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: June 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 112,466,896 as of August 10, 2015.

Table of Contents

SYNERGY PHARMACEUTICALS INC.

FORM 10-Q

TABLE OF CONTENTS

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)

	June 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 61,695	$ 146,470
Available-for-sale securities	99,984	49,897

Prepaid expenses and other current assets	2,287	3,836
Total Current Assets	163,966	200,203
Property and equipment, net	584	642
Security deposits	219	163
Total Assets	$ 164,769	$ 201,008
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 10,606	$ 13,869
Accrued expenses	3,934	1,962
Interest payable on Senior Convertible Debentures	2,222	2,500
Total Current Liabilities	16,762	18,331
Senior Convertible Debentures, net of deferred financing costs of $9,820 and $12,336 as of June 30, 2015 and December 31, 2014, respectively	167,967	187,664
Derivative financial instruments, at estimated fair value-warrants	1,981	172
Total Liabilities	186,710	206,167
Commitments and contingencies	—	—
Stockholders' Deficit:		
Preferred stock, Authorized 20,000,000 shares and none outstanding, at June 30, 2015 and December 31, 2014	—	—
Common stock, par value of $.0001, 350,000,000 shares and 200,000,000 shares authorized at June 30, 2015 and December 31, 2014, respectively. Issued and outstanding 107,188,192 shares and 96,609,764 shares at June 30, 2015 and December 31, 2014, respectively.	12	11
Additional paid-in capital	305,989	261,715
Accumulated deficit	(327,942)	(266,885)
Total Stockholders' Deficit	(21,941)	(5,159)
Total Liabilities and Stockholders' Deficit	$ 164,769	$ 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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenues	$ —	$ —	$ —	$ —
Costs and Expenses:				
Research and development	19,525	24,479	37,723	37,778
General and administrative	7,394	2,279	12,000	5,457
Loss from Operations	(26,919)	(26,758)	(49,723)	(43,235)
Other Income/(Loss)				
Interest and investment income/(expense), net (includes interest expense of $3,388 and $7,139 on Senior Convertible Debentures and $1,899 and $2,516 in amortization of deferred financing costs for the three and six months ended June 30, 2015)	(5,207)	(1)	(9,524)	28
State R&D tax credits	—	83	—	83
Change in fair value of derivative instruments-warrants	(1,542)	756	(1,810)	979
Total Other Income/(Loss)	(6,749)	838	(11,334)	1,090
Net Loss	$ (33,668)	$ (25,920)	$ (61,057)	$ (42,145)
Weighted Average Common Shares Outstanding				
Basic and Diluted	100,343,637	94,069,703	98,523,696	93,068,476

Net Loss per Common Share, Basic and Diluted				
Net Loss per Common Share, Basic and Diluted	$ (0.34)	$ (0.28)	$ (0.62)	$ (0.45)

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	$ 11	$ 261,715	$ (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)
Shares issued in connection with conversion of Senior Convertible Debentures	7,142,430	1	22,212	—	22,213
Stock based compensation expense	—		7,794	—	7,794
Net loss for the period	—	—	—	(61,057)	(61,057)
Balance June 30, 2015	107,188,192	$ 12	$ 305,989	$ (327,942)	$ (21,941)

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)

	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Cash Flows From Operating Activities:		
Net loss	$ (61,057)	$ (42,145)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	67	57
Amortization of deferred financing costs	2,516	—
Stock-based compensation expense	7,794	2,264
Accretion of discount/premium on available for sale securities	(87)	28
Change in fair value of derivative instruments—warrants	1,810	(979)
Changes in operating assets and liabilities:		
Security deposit	(56)	(69)
Accounts payable and accrued expenses	(1,294)	2,421
Prepaid expenses and other current assets	1,549	(1,086)
Accrued interest expense on Senior Convertible Debentures	(277)	—
Total Adjustments	12,022	2,636
Net Cash used in Operating Activities	(49,035)	(39,509)
Cash Flows From Investing Activities:		
Net purchases of available-for-sale securities	(50,000)	
Additions to property and equipment	(8)	(57)
Repayment on ContraVir loan receivable	—	455
Net Cash (used in) / provided by Investing Activities	(50,008)	398
Cash Flows From Financing Activities:		
Proceeds of sale of common stock	14,672	22,795
Proceeds of sale of common stock — ContraVir	—	3,224
Fees and expenses — sale of common stock	(404)	(644)
Proceeds from exercise of stock options	—	36

Distribution associated with ContraVir Spinoff		(3,230)
Net Cash provided by Financing Activities	14,268	22,181
Net decrease in cash and cash equivalents	(84,775)	(16,930)
Cash and cash equivalents at beginning of period	146,470	18,130
Cash and cash equivalents at end of period	$ 61,695	$ 1,200
Supplementary disclosure of cash flow information:		
Cash paid for interest on Senior Convertible Debentures	$ 7,416	—
Cash paid for taxes	$ 224	$ 30
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	$ 22,213	$ —

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 of novel therapies to treat gastrointestinal (GI) diseases and disorders. Our proprietary GI platform is based on uroguanylin, a naturally occurring human peptide that plays a key role in regulating normal GI activity. We discovered and are developing two fully-owned late-stage clinical assets, plecanatide and dolcanatide (formerly SP-333), which are both analogues of natural uroguanylin. Plecanatide is our first generation uroguanylin analogue being developed for both chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). Plecanatide is structured identical to uroguanylin with the exception of a single key amino acid substitution, resulting in improved activity but still retaining attribute of uroguanylin that are important for natural pH-regulated activity. Taken as a tablet once-a-day, plecanatide is designed to mimic the role of uroguanylin by working locally in the upper GI tract to activate and regulate fluid movement required for normal bowel function. We recently announced positive top-line data results in two phase 3 clinical trials of plecanatide in patients with CIC and we intend to file our first new drug application (NDA) with plecanatide in the CIC indication in January 2016. We are continuing to progress our two ongoing phase 3 clinical trials of plecanatide in patients with IBS-C and we intend to file our second NDA with plecanatide in the IBS-C indication in 4Q 2016. Dolcanatide is our next generation uroguanylin analogue designed to be highly stable and resistant to proteolysis in gastric and intestinal fluids but still operate in the same pH-dependent fashion as uroguanylin. Dolcanatide has successfully completed a phase 2 clinical trial in patients with opioid-induced constipation and is currently being evaluated in a phase 1b exploratory study for ulcerative colitis.

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.

The value of Senior Convertible Debentures is stated at its carrying value at June 30, 2015. The Company believes it could obtain borrowings at June 30, 2015 at comparable interest rates as the November 2014 debentures, 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 June 30, 2015 and December 31, 2014, the amount of cash and cash equivalents was $61.7 million and $146.5 million, respectively and consists of checking accounts and short-term money market mutual funds held at U.S. commercial banks.

The Company's available-for-sale securities as of June 30, 2015 and December 31, 2014 consist of approximately $100 million and $49.9 million, respectively, in U.S. Treasury securities with maturities of less than one year and have been classified and accounted for as available-for-sale. Management determines the appropriate classification of its investments at the time of purchase and reevaluates the available-for-sale designations as of each balance sheet date. As of June 30, 2015, there were no unrealized losses on available-for-sale securities.

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 for three and six months ended June 30, 2015 was $3.4 million and $7.1 million, respectively. There was no such expense in the three and six months ended June 30, 2014. On May 1, 2015 Synergy made its first semiannual interest payment of $7.4 million. Accrued interest was $2.2 million and $2.5 million as of June 30, 2015 and December 31, 2015 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

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 month of June 2015, $22.2 million aggregate principal amount was converted into approximately 7.1 million shares of Synergy common stock.

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 six months ended June 30, 2015 were $1.9 million and $2.5 million, respectively. There were no such expenses in the three and six months ended June 30, 2014. The remaining transaction costs have been presented as a reduction of the Notes in accordance with the newly adopted Accounting Standards Update ("ASU") No. 2015-03 "*Simplifying the Presentation of Debt Issuance Costs".* A summary of quarterly activity and balances associated with the Notes and related deferred transaction costs is presented below:($ 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)	—
Balance December 31, 2014	200,000	12,336	187,664
Less: amortization three months ended March 31, 2015	—	(617)	—
Balance March 31, 2015	200,000	11,719	188,281
Less: amortization three months ended June 30, 2015 (1)	—	(1,899)	—
Conversions	(22,213)	—	—
Balance June 30, 2015	$ 177,787	$ 9,820	$ 167,967

(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.

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

Table of Contents

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 follow:

	Three Months Ended June 30,		Six Months Ended June 30	
($ in thousands)	2015	2014	2015	2014
Subtotal employee stock based compensation	1,115	$ 906	2,216	$ 1,727
Subtotal non-employee stock based compensation	4,274	93	5,578	537
Total stock-based compensation expense	$ 5,389	$ 999	$ 7,794	$ 2,264

The unrecognized compensation cost related to non-vested stock options outstanding at June 30, 2015, net of expected forfeitures, was approximately $8.3 million to be recognized over a weighted-average remaining vesting period of approximately 1.7 years. This unrecognized compensation cost does not include amounts related to 4,346,000 shares of stock options which vest upon a change of control.

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

	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Risk-free interest rate	1.46%-2.35%	1.78%-1.98%
Dividend yield	—	—
Expected volatility	60%	60%

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, 2014(1)	16,567,020	$ 0.44-17.79	$ 3.20	$ 8,949	7.29 years
Granted	625,000	$ 2.94-9.33	6.54		
Forfeited	(153,631)	$ 2.94-9.45	6.26		
Balance outstanding, June 30, 2015(1)	17,038,389	$ 0.44-9.12	$ 3.30	$ 80,864	7.14 years
Exercisable, at June 30, 2015	7,703,334	$ 0.44-9.12	$ 3.20	$ 35,550	5.78 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.

Table of Contents

From January 1, 2015 through June 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 June 30, 2015 were $0.4 million.

From January 1, 2015 through June 30, 2015, $22.2 million aggregate principal amount of the Notes was converted into approximately 7.1 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.

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 $1.9 million as of June 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:

	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Fair value of Synergy common stock	$ 8.30	$ 4.07
Expected warrant term	0.25 — 2.9 years	1.0 — 3.7 years
Risk-free interest rate	0.185%-1.01%	0.11%-1.32%
Expected volatility	57%-80%	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:

Table of Contents

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	—	1,542
6/30/2015	Expiration of warrants	(324,000)	(1)
6/30/2015	Balance of derivative financial instruments liability	534,469	$ 1,981

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 June 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 June 30, 2015
Derivative liabilities related to Warrants	$ —	$ —	$ 172	$ 172	$ —	$ —	$ 1,981	$ 1,981

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the six months ended June 30, 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 June 30, 2015
Derivative liabilities related to Warrants	$ 172	$ 1,810	$ (1)	$ 1,981

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. For the three and six months ended June 30, 2015 and 2014 the effect of 17,041,722 and 12,862,860, respectively outstanding stock options, at the end of each period, were excluded from the calculation of diluted loss per share because the effect was antidilutive. For the three months and six months ended June 30, 2015 and 2014, the effect of 5,246,703 and 5,647,203, respectively outstanding warrants (which include warrants accounted for as equity and derivative liabilities) were excluded from the calculation of diluted loss per share because the effect was antidilutive.

Table of Contents

12. Subsequent Events

From July 1, 2015 through August 10, 2015, approximately $16 million aggregate principal amount of the Notes was converted into approximately 5 million shares of Synergy common stock. These conversions decreased the principal amount of the Notes to approximately $162 million as of August 10, 2015 from approximately $178 million as of June 30, 2015.

From July 1, 2015 through August 10, 2015 warrants to purchase 189,412 shares of common stock were exercised, yielding proceeds to the Company of $1,011,343. In addition employee stock options to purchase 62,965 shares of common stock were exercised yielding proceeds of $353,234.

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 of novel therapies to treat gastrointestinal (GI) diseases and disorders. Our proprietary GI platform is based on uroguanylin, a naturally occurring human peptide that plays a key role in regulating normal GI activity. We discovered and are developing two fully-owned late-stage clinical assets, plecanatide and dolcanatide (formerly SP-333), which are both analogues of natural uroguanylin. Plecanatide is our first generation uroguanylin analogue being developed for both chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). Plecanatide is structured identical to uroguanylin with the exception of a single key amino acid substitution, resulting in improved activity but still retaining attributes of uroguanylin that are important for natural pH-regulated activity. Taken as a tablet once-a-day, plecanatide is designed to mimic the role of uroguanylin by working locally in the upper GI tract to activate and regulate fluid movement required for normal bowel function. We recently announced positive top-line data results in two phase 3 clinical trials of plecanatide in patients with CIC and we intend to file our first new drug application (NDA) with plecanatide in the CIC indication in January 2016. We are continuing to progress our two ongoing phase 3 clinical trials of plecanatide in patients with IBS-C and we intend to file our second NDA with plecanatide in the IBS-C indication in the fourth quarter of 2016. Dolcanatide is our next generation uroguanylin analogue designed to be highly stable and resistant to proteolysis in gastric and intestinal fluids but still operate in the same pH-dependent fashion as uroguanylin. Dolcanatide has successfully completed a phase 2 clinical trial in patients with opioid-induced constipation and is currently being evaluated in a phase 1b exploratory study for ulcerative colitis.

Recent Developments

On June 17, 2015 we announced positive top-line results from the first 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 1,346 adult patients with chronic idiopathic constipation (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). Notably, 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 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.

Table of Contents

On June 23, 2015 we announced the initiation of 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 patients with irritable bowel syndrome with constipation (IBS-C). The phase 3 IBS-C program includes two randomized, 12-week, double-blind, placebo-controlled pivotal trials conducted in the United States and each trial is expected to enroll approximately 1050 adult patients with IBS-C. 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. 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 the abdominal pain intensity reduction and stool frequency increase criteria in the same week) for at least 6 of the 12 treatment weeks.

On July 1, 2015, we announced the appointments of Timothy Callahan and Richard Daly to the Synergy Board of Directors. Both Mr. Callahan and Mr. Daly have direct experience in primary care and gastrointestinal markets and have led large organizational change and successful business growth, in a variety of areas, including all aspects of commercial, acquisitions, partnerships and product launches.

On July 8, 2015, we announced the appointment of Troy Hamilton as Chief Commercial Officer. Mr. Hamilton will be responsible for Synergy's overall commercial strategy and execution, and will implement marketing, sales, and commercial operations and infrastructure for the U.S. launch of plecanatide. Mr. Hamilton has over 19 years of experience in the pharmaceutical industry, with an emphasis on general management, P&L responsibility, commercialization, partnerships, acquisitions, and global product launches in the gastroenterology and primary care markets. Prior to joining Synergy, Mr. Hamilton held multiple commercial leadership roles over a nine year period within Shire Pharmaceuticals' GI Business Unit.

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 1337 adult patients with chronic idiopathic constipation (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.

Plecanatide

Plecanatide is a synthetic analogue of uroguanylin, a naturally occurring human peptide that plays a key role in regulating normal GI activity. 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.

Constipation can be the by-product of other disease states, as well as due to certain drug therapies (e.g., narcotics) or anatomic anomalies. CIC, in contrast, is defined as having no identifiable causes. Patients diagnosed with CIC have experienced symptoms for 6

months or more, and commonly have less than 3 bowel movements a week and often less than one. They suffer from very hard stool and abdominal symptoms such as bloating, discomfort, gas, and a feeling of incomplete evacuation. The prescription drugs currently available have significant side effects and are generally only effective in less than half of patients treated. Plecanatide offers hope for a more effective and tolerable treatment that can relieve the significant burden which CIC places on patients' lives.

In addition to CIC, plecanatide is also being developed to treat IBS-C. IBS is generally characterized by symptoms of abdominal pain or discomfort such as cramping, bloating, gas, and constipation or diarrhea or both. IBS is one of the most commonly diagnosed GI illnesses in the United States. As many as 14% of, or up to 42 million adult Americans suffer from IBS. Depending on the criteria used to define bowel habit predominance, it is estimated that 16% to 30% of IBS patients (approximately 7 to 13 million) experience symptoms consistent with the IBS-C subtype. IBS profoundly impacts patients' physical, social and working lives. A quarter of patients describe their abdominal pain as constant. IBS is one of the most common reasons for work or school absenteeism, second only to the common cold. Fewer than 1 in 10 patients say they are satisfied with available IBS treatments. Healthcare systems spend billions of dollars annually to diagnose and treat this disorder. In the U.S., the annual cost of IBS treatment is estimated to be as much as $8 billion in direct medical costs, including doctor and hospital visits and diagnostic procedures. IBS-C is the subtype of IBS that plecanatide is being developed to treat.

Table of Contents

Plecanatide Phase 3 CIC Program

Design

The plecanatide phase 3 CIC program included two randomized, 12-week, double-blind, placebo-controlled pivotal trials that evaluated 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 included a two-week pre-treatment baseline period, a 12-week treatment period, and a two-week post-treatment period. The phase 3 CIC program was 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 1337 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 was the proportion of durable overall responders (%), which is the current regulatory endpoint required for U.S. approval in CIC. The FDA has defined a weekly responder 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 for at least 3 of the last 4 treatment weeks in order to be considered a *durable* overall responder. Plecanatide would be the first drug approved for CIC using the more stringent regulatory requirement for durability in the response.

Patient Population

Patients were selected using Rome 3 criteria modified 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 for 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

Table of Contents

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 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 1337 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.

We plan to present additional data results from both phase 3 CIC trials at appropriate scientific conferences. The company plans to file its first new drug application (NDA) with plecanatide in 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 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 1050 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 the abdominal pain intensity reduction and stool frequency increase criteria in the same week) for at least 6 of the 12 treatment weeks.

Table of Contents

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.

Synergy 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 in the fourth quarter of 2016.

Dolcanatide (formerly called SP-333)

Dolcanatide is our next generation uroguanylin analogue currently being evaluated for the treatment of ulcerative colitis.. Dolcanatide is designed to be highly stable and resistant to proteolysis in gastric and intestinal fluids but still operate in the same pH-regulated fashion as natural uroguanylin. Deficiency of uroguanylin is thought to be one of the primary reasons for the formation of polyps that can lead to colon cancer, as well as debilitating and difficult-to-treat GI inflammatory disorders such as ulcerative colitis and Crohn's disease.

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. Preliminary 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 JUNE 30, 2015 AND JUNE 30, 2014

We had no revenues during the three months ended June 30, 2015 and 2014 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the three months ended June 30, 2015 ("Current Year Quarter") decreased approximately $5 million or 20%, to approximately $19.5 million from approximately $24.5 million for the three months ended June 30, 2014 ("Prior Year Quarter"). This decrease in research and development expenses was largely attributable to completing clinical trials of our plecanatide and dolcanatide product candidates. The following table sets forth our research and development expenses directly related to our product candidates for the three months ended June 30, 2015 and 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) Three Months Ended June 30,	
Drug candidates	**2015**	**2014**
Plecanatide	$ 16,444	$ 18,741
Dolcanatide (formerly SP-333)	843	3,913
Total direct costs	17,287	22,654
Total indirect costs	2,238	1,825
Total Research and Development	$ 19,525	$ 24,479

Indirect research and development costs related to 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 $2.2 million in the Current Year Quarter, as compared to $1.8 million during the Prior Year Quarter primarily due to higher stock based compensation expenses.

General and administrative expenses increased $5.1 million or 224%, to $7.4 million for the Current Quarter from approximately $2.3 million for the Prior Quarter. These increased expenses were primarily the result of (a) higher stock based compensation of $5.4 million for the Current Year Quarter, as compared to $1 million for the Prior Year Quarter. (b) higher facilities and advisory fees of approximately $1.4 million during the Current Year Quarter as compared to approximately $1 million during the Prior Year Quarter.

Table of Contents

Net loss for the Current Year Quarter was $33.7million as compared to a net loss of a $25.9 million incurred for the Prior Year Quarter. This increase in our net loss of $7.8 million or 30% was a result of the changes in operating expenses discussed above, plus a) interest and transaction costs amortization of $5.2 million on Senior Convertible Debentures for Current Year Quarter with none in Prior Year Quarter, b) and a loss from changes in fair value of derivative instruments-warrants of $1.5 million during the Current Year Quarter, as compared to a gain on derivative instruments-warrants of $0.8 million during the Prior Year Quarter.

SIX MONTHS ENDED JUNE 30, 2015 AND JUNE 30, 2014

We had no revenues during the six months ended June 30, 2015 and 2014 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the six months ended June 30, 2015 ("Current Year Period") decreased approximately $0.1 million to approximately $37.7 million from approximately $37.8 million for the six months ended June 30, 2014 ("Prior Year Period"). This decrease in research and development expenses was largely attributable to decreased completing 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 six months ended June 30, 2015 and 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) Six Months Ended June 30,	
Drug candidates	**2015**	**2014**
Plecanatide	$ 30,947	$ 27,739
Dolcanatide (formerly SP-333)	2,436	6,581
Total direct costs	33,383	34,320
Total indirect costs	4,340	3,458
Total Research and Development	$ 37,723	$ 37,778

Indirect research and development costs related to 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 $4.3 million in the Current Year Period, as compared to $3.5 million during the Prior Year Period primarily due to higher stock based compensation expenses.

General and administrative expenses increased $6.5 million or 118%, to $12 million for the Current Period from approximately $5.5 million for the Prior Period. These increased expenses were primarily the result of (a) higher stock based compensation expenses of $7.8 million for the Current Year Period, as compared to $2.3 million for the Prior Year Period. (b) higher facilities and advisory fees of approximately $2.9 million Current Year Period as compared to approximately $1.9 million during the Prior Year Period.

Net loss for the Current Year Period was $61.1 million as compared to a net loss of a $42.1 million incurred for the Prior Year Period. This increase in our net loss of $19 million or 45% was a result of the changes in operating expenses discussed above, plus a) interest and transaction costs amortization of $9.5 million on Senior Convertible Debentures for Current Year Period with none in Prior Year Period, b) and a loss from changes in fair value of derivative instruments-warrants of $1.8 million during the Current Year Period, as compared to a gain on derivative instruments-warrants of $1 million during the Prior Year Period.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2015, we had $61.7 million in cash and cash equivalents and $100 million in available for sale securities, compared to $146.5 million in cash and cash equivalents and $50 million in available for sale securities as of December 31, 2014. Net cash used in operating activities was $49.0 million and 39.5 million, respectively, for the six months ended June 30, 2015 and 2014. $14.3 million and $22.2 million, respectively was provided by financing transactions, net of fees and expenses, for the six months ended June 30, 2015 and 2014. As of June 30, 2015, we had working capital of $147 million, as compared to working capital of $181.8 million on December 31, 2014.

From January 1, 2015 through June 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. Selling agent fees related to above financings from January 1, 2015 through June 30, 2015 were $0.4 million. As of July 10, 2015, the Form S-3 registration statement related to the Agreement expired.

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

Table of Contents

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.

On May 1, 2015, we made our first semiannual interest payment of $7.4 million, on our 7.50% Convertible Senior Notes, interest payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2015. The May 1, 2015 payment was slightly less than a full six months (178 days) because the Notes were issued November 3, 2014.

From January 1, 2015 through June 30, 2015, $22.2 million aggregate principal amount was converted into approximately 7.1 million shares of our common stock. From July 1, 2015 through August 10, 2015, approximately $16 million aggregate principal amount of the Notes was converted into approximately 5 million shares of Synergy common stock. These conversions decreased the principal amount of the Notes to approximately $162 million as of August 10, 2015 from approximately $178 million as of June 30, 2015.

From July 1, 2015 through August 10, 2015 warrants to purchase 189,412 shares of common stock were exercised, yielding proceeds to the Company of $1,011,343. In addition employee stock options to purchase 62,965 shares of common stock were exercised yielding proceeds of $353,234.

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 will 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 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 its self 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 June 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 securities held in money market mutual funds, U.S. Treasury Bills, U.S. Government Agency Notes and Bonds, and the FDIC insurance limit on our bank balances. As of June 30, 2015, we held approximately $61.7 million in checking and money market mutual funds and available-for-sale securities of $100 million in U.S. Treasury securities and U.S. Government Agency Notes. 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 June 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

Table of Contents

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 June 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 June 30, 2015, filed on August 10, 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: August 10, 2015

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

Date: August 10, 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: August 10, 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: August 10, 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 JUNE 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 June 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: August 10, 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 JUNE 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 June 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: August 10, 2015

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