees related to above financings from January 1, 2015 through September 30, 2015 were $0.4 million.

From January 1, 2015 through September 30, 2015, $41.0 million aggregate principal amount of the Notes was converted into approximately 13.2 million shares of Synergy common stock.

On June 8, 2015, Synergy amended its Articles of Incorporation and increased the number of shares of its common stock authorized for issuance from 200,000,000 to 350,000,000 shares.

On July 2, 2015, Synergy filed a "shelf" registration statement on Form S-3 to offer and sell, from time to time in one or more offerings, any combination of common stock, preferred stock, debt securities, warrants to purchase common stock, preferred stock or debt securities, or any combination of the foregoing, either individually or as units comprised of one or more of the other securities, having an aggregate initial offering price not exceeding $250,000,000. The registration statement was declared effective by the SEC on July 15, 2015. This shelf registration does not currently encompass a Controlled Equity Sales (ATM) program.

From July 1, 2015 through September 30, 2015 warrants to purchase 189,412 shares of common stock were exercised, yielding proceeds to the Company of $1.0 million. In addition employee stock options to purchase 248,387 shares of common stock were exercised yielding proceeds of $1.1 million.

9. 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, and clinical insurance.

In accordance with FASB ASC Topic 730-10-55, *Research and Development*, Synergy recorded prepaid research and development costs of approximately $0.7 million as of September 30, 2015 and $3.6 million as of December 31, 2014, for nonrefundable pre-payments 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.

10. 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, 2015	Nine Months Ended September 30, 2014
Fair value of Synergy common stock	$ 5.30	$ 2.79
Expected warrant term	0.01-2.4 years	0.75-3.4 years
Risk-free interest rate	0.00%-0.78%	0.08%-1.25%
Expected volatility	80%	52%-60%
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)
12/31/2014	Balance of derivative financial instruments liability	858,469	$ 172
3/31/2015	Change in fair value of warrants during the quarter	—	268
6/30/2015	Change in fair value of warrants during the quarter	—	1,541
6/30/2015	Expiration of warrants	(324,000)	—

9/30/2015	Change in fair value of warrants during the quarter	—	(1,445)
9/30/2015	Exercise of warrants	(30,000)	—
9/30/2015	Expiration of warrants	(2,469)	(3)
9/30/2015	Balance of derivative financial instruments liability	502,000	$ 533

Table of Contents

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, 2014 and September 30, 2015:

($ 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, 2014	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, 2015
Derivative liabilities related to Warrants	$ —	$ —	$ 172	$ 172	$ —	$ —	$ 533	$ 533

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, 2015:

($ in thousands)

Description	Balance at December 31, 2014	(Gain) or loss recognized in earning from Change in Fair Value	Expiration of warrants	Balance as of September 30, 2015
Derivative liabilities related to Warrants	$ 172	$ 364	$ (3)	$ 533

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 ASC60-10-45-35 through o ASC 60-10-45-37:

	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
Stock Options	19,767,956	12,862,860
Warrants	5,068,823	5,647,203
Senior Convertible Notes	51,128,939	—
Total shares issuable upon exercise or conversion	75,965,718	18,510,063

Table of Contents

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 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, 2014 and other periodic reports filed with the United States Securities and Exchange Commission (“SEC”), on March 16, 2015. 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

We are a biopharmaceutical company focused on the development and commercialization of novel gastrointestinal (GI) therapies. Our proprietary GI platform includes two fully-owned, late-stage clinical assets - plecanatide and dolcanatide. We designed both plecanatide and dolcanatide to be pharmacologically superior versions of the naturally occurring human GI peptide, uroguanylin, which is an important regulator for digestive fluid movement and gut health. Plecanatide is our first novel uroguanylin analog being developed for chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). Taken as a tablet once-a-day, plecanatide is designed to mimic the natural role of uroguanylin by working locally in the upper GI tract to activate and regulate fluid movement required for normal bowel function. In the summer of 2015, we announced positive phase 3 data from two plecanatide clinical trials for CIC. We intend to file our first new drug application (NDA) with plecanatide in the CIC indication by January 2016. Plecanatide is also being evaluated in two ongoing pivotal phase 3 clinical trials for IBS-C. We intend to file our second NDA with plecanatide in the IBS-C indication by year-end 2016. Dolcanatide is our second novel uroguanylin analog currently being evaluated in a phase 1b exploratory study for the treatment of ulcerative colitis. Dolcanatide is designed to have enhanced resistance to proteolysis in intestinal fluid relative to uroguanylin and yet still retain the same physiologic characteristics as natural uroguanylin. In November 2014, we announced positive data with dolcanatide from our phase 2 clinical trial for opioid-induced constipation (OIC).

Recent Developments

- On July 30, 2015 we announced positive top-line results from the second of two pivotal phase 3 clinical trials evaluating the efficacy and safety of two different plecanatide treatment doses (3.0 mg and 6.0 mg), taken as a tablet once-a-day, in 1,337 adult patients with CIC. Both doses of plecanatide met the study’s primary and key secondary endpoints and demonstrated excellent tolerability profile with only 3.2% of patients in 3.0 mg and 4.5% of patients in 6.0 mg dose groups reporting diarrhea compared to 1.3% of placebo-treated patients. Discontinuations due to diarrhea were infrequent (1.1% in 3.0 mg and 1.1% in 6.0 mg dose groups compared to 0.4% in placebo.

- We are continuing efforts to prepare our first NDA for plecanatide for the CIC indication and we intend to file with the U.S. Food and Drug Administration (FDA) in January 2016.

- We are continuing to enroll CIC patients into our ongoing open-label, long-term safety trial with plecanatide. Patients who completed either of the two12-week phase 3 CIC trials were allowed to enroll and receive either 3.0 mg or 6.0 mg plecanatide, once-daily, for one year or more. The objective of this trial is to evaluate the long-term safety and tolerability of plecanatide in patients with CIC.

- We are continuing to advance our two pivotal phase 3 clinical trials with plecanatide for IBS-C. Each randomized, 12-week, double-blind placebo-controlled trial is evaluating the efficacy and safety of both 3.0 mg and 6.0 mg plecanatide treatment doses, taken as a tablet once-a-day, in approximately 1,050 adult patients with IBS-C. The IBS-C program is designed to support regulatory submission in the U.S. and we intend to file our second NDA with plecanatide in the IBS-C indication by year-end 2016.

- We are also continuing to progress our phase 1b exploratory study with dolcanatide in patients with mild-to-moderate ulcerative colitis. The double-blind, placebo-controlled, four-week study is being conducted in the United States and is expected to enroll approximately 24 patients.

- We continue to build our commercial expertise with the appointments of Timothy Callahan and Richard Daly to our Board of Directors and Troy Hamilton as our Chief Commercial Officer. This expanded leadership team is now fully engaged in building our commercial expertise with key hires and a clear and focused commercial strategy for our eventual U.S. launch with plecanatide.

Table of Contents

Plecanatide

Plecanatide is our first novel uroguanylin analog being developed for chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). Taken as a tablet once-a-day, plecanatide is designed to mimic the natural role of uroguanylin by working locally in the upper GI tract to activate and regulate fluid movement required for normal bowel function.

Plecanatide Phase 3 CIC Program

Design

The plecanatide phase 3 CIC program includes two randomized, 12-week, double-blind, placebo-controlled pivotal trials evaluating the efficacy and safety of two different plecanatide treatment doses (3.0 mg and 6.0 mg), taken as a tablet once-a-day, in patients with CIC. Both trials include a two-week pre-treatment baseline period, a 12-week treatment period, and a two-week post-treatment period. The phase 3 CIC program is designed to support regulatory submission in the U.S.

The first phase 3 CIC trial was conducted in North America and assessed 1,346 adult patients (19.2% males and 80.8% females) that were randomly assigned to take 3.0 mg or 6.0 mg plecanatide or placebo once-a-day during the 12 week treatment period (453 patients in the 3 mg dose group, 441 patients in the 6.0 mg dose group and 452 patients in the placebo group).

The second phase 3 CIC trial was conducted in the United States and assessed 1,337 adult patients (21.6% males and 78.4% females) that were randomly assigned to take 3.0 mg or 6.0 mg plecanatide or placebo once-a-day during the 12 week treatment period (443 patients in the 3.0 mg dose group, 449 patients in the 6.0 mg dose group and 445 patients in the placebo group).

Primary Endpoint

The primary endpoint for both trials is the proportion of durable overall responders (%), which is the current regulatory endpoint required for U.S. approval in CIC. The FDA has defined an overall responder as a patient who fulfills both $\geq$ 3 complete spontaneous bowel movements (CSBMs) per week plus an increase of $\geq$ 1 CSBM from baseline in the same week, for 9 out of the 12 treatment weeks. In addition, the same patient must be a weekly responder for at least 3 of the last 4 treatment weeks in order to be considered a *durable* overall responder. Plecanatide has the potential to be the first drug approved for CIC using the more stringent regulatory requirement for durability of the overall response.

Patient Population

Patients were selected using the modified Rome 3 criteria for CIC and had (1) fewer than 3 defecations per week, (2) loose stools occurring rarely without laxatives, (3) inadequate criteria for irritable bowel syndrome with constipation (IBS-C), and (4) at least two of the following applied to at least 25% of defecations: (a) straining during evacuation, (b) lumpy or hard stools, (c) sensation of anorectal obstruction or blockage. Rome 3 requires patients to fulfill the criteria over the last 3 months with symptom onset at least 6 months prior to diagnosis.

First Phase 3 CIC Trial Top-line Results

On June 17, 2015 we announced positive top-line results from the first of two pivotal phase 3 clinical trials of plecanatide in 1,346 adult patients with CIC. Preliminary analysis of the data indicates that both plecanatide 3.0 mg and 6.0 mg doses met the study's primary endpoint and demonstrated statistical significance in the proportion of patients in the intention-to-treat population who were durable overall responders compared to placebo during the 12-week treatment period (21.0% in 3.0 mg and 19.5% in 6.0 mg dose groups compared to 10.2% in placebo; $p<0.001$ for both doses). Plecanatide was safe and well tolerated at both doses; the most common adverse event was diarrhea, which occurred in 5.9% of patients in 3.0 mg and 5.5% of patients in 6.0 mg dose groups compared to 1.3% of placebo-treated patients. Stool consistency was the key secondary endpoint reported with top-line analyses; both 3.0 mg and 6.0 mg plecanatide doses showed statistically significant improvement from baseline in Bristol Stool Form Scale (BSFS) scores compared to placebo (mean increase of 1.53 in 3.0 mg and 1.52 in 6.0 mg dose groups compared to a mean increase of 0.77 in placebo; $p<0.001$ for both doses). The observed improvements began at Week 1, continued throughout the 12-week treatment period, and returned towards baseline with no indication of an exaggerated or rebound effect following discontinuation of treatment. 15 patients in the trial (1.1%) experienced serious adverse events but there was no imbalance across treatment groups in either incidences or individual serious adverse events. Overall, the rates of withdrawal from treatment because of an adverse event were low (5.1 % in 3.0 mg and 5.0% in 6.0 mg dose groups compared to 1.3% in placebo) and discontinuations due to diarrhea were infrequent (2.7% in 3.0 mg and

Table of Contents

2.4% in 6.0 mg dose groups compared to 0.4% in placebo). No clinically relevant abnormalities were observed in serum chemistries, hematology, urinalysis, ECG or vital signs measurements.

Second Phase 3 CIC Trial Top-line Results

On July 30, 2015 we announced positive top-line results from the second of two pivotal phase 3 clinical trials of plecanatide in 1,337 adult patients with CIC. Preliminary analysis of the data indicates that both plecanatide 3.0 mg and 6.0 mg doses met the study's primary endpoint and demonstrated statistical significance in the proportion of patients in the intention-to-treat population who were durable overall responders compared to placebo during the 12-week treatment period (20.1% in 3.0 mg and 20.0% in 6.0 mg dose groups compared to 12.8% in placebo; $p=0.004$ for both doses). Importantly, plecanatide was safe and well tolerated at both doses; the most common adverse event was diarrhea, which occurred in 3.2% of patients in 3.0 mg and 4.5% of patients in 6.0 mg dose groups compared

to 1.3% of placebo-treated patients. Stool consistency was the key secondary endpoint reported with top-line analyses; both 3.0 mg and 6.0 mg plecanatide doses showed statistically significant improvement from baseline in Bristol Stool Form Scale (BSFS) scores compared to placebo (mean increase of 1.49 in 3.0 mg and 1.50 in 6.0 mg dose groups compared to a mean increase of 0.87 in placebo; $p<0.001$ for both doses). The observed improvements began at Week 1, continued throughout the 12-week treatment period, and returned towards baseline with no indication of an exaggerated or rebound effect following discontinuation of treatment. 20 patients in the trial (1.4%) experienced serious adverse events but there was no imbalance across treatment groups in either incidences or individual serious adverse events. Overall, the rates of withdrawal from treatment because of an adverse event were low (3.2% in 3.0 mg and 3.8% in 6.0 mg dose groups compared to 3.0% in placebo) and discontinuations due to diarrhea were infrequent (1.1% in 3.0 mg and 1.1% in 6.0 mg dose groups compared to 0.4% in placebo). No clinically relevant abnormalities were observed in serum chemistries, hematology, urinalysis, ECG or vital signs measurements.

Long-term Safety Study

We are continuing to enroll CIC patients into our ongoing open-label, long-term safety trial with plecanatide. Patients who completed either of the two 12-week phase 3 CIC trials were allowed to enroll and receive either 3.0 mg or 6.0 mg plecanatide, once-daily, for one year or more. The objective of this trial is to evaluate the long-term safety and tolerability of plecanatide in patients with CIC.

We plan to present additional data results from both phase 3 CIC trials at appropriate scientific conferences. We intend to file our first new drug application (NDA) with plecanatide for the CIC indication in January 2016.

Plecanatide Phase 3 IBS-C Program

Design

The plecanatide phase 3 IBS-C program includes two randomized, 12-week, double-blind, placebo-controlled pivotal trials evaluating the efficacy and safety of two different plecanatide treatment doses (3.0 mg and 6.0 mg), taken as a tablet once-a-day, in patients with IBS-C. Each phase 3 trial is expected to enroll approximately 1,050 patients with IBS-C and includes a two-week pre-treatment baseline period, a 12-week treatment period, and a two-week post-treatment period. The phase 3 IBS-C program was designed to support regulatory submissions in the U.S.

Primary Endpoint

The primary efficacy endpoint for 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.

Patient Population

Patients with IBS-C are defined by Rome III Criteria as having a history of constipation and abdominal pain for at least 6 months, including hard or lumpy stools for 25% or more of defecations, loose or watery stools for 25% or less of defecations, and abdominal pain or discomfort for 3 days or more per month for the last 3 months.

We announced the start of the first phase 3 IBS-C trial with plecanatide in December 2014 and the second trial was initiated in June 2015. We intend to file our second NDA with plecanatide in the IBS-C indication by year-end 2016.

Table of Contents

Dolcanatide (formerly called SP-333)

Dolcanatide is our second novel uroguanylin analog currently being evaluated in a phase 1b exploratory study for the treatment of ulcerative colitis. Dolcanatide is designed to have enhanced resistance to proteolysis in intestinal fluid relative to uroguanylin and yet still retain the same physiologic characteristics as natural uroguanylin.

On November 19, 2014 we announced positive top-line results from a phase 2 trial assessing safety, efficacy and dose-response of three different once-daily oral dolcanatide tablets (1.0, 3.0 and 6.0 mg) compared with placebo in 289 patients with OIC. Analysis of the data indicates dolcanatide met the study's primary endpoint and demonstrated statistically significant improvement in mean change from baseline in the number of spontaneous bowel movements (SBMs) during Week 4 of the treatment period. Dolcanatide was safe and well tolerated at all doses.

We continue to advance our ongoing phase 1b exploratory study of dolcanatide in patients with mild-to-moderate ulcerative colitis. Our double-blind, placebo-controlled, four-week study is being conducted in the United States and is expected to enroll approximately 24 patients.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2015 AND SEPTEMBER 30, 2014

We had no revenues during the three months ended September 30, 2015 and three corresponding months in 2014 because we do not have any commercial biopharmaceutical products.

Research and development expenses for the three months ended September 30, 2015 ("Current Year Quarter") decreased approximately $0.5 million or 2%, to approximately $20.4 million from approximately $20.9 million for the three months ended September 30, 2014 ("Prior Year Quarter"). This decrease in research and development expenses reflects a decrease in development costs related to our plecanatide CIC clinical trials. Our plecanatide IBS-C clinical trials are ongoing, as is our NDA application preparation process for the CIC indication.

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, 2015 and 2014. 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. Indirect research and development costs include in-house staff compensation, facilities, depreciation, stock-based compensation and research and development support services not directly allocated to specific drug candidates.

	($ in thousands) Three Months Ended September 30,	
	2015	2014
Plecanatide	$ 16,828	$ 17,151
Dolcanatide (formerly SP-333)	1,879	1,874
Total direct costs	18,707	19,025
Total indirect costs	1,717	1,921
Total Research and Development	$ 20,424	$ 20,946

Selling, general and administrative expenses increased $0.2 million or 9%, to $2.7 million for the Current Quarter from approximately $2.5 million for the Prior Quarter. The increase in expenses were primarily the result of (a) higher consulting fees of $0.8 million for the Current Year Quarter, as compared to $0.4 million for the Prior Year Quarter; (b) higher regulatory fees of approximately $0.4 million during the Current Year Quarter as compared to approximately $0.1 million during the Prior Year Quarter; (c) increased compensation of $0.3 million; and (d) an increase in facilities overhead expense of $0.2 million, which were offset by $1.1 million decrease in stock based compensation.

Net loss for the Current Year Quarter was $26.0 million as compared to a net loss of a $23.0 million incurred for the Prior Year Quarter. This increase in our net loss of $3.0 million or 13% was a result of a decrease of $0.3 million in total operating expenses discussed above, plus a) interest and transaction costs amortization of $4.3 million on Senior Convertible Notes for Current Year Quarter with none in Prior Year Quarter, b) offset by a gain from changes in fair value of derivative instruments-warrants of $1.4 million during the Current Year Quarter, as compared to a gain on derivative instruments-warrants of $0.4 million during the Prior Year Quarter.

Table of Contents

NINE MONTHS ENDED SEPTEMBER 30, 2015 AND SEPTEMBER 30, 2014

We had no revenues during the nine months ended September 30, 2015 and nine corresponding months in 2014 because we do not have any commercial biopharmaceutical products.

Research and development expenses for the nine months ended September 30, 2015 ("Current Year Period") decreased approximately $0.6 million or 1% to approximately $58.1 million from approximately $58.7 million for the nine months ended September 30, 2014 ("Prior Year Period"). This decrease in research and development expenses was largely attributable to decreased clinical trials activities of our product candidate dolcanatide and offset by increased clinical activities of our product candidate plecanatide. The following table sets forth our research and development expenses directly related to our product candidates for the nine months ended September 30, 2015 and nine corresponding months in 2014. These direct expenses were 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, as follows:

	($ in thousands) Nine Months Ended September 30,	
Drug candidates	2015	2014
Plecanatide	$ 47,981	$ 44,620
Dolcanatide (formerly SP-333)	4,316	8,725
Total direct costs	52,297	53,345
Total indirect costs	5,850	5,379
Total Research and Development	$ 58,147	$ 58,724

Indirect research and development costs are related to in-house staff compensation, facilities, depreciation, stock-based compensation and research and development support services and are not directly allocated to specific drug candidates. Indirect costs were $5.9 million in the Current Year Period, as compared to $5.4 million during the Prior Year Period primarily due to higher stock based compensation expenses.

Selling, general and administrative expenses increased $6.7 million or 84%, to $14.7 million for the Current Period from approximately $8.0 million for the Prior Period. These increased expenses were primarily the result of (a) higher stock based compensation expenses of $6.0 million for the Current Year Period, as compared to $1.8 million for the Prior Year Period, (b) higher

compensation and recruiting expenses of $3.1 million in the Current Year Period as compared to approximately $2.3 million during the Prior Year Period, (c) higher consulting cost including, advisory costs associated with commercial launch planning of approximately $1.8 million in the Current Year Period as compared to approximately $0.9 million during the Prior Year Period and (d) higher regulatory expenses of $1.0 million in the Current Year Period as compared to approximately $0.5 million during the Prior Year Period.

Net loss for the Current Year Period was $87.1 million as compared to a net loss of a $65.2 million incurred for the Prior Year Period. This increase in our net loss of $21.9 million or 34% was a result of the increase in operating expenses of $6.3 million discussed above, plus a) interest and transaction costs amortization of $13.8 million on Senior Convertible Debentures for Current Year Period with none in Prior Year Period, and b) a loss from changes in fair value of derivative instruments-warrants of $0.4 million during the Current Year Period, as compared to a gain on derivative instruments-warrants of $1.4 million during the Prior Year Period.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2015, we had $41.9 million in cash and cash equivalents and $100.1 million in available for sale securities, compared to $146.5 million in cash and cash equivalents and $49.9 million in available for sale securities as of December 31, 2014. Net cash used in operating activities was $70.7 million and $60.6 million, respectively, for the nine months ended September 30, 2015 and 2014. $16.4 million and $24.9 million, respectively was provided by financing transactions, net of fees and expenses, for the nine months ended September 30, 2015 and 2014. As of September 30, 2015, we had working capital of $123.4 million, as compared to working capital of $181.9 million on December 31, 2014.

From January 1, 2015 through September 30, 2015, we sold 3,435,998 shares of common stock, pursuant to the Agreement (the Agreement, see footnote 8) with Cantor, yielding gross proceeds of $14.7 million, at an average selling price of $4.27 per share. As of July 10, 2015, the Form S-3 registration statement related to the Agreement expired.

Table of Contents

On July 2, 2015, we filed a “shelf” registration statement on Form S-3 to offer and sell, from time to time in one or more offerings, any combination of common stock, preferred stock, debt securities, warrants to purchase common stock, preferred stock or debt securities, or any combination of the foregoing, either individually or as units comprised of one or more of the other securities, having an aggregate initial offering price not exceeding $250,000,000. On July 15, 2015 the registration statement was declared effective by the SEC. This shelf registration does not currently encompass a Controlled Equity Sales (ATM) program.

From January 1, 2015 through September 30, 2015, $41.0 million aggregate principal amount of our 7.50% Convertible Senior Notes (the “Notes”) was converted into approximately 13.2 million shares of our common stock. These conversions decreased the principal amount of the Notes to $159 million as of September 30, 2015 from $200 million as of December 31, 2014. On November 1, 2015, we made our semiannual interest payment of $5.9 million, on our 7.50% Convertible Senior Notes, timely. This November 1, 2015 payment was approximately 20% less than the $7.4 million we paid on May 1, 2015, due to the decrease in principal discussed above.

From January 1, 2015 through September 30, 2015 warrants to purchase 189,412 shares of common stock were exercised, yielding proceeds to us of $1.0 million, at a weighted average exercise price of $5.34 per share. In addition employee stock options to purchase 248,387 shares of common stock were exercised, yielding proceeds of $1.1 million, at an average exercise price of $4.34 per share.

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.

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, 2014, filed with the SEC on March 16, 2015. There have been no other changes to our critical accounting policies since December 31, 2014.

In April 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2015-03 *Simplifying the Presentation of Debt Issuance Costs* , which changes the presentation of debt issuance costs in the financial statements. Under the standard, debt issuance costs are presented in the balance sheet as a direct deduction from the related debt liability rather than as an asset. In addition amortization of debt issuance costs are to be combined with interest expense in the statement of operations. The guidance is effective for annual and interim reporting periods beginning after December 15, 2015. The Company adopted this guidance during the quarter ended June 30, 2015.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2015.

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, U.S. Treasury Bills and Notes of U.S. Government Sponsored Entities. As of September 30, 2015, we held $41.9 million in checking and money market mutual funds and also held available-for-sale securities of $100.1 million in U.S. Treasury Bills and Notes of U.S. Government Sponsored Agencies. 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.

Table of Contents

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, 2015, 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 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, 2015.

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, 2014, filed on March 16, 2015.

ITEM 1a. RISK FACTORS

There have been no material changes in our risk factors since the filing on March 16, 2015 of our Form 10-K for the year ended December 31, 2014.

ITEM 2. PROPERTIES

There have been no material changes in our properties since the filing on March 16, 2015 of our Form 10-K for the year ended December 31, 2014.

Table of Contents

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, 2015, filed on November 9, 2015, 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 (iv) the Condensed Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements tagged as blocks of text.

Table of Contents

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, 2015 By: /s/ GARY S. JACOB
Gary S. Jacob
President, Chairman of Board, and Chief Executive Officer

Date: November 9, 2015 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 9, 2015

/s/ GARY S. JACOB

Gary S. Jacob

President, Chairman of Board, 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 9, 2015

/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, 2015
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, 2015 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, 2015

/s/ GARY S. JACOB
Gary S. Jacob
President, Chairman of Board, 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, 2015
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, 2015 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, 2015

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