

SYNERGY PHARMACEUTICALS, INC.

Form 10-Q

November 10, 2014

[Table of Contents](#)

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: SEPTEMBER 30, 2014

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

For the transition period from _____ to _____

Commission File Number: 333-131722

SYNERGY PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

33-0505269

(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 96,609,764 as of November 10, 2014.

Table of Contents

SYNERGY PHARMACEUTICALS INC.

FORM 10-Q

TABLE OF CONTENTS

	Page
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	
Financial Statements	4
Condensed Consolidated Balance Sheets as of September 30, 2014 (unaudited) and December 31, 2013	4
Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2014 and 2013 (unaudited)	5
Condensed Consolidated Statement of Changes in Stockholders' Equity for the nine months ended September 30, 2014 (unaudited)	6
Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2014 and 2013 (unaudited)	7
Notes to Condensed Consolidated Financial Statements (unaudited)	8
Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Quantitative and Qualitative Disclosures About Market Risk	21
Controls and Procedures	21
<u>Item 2.</u>	
<u>Item 3.</u>	
<u>Item 4.</u>	
<u>PART II OTHER INFORMATION</u>	
<u>Item 1.</u>	
Legal Proceedings	22
<u>Item 2.</u>	
Properties	26
<u>Item 6.</u>	
Exhibits	27
<u>SIGNATURES</u>	

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. 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, 2013 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, 2014	December 31, 2013
	(unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 12,769	\$ 18,130
Available-for-sale securities	19,999	50,027
Prepaid expenses and other current assets	4,106	3,718
Total Current Assets	36,874	71,875
Property and equipment, net	607	589
Security deposits	163	94
Total Assets	\$ 37,644	\$ 72,558
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	\$ 15,246	\$ 13,542
Accrued expenses	3,355	2,134
Total Current Liabilities	18,601	15,676
Derivative financial instruments, at estimated fair value-warrants	130	1,534
Total Liabilities	18,731	17,210
Stockholders' Equity:		
Preferred stock, Authorized 20,000,000 shares, at September 30, 2014 and December 31, 2013, none outstanding		
Common stock, par value of \$.0001 authorized 200,000,000 shares at September 30, 2014 and December 31, 2013. Issued and outstanding 94,796,244 and 90,182,115 shares at September 30, 2014 and December 31, 2013, respectively.	10	10
Additional paid-in capital	255,233	226,515
Accumulated deficit	(236,330)	(171,177)
Total Stockholders' Equity	18,913	55,348
Total Liabilities and Stockholders' Equity	\$ 37,644	\$ 72,558

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,	
	2014	2013	2014	2013
Revenues	\$	\$	\$	\$
Costs and Expenses:				
Research and development	20,946	10,782	58,724	34,181
General and administrative	2,506	2,692	7,963	8,773
Loss from Operations	(23,452)	(13,474)	(66,687)	(42,954)
Other Income/(Loss)				
Interest and investment income -net	19	14	47	48
State R&D tax credits			83	
Change in fair value of derivative instruments-warrants	425	(77)	1,404	633
Total Other Income	444	(63)	1,534	681
Net Loss	\$ (23,008)	\$ (13,537)	\$ (65,153)	\$ (42,273)
<i>Weighted Average Common Shares Outstanding</i>				
Basic and Diluted	94,738,048	90,182,115	93,631,115	83,548,398
<i>Net Loss per Common Share, Basic and Diluted</i>				
Net Loss per Common Share, Basic and Diluted	\$ (0.24)	\$ (0.15)	\$ (0.70)	\$ (0.51)

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

[Table of Contents](#)

SYNERGY PHARMACEUTICALS INC.

(Unaudited)

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Accumulated Deficit	Non-Controlling Interest	Total Stockholders Equity
Balance, January 1, 2014	90,182,115	\$ 10	\$ 226,515	\$ (171,177)		\$ 55,348
Common stock issued pursuant to a controlled equity at-the-market sales agreement	4,604,130		25,612			25,612
Fees and expenses related to controlled equity sales			(706)			(706)
Stock based compensation expense			3,187			3,187
Exercise of stock options	9,999		36			36
Private placement of ContraVir common stock			3,224			3,224
Fees and expenses associated with ContraVir Private Placement			(15)			(15)
Fair value of ContraVir warrants issued in connection with private placement			(880)			(880)
Noncontrolling interest of ContraVir					(1,622)	(1,622)
Distribution of ContraVir common stock to Synergy shareholders			(1,740)			(1,740)
Elimination of noncontrolling interest of ContraVir upon distribution					1,622	1,622
Net loss for the period				(65,153)		(65,153)
Balance, September 30, 2014	94,796,244	\$ 10	\$ 255,233	\$ (236,330)	\$	\$ 18,913

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

Table of Contents

SYNERGY PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Cash Flows From Operating Activities:		
Net loss	\$ (65,153)	\$ (42,273)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	86	28
Stock-based compensation expense	3,187	3,258
Accretion of discount/premium on investment securities	28	45
Change in fair value of derivative instruments-warrants	(1,404)	(633)
Changes in operating assets and liabilities:		
Security deposit	(69)	
Accounts payable and accrued expenses	3,086	4,575
Prepaid expenses and other current assets	(394)	(3,697)
Total Adjustments	4,520	3,576
Net Cash Used in Operating Activities	(60,633)	(38,697)
Cash Flows From Investing Activities:		
Loans to related parties		(270)
Net proceeds/ (purchases) of available-for-sale securities	30,000	(50,000)
Additions to property and equipment	(104)	(615)
Repayment on ContraVir loan receivable	455	
Net Cash Provided by /(Used in) Investing Activities	30,351	(50,885)
Cash Flows From Financing Activities:		
Issuance of common stock pursuant to controlled equity sales agreement	25,612	94,734
Issuance of common stock of ContraVir	3,224	
Fees and expenses related to equity issuances	(721)	(5,623)
Proceeds from exercise of stock options	36	119
Distribution of cash associated with ContraVir Spinoff	(3,230)	
Net Cash Provided by Financing Activities	24,921	89,230
Net decrease in cash and cash equivalents	(5,361)	(352)
Cash and cash equivalents at beginning of period	18,130	12,416
Cash and cash equivalents at end of period	\$ 12,769	\$ 12,064
Supplementary disclosure of cash flow information:		
Cash paid for taxes	\$ 55	\$ 37
Supplementary disclosure of non-cash investing and financing activities:		
Value of warrants classified as derivative liability-net	\$	\$ (3,575)
Recapitalization of Synergy	\$	\$ 4,904
Distribution of net assets of ContraVir	\$ 84	\$

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 (Synergy or the Company) is a biopharmaceutical company focused on the development of novel therapies based on the naturally occurring human hormone, uroguanylin, to treat GI diseases and disorders. Synergy has created two unique analogs of uroguanylin, plecanatide and SP-333, designed to mimic the natural hormone's activity on the intestinal guanylate cyclase-C (GC-C) receptor and target a variety of GI conditions. Plecanatide is currently in two pivotal phase 3 trials for chronic idiopathic constipation (CIC) and recently reached the halfway mark for patient enrollment in the first CIC registration trial. Synergy plans to release topline data from the first CIC registration trial in the second quarter of 2015. In April 2014, the Company announced positive top-line data results with plecanatide in a phase 2b study for irritable bowel syndrome with constipation (IBS-C). Synergy plans to initiate its pivotal phase 3 IBS-C clinical development program with plecanatide in the fourth quarter of this year.

SP-333 is Synergy's next-generation uroguanylin analog in development for the treatment of opioid-induced constipation (OIC) and mild-to-moderate ulcerative colitis. SP-333 is designed to be a highly potent and stable version of the naturally occurring gastrointestinal (GI) hormone, uroguanylin, and resistant to proteolysis in gastric intestinal fluids. SP-333 has completed phase 1 single and multiple ascending dose studies in healthy volunteers and is currently in a phase 2 clinical trial for OIC. Synergy is also developing a unique formulation of SP-333 for treating GI inflammation in patients with ulcerative colitis.

Recent Developments

On November 3, 2014 Synergy announced the closing of 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 are unsecured, senior obligations of Synergy and bear interest at a rate of 7.50% per year, payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2015. The notes will mature on November 1, 2019, unless earlier purchased or converted. The holders of the notes have the ability to require the Company to repurchase the notes in whole or in part for cash in the event of a fundamental change. In such case, the repurchase price would generally be 100% of the principal amount of the notes plus any accrued and unpaid interest. The notes are convertible, at any time, into shares of the Company'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. The net proceeds from this offering were approximately \$187.3 million, after deducting estimated expenses and the initial purchasers' discount.

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, 2013 contained in the Company's Annual Report on Form 10-K filed with the Securities Exchange Commission (SEC) on March 17, 2014. All intercompany balances and transactions have been eliminated.

On February 18, 2014, Synergy completed the distribution of ContraVir common stock (its previous wholly-owned subsidiary), to the Company's stockholders on a pro rata basis with a stock dividend of .0986 ContraVir shares for each Synergy common stock share held as of the record date of February 6, 2014. Synergy accounted for this distribution according to FASB ASC Topic 505-60, *Spinoffs and reverse spinoffs* by eliminating ContraVir's net assets of approximately \$1.7 million, with a corresponding decrease in additional paid in capital and eliminating the non-controlling interest of \$1.6 million. The spin-off of ContraVir's operation had an immaterial effect on Synergy's financial statements.

3. Recent Accounting Pronouncements

On June 13, 2014, the FASB issued ASU 2014-101(Elimination of Certain Financial Reporting Requirements, including an Amendment to Variable Interest Entities Guidance in ASC Topic 810, Consolidation) to eliminate the concept of a development stage entity (DSE) from U.S. GAAP. This change rescinds certain financial reporting requirements that have historically applied to DSEs and is intended to result in cost-savings for affected entities, such as certain start-up or research and development entities. In addition, ASU 2014-10 introduces new disclosure requirements about the reporting entity's risks and uncertainties. ASU 2014-101 is effective prospectively for fiscal

Table of Contents

years, and interim periods within those years, beginning after December 15, 2014, with an option for early adoption. Synergy elected early adoption as of June 30, 2014 and does not believe the adoption of the standard had a material impact on its financial position, results of operations or related financial statement disclosures.

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, available-for-sale securities, accounts payable and derivative instruments. These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short term nature, except available-for-sale securities and derivative instruments which are marked to market at the end of each reporting period. (footnote 5 and footnote 9)

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, 2014, the amount of cash and cash equivalents was \$12.8 million and consists of checking accounts and short-term money market funds held at U.S. commercial banks. As of December 31, 2013, the amount of cash and cash equivalents was approximately \$18.1 million and consisted of checking accounts and short-term money market funds with U.S. commercial banks. At any point in time, the Company's balance of cash and cash equivalents may exceed federally insured limits.

The Company's available-for-sale securities as of September 30, 2014 and December 31, 2013 consist of approximately \$20 million and \$50 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 September 30, 2014, gross unrealized losses were not material. The Company recognized no net realized gains or losses for the three and nine months ended September 30, 2014. The Company considers the declines in market value of its marketable securities investment portfolio to be temporary in nature. Fair values were determined for each individual security in the investment portfolio. When evaluating the investments for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, and the Company's intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment's amortized cost basis. During the three and nine months ended September 30, 2014 and the year ended December 31, 2013, the Company did not recognize any impairment charges. As of September 30, 2014 and December 31, 2013, the Company did not consider any of its investments to be other-than-temporarily impaired.

6. Accounting for Shared-Based Payments

Stock Options

ASC Topic 718 *Compensation - Stock Compensation* requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. ASC Topic 718 did not change the way Synergy accounts for non-employee stock-based compensation. Synergy continues to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 *Equity -Based Payment to Non-Employees* and accordingly the value of the stock compensation to non-employees is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly the fair value of these options is being marked to market quarterly until the measurement date is determined.

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

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

Table of Contents

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 January 17, 2013, 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 7,500,000 to 15,000,000.

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

(\$ in thousands)	Three Months Ended September 30,		Nine Months Ended September 30	
	2014	2013	2014	2013
Research and development	\$ 522	\$ 391	\$ 1,391	\$ 1,082
General and administrative	400	699	1,796	2,176
Total stock-based compensation expense	\$ 922	\$ 1,090	\$ 3,187	\$ 3,258

The unrecognized compensation cost related to non-vested stock options outstanding at September 30, 2014, net of expected forfeitures, was approximately \$6.2 million to be recognized over a weighted-average remaining vesting period of approximately 1.6 years. This unrecognized compensation cost does not include amounts related to 4,364,000 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.

	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Risk-free interest rate	1.78%-2.30%	0.41% 2.64%
Dividend yield		
Expected volatility	52%-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, 2013(1)	11,324,049	\$ 0.44-20.01	\$ 3.31	\$ 37,521	6.94 years
Granted	1,664,000	\$ 3.70-5.97	\$ 4.63		
Exercised	(9,999)	\$ 3.40-3.95	\$ 3.58	\$ 23	
Forfeited	(110,190)	\$ 8.34-20.01	\$ 17.51		
Balance outstanding, September 30, 2014(1)	12,867,860	\$ 0.44-13.90	\$ 3.36	\$ 7,555	6.69 years

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

Exercisable, at September 30, 2014	5,880,483	\$	0.44-13.90	\$	2.96	\$	4,552	5.91 years
------------------------------------	-----------	----	------------	----	------	----	-------	------------

(1) Number of options represented above includes 4,364,000 options vesting upon 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.

7. Stockholders' Equity

On March 5, 2014, Synergy entered into Amendment No. 1 (the "Amendment") to its Controlled Equity Offering Sales 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 intends to use the net proceeds of this offering to fund its research and development activities, including further clinical development of plecanatide and SP-333, and for working capital and other general corporate purposes, and possible acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated.

Under the Agreement, Cantor may sell the Shares by methods deemed to be an at-the-market offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on The NASDAQ Global

Table of Contents

Select Market, on any other existing trading market for the Shares or to or through a market maker. In addition, under the Agreement, Cantor may sell the Shares by any other method permitted by law, including in privately negotiated transactions. Subject to the terms and conditions of the Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The NASDAQ Global Select Market, to sell the Shares from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose).

Synergy is not obligated to make any sales of the Shares under the Agreement. The offering of Shares pursuant to the Agreement will terminate upon the earlier of (1) the sale of all of the Shares subject to the Agreement or (2) the termination of the Agreement by Cantor or the Company. The Company will pay Cantor a commission 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.

From January 1, 2014 through September 30, 2014, Synergy sold 4,604,130 shares of common stock, pursuant to the original and the Amendment agreement with Cantor, yielding gross proceeds of \$25.6 million, at an average selling price of \$5.56 per share. Selling agent fees related to above financings from January 1, 2014 through September 30, 2014 were \$706,340.

Proceeds from exercise of stock options were \$36,000 from January 1, 2014 through September 30, 2014.

ContraVir

Private Placement

On February 4, 2014, Synergy's wholly owned subsidiary, ContraVir Pharmaceuticals, Inc. (ContraVir) entered into a securities purchase agreement with accredited investors to sell securities and raise gross proceeds of approximately \$3.2 million in a private placement and incurred expenses of \$15,000 related to this placement. ContraVir sold 9,485,294 units to the investors with each unit consisting of one share of ContraVir's common stock and one warrant to purchase an additional one half share of ContraVir's common stock. The purchase price paid by the investors was \$0.34 for each unit. The 4.7 million warrants expire after six years and are exercisable at \$0.37 per share. Based upon the ContraVir's analysis of the criteria contained in ASC Topic 815-40, Derivatives and Hedging Contracts in Entity's Own Equity ContraVir recorded approximately \$0.88 million of derivative liability on the warrants issued in connection with this transaction.

Spin-off

On February 18, 2014, Synergy completed the distribution of the ContraVir common stock (its previous wholly-owned subsidiary) to Synergy's stockholders on a pro rata basis with a stock dividend of .0986 ContraVir shares for each Synergy common stock share held as of the record date of February 6, 2014.

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

Synergy accounted for this distribution according to FASB ASC Topic 505-60, *Spinoffs and reverse spinoffs* by eliminating ContraVir's net assets of approximately \$1.7 million, with a corresponding decrease in additional paid in capital and the non-controlling interest of \$1.6 million.

Net assets of ContraVir eliminated in connection with this spin-off was as follows:

(\$ in thousands)	Balance February 18, 2014 (unaudited)
Assets	
Cash	\$ 3,230
Prepaid expense	6
Total assets	3,236
Accounts payable and other liabilities	(107)
Note Payable to Synergy	(455)
Due to Synergy	(54)
Derivative financial instruments, at estimated fair value-warrants	(880)
Total Liabilities	(1,496)
Net assets	\$ 1,740

As a result of the ContraVir distribution, an adjustment was made to the exercise price of all outstanding Synergy warrants in accordance with their terms. Accordingly the exercise price decreased approximately \$0.011 per share on the record date. As of September 30, 2014, there were 5,647,203 Synergy non-public warrants outstanding with a weighted average exercise price of \$5.37 per share pre-distribution and \$5.359 per share as adjusted. The spin-off of ContraVir's operation had an immaterial effect on Synergy's financial statements.

Table of Contents

Loan and Security Agreement

On June 5, 2013, ContraVir entered into a Loan and Security Agreement with Synergy pursuant to which Synergy agreed to lend ContraVir up to five hundred thousand dollars (\$500,000) for working capital purposes (the "Loan Agreement"). Also on June 5, 2013, August 29, 2013, October 18, 2013 and January 9, 2014, pursuant to the Loan Agreement, Synergy made an advance to ContraVir of \$100,000, \$100,000, \$150,000 and \$100,000, respectively, under a promissory note (the "Note"). The Note bears interest at six percent (6%) per annum. In connection with the Loan Agreement ContraVir granted Synergy a security interest in all of its assets, including its intellectual property, until the Note is repaid in full. On November 18, 2013, ContraVir entered into an amendment to the Loan Agreement with Synergy pursuant to which Synergy agreed to increase the aggregate amount available to ContraVir under the Loan Agreement from five hundred thousand dollars (\$500,000) to one million dollars (\$1,000,000). On March 27, 2014, ContraVir paid \$461,236 to Synergy in full repayment of the advance, including accrued but unpaid interest thereon.

Shared Services Agreement

On July 8, 2013, ContraVir entered into a Shared Services Agreement, as amended and restated August 5, 2013, with Synergy, effective May 16, 2013. Under the Shared Services Agreement, Synergy provided and/or made available to ContraVir various administrative, financial (accounting), insurance, facility, information technology, and other services. In consideration for such services, ContraVir paid fees to Synergy sufficient to allow Synergy to recover all of its direct and indirect costs incurred in providing those services. Effective April 1, 2014, Synergy terminated the shared services agreement with ContraVir.

8. Research and Development Expense

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

In accordance with FASB ASC Topic 730-10-55, *Research and Development*, Synergy recorded prepaid research and development costs of approximately \$3.6 million as of September 30, 2014 and December 31, 2013 respectively, 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.

9. Derivative Financial Instruments

Synergy Derivative Financial Instruments

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

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 were:

	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Fair value of Synergy common stock	\$ 2.79	\$ 4.57
Expected warrant term	0.75-3.4 years	1.8-4.4 years
Risk-free interest rate	0.08%-1.25%	0.33%-1.39%
Expected volatility	52% - 60%	60%
Dividend yield		

Fair value of stock is the closing market price of the Company's common stock on the date of warrant issuance and at the end of each reporting period when the derivative instruments are marked to market. Expected volatility is 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 of grant or quarterly revaluation.

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

Table of Contents

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)
12/31/2012	Balance of derivative financial instruments liability	2,265,160	\$ 5,258
3/31/2013	Change in fair value of warrants during the quarter		1,093
3/31/2013	Balance of derivative financial instruments liability	2,265,160	6,351
6/30/2013	Fair value of new warrants issued during the quarter		
6/30/2013	Reclassification of derivative liability to equity during the quarter	(1,406,691)	(3,575)
6/30/2013	Change in fair value of warrants during the quarter		(1,803)
6/30/2013	Balance of derivative financial instruments liability	858,469	973
9/30/2013	Fair value of new warrants issued during the quarter		
9/30/2013	Change in fair value of warrants during the quarter		77
9/30/2013	Balance of derivative financial instruments liability	858,469	1,050
12/31/2013	Fair value of new warrants issued during the quarter		
12/31/2013	Change in fair value of warrants during the quarter		484
12/31/2013	Balance of derivative financial instruments liability	858,469	1,534
3/31/2014	Fair value of new warrants issued during the quarter		
3/31/2014	Change in fair value of warrants during the quarter		(223)
3/31/2014	Balance of derivative financial instruments liability	858,469	1,311
6/30/2014	Fair value of new warrants issued during the quarter		
6/30/2014	Change in fair value of warrants during the quarter		(756)
6/30/2014	Balance of derivative financial instruments liability	858,469	555
9/30/2014	Fair value of new warrants issued during the quarter		
9/30/2014	Change in fair value of warrants during the quarter		(425)
9/30/2014	Balance of derivative financial instruments liability	858,469	\$ 130

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, 2013 and September 30, 2014:

(\$ in thousands)

Description	Quoted Prices in Active Markets	Significant Other Observable Inputs	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2013	Quoted Prices in Active Markets	Significant Other Observable Inputs	Significant Unobservable Inputs (Level 3)	Balance as of September 30, 2014
-------------	---------------------------------	-------------------------------------	---	---------------------------------	---------------------------------	-------------------------------------	---	----------------------------------

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

	for Identical Assets and Liabilities (Level 1)	(Level 2)				for Identical Assets and Liabilities (Level 1)	(Level 2)			
Derivative liabilities related to Warrants	\$	\$	\$	1,534	\$	1,534	\$	\$	\$	130
										130

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, 2014:

Description	Balance at December 31, 2013	Fair Value of warrants upon issuance	(Gain) or loss recognized in earning from Change in Fair Value	Balance as of September 30, 2014
Derivative liabilities related to Warrants	\$ 1,534	\$	\$ (1,404)	\$ 130

Table of Contents

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.

On January 28, 2014, the Synergy Board of Directors declared a stock dividend of .0986 ContraVir shares for each share of Synergy common stock held as of the record date of February 6, 2014, which was distributed on February 18, 2014. As a result of the distribution, an adjustment was made to the exercise price of all outstanding warrants in accordance with their terms and accordingly the exercise price decreased approximately \$0.011 per share on the record date and was reflected in the fair value calculation of the warrants. As of the record date there were 5,647,203 warrants outstanding (which includes 858,469 warrants recorded as derivatives, see footnote 9) with a weighted average exercise price of \$5.37 per share pre-distribution and \$5.359 per share as adjusted.

10. 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 would be antidilutive. For the three and nine months ended September 30, 2014 and September 30, 2013 the effect of 12,867,860 and 10,463,063, 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 and nine months ended September 30, 2014 and September 30, 2013, the effect of 5,647,203 outstanding warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive.

11. Subsequent Events

From October 1, 2014 through October 24, 2014, Synergy sold an additional 1,813,520 shares of common stock, under Synergy's Amended Controlled Equity Sales Agreement with Cantor (footnote 7). These sales yielded gross proceeds of \$5.1 million, at an average selling price of \$2.81 per share. As of November 10, 2014, there is approximately \$41 million of common stock available unsold under the Agreement.

On November 3, 2014 Synergy announced the closing of 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 are unsecured, senior obligations of Synergy and bear interest at a rate of 7.50% per year, payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2015. The notes will mature on November 1, 2019, unless earlier purchased or converted. The holders of the notes have the ability to require the Company to repurchase the notes in whole or in part for cash in the event of a fundamental change. In such case, the repurchase price would generally be 100% of the principal amount of the notes plus any accrued and unpaid interest. The notes are convertible, at any time, into shares of the Company'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.

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

The net proceeds from the offering were approximately \$187.3 million after deducting the initial purchasers' discounts and estimated offering expenses. Synergy is evaluating the accounting for this convertible debt instrument under ASC Topic 470, *Debt*, Subtopic 470-20 specifically *Convertible Debt Instruments*, as well as ASC Topic 815, *Derivatives and Hedging*.

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, 2013 and other periodic reports filed with the United States Securities and Exchange Commission (SEC), on March 17, 2014. 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 primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. Our lead product candidate is plecanatide (formerly called SP-304), a Phase 3 guanylate cyclase C, or GC-C, receptor agonist, designed to treat GI disorders, primarily chronic idiopathic constipation, or CIC, and constipation-predominant irritable bowel syndrome, or IBS-C. CIC and IBS-C are functional gastrointestinal disorders that afflict millions of individuals worldwide. CIC is primarily characterized by constipation symptoms with straining, bloating and abdominal discomfort reported by a majority of such patients. IBS-C is characterized by frequent and recurring abdominal pain and/or discomfort associated with chronic constipation. SP-333 is our next-generation uroguanylin analog in development for the treatment of opioid induced constipation, or OIC, and mild-to-moderate ulcerative colitis. SP-333 is designed to be a highly potent and stable version of the naturally occurring GI hormone, uroguanylin, and resistant to proteolysis in gastric intestinal fluids. We have completed phase 1 single and multiple ascending dose studies in healthy volunteers and are currently in a phase 2 clinical trial for OIC. We are also developing a unique formulation of SP-333 for treating GI inflammation in patients with ulcerative colitis.

Our patented GI drug candidates were discovered and developed in-house by our scientists. Today there are few available therapies for CIC and IBS-C, the common side effects of such therapies which are diarrhea and nausea.

Recent Developments

On November 3, 2014 we announced the closing of 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

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

aggregate principal amount of 7.50% Convertible Senior Notes due 2019). The notes are unsecured, senior obligations and bear interest at a rate of 7.50% per year, payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2015. The notes will mature on November 1, 2019, unless earlier purchased or converted. The holders of the notes have the ability to require us to repurchase the notes in whole or in part for cash in the event of a fundamental change. In such case, the repurchase price would generally be 100% of the principal amount of the notes plus any accrued and unpaid interest. The notes are convertible, at any time, into shares of our 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. The net proceeds from this offering was approximately \$187.3 million, after deducting estimated expenses payable by us and the initial purchasers discount.

On October 20, 2014, we presented additional positive results from our phase 2b dose-ranging study assessing plecanatide's safety and efficacy in patients with IBS-C. The data were presented at the American College of Gastroenterology's 2014 Annual Scientific Meeting in Philadelphia, Pennsylvania. Plecanatide 1.0, 3.0 and 9.0 mg doses demonstrated statistically significant improvement in complete spontaneous bowel movement (CSBM) frequency, the trial's primary endpoint, with the highest two doses showing the greatest response (increase from baseline of 2.12, 2.74, 2.44 and 1.27 for 1.0, 3.0, 9.0 mg and placebo dose groups, respectively). Increasing efficacy was also observed at the higher dose range in other key secondary endpoints including overall responder rate (the end point for FDA approval) and abdominal pain responder rate. All doses were safe and well tolerated with no treatment-related serious adverse events.

Plecanatide

Plecanatide is a synthetic analog of uroguanylin, a natural human hormone that regulates ion and fluid transport in the intestine. Orally-administered, plecanatide binds to the same receptors on the inside of the gastrointestinal tract as uroguanylin, and we believe it is

Table of Contents

capable of restoring the normal balance of fluid, thus restoring the regular function of the intestine in patients suffering from GI disorders such as CIC and IBS-C.

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, has no identifiable causes. Patients diagnosed with CIC have had 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 available have significant side effects and are 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 CIC places on patients' lives.

On January 2, 2013, we announced positive results from our large multicenter clinical trial of our lead investigational drug plecanatide in patients with CIC. On May 15, 2013, at Digestive Disease Week 2013, we presented a late-breaking abstract, the title of which is: Plecanatide, a Novel Guanylate Cyclase C (GC-C) Receptor Agonist, is Efficacious and Safe in Patients with Chronic Idiopathic Constipation (CIC): Results from a 951-Patient, 12-Week, Multi-Center Trial.

On August 5, 2013, we announced that we had successfully completed an End-of-Phase 2 meeting with the FDA regarding plecanatide for the treatment of CIC.

Phase 3 Clinical Trial for CIC

On November 13, 2013, we announced the start of the first of two planned pivotal Phase 3 clinical trials to confirm the safety and efficacy of plecanatide in adult patients with CIC. The pivotal Phase 3 trial is a randomized, double-blind, clinical trial to compare a 12-week, dose-ranging regimen of plecanatide (3.0 and 6.0mg) against placebo in adult patients with CIC. The study is expected to be conducted at approximately 180 sites in the United States and Canada and is expected to enroll approximately 1,350 patients with CIC. The primary endpoint of the study is the proportion of patients who are overall responders for the 12-week treatment period. We currently expect this trial to be completed during the second quarter of 2015.

On April 28, 2014, we initiated our second pivotal Phase 3 clinical trial for plecanatide. The primary objective of this trial is to confirm the safety and efficacy of plecanatide, a GC-C receptor agonist and once-daily oral treatment, in adult patients with CIC. This Phase 3 trial is a randomized, double-blind clinical trial to compare a 12-week, dose-ranging regimen of plecanatide (3.0 and 6.0mg) against placebo in adult patients with CIC. The study is expected to be conducted at approximately 180 sites in the United States and is expected to enroll approximately 1,350 patients with CIC. The primary endpoint of the study is the proportion of patients who are overall responders for the 12-week treatment period. This study is intended to be in parallel with the first Phase 3 CIC trial that was initiated in November 2013. The Phase 3 program is expected to enroll a total of approximately 2,700 patients with CIC over both studies.

On July 14, 2014, we announced that we had reached the halfway mark for total enrollment in the first pivotal Phase 3 trial of plecanatide in patients with CIC.

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

On September 18, 2014, we announced the halfway mark for total enrollment in the second pivotal phase 3 trial of plecanatide in patients with CIC. This is the second of two ongoing pivotal phase 3 trials designed to confirm the efficacy and safety of both 3.0 and 6.0 mg plecanatide versus placebo in patients with CIC. The trial is being conducted at 180 sites and has randomized over 675 CIC patients.

We plan to release top-line data from the first Phase 3 CIC trial in the second quarter of 2015 and top-line data from the second study in the third quarter of 2015.

Phase 2b Clinical Trial for IBS-C

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-C is the subtype of IBS that plecanatide is being developed to treat. 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.

On December 27, 2012, we commenced a Phase 2b clinical trial of plecanatide to treat patients with IBS-C. This study was conducted at 70 sites in the U.S. To qualify for enrollment, patients had to meet the Rome III criteria for IBS-C as modified for this study. Abdominal pain is a major part of this syndrome and patients need to have pain scores of 3 or more (on a scale of 1 to 10) for 3 days in each of the two pre-treatment weeks. Qualified patients were randomized to receive 0.3, 1, 3 or 9 mg of plecanatide or placebo once daily for 12 weeks, and

Table of Contents

were seen at the clinical site once a month during the study. At the end of treatment, patients were followed for two weeks, and returned for an end of study visit. The primary objective of this study was to select doses for the following Phase 3 studies, based on safety and efficacy endpoints including bowel movements, stool consistency, time to first bowel movement, reduction of abdominal pain, and quality of life measures.

On April 30, 2014, we announced positive top-line results from our Phase 2b dose-ranging trial assessing plecanatide's safety and efficacy in 424 patients with IBS-C. The primary objective of this trial was to determine an effective, safe and well tolerated dose for plecanatide Phase 3 trials with IBS-C patients. Preliminary analysis of the data indicates that plecanatide demonstrated statistically significant improvement in complete spontaneous bowel movement (CSBM) frequency the study's primary endpoint and was safe and well tolerated. Notably, patients taking the plecanatide 3.0mg dose experienced statistically significant improvement in change from baseline versus placebo in worst abdominal pain and met the U.S. Food and Drug Administration, or FDA, overall responder endpoint for IBS-C over the 12-week treatment. An overall responder for the FDA endpoint fulfills both 30% reduction in worst abdominal pain and an increase of 1 CSBMs from baseline in the same week for at least 50% of the weeks (i.e. 6/12 weeks).

On July 8, 2014, we announced that we had successfully completed an End-of-Phase 2 meeting with the FDA and that agreement was reached on the plecanatide pivotal phase 3 IBS-C clinical development plan and primary endpoint for registration trials. The pivotal phase 3 IBS-C program is scheduled to begin in the fourth quarter of this year and will include two trials to evaluate the efficacy and safety of plecanatide 3.0 and 6.0 mg doses, consistent with the ongoing CIC registration trials. IBS-C patients successfully completing either of the 12-week placebo-controlled registration trials will be offered enrollment into a long-term safety trial in order to support the ongoing long-term safety database for the CIC indication.

On October 20, 2014, we presented additional positive results from our phase 2b dose-ranging study assessing plecanatide's safety and efficacy in patients with IBS-C. The data were presented at the American College of Gastroenterology's 2014 Annual Scientific Meeting in Philadelphia, Pennsylvania. Plecanatide 1.0, 3.0 and 9.0 mg doses demonstrated statistically significant improvement in complete spontaneous bowel movement (CSBM) frequency, the trial's primary endpoint, with the highest two doses showing the greatest response (increase from baseline of 2.12, 2.74, 2.44 and 1.27 for 1.0, 3.0, 9.0 mg and placebo dose groups, respectively). Increasing efficacy was also observed at the higher dose range in other key secondary endpoints including overall responder rate (the end point for FDA approval) and abdominal pain responder rate. All doses were safe and well tolerated with no treatment-related serious adverse events.

SP-333

We are developing a second-generation GC-C receptor analog, SP-333, for the treatment of opioid induced constipation, or OIC, and also for the treatment of ulcerative colitis (UC), an inflammatory bowel disease. SP-333 is a synthetic analog of uroguanylin, a natriuretic hormone that is normally produced in the body's intestinal tract. Deficiency of this hormone is thought to be one of the primary reasons for the formation of polyps that can lead to colon cancer, as well as debilitating and difficult-to-treat GI inflammatory disorders such as UC and Crohn's disease. SP-333 is designed to be a highly potent and stable version of uroguanylin, and resistant to proteolysis in gastric intestinal fluids. We are also developing a unique formulation of SP-333 that we plan to use in a proof-of-concept study planned for patients with mild-to-moderate UC.

On September 7, 2012, we submitted an Investigational New Drug, or IND, application for clinical evaluation of SP-333 to treat inflammatory bowel disease, or IBD.

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

On December 28, 2012, we successfully completed a Phase 1 placebo-controlled, dose escalating, single-dose study of 70 healthy adult volunteers.

In January 2013, we commenced a multiple ascending oral dosing study of healthy volunteers in a Phase 1 trial of SP-333 which was completed during the quarter ended June 30, 2013.

On October 2, 2013 we announced plans to move forward with SP-333 in a Phase 2 study for the treatment of OIC. The Phase 2 trial is designed as a dose-ranging study to evaluate a 4-week regimen of SP-333, a once daily oral treatment, in adult patients taking opioid analgesics for chronic, non-cancer pain for at least three months.

On October 30, 2013 we announced the start of the Phase 2 clinical trial to evaluate the safety and efficacy of SP-333 in adult patients with OIC. The multi-center, randomized, double-blind clinical trial will compare a 4-week, dose-ranging regimen of SP-333 (1.0, 3.0 and 6.0mg) against placebo in adult patients taking opioid analgesics for chronic, non-cancer pain for at least three months. The study plans to enroll approximately 260 patients with OIC who have less than 3 spontaneous bowel movements (SBMs) per week and who experience constipation-related symptoms. The primary endpoint of the study is mean change from baseline in the number of SBMs during Week 4 of the treatment period.

On July 17, 2014, we announced the successful completion of patient enrollment for our phase 2 trial of SP-333, our next-generation uroguanylin analog, in adult patients with opioid-induced constipation (OIC). Top-line data for this trial is expected in the fourth quarter of 2014.

Table of Contents

FV-100

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

On May 15, 2013, we formed ContraVir Pharmaceuticals, Inc. (ContraVir), a Delaware corporation, for the purpose of developing the FV-100 asset and entered into a Contribution Agreement with ContraVir transferring the FV-100 Product to ContraVir, in exchange for the issuance to us of 9,000,000 shares of ContraVir common stock, par value \$0.0001 per share, representing 100% of the outstanding shares of common stock as of immediately following such issuance.

Spin-Off

On August 8, 2013, ContraVir Pharmaceuticals, Inc. filed an initial Form 10 Registration Statement with the U.S. Securities and Exchange Commission covering the 9,000,000 shares of ContraVir held by us. The separation contemplated a 100% distribution of the ContraVir shares of common stock to our stockholders on a pro-rata basis. On January 28, 2014, our Board of Directors declared a stock dividend of .0986 ContraVir shares for each share of our common stock held as of the record date of February 6, 2014, which was distributed on February 18, 2014.

We accounted for this distribution according to FASB ASC Topic 505-60, *Spinoffs and reverse spinoffs* by eliminating ContraVir's net assets of approximately \$1.7 million as of February 18, 2014, with a corresponding decrease in additional paid in capital. The spin-off of ContraVir's operation had immaterial effect on Synergy's financial statements. As a result of the distribution, an adjustment was made to the exercise price of all outstanding Synergy warrants in accordance with their terms and accordingly the exercise price decreased approximately \$0.011 per share on the record date. As of the record date there were 5,647,203 Synergy warrants subject to adjustment with a weighted average exercise price of \$5.37 per share pre-Distribution and \$5.359 per share as adjusted.

FINANCIAL OPERATIONS OVERVIEW

From inception through September 30, 2014, we have sustained cumulative net losses of approximately \$236 million. From inception through September 30, 2014, we have not generated any revenue from operations and expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products. We do not expect to have such for several years, if at all.

On February 4, 2014, ContraVir entered into a securities purchase agreement with accredited investors to sell securities and raise gross proceeds of approximately \$3.2 million in a private placement and expenses of \$15,000 related to this placement. ContraVir sold 9,485,294 units to the

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

investors with each unit consisting of one share of ContraVir common stock and one warrant to purchase an additional one half share of ContraVir common stock.

On February 18, 2014, we completed distribution of ContraVir common stock (its previous wholly-owned subsidiary) to our stockholders on a pro rata basis with a stock dividend of .0986 ContraVir shares to each Synergy common stock share held as of the record date of February 6, 2014. We accounted for this distribution according to FASB ASC Topic 505-60, *Spinoffs and reverse spinoffs* by eliminating ContraVir's net assets of approximately \$1.7 million, with a corresponding decrease in additional paid in capital and eliminating the non-controlling interest of \$1.6 million. The spin-off of ContraVir's operation had immaterial effect on our financial statements.

On March 5, 2014, we entered into Amendment No. 1 to our Controlled Equity Offering Sales Agreement, dated June 21, 2012 (as amended, the Agreement), with Cantor Fitzgerald & Co., as sales agent (Cantor), pursuant to which we may offer and sell, from time to time, through Cantor shares of our common stock, par value \$0.0001 per share (the Shares), up to an additional aggregate offering price of \$50.0 million. We intend to use the net proceeds of this offering to fund our research and development activities, including further clinical development of plecanatide and SP-333, and for working capital and other general corporate purposes, and possible acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated.

Under the Agreement, Cantor may sell the Shares by methods deemed to be an at-the-market offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the Securities Act), including sales made directly on The NASDAQ Global Select Market, on any other existing trading market for the Shares or to or through a market maker. In addition, under the Agreement, Cantor may sell the Shares by any other method permitted by law, including in privately negotiated transactions. Subject to the terms and conditions of the Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The NASDAQ Global Select Market, to sell the Shares from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose).

Table of Contents

We are not obligated to make any sales of the Shares under the Agreement. The offering of Shares pursuant to the Agreement will terminate upon the earlier of (1) the sale of all of the Shares subject to the Agreement or (2) the termination of the Agreement by Cantor or us. We will pay Cantor a commission of up to 3.0% of the gross sales price per share sold and we agreed to provide Cantor with customary indemnification and contribution rights.

From January 1, 2014 through September 30, 2014, we sold 4,604,130 shares of common stock, pursuant to the original and the Amendment agreement with Cantor, yielding gross proceeds of \$25.6 million, at an average selling price of \$5.56 per share. Selling agent fees related to above financings from January 1, 2014 through September 30, 2014 were \$706,340.

From October 1, 2014 through October 24, 2014, we sold an additional 1,813,520 shares of common stock, under the Amendment, yielding gross proceeds of \$5.1 million, at an average selling price of \$2.81 per share.

On November 3, 2014 we announced the closing of 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 are unsecured, senior obligations and bear interest at a rate of 7.50% per year, payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2015. The notes will mature on November 1, 2019, unless earlier purchased or converted. The holders of the notes have the ability to require us to repurchase the notes in whole or in part for cash in the event of a fundamental change. In such case, the repurchase price would generally be 100% of the principal amount of the notes plus any accrued and unpaid interest. The notes are convertible, at any time, into shares of our 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. The net proceeds from this offering was approximately \$187.3 million, after deducting estimated expenses payable by us and the initial purchasers discount.

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

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA of our Annual Report on Form 10-K as of and for year ended December 31, 2013, filed with the SEC on March 17, 2014. We adopted ASU 2014-101 effective June 30, 2014 and accordingly no longer presents inception to date results on the Company's statements of operations, changes in stockholder's equity and cash flow (footnote 3). There have been no other changes to our critical accounting policies since December 31, 2013.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

For a discussion of our contractual obligations see (i) our Financial Statements and Notes To Consolidated Financial Statements Note 6. *Commitments and Contingencies*, and (ii) Item 7 Management Discussion and Analysis of Financial Condition and Results of Operations *Contractual Obligations and Commitment*, included in our Annual Report on Form 10-K as of December 31, 2013.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2014.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2014 AND 2013

We had no revenues during the three months ended September 30, 2014 and 2013 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the three months ended September 30, 2014 (Current Quarter) increased approximately \$10.1 million to approximately \$20.9 million from approximately \$10.8 million for the three months ended September 30, 2013 (Prior Year Quarter). This increase in research and development expenses was primary due to higher drug production and clinical trial activities of approximately \$9.7 million for plecanatide and SP-333 during the Current Quarter. The following table sets forth our research and development expenses directly related to our product candidates for the three months ended September 30, 2014 and 2013. These expenses were primarily external costs associated with chemistry, manufacturing and controls (CMC), including costs of drug substance and product, as well as preclinical studies and clinical trial costs, as follows:

Table of Contents

Drug candidates	(\$ in thousands)			
	Three Months Ended September 30,		2014	
Plecanatide	\$	17,151	\$	6,693
SP-333		1,874		2,618
Total direct costs		19,025		9,311
Total indirect costs		1,921		1,471
Total Research and Development	\$	20,946	\$	10,782

Indirect research and development costs related to in-house staff compensation, facilities, depreciation, share-based compensation and research and development support services are not directly allocated to specific drug candidates.

General and administrative expenses decreased approximately \$0.2 million, to approximately \$2.5 million for the Current Quarter from approximately \$2.7 million for the Prior Year Quarter. These decreased expenses were primarily the result of lower corporate legal of approximately \$0.3 million for the Current Quarter, as compared to \$0.6 million for the Prior Year Quarter, offsetting by higher advisory services of \$0.1 million for the Current Quarter.

Net loss for the Current Quarter was approximately \$23 million as compared to a net loss of approximately \$13 million incurred for the Prior Year Quarter. This increase in our net loss of approximately \$10 million or 77% was a result of the increases in operating expenses discussed above, offsetting by gain from changes in fair value of derivative instruments-warrants of \$0.4 million during the Current Quarter, as compared to a loss on derivative instruments-warrants of approximately \$77,000 during the Prior Year Quarter.

NINE MONTHS ENDED SEPTEMBER 30, 2014 AND 2013

We had no revenues during the nine months ended September 30, 2014 and 2013 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the nine months ended September 30, 2014 (Current Period) increased approximately \$24.5 million to approximately \$58.7 million from approximately \$34.2 million for the nine months ended September 30, 2013 (Prior Year Period). This increase in research and development expenses was primary due to higher drug production and clinical trial activities of approximately \$23.8 million for plecanatide and SP-333 during the Current Period. The following table sets forth our research and development expenses directly related to our product candidates for the nine months ended September 30, 2014 and 2013. These expenses were primarily external costs associated with chemistry, manufacturing and controls (CMC), including costs of drug substance and product, as well as preclinical studies and clinical trial costs, as follows:

Drug candidates	(\$ in thousands)			
	Nine Months Ended September 30,		2014	
Plecanatide	\$	44,620	\$	21,545
SP-333		8,725		8,042
Total direct costs		53,345		29,587

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

Total indirect costs		5,379		4,594
Total Research and Development	\$	58,724	\$	34,181

Indirect research and development costs related to in-house staff compensation, facilities, depreciation, share-based compensation and research and development support services are not directly allocated to specific drug candidates.

General and administrative expenses decreased approximately \$0.8 million to approximately \$8 million for the Current Period from approximately \$8.8 million for the Prior Year Period. These decreased expenses were primarily the result of lower corporate legal of approximately \$0.9 million for the Current Period, as compared to \$1.5 million for the Prior Year Period.

Net loss for the Current Period was approximately \$65 million as compared to a net loss of approximately \$42 million incurred for the Prior Year Period. This increase in our net loss of approximately \$23 million or 55% was a result of the increases in operating expenses discussed above, offset by a gain resulting from the change in fair value of derivative instruments-warrants of \$1.4 million during the Current Period, as compared to a gain on derivative instruments-warrants of approximately \$ 0.6 million during the Prior Year Period.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2014, we had approximately \$12.8 million in cash and cash equivalents and approximately \$20 million in available for sale securities, compared to approximately \$18.1 million in cash and cash equivalents and approximately \$50 million in available for sale securities as of December 31, 2013. Net cash used in operating activities was approximately \$60.6 million for the nine months ended September 30, 2014 as compared to approximately \$38.7 million during the nine months ended September 30, 2013. Approximately \$24.9

Table of Contents

million was provided by financing transactions, net of fees and expenses, for the nine months ended September 30, 2014, and \$89.2 million, net of fees and expenses, for the nine months ended September 30, 2013. As of September 30, 2014, we had working capital of approximately \$18.3 million, as compared to working capital of \$56.2 million on December 31, 2013.

From October 1, 2014 through October 24, 2014, we sold an additional 1,813,520 shares of common stock, under the Agreement. These sales yielded gross proceeds of \$5.1 million, at an average selling price of \$2.81 per share. As of November 10, 2014, there is approximately \$41 million of common stock available unsold under the Agreement.

On November 3, 2014 we announced the closing of 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 are unsecured, senior obligations and bear interest at a rate of 7.50% per year, payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2015. The notes will mature on November 1, 2019, unless earlier purchased or converted. The holders of the notes have the ability to require us to repurchase the notes in whole or in part for cash in the event of a fundamental change. In such case, the repurchase price would generally be 100% of the principal amount of the notes plus any accrued and unpaid interest. The notes are convertible, at any time, into shares of our 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. The net proceeds from this offering were approximately \$187.3 million, after deducting estimated expenses payable by us and the initial purchasers discount.

As of September 30, 2014, we had an accumulated deficit of approximately \$236 million and expect to incur significant and increasing operating losses for the next several years as we continue to expand our research, development and clinical trials of plecanatide and SP-333 for the treatment of GI diseases and disorders, acquires or licenses technologies, advances other product candidates into clinical development, seeks regulatory approval and, if FDA approval is received, commercializes products. Because of the numerous risks and uncertainties associated with product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all. However, we believe that our cash on hand as of November 10, 2014 will be sufficient to meet our projected operating needs at least through the next twelve months.

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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk on the fair values of certain assets is related to credit risk associated with securities held in money market accounts, U.S. Treasury Bills and Notes, and the FDIC insurance limit on our bank balances. As of September 30, 2014, we held approximately \$12.8 million in checking and money market accounts and approximately \$20 million in U.S. Treasury securities. Our cash, cash equivalents balances

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

are in excess of federally insured limits. Our available-for-sale securities are comprised solely of U.S. Treasury securities. We believe our cash, cash equivalents and available-for-sale securities do not contain excessive risk, however we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. Given the current instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits and investments.

ITEM 4. CONTROLS AND PROCEDURES

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, our Chief Executive Officer and Principal Financial Officer have concluded that as of September 30, 2014, 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.

Table of Contents

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded there were no changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that could significantly affect internal controls over financial reporting during the quarter ended September 30, 2014.

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, 2013, except that on October 20, 2014, we entered into a stipulation and agreement of compromise, settlement and release, or the Settlement, with the plaintiffs in the putative class action lawsuits in Delaware and New York brought by certain former Callisto Pharmaceuticals, Inc., or Callisto, stockholders challenging our merger with Callisto that closed in January 2013. The Settlement is subject to certain conditions, including, but not limited to, final approval by the court and dismissal with prejudice of both complaints.

ITEM 1a. RISK FACTORS

There have been no material changes in our risk factors since the filing on April 1, 2014 of our Form 10-K for the year ended December 31, 2013, except the additional risk factors as set forth below which are a result of our closing on November 3, 2014 of a private offering of \$200 million aggregate principal amount of 7.50% Convertible Senior Notes due 2019. The notes are unsecured, senior obligations and bear interest at a rate of 7.50% per year, payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2015. The notes will mature on November 1, 2019, unless earlier purchased or converted. The holders of the notes have the ability to require us to repurchase the notes in whole or in part for cash in the event of a fundamental change. In such case, the repurchase price would generally be 100% of the principal amount of the notes plus any accrued and unpaid interest. The notes are convertible, at any time, into shares of our 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.

The indenture contains covenants limiting our financial and operating flexibility.

The indenture contains covenants that will restrict our ability and the ability of certain of our subsidiaries to:

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

- incur or guarantee additional indebtedness, other than subordinated debt;
- declare or pay any dividends on our or our subsidiaries' capital stock;
- redeem or repurchase capital stock or prepay or repurchase subordinated debt; or
- sell or license rights in North America to or otherwise encumber any of the intellectual property related to plecanatide.

These restrictive covenants could limit our ability to pursue our growth plans, restrict our flexibility in planning for, or reacting to, changes in our business and industry and increase our vulnerability to general adverse economic and industry conditions. We may enter into additional financing arrangements in the future, which could further restrict our flexibility.

Any defaults of covenants contained in the notes may lead to an event of default under the notes and the indenture. We may not be able to pay any amounts due to holders of the notes in the event of such default, and such default may significantly impair our ability to satisfy our obligations under the notes.

We will not make any adjustment to the conversion rate for notes converted in connection with a fundamental change, and the holders of the notes will not be compensated for any lost value of their notes as a result of such transaction.

We will not increase or make any other adjustment to the conversion rate upon a conversion of notes in connection with a fundamental change or similar event. Therefore, the holders of the notes will not be compensated for any lost value of their notes as a result of such transaction.

Table of Contents

The notes are effectively subordinated to any of our future secured debt and any liabilities of our subsidiaries.

The notes will rank senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the notes; equal in right of payment to our trade payables and other future unsecured indebtedness that is not so subordinated; effectively junior to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all future indebtedness (including trade payables) incurred by our subsidiaries. In the event of our bankruptcy, liquidation, reorganization or other winding up, our assets that secure debt ranking senior or equal in right of payment to the notes will be available to pay obligations on the notes only after the secured debt has been repaid in full. There may not be sufficient assets remaining to pay amounts due on any or all of the notes then outstanding.

Servicing our debt will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Recent regulatory actions may adversely affect the trading price and liquidity of the notes.

We expect that investors in, and potential purchasers of, the notes may employ, or seek to employ, an arbitrage strategy with respect to the notes. Investors that employ an arbitrage strategy with respect to the notes typically implement that strategy by selling short the common stock underlying the notes and dynamically adjusting their short position while they hold the notes. Investors may also implement this hedging strategy by entering into swaps on our common stock in lieu of or in addition to short selling the common stock.

The Securities and Exchange Commission (SEC) and other regulatory and self-regulatory authorities have implemented various rules and may adopt additional rules in the future that may impact those engaging in short selling activity involving equity securities (including our common stock), including Rule 201 of SEC regulation SHO, the Financial Industry Regulatory Authority, Inc.'s Limit Up-Limit Down program, market-wide circuit breaker systems that halt trading of stock for certain periods following specific market declines, and rules stemming from the enactment and implementation of the Dodd-Frank Wall Street Reform and Consumer Protection Act. Past regulatory actions, including emergency actions or regulations, have had a significant impact on the trading prices and liquidity of equity-linked instruments. Any governmental action that similarly restricts the ability of investors in, or potential purchasers of, the notes to effect short sales of our common stock could similarly adversely affect the trading price and the liquidity of the notes.

Volatility in the market price and trading volume of our common stock could adversely impact the trading price of the notes.

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

The stock market in recent years has experienced significant price and volume fluctuations that have often been unrelated to the operating performance of companies. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this section or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. A decrease in the market price of our common stock would likely adversely impact the trading price of the notes. The market price of our common stock could also be affected by possible sales of our common stock by investors who view the notes as a more attractive means of equity participation in us and by hedging or arbitrage trading activity that we expect to develop involving our common stock. This trading activity could, in turn, affect the trading prices of the notes. This may result in greater volatility in the trading price of the notes than would be expected for non-convertible debt securities.

Subject to certain limitations, we will continue to have the ability to incur debt in the future; if we incur substantial additional debt, these higher levels of debt may affect our ability to pay the principal of and interest on the notes.

Subject to certain limitations we and our subsidiaries may be able to incur substantial additional debt in the future, some of which may be secured debt. The indenture governing the notes does not restrict our ability to incur additional subordinated indebtedness or require us to maintain financial ratios or specified levels of net worth or liquidity. If we incur substantial additional indebtedness in the future, these higher levels of indebtedness may affect our ability to pay the principal of and interest on the notes, or any fundamental change purchase price, and our creditworthiness generally.

We may not have the ability to raise the funds necessary to purchase the notes as required upon a fundamental change, and our future debt may contain limitations on our ability to purchase of the notes.

Following a fundamental change as described, holders of notes will have the right to require us to purchase their notes for cash. A fundamental change may also constitute an event of default or prepayment under, and result in the acceleration of the maturity of, our then-existing indebtedness. We cannot assure you that we will have sufficient financial resources, or will be able to arrange financing, to pay the fundamental change purchase price in cash with respect to any notes surrendered by holders for purchase upon a fundamental change. In

Table of Contents

addition, restrictions in our then existing credit facilities or other indebtedness, if any, may not allow us to purchase the notes upon a fundamental change. Our failure to purchase the notes upon a fundamental change when required would result in an event of default with respect to the notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and purchase the notes.

Some significant restructuring transactions may not constitute a fundamental change, in which case we would not be obligated to offer to purchase the notes.

Upon the occurrence of a fundamental change, the holders of the notes have the right to require us to purchase their notes. However, the fundamental change provisions will not afford protection to the holders of the notes in the event of certain transactions that could adversely affect the notes. For example, transactions such as leveraged recapitalizations, refinancings, restructurings or acquisitions initiated by us would not constitute a fundamental change requiring us to repurchase the notes. In addition, the holders of the notes will not be entitled to require us to purchase their notes upon a significant change in the composition of our board. In the event of any such transaction, the holders of the notes would not have the right to require us to purchase their notes, even though each of these transactions could increase the amount of our indebtedness, or otherwise adversely affect our capital structure or any credit ratings, thereby adversely affecting the holders of the notes.

Future sales of our common stock in the public market could lower the market price for our common stock and adversely impact the trading price of the notes.

In the future, we may sell additional shares of our common stock to raise capital. In addition, a substantial number of shares of our common stock are reserved for issuance upon the exercise of stock options and warrants and upon conversion of the notes. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance and sale of substantial amounts of common stock, or the perception that such issuances and sales may occur, could adversely affect the trading price of the notes and the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

The notes may not have an active market, and the price may be volatile, so the holders of the notes may be unable to sell their notes at the price the holders of the notes desire or at all.

The notes are a new issue of securities for which there is currently no active trading market. We cannot assure the holders of the notes that a liquid market will develop for the notes, that the holders of the notes will be able to sell any of the notes at a particular time (if at all) or that the prices the holders of the notes receive if or when they sell the notes will be above their initial offering price. In addition, we do not intend to apply to list the notes on any securities exchange or for inclusion of the notes on any automated dealer quotation system. The initial purchasers have advised us that they intend to make a market in the notes, but they are not obligated to do so and may discontinue any market-making in the notes at any time in their sole discretion and without notice. Future trading prices of the notes on any market that may develop will depend on many factors, including our operating performance and financial condition, prevailing interest rates, the market for similar securities and general economic conditions.

Edgar Filing: SYNERGY PHARMACEUTICALS, INC. - Form 10-Q

Moreover, even if the holders of the notes are able to sell their notes, the holders of the notes may not receive a favorable price for their notes. Future trading prices of the notes will depend on many factors, including, among other things, prevailing interest rates, our operating results, the price of our common stock and the market for similar securities. Historically, the market for convertible debt has been subject to disruptions that have caused volatility in prices. It is possible that the market for the notes will be subject to disruptions that may have a negative effect on the holders of the notes, regardless of our prospects or financial performance.

Any adverse rating of the notes may negatively affect the trading price and liquidity of the notes and the price of our common stock.

We do not intend to seek a rating on the notes. However, if a rating service were to rate the notes and if such rating service were to assign the notes a rating lower than the rating expected by investors or were to lower its rating on the notes below the rating initially assigned to the notes or otherwise announce its intention to put the notes on credit watch, the trading price or liquidity of the notes and the price of our common stock could decline.

The conversion rate of the notes may not be adjusted for all dilutive events.

The conversion rate of the notes is subject to adjustment for certain events, including, but not limited to, the issuance to all or substantially all holders of our common stock of stock dividends, certain rights, options or warrants, capital stock, indebtedness, assets or cash, and subdivisions and combinations of our common stock, and certain issuer tender or exchange offers as defined. However, the conversion rate will not be adjusted for other events, such as a third-party tender or exchange offer or an issuance of common stock for cash, that may adversely affect the trading price of the notes or the common stock. An event that adversely affects the value of the notes may occur, and that event may not result in an adjustment to the conversion rate.

Table of Contents

The notes are protected by restrictive covenants only to a limited extent.

The indenture governing the notes does not contain any financial or operating covenants or restrictions on the payment of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by us or any of our subsidiaries. The indenture does not contain covenants or other provisions to afford protection to holders of the notes in the event of a fundamental change. We could engage in many types of transactions, such as acquisitions, refinancings or recapitalizations that could substantially affect our capital structure and the value of the notes and shares of our common stock but may not constitute a fundamental change that permits the holders of the notes to require us to purchase their notes.

The issuance of shares of common stock upon conversions of the notes will dilute the ownership interest of our existing stockholders, including holders who had previously converted their notes.

The issuance of shares of common stock upon the conversion of some or all of the notes will dilute the ownership interests of our existing stockholders. Any sales in the public market of such shares of our common stock could adversely affect prevailing market prices of our common stock. In addition, the existence of the notes may encourage short selling by market participants because the conversion of the notes could depress the price of our common stock.

The holders of the notes are not entitled to any rights with respect to our common stock, but are subject to all changes made with respect to our common stock to the extent the holders of the notes convert their notes and receive shares of our common stock.

Holders who convert their notes will not be entitled to any rights with respect to our common stock (including, without limitation, voting rights and rights to receive any dividends or other distributions on our common stock) until the conversion date relating to such notes, but holders of notes will be subject to all changes affecting our common stock. For example, if an amendment is proposed to our certificate of incorporation or by-laws requiring stockholder approval and the record date for determining the stockholders of record entitled to vote on the amendment occurs prior to the conversion date with respect to any notes surrendered for conversion, then the holder surrendering such notes will not be entitled to vote on the amendment, although such holder will nevertheless be subject to any changes affecting our common stock.

Upon conversion of the notes, the holders of the notes may receive less valuable consideration than expected because the value of our common stock may decline after the holders of the notes exercise their conversion right but before we settle our conversion obligation.

Under the notes, a converting holder will be exposed to fluctuations in the value of our common stock during the period from the date such holder surrenders notes for conversion until the date we settle our conversion obligation.

Upon conversion of the notes, we will be required to deliver the shares of our common stock, together with cash for any fractional share, on the third business day following the relevant conversion date. Accordingly, if the price of our common stock decreases during this period, the value of the shares that the holders of the notes receive will be adversely affected and would be less than the conversion value of the notes on the conversion date.

The fundamental change purchase feature of the notes may delay or prevent an otherwise beneficial attempt to take over our company.

The terms of the notes require us to offer to purchase the notes for cash in the event of a fundamental change. A non-stock takeover of our company may trigger the requirement that we purchase the notes. This feature may have the effect of delaying or preventing a takeover of our company that would otherwise be beneficial to investors.

We have not registered the notes or the common stock, if any, issuable upon conversion, which will limit the ability of holders of the notes to resell them.

The notes and the shares of common stock issuable upon conversion of the notes have not been registered under the Securities Act or any state securities laws. Unless the notes and the shares of common stock issuable upon conversion of the notes have been registered, they may not be transferred or resold except in a transaction exempt from or not subject to the registration requirements of the Securities Act and applicable state securities laws. We do not intend to file a registration statement for the resale of the notes and the common stock into which the notes are convertible.

The notes will initially be held in book-entry form and, therefore, holders must rely on the procedures and the relevant clearing systems to exercise their rights and remedies.

Unless and until certificated notes are issued in exchange for book-entry interests in the notes, owners of the book-entry interests will not be considered owners or holders of notes. Instead, DTC, or its nominee, will be the sole holder of the notes. Payments of principal, interest and other amounts owing on or in respect of the notes in global form will be made to the paying agent, which will make payments to DTC. Thereafter, such payments will be credited to DTC participants' accounts that hold book-entry interests in the notes in global form and credited by such participants to indirect participants. Unlike holders of the notes themselves, owners of book-entry interests will not have the direct right to act upon our solicitations for consents or requests for waivers or other actions from holders of the notes. Instead, if a holder owns a book-entry interest, such holder will be permitted to act only to the extent such holder has received appropriate proxies to do so from DTC or,

Table of Contents

if applicable, a participant. We cannot assure holders that the procedures implemented for the granting of such proxies will be sufficient to enable holders to vote on any requests or actions on a timely basis.

ITEM 2. PROPERTIES

On June 30, 2014, we entered into a Lease Amendment of our New York office, a.) adding approximately 1,800 square feet of contiguous office to our existing lease of approximately 6,700 square feet and b.) extending our existing lease for additional three years to March 2022, to be coterminous with our new space. This lease amendment results in total monthly rent of approximately \$51,000 on straight line basis, prospectively.

Table of Contents

ITEM 6. EXHIBITS

- (a) Exhibits
- 4.1 Indenture related to the 7.50% Convertible Senior Notes due 2019, dated as of November 3, 2014, by and between Synergy Pharmaceuticals Inc. and Wells Fargo Bank, National Association, as trustee (incorporated by reference to Exhibit 4.1 of Form 8-K filed on November 3, 2014).
- 4.2 Form of 7.50% Convertible Senior Note due 2019 (incorporated by reference to Exhibit 4.1 of Form 8-K filed on November 3, 2014).
- 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, 2014, filed on November 10, 2014, 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 10, 2014

By:

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

Date: November 10, 2014

By:

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