SYNERGY PHARMACEUTICALS, INC.
Form 10-Q
November 09, 2010
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, 2010

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)

Florida	**20-3823853**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

420 Lexington Avenue, Suite 1609, New York, New York (Address of principal executive offices)	**10170** (Zip Code)

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

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

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

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

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

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

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

The number of the registrant s shares of common stock outstanding was 92,188,164 as of November 8, 2010.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

FORM 10-Q

TABLE OF CONTENTS

Table of Contents

INTRODUCTORY NOTE

This Report on Form 10-Q for Synergy Pharmaceuticals, Inc. (Synergy or the Company) may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements, including the risks set forth in our Annual Report on Form 10-K/A for the year ended December 31, 2009 and other periodic filings with the Securities and Exchange Commission.

In some cases, you can identify forward-looking statements by terminology, such as expects, anticipates, intends, estimates, plans, believe seeks, may, should , could or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this Report on Form 10-Q.

You should read this Report on Form 10-Q and the documents that we reference herein, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this Report on Form 10-Q is accurate as of their respective dates. Our business, financial condition, results of operations and prospects may change. We may not update these forward-looking statements, even though our situation may change in the future, unless required by law to update and disclose material developments related to previously disclosed information. We qualify all of the information presented in this Report on Form 10-Q, and particularly our forward-looking statements, by these cautionary statements.

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

SYNERGY PHARMACEUTICALS, INC.

(A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2010 (unaudited)	December 31, 2009
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 573,220	$ 7,152,568
Prepaid expenses and other current assets	584,160	1,061,630
Total Current Assets	1,157,380	8,214,198
Property and equipment, net	8,243	9,725
Security deposits	14,025	14,025
Due from Controlling shareholder	1,514,621	972,552
Total assets	$ 2,694,269	$ 9,210,500
LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$ 2,374,463	$ 1,283,466
Accrued expenses	1,048,011	443,266
Total Current Liabilities	3,422,474	1,726,732
Derivative financial instruments, at estimated fair value-warrants	1,098,182	
Total Liabilities	4,520,656	1,726,732
Stockholders Equity:		
Common stock, par value of $.0001 authorized 200,000,000 shares, outstanding 90,236,929 and 88,423,359 shares at September 30, 2010 and December 31, 2009	9,024	8,844
Preferred stock, Authorized 20,000,000 shares and 0 shares outstanding at September 30, 2010 and December 31, 2009		
Additional paid-in capital	49,602,277	47,395,465
Deficit accumulated during development stage	(51,437,688)	(39,920,541)
Total stockholders (deficit) equity	(1,826,387)	7,483,768
Total liabilities and stockholder s equity	$ 2,694,269	$ 9,210,500

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30		November 15, 2005 (inception) to
	2010	2009	2010	2009	September 30, 2010
Revenues	$	$	$	$	$
Costs and Expenses:					
Research and development(1)	2,295,362	1,023,225	7,874,490	2,397,725	13,310,282
Purchased in-process research and development					28,156,502
General and administrative(1)	1,220,427	1,199,346	3,837,729	2,796,054	10, 174,071
Loss from Operations	(3,515,789)	(2,222,571)	(11,712,219)	(5,193,779)	(51,640,855)
Interest and investment income	23,171	10,862	84,135	11,008	164,051
Change in fair value of derivative instruments-warrants	110,937		110,937		110,937
Total other income	134,108	10,862	195,072	11,008	274,988
Loss from Continuing Operations	(3,381,681)	(2,211,709)	(11,517,147)	(5,182,771)	(51,365,867)
Loss from discontinued operations					(71,821)
Net Loss	$ (3,381,681)	$ (2,211,709)	$ (11,517,147)	$ (5,182,771)	$ (51,437,688)
Weighted Average Common Shares Outstanding					
Basic and Diluted	90,102,405	75,769,105	89,002,114	69,646,019	
Net Loss per Common Share, Basic and Diluted	$ (0.04)	$ (0.03)	$ (0.13)	$ (0.07)	

(1) Patent costs reclassified from Research and Development to General and Administrative in 2009. See Note 2.

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.

(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)

(Unaudited)

	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders Equity (Deficit)
Balance at inception, November 15, 2005					
Sale of unregistered common stock to founder	151,381,215	$ 15,138	$ (13,138)	$	$ 2,000
Sale of common stock	13,700,000	1,370	16,730		18,100
Net loss for the year				(16)	(16)
Balance, December 31, 2005	165,081,215	16,508	3,592	(16)	20,084
Net loss for the year				(20,202)	(20,202)
Balance, December 31, 2006	165,081,215	16,508	3,592	(20,218)	(118)
Capital contribution by shareholders			8,893		8,893
Net loss for the year				(20,043)	(20,043)
Balance, December 31, 2007	165,081,215	16,508	12,485	(40,261)	(11,268)
Cancellation of unregistered founder shares	(149,981,208)	(14,998)	14,998		
Common stock issued via Exchange Transaction	45,464,760	4,546	27,274,315		27,278,861
Common stock issued via private placement July 14, 2008	5,000,000	500	2,999,500		3,000,000
Common stock issued via private placement August 25, 2008	41,667	4	24,996		25,000
Fees and expenses related to private placements			(73,088)		(73,088)
Stock based compensation expense			379,883		379,883
Net loss for the year				(31,755,180)	(31,755,180)
Balance, December 31, 2008	65,606,434	6,560	30,633,089	(31,795,441)	(1,155,792)
Common stock issued via private placements	22,814,425	2,282	15,967,818		15,970,100
Fees and expenses related to private placements			(260,002)		(260,002)
Common stock Issued for services rendered	2,500	2	1,498		1,500

Stock based compensation expense			1,053,062		1,053,062
Net loss for the year				(8,125,100)	(8,125,100)
Balance, December 31, 2009	88,423,359	8,844	47,395,465	(39,920,541)	7,483,768
Common stock issued via registered direct offering and private placement	746,765	75	3,153,925		3,154,000
Warrants reclassified to derivative liability			(1,209,119)		(1,209,119)
Fees and expenses related to direct offering			(294,130)		(294,130)
Common stock issued to extend lock-up agreements related to unregistered shares	1,061,867	105	(105)		
Common stock Issued for services rendered	4,938		18,271		18,271
Stock based compensation expense			537,970		537,970
Net loss for the period				(11,517,147)	11,517,147
Balance, September 30, 2010	90,236,929	$ 9,024	$ 49,602,277	$ (51,437,688)	$ 1,826,387

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30, 2010	Nine Months Ended September 30, 2009	Period from November 15, 2005 (Inception) to September 30, 2010
Cash Flows From Operating Activities:			
Net loss	$ (11,517,147)	$ (5,182,771)	$ (51,437,688)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,482	988	4,680
Stock-based compensation expense	556,241	860,428	1,990,686
Purchased in-process research and development			28,156,502
Change in fair value of derivative instruments-warrants	(110,937)		(110,937)
Changes in operating assets and liabilities:			
Security deposit		(9,625)	(14,025)
Accounts payable and accrued expenses	1,695,742	434,841	2,699,431
Prepaid expenses and other current assets	477,470	(89,810)	(584,160)
Total Adjustments	2,619,998	1,196,822	32,142,177
Net Cash Used in Operating Activities	(8,897,149)	(3,985,949)	(19,295,511)
Cash Flows From Investing Activities:			
Net cash paid on Exchange Transaction			(155,326)
Loans to related parties	(542,069)	(131,387)	(1,514,621)
Additions to property and equipment			(12,195)
Net Cash Used in Investing Activities	(542,069)	(131,387)	(1,682,142)
Cash Flows From Financing Activities:			
Capital contribution by shareholders			8,893
Issuance of common stock			2,000
Proceeds of sale of common stock and warrants	3,154,000	7,232,500	22,149,100
Fees and expenses related to sale of common stock and warrants	(294,130)	(245,000)	(627,220)
Proceeds from sale of common stock to founders			18,100
Net Cash Provided by Financing Activities	2,859,870	6,987,500	21,550,873
Net (decrease) increase in cash and cash equivalents	(6,579,348)	2,870,164	573,220
Cash and cash equivalents at beginning of period	7,152,568	216,007	
Cash and cash equivalents at end of period	$ 573,220	$ 3,086,171	$ 573,220
Supplementary disclosure of cash flow information:			

Cash paid for taxes	$ 19,071	$ 2,473	$ 21,577
Cash paid for interest	$	$	$
Value of common stock issued via Exchange Transaction	$	$	$ 27,278,861
Value of common stock issued to induce stockholders to extend lock-up agreements (see Note 5)	$ 2,798,020	$	$ 2,798,020

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Business Overview

Synergy Pharmaceuticals, Inc., incorporated in Florida on November 15, 2005, (Synergy or the Company) is a biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. Synergy s lead drug candidate is plecanatide (previously designated SP-304), a guanylyl cyclase C, or GC-C, receptor agonist, to treat GI disorders, primarily chronic constipation, or CC, and constipation-predominant irritable bowel syndrome, or IBS-C. CC and IBS-C are functional gastrointestinal disorders that afflict millions of sufferers worldwide. CC is primarily characterized by constipation symptoms but a majority of these patients report experiencing bloating and abdominal discomfort as among their most bothersome symptoms. IBS-C is characterized by frequent and recurrent abdominal pain and/or discomfort associated with chronic constipation.

In March 2010, Synergy initiated dosing in a Phase 2a randomized, double-blind, placebo-controlled, dose-escalation, cohort-design, multi-center clinical trial of plecanatide in patients with CC. This Phase 2a clinical trial used modified Rome III criteria for enrollment, was designed primarily as a safety trial, but included measures of bowel function and patient-reported symptoms to provide us information on the pharmacodynamic effects of plecanatide on patients with CC. Seventy-eight evaluable patients were enrolled and dosed with placebo or plecanatide once-daily for 14 consecutive days at oral doses of 0.3 mg, 1.0 mg, 3.0 mg or 9.0 mg, respectively. Patients were monitored for a number of spontaneous and complete-spontaneous bowel movements, stool consistency using the Bristol Stool Form Scale, and ease of stool passage, abdominal discomfort, constipation severity and overall relief.

On October 6, 2010, Synergy announced the results of this Phase 2a clinical trial. Plecanatide given orally once daily, over 14 consecutive days, at doses of 0.3 mg, 1.0 mg, 3.0 mg and 9.0 mg improved bowel function in patients with CC. Benefits were observed in increased frequency of bowel movements, decreased straining and abdominal discomfort, and improvement in other associated clinical measures. Plecanatide treatment exhibited a favorable safety profile. No severe adverse events were observed, and notably no patients receiving plecanatide reported diarrhea. Additionally, no systemic absorption of plecanatide was detected in patients at any of the dose levels studied.

Synergy plans to initiate an approximately 450 patient, Phase 2b 28-day repeated-oral-dose, placebo-controlled clinical trial of plecanatide for the treatment of CC in the first quarter of 2011, and a Phase 2b 90-day clinical trial of plecanatide in IBS-C patients in the third quarter of 2011.

2. Basis of Presentation and Going Concern

These unaudited condensed consolidated financial statements include Synergy and its wholly-owned subsidiaries: (1) Synergy Pharmaceuticals, Inc. (Delaware), (2) Synergy Advanced Pharmaceuticals, Inc. 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, 2009 contained in the Company s Annual Report on Form 10-K/A, as well as other periodic reports, filed with the Securities Exchange Commission. Certain items in the prior year s financial statements have been reclassified to conform to the current year s presentation. Specifically, legal costs associated with patent applications and maintenance have been classified as general and administrative expense, where previously these costs were classified as research and development expense in our statement of operations. All intercompany balances and transactions have been eliminated. The results of operations for the nine months ended September 30, 2010 are not necessarily indicative of the results of operations to be expected for the full year ended December 31, 2010.

These unaudited condensed consolidated financial statements as of September 30, 2010 and December 31, 2009 have been prepared under the assumption that Synergy will continue as a going concern for the next twelve months. Synergy s ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. These condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

2. Basis of Presentation and Going Concern (Continued)

As of September 30, 2010, Synergy had an accumulated deficit of $51,437,688. Synergy expects to incur significant and increasing operating losses for the next several years as Synergy expands its research and development, continues clinical trials of plecanatide for the treatment of GI disorders, acquires or licenses technologies, advances other product candidates into clinical development, seeks regulatory approval and, if FDA approval is received, commercializes products. Because of the numerous risks and uncertainties associated with product development efforts, Synergy is unable to predict the extent of any future losses or when Synergy will become profitable, if at all. Net cash used in operating activities was $8,897,149 for the nine months ended September 30, 2010. As of September 30, 2010 Synergy has $573,220 of cash. During the nine months ended September 30, 2010, Synergy incurred net losses from continuing operations of $11,517,147. To date, Synergy s sources of cash have been primarily limited to the sale of common stock and warrants.

On October 1, 2010 the Company entered into a securities purchase agreement with an investor and raised gross proceeds of $2,500,000 in a registered direct offering. The Company paid a fee of $50,000 to a non-U.S. selling agent. The Company sold to the investor 1,000,000 shares of its common stock and warrants to purchase 400,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investor was $2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $2.75 per share.

On October 18, 2010 the Company entered into a securities purchase agreement with certain investors and raised gross proceeds of $1,525,000 in a registered direct offering. The Company paid a fee of $91,000 to a non-U.S. selling agent. The Company sold 610,000 shares of its common stock and warrants to purchase 244,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investors was $2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $2.75 per share.

The October 1, 2010 and October 18, 2010 offerings were made pursuant to a shelf registration statement on Form S-3 (SEC File No. 333-163316, the base prospectus effective December 10, 2009), as supplemented by prospectus supplements filed with the Securities and Exchange Commission on October 1, 2010 and October 18, 2010.

Synergy will be required to raise additional capital during the current year to complete the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Synergy cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Synergy raises additional funds by issuing equity securities, Synergy s

stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Synergy s ability to conduct business. If Synergy is unable to raise additional capital when required or on acceptable terms, Synergy may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that Synergy would otherwise seek to develop or commercialize ourselves on unfavorable terms.

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Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

2. Basis of Presentation and Going Concern (Continued)

Recent worldwide economic conditions, as well as domestic and international equity and credit markets, have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult to obtain additional equity or credit financing, when needed.

3. Recent Accounting Pronouncements

In April 2010, the FASB issued ASU 2010-13, Compensation Stock Compensation (Topic 718) Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in Which the Underlying Equity Security Trades. ASU 2010-13 provides amendments to Topic 718 to clarify that an employee share-based payment award with an exercise price denominated in the currency of a market in which a substantial portion of the entity s equity securities trades should not be considered to contain a condition that is not a market, performance, or service condition. Therefore, an entity would not classify such an award as a liability if it otherwise qualifies as equity. The amendments in ASU 2010-13 are effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2010. Synergy expects the adoption of this standard will not have a material effect on its results of operation or its financial position.

In February 2010, the FASB issued ASU 2010-09, Subsequent Events (Topic 855) Amendments to Certain Recognition and Disclosure Requirements. ASU 2010-09 requires an entity that is an SEC filer to evaluate subsequent events through the date that the financial statements are issued and removes the requirement that an SEC filer disclose the date through which subsequent events have been evaluated. ASC 2010-09 was effective upon issuance. The Company adopted ASU 2010-09 upon issuance and such adoption had no effect on its results of operation or its financial position. (see Note 12. below)

In January 2010, the FASB issued Accounting Standards Update (ASU) 2010-06, Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements (ASU 2010-06). ASU 2010-06 includes new disclosure requirements related to fair value measurements, including transfers in and out of Levels 1 and 2 and information about purchases, sales, issuances and settlements for Level 3 fair value measurements. This update also clarifies existing disclosure requirements relating to levels of disaggregation and disclosures of inputs and valuation techniques. The Company adopted ASU 2010-06 upon issuance and such adoption did not have a material impact on the Company s financial statements. (see Note 9. below)

4. Accounting for Shared-Based Payments

Stock Options

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

Synergy adopted the 2008 Equity Compensation Incentive Plan (the Plan) on July 3, 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. Synergy periodically issues stock options to employees and non-employees and has adopted ASC Topic 718 for employee awards on July 3, 2008. 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 whereas the value of the stock compensation 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.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for Shared-Based Payments (Continued)

Stock-based compensation expense, including all options, common stock, and restricted stock units, has been recognized in operating results as follow:

	Three Months Ended September 30,		Nine Months Ended September 30		November 15, 2005 (inception) to September 30,
	2010	2009	2010	2009	2010
Employees included in research and development	$ 45,991	$ 115,615	$ 145,254	$ 201,911	$ 477,325
Employees included in general and administrative	46,553	185,133	164,501	297,902	635,397
Non-employees included in research and development	26,819	8,548	43,636	25,366	86,097
Non-employees included in general and administrative	59,473	196,847	202,850	335,249	791,867
Total stock-based compensation expense	$ 178,836	$ 506,143	$ 556,241	$ 860,428	$ 1,990,686

The estimated fair value of each Synergy stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions:

	Nine months ended September 30,	
	2010	2009
Risk free interest rate	2.31 to 2.71%	2.55-2.67%
Dividend yield	n/a	n/a
Expected volatility	90%	90%
Expected term	6 years	6 years

Risk-free interest rate Based upon observed US Treasury yield curve interest rates for Treasury instruments with maturities which correspond to the expected term of Synergy s employee stock options at the date of grant.

Dividend yield Synergy has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future.

Expected volatility Based on the historical volatility of similar publicly traded stocks in Synergy s industry segment with comparable market capitalization and stage of development.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for Shared-Based Payments (Continued)

Expected term Synergy has had no stock options exercised since inception. The expected option term represents the period that stock-based awards are expected to be outstanding based on the simplified method provided in Staff Accounting Bulletin (SAB) No. 107, *Share-Based Payment* , (SAB No. 107), which averages an award s weighted-average vesting period and expected term for plain vanilla share options. Under SAB No. 107, options are considered to be plain vanilla if they have the following basic characteristics: (i) granted at-the-money ; (ii) exercisability is conditioned upon service through the vesting date; (iii) termination of service prior to vesting results in forfeiture; (iv) limited exercise period following termination of service; and (v) options are non-transferable and non-hedgeable.

In December 2007, the SEC issued SAB No. 110, *Share-Based Payment* , (SAB No. 110). SAB No. 110 was effective January 1, 2008 and expresses the views of the Staff of the SEC with respect to extending the use of the simplified method, as discussed in SAB No. 107, in developing an estimate of the expected term of plain vanilla share options in accordance with ASC Topic 718. The Company will continue to use the simplified method until it has the historical data necessary to provide a reasonable estimate of expected life in accordance with SAB No. 107, as amended by SAB No. 110. For the expected term, the Company has plain-vanilla stock options, and therefore used a simple average of the vesting period and the contractual term for options granted subsequent to January 1, 2006 as permitted by SAB No. 107.

Forfeitures ASC Topic 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Synergy s estimated future unvested option forfeitures is based on the historical experience of its controlling shareholder, Callisto Pharmaceuticals, Inc.

The unrecognized compensation cost related to non-vested stock options outstanding at September 30, 2010, net of expected forfeitures, was $470,839, to be recognized over the next three quarters.

On March 1, 2010, a majority of our shareholders acting by written consent approved an amendment to the Plan increasing the number of shares reserved under the Plan to 15,000,000 shares.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for Shared-Based Payments (Continued)

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
Balance outstanding, December 31, 2009	4,214,016	$ 0.25 - 0.95	$ 0.30	$ 22,320,436
Granted	4,465,000(1)	0.70	0.70	
Exercised				
Forfeited	(75,000)	0.70	0.70	
Balance outstanding, September 30, 2010	8,604,016	$ 0.25 - 0.95	$ 0.51	$ 17,158,986
Exercisable at September 30, 2010	2,722,469	$ 0.25 - 0.95	$ 0.29	$ 6,029,305

(1) These stock options will vest and become exercisable only upon a change of control of the Company. Because of this contingent vesting the Company did not record any stock based compensation expense on these stock options during the nine months ended September 30, 2010. The weighted average fair value of these stock options at the date of grant was $6.77 per share as calculated by the Black-Scholes model, using the assumptions noted in the table above.

Synergy Restricted Stock Awards

Restricted stock awards, which entitle the holder to earn, at the end of a vesting term, a specified number of shares of Synergy common stock are accounted for as stock based compensation in accordance with ASC Topic 718 in the same manner as stock options using fair value at the date of issuance. Restricted shares awarded are subject to a repurchase agreement, assumed by Synergy pursuant to the Exchange Transaction, whereby 50% of the shares vest after 1 year of continuous service and the remaining 50% vest after 2 years of continuous service from the issuance date. The fair value at the date of issuance was expensed ratably by month over the 2 year service period ended July 3, 2008. As of July 3, 2010, we no longer have any restricted stock awards subject to repurchase.

The fair value of the 874,760 restricted stock units on July 3, 2008, the date of issuance, was $524,856 of which $1,077, $64,705 and $524,856 was recorded as stock-based compensation expense during the three and nine months ended September 30, 2010 and for the period from inception to September 30, 2010.

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 tax benefits have been recognized in the cash flow statement.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

5. Stockholder s Equity

On August 16, 2010, Synergy entered into a securities purchase agreement with an accredited investor to sell securities and raise gross proceeds of $400,000 in a private placement. The Company sold 98,765 units to the investor with each unit consisting of one share of the Company s common stock and one warrant to purchase one additional share of the Company s common stock. The purchase price paid by the investor was $4.05 for each unit. The warrants expire after five years and are exercisable at $4.25 per share. In accordance with ASC 815-40, Derivatives and Hedging Contracts in Entity s Own Equity the warrants have been classified as a derivative liability. (See Note 8 below)

On July 13, 2010 Synergy issued 1,061,867 shares of its common stock as consideration for an agreement by certain holders of the Company s common stock to extend their lock-up of such shares from August 15, 2010 to January 15, 2011 or enter into a lock-up agreement until such date, as the case may be. This issuance was approved by the Company s Board of Directors on June 22, 2010 and represents 5% of the shares of previously issued common stock currently subject to a lock-up agreement or being requested to lock-up, as the case maybe. The fair value of the common stock issued to accomplish this lock-up extension totaled $2,798,020, based on the estimated fair value of the shares issued in connection with the June 30, 2010 registered direct offering. This amount will be charged to additional paid in capital as a cost of facilitating the June 30, 2010 registered direct offering.

On June 30, 2010, Synergy entered into securities purchase agreements to sell securities to investors and raise gross proceeds of approximately $2,754,000 in a registered direct offering. The Company paid a fee of $261,630 to a non-US selling agent plus legal and accounting fees of $32,500 associated with this offering. Synergy sold 648,000 units at $4.25 per share to investors. Each unit consists of one share of Synergy s common stock and one warrant to purchase one additional share of Synergy common stock. The warrants expire after five years and are exercisable at $4.50 per share. In accordance with ASC 815-40, Derivatives and Hedging Contracts in Entity s Own Equity the warrants have been classified as a derivative liability. (See Note 8 below).

6. Research and Development Expense

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

In accordance with FASB ASC Topic 730-10-55, Research and Development, Synergy recorded prepaid research and development costs of $501,711 and $1.0 million as of September 30, 2010 and December 31, 2009, respectively, for nonrefundable pre-payments for production of plecanatide drug substance and analytical testing services of our drug candidate SP-304 and SP-333. In accordance with this guidance, Synergy expenses deferred research and development costs when drug compound is delivered and services are performed.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

7. Loss per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, *Earnings per Share* , (ASC Topic 260) for all periods presented. In accordance with ASC Topic 260, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares because shares issuable pursuant to the exercise of stock options would have been antidilutive. For the three and nine months ended September 30, 2010 the effect of 8,604,016 outstanding stock options and 751,703 warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive. For the three and nine months ended September 30, 2009 the effect of 4,080,016 outstanding stock options was excluded from the calculation of diluted loss per share because the effect was antidilutive.

8. Derivative Financial Instruments

Based upon the Company s analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that the warrants, issued in connection with the issuance of its 2010 registered direct offerings, must be recorded as derivative liabilities with a charge to additional paid in capital. In accordance with ASC Topic 815-40, the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded as other income (expense) in the Company s statement of operations. The Company estimates the fair value of the 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 assumptions used to determine the fair value of the warrants during the nine months ended September 30, 2010 were:

	Nine month ended September 30, 2010
Estimated fair value of stock	$2.50 - $3.70
Expected warrant term	5 years
Risk-free interest rate	1.20 - 1.79%
Expected volatility	90%
Dividend yield	0%

Estimated fair value of the stock is based on an apportionment of the $4.25 unit price paid for the shares and warrants issued June 30, 2010 in the Company s registered direct offering, which was an arms-length negotiated price.

Expected volatility is based on historical volatility of the Company s controlling shareholder 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 consistent with the expected term of the warrants.

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

Date	Description	New Warrants		Derivative Instrument Liability
6/30/2010	Initial relative fair value of warrants upon issuance	648,000	$	1,045,214
9/30/2010	Fair value of new warrants issued during the quarter	103,703	$	163,905
9/30/2010	Change in fair value of warrants during the quarter recognized as other income in the statement of operations		$	(110,937)
9/30/2010	Balance of derivative financial instruments liability	751,703	$	1,098,182

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

9. 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 September 30, 2010:

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of September 30, 2010
Derivative liabilities related to Warrants	$	$	$ 1,098,182	$ 1,098,182

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, 2010:

Description	Balance at December 31, 2009	Unrealized (gains) or losses	Balance as of September 30, 2010
Derivative liabilities related to Warrants	$	$ (110,937)	$ (110,937)

The unrealized gains or losses on the derivative liabilities will be classified in other income or expense as a change in derivative liabilities in the Company s statement of operations.

A financial instrument s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade

infrequently and therefore have little or no price transparency are classified as Level 3.

10. Related Parties

As of September 30, 2010, Synergy s controlling shareholder, Callisto, owned 49.4% of its outstanding shares. As of September 30, 2010 Synergy had advanced Callisto $1,514,621which is Callisto s share of Synergy payments for common operating costs since July 2008. These common operating expenses paid by Synergy and charged to Callisto include salaries and consulting fees of certain shared executives. These shared executives are Synergy s (i) Chairman, (ii) President and Chief Executive Officer, (iii) Senior Vice President, Finance and (iv) Executive Director of Clinical Operations. These executives serve in similar capacities at Callisto and devote approximately 5% to 20% of their time to Callisto. Synergy and Callisto do not have similar drug compounds in development.

Part of this indebtedness is evidenced by an unsecured promissory note for the December 31, 2009 balance. The current balance bears interest at 6% per annum. Due to the uncertainty surrounding Callisto s ability to raise capital Synergy is unable to determine when this balance will be repaid and accordingly Synergy has classified the balance due as a long term asset.

As of December 31, 2008, December 31, 2009 and September 30, 2010, the balances due from Callisto Pharmaceuticals, Inc. are comprised of the following amounts:

Table of Contents

	December 31, 2008	December 31, 2009	September 30, 2010
Rent, utilities and property taxes	$	$ 31,627	$ 55,640
Insurance and other facilities related overhead		50,101	125,865
Independent accountants and legal	17,404	187,105	349,780
Financial printer and transfer agent fees		39,696	134,201
Salaries and consulting fees of shared executives	22,917	120,311	190,811
Working capital advances	650,012	543,712	658,324
Total due from Callisto	$ 690,333	$ 972,552	$ 1,514,621

11. Income Taxes

At December 31, 2009, Synergy-DE had net operating loss carryforwards (NOLs) aggregating approximately $30 million, expiring through 2029. The utilization of these NOLs is subject to limitations based on past and future changes in ownership of Synergy pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. The Company has determined that an ownership change occurred as of April 30, 2003 pursuant to Section 382 of the Code.

During the quarter ended September 30, 2010 the Company has determined that an additional ownership change has occurred, as a result of the shares of common stock issued since December 31, 2009. Accordingly, the Company s ability to utilize its net operating loss carry forwards, which have been incurred since April 30, 2003, are also limited.

12. Subsequent Events

On October 1, 2010 the Company entered into a securities purchase agreement with an investor and raised gross proceeds of $2,500,000 in a registered direct offering. The Company paid a fee of $50,000 to a non-US selling agent. The Company sold to the investor1,000,000 shares of its common stock and warrants to purchase 400,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investor was $2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $2.75 per share.

On October 18, 2010 the Company entered into a securities purchase agreement with certain investors and raised gross proceeds of $1,525,000 in a registered direct offering. The Company paid a fee of $91,000 to a non-US selling agent. The Company sold to the investors 610,000 shares of its common stock and warrants to purchase 244,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investor was $2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $2.75 per share.

The October 1, 2010 and October 18, 2010 offerings were made pursuant to a shelf registration statement on Form S-3 (SEC File No. 333-163316, the base prospectus effective December 10, 2009), as supplemented by prospectus supplements filed with the Securities and Exchange Commission on October 1, 2010 and October 18, 2010.

On October 29, 2010 the Company received notice from the Internal Revenue Service that a grant in the total amount of $244,479, for qualified investments in a qualifying therapeutic discovery project under section 48D of the Internal Revenue Code for Agonists of Guanylate Cyclase-C, was approved.

Table of Contents

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

RECENT DEVELOPMENTS

On October 6, 2010, we announced the results of our Phase 2a clinical trial of plecanatide to treat chronic constipation, or CC. Plecanatide given orally once daily, over 14 consecutive days, at doses of 0.3 mg, 1.0 mg, 3.0 mg and 9.0 mg improved bowel function in patients with CC. Benefits were observed in increased frequency of bowel movements, decreased straining and abdominal discomfort, and improvement in other associated clinical measures. Plecanatide treatment exhibited a favorable safety profile. No severe adverse events were observed, and notably no patients receiving plecanatide reported diarrhea. Additionally, no systemic absorption of plecanatide was detected in patients at any of the dose levels studied. We presented these results on October 18, 2010 at the American College of Gastroenterology Annual Scientific Meeting in San Antonio, Texas.

On October 1, 2010 we entered into a securities purchase agreement with a certain investor and raised gross proceeds of $2,500,000 in a registered direct offering. We paid a fee of $50,000 to a non-US selling agent. We sold to the investor 1,000,000 shares of common stock and warrants to purchase 400,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investor was $2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $2.75 per share.

On October 18, 2010 we entered into a securities purchase agreement with certain investors and raised gross proceeds of $1,525,000 in a registered direct offering. We paid a fee of $91,000 to a non-US selling agent. We sold to the investors 610,000 shares of common stock and warrants to purchase 244,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investor was $2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $2.75 per share.

FINANCIAL OPERATIONS OVERVIEW

From inception through September 30, 2010, we have sustained cumulative net losses of $51,437,688. From inception through September 30, 2010, we have not generated any revenue from operations and expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products. We do not expect to have such for several years, if at all. Our product development efforts are 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 the year ended December 31, 2009, filed with the SEC on March 15, 2010. There have been no changes to our critical accounting policies since December 31, 2009.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

For a discussion of our contractual obligations see (i) our Financial Statements and Notes To Consolidated Financial Statements Note 7. *Commitments and Contingencies* , and (ii) Item 7 Management Discussion and Analysis of Financial Condition and Results of Operations *Contractual Obligations and Commitments* , included in our Annual Report on Form 10-K as of December 31, 2009. There have been no material changes in our contractual obligations and commitments during the three and nine months ended September 30, 2010.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2010.

Table of Contents

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009

We had no revenues during the three months ended September 30, 2010 and 2009 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all. Certain reclasses have been made in prior periods to conform to current year presentation. (See Note 2 to Notes to the Condensed Consolidated Financial Statements)

Research and development expenses for the three months ended September 30, 2010 increased $1,272,137 or 124%, to $2,295,362 from $1,023,225 for the three months ended September 30, 2009. This increase was primarily due to (i) higher program expenses, including animal studies, analytical testing, clinical data monitoring and patient costs, which increased by approximately $636,000 during the three months ended September 30, 2010 to approximately $1,404,000 related to our continuing Phase 2a trial of plecanatide in CC patients which began March 19, 2010, (ii) drug production expenses increased to approximately $404,000 in support of ongoing and planned clinical trials, as compared to no such expenses during the three months ended September 30, 2009, (iii) scientific advisors fees and expenses increased approximately $60,000 to approximately $117,000 and (iv) staff compensation cost increased approximately $152,000 to $369,000 as we hired additional product development personnel.

General and administrative expenses increased $21,081 or 2%, to $1,220,427 for the three months ended September 30, 2010 from $1,199,346 for the three months ended September 30, 2009. This increase was primarily due to higher accounting, financial advisory fees, and travel which increased by approximately $175,000 as compared to three months ended September 30, 2009 offset by lower compensation related expenses which decreased by approximately $165,000 principally stock based compensation expense, during the three months ended September 30, 2010, as compared to three months ended September 30, 2009.

Net loss for the three months ended September 30, 2010 was $3,381,681 compared to a net loss of $2,211,709 incurred for the three months ended September 30, 2009. This increase in our net loss of $1,169,972, or 53% was a result of the increases in research and development expenses discussed above, partially offset by a gain resulting from the change in fair value of our derivative liability of $110,937, (see Note 8 to the Notes to the Condensed Consolidated Financial Statements) and higher interest income of $10,000 on higher related party balances.

NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009

We had no revenues during the nine months ended September 30, 2010 and 2009 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all. Certain reclasses have been made in prior periods to conform to current year presentation. (See Note 2 to Notes to Condensed Consolidated Financial Statements)

Research and development expenses for the nine months ended September 30, 2010 increased $5,476,765 or 228%, to $7,874,490 from $2,397,725 for the nine months ended September 30, 2009. This increase was primarily due to (i) higher program expenses, including animal studies, analytical testing, clinical data monitoring and patient costs, which increased by approximately $3,295,000 during the nine months

ended September 30, 2010 to approximately $4,163,000 related to our Phase 2a clinical trial of plecanatide in CC patients which began March 19, 2010, (ii) drug production expenses increased approximately $1,739,000 to approximately $2,621,000 in support of ongoing and planned clinical trials, (iii) scientific advisors fees and expenses increased approximately $126,000 to approximately $289,000 and (iv) staff compensation cost increased approximately $316,000 to approximately $800,000 as we hired additional product development personnel.

General and administrative expenses increased $1,041,675 or 37%, to $3,837,729 for the nine months ended September 30, 2010 from $2,796,054 for the nine months ended September 30, 2009. This increase was primarily due to (i) approximately $705,000 of higher financial advisory fees, accounting services, and travel expenses related to our public offerings, (ii) approximately $220,000 of increased facilities overhead and (iii) approximately $280,000 of higher patent legal expense, partially offset by lower stock based compensation expenses, which decreased by approximately $250,000 to approximately $368,000 for the nine months ended September 30, 2010.

Net loss for the nine months ended September 30, 2010 was $11,517,147 compared to a net loss of $5,182,771 reported for the nine months ended September 30, 2009. This increase in our net loss of $6,334,376, was a result of the increases in research and development expenses and operating expenses discussed above, partially offset by a gain of $110,937 resulting from the change in fair value of our derivative liability (see Note 8 to Notes to Condensed Consolidated Financial Statements) and higher interest income of $73,000 on higher related party balances.

Table of Contents

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2010 we had $573,220 in cash and cash equivalents, compared to $7,152,568 as of December 31, 2009. Net cash used in operating activities was $8,897,149 for the nine months ended September 30, 2010. As of September 30, 2010 we had negative working capital of $2,265,094 as compared to working capital of $6,487,466 as of December 31, 2009.

On June 30, 2010, we entered into securities purchase agreements to sell securities to investors and raise gross proceeds of approximately $2,754,000 in a registered direct offering. We paid a fee of $261,630 to a non-US selling agent plus legal and accounting fees of $32,500 associated with this offering. We sold 648,000 units at $4.25 per share to investors. Each unit consists of one share of our common stock and one warrant to purchase one additional share of common stock. The warrants expire after five years and are exercisable at $4.50 per share.

On August 16, 2010, we entered into a securities purchase agreement with an accredited investor to sell securities and raise gross proceeds of $400,000 in a private placement. We sold 98,765 units to the investor with each unit consisting of one share of our common stock and one warrant to purchase one additional share of our common stock. The purchase price paid by the investor was $4.05 for each unit. The warrants expire after five years and are exercisable at $4.25 per share. In accordance with ASC 815-40, Derivatives and Hedging Contracts in Entity s Own Equity the warrants have been classified as a derivative liability.(see Note 8 to Notes to Condensed Consolidated Financial Statements)

On October 1, 2010 we entered into a securities purchase agreement with an investor and raised gross proceeds of $2,500,000 in a registered direct offering. We paid a fee of $50,000 to a non-US selling agent. We sold to the investor 1,000,000 shares of common stock and warrants to purchase 400,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investor was $2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $2.75 per share.

On October 18, 2010 we entered into a securities purchase agreement with certain investors and raised gross proceeds of $1,525,000 in a registered direct offering. We paid a fee of $91,000 to a non-US selling agent. We sold to the investors 610,000 shares of common stock and warrants to purchase 244,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investor was $2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $2.75 per share.

These registered direct offerings were made pursuant to a shelf registration statement on Form S-3 (SEC File No. 333-163316, the base prospectus effective December 10, 2009), as supplemented by prospectus supplements filed with the Securities and Exchange Commission on October 1, 2010 and October 18, 2010.

We will be required to raise additional capital within the next year to complete 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. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than

otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Recent worldwide economic conditions, as well as domestic and international equity and credit markets, have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult to obtain additional equity or credit financing, when needed.

Table of Contents

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 and the FDIC insurance limit on our bank balances. At September 30, 2010, we had approximately $270,000 in money market balances.

ITEM 4. CONTROLS AND PROCEDURES

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of September 30, 2010, our Chief Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were not 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.

In connection with the preparation of our annual financial statements, our management performed an assessment of the effectiveness of internal control over financial reporting as of December 31, 2009. Management s assessment included an evaluation of the design of our internal control over financial reporting and the operational effectiveness of those controls. Based on this evaluation, management determined that, as of December 31, 2009, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management s assessment were (i) a lack of sufficient internal accounting expertise to provide reasonable assurance that our financial statements and notes thereto, are prepared in accordance with generally accepted accounting principles (GAAP) and (ii) a lack of segregation of duties to ensure adequate review of financial statement preparation. In light of these material weaknesses, management concluded that, as of December 31, 2009, we did not maintain effective internal control over financial reporting. As defined by Regulation S-X, Rule 1-02(a)(4), a material weakness is a deficiency or a combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Management, in coordination with the input, oversight and support of our Audit Committee, has identified the following measures to strengthen our internal control over financial reporting and to address the material weaknesses described above. During the quarter ended December 31, 2009 we hired a controller to: (i) prepare annual and quarterly consolidated financial statements, (ii) prepare annual and quarterly account reconciliations and (iii) prepare annual and quarterly journal entries. This hire allows for better segregation of duties within our financial department. During the quarter ended June 30, 2010 we also retained a GAAP advisor to assist management with GAAP accounting and reporting matters. While these remedial actions have been implemented, they may not be in place for a sufficient period of time to help us certify that material weaknesses have been fully remediated as of the end of calendar year 2010. We will continue to develop our remediation plans and implement additional measures during calendar year 2010 and possibly into calendar year 2011.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the relationship between the benefit of desired controls and procedures and the cost of implementing new controls and procedures.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As of September 30, 2010, we are in the process of remediating the material weakness which existed at December 31, 2009. If the remedial measures described above are insufficient to address any of the identified material weaknesses or are not implemented effectively, or additional deficiencies arise in the future, material misstatements in our interim or annual financial statements may occur in the future. We are currently working to improve and simplify our internal processes and implement enhanced controls, as discussed above, to address the material weaknesses in our internal control over financial reporting and to remedy the ineffectiveness of our disclosure controls and procedures. A key element of our remediation effort is the ability to recruit and retain qualified individuals to support our remediation efforts. While our Audit Committee and Board of Directors have been supportive of our efforts by supporting the hiring of a controller in our finance department as well as funding efforts to improve our financial reporting system, improvement in internal control will be hampered if we can not recruit and retain more qualified professionals.

Other than described above, 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, 2010.

Table of Contents

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, 2009.

ITEM 1A. RISK FACTORS

Risks Related to Our Business

We are at an early stage of development as a company, currently have no source of revenue and may never become profitable.

We are a development stage biopharmaceutical company. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue. Our ability to generate revenue depends heavily on:

- demonstration in current and future clinical trials that our product candidate, plecanatide for the treatment of GI disorders, is safe and effective;
- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;
- the successful commercialization of our product candidates; and
- market acceptance of our products.

All of our existing product candidates will require extensive additional clinical evaluation, regulatory review, significant marketing efforts and substantial investment before they could provide us with any revenue. As a result, if we do not successfully develop and commercialize plecanatide, we will be unable to generate any revenue for many years, if at all. We do not anticipate that we will generate revenue for several years, at the earliest, or that we will achieve profitability for at least several years after generating material revenue, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

To date, we have funded our operations primarily from sales of our securities. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future.

As of December 31, 2009 and September 30, 2010, we had an accumulated deficit of $39,920,541 and $51,437,688, respectively. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development, continue our clinical trials of plecanatide for the treatment of GI disorders, acquire or license technologies, advance other product candidates into clinical development, including SP-333, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock will likely decline.

We will need to raise substantial additional capital within the next year to fund our operations, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- continue clinical development of plecanatide to treat GI disorders;
- continue development of other product candidates, including SP-333;
- finance our general and administrative expenses;
- prepare regulatory approval applications and seek approvals for plecanatide and other product candidates, including SP-333;
- license or acquire additional technologies;

- launch and commercialize our product candidates, if any such product candidates receive regulatory approval; and

- develop and implement sales, marketing and distribution capabilities.

Table of Contents

We will be required to raise additional capital within the next year to complete the development and commercialization of our current product candidates and to continue to fund operations at the current cash expenditure levels. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our clinical trials and other development activities;
- any future decisions we may make about the scope and prioritization of the programs we pursue;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of regulatory approval;
- the costs of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and
- general market conditions for offerings from biopharmaceutical companies.

Worldwide economic conditions and the international equity and credit markets have recently significantly deteriorated and may remain depressed for the foreseeable future. These developments could make it more difficult for us to obtain additional equity or credit financing, when needed.

We cannot be certain that funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

- seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and/or

- relinquish license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

We are largely dependent on the success of our lead product candidate, plecanatide, and we cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized.

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. We are not permitted to market any of our product candidates in the United States until we receive approval of a new drug application, or NDA, for a product candidate from the FDA or the equivalent approval from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have one lead product candidate, plecanatide for the treatment of GI disorders, and the success of our business currently depends on its successful development, approval and commercialization. This product candidate has not completed the clinical development process; therefore, we have not yet submitted an NDA or foreign equivalent or received marketing approval for this product candidate anywhere in the world.

The clinical development program for plecanatide may not lead to commercial products for a number of reasons, including if we fail to obtain necessary approvals from the FDA or foreign regulatory authorities because our clinical trials fail to demonstrate to their satisfaction that this product candidate is safe and effective. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. Any failure or delay in completing clinical trials or obtaining regulatory approval for plecanatide in a timely manner would have a material adverse impact on our business and our stock price.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely impact our business.

Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Our independent registered public accounting firm has expressed doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

22

Table of Contents

Our consolidated financial statements as of December 31, 2009 were prepared under the assumption that we will continue as a going concern for the next twelve months. Our independent registered public accounting firm has issued a report that included an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- if plecanatide receives regulatory approval, the level of underlying demand for that product and wholesalers buying patterns.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially.

A substantial amount of our common stock is owned by a single stockholder, and it may therefore be able to substantially control our management and affairs.

Callisto Pharmaceuticals, Inc., or Callisto, owns 49.4% of our outstanding common stock as of September 30, 2010. Therefore, Callisto will be able to have substantial influence over any election of our directors and our operations. It should also be noted that for the most part, authorization to modify our Articles of Incorporation, as amended, requires only majority stockholder consent and approval to modify our amended and restated By- Laws requires authorization of only a majority of the board of directors. This concentration of ownership could also have the effect of delaying or preventing a change in our control.

Our management overlaps substantially with the management and beneficial owners of our principal stockholder, which may give rise to potential conflicts of interest.

Several of our executive officers and directors are also officers and/or directors of our principal stockholder, Callisto, and certain of such executive officers and directors are, in turn, the principal stockholders of Callisto. Accordingly, there may be inherent, albeit non-specific, potential conflicts involved in the participation by members of each company s management, audit committee, compensation committee, nominating committee and other applicable board committees which will oversee questions of possible conflicts of interest and compensation, notwithstanding an effort to appoint independent directors that do not have these inherent conflicts. In addition, as a matter of practicality, efficiency and appropriate accounting, the costs of certain service (including salaries of executive officers) are allocated, which creates inter-company obligations.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

In order to receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive clinical trials to demonstrate safety and efficacy of these product candidates for the intended indication of use. Clinical testing is expensive, can take many years to complete, if at all, and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials of new drugs do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support filing of an NDA or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a

Table of Contents

clinical trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidates versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and delay our ability to generate revenue.

The FDA s expectations for clinical trials may change over time, complicating the process of obtaining evidence to support approval of our product candidates.

In March 2010, the FDA s Center for Drugs Evaluation and Research, or CDER, released a draft guidance entitled: Irritable Bowel Syndrome Clinical Evaluation of Products for Treatment to assist the product sponsors developing new drugs for the treatment of IBS. In pertinent part, this document provides recommendations for IBS clinical trial design and endpoints, and describes the need for the future development of patient-reported outcome, or PRO, instruments for use in IBS clinical trials. The clinical trials we have planned for plecanatide are designed to follow the recommendations included in this draft guidance. We cannot predict when the draft guidance will be finalized and, if it is finalized, whether the final version will include the same recommendations, or whether our currently planned clinical trials of plecanatide will meet the final recommendations.

When finalized, the guidance document will represent the FDA s thinking on the clinical evaluation of products for the treatment of IBS. FDA guidance documents, however, do not establish legally enforceable requirements, should be viewed only as recommendations, and may be changed at any time. Therefore, even insofar as we intend to follow the recommendations provided in the draft guidance document and the final guidance document when revealed, we cannot be sure that the FDA will accept the results of our clinical research even if such research follows the recommendations in the guidance document.

We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a developer of pharmaceuticals, even though we do not intend to make referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which we conduct our business. The laws include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Table of Contents

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidates.

We need FDA approval prior to marketing our product candidates in the United States. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States and we will not generate any revenue.

The FDA s review and approval process, including among other things, evaluation of preclinical studies and clinical trials of a product candidate as well as the manufacturing process and facility, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we will submit a new drug application, or NDA, for approval for any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval or may contain significant limitations on the conditions of use.

The FDA has substantial discretion in the NDA review process and may either refuse to file our NDA for substantive review or may decide that our data are insufficient to support approval of our product candidates for the claimed intended uses. In addition, even if we obtain approval of an application to market our product candidates, the FDA may subsequently seek to withdraw approval of our NDA if it determines that new data or a reevaluation of existing data show the product is unsafe under the conditions of use upon the basis of which the NDA was approved, or based on new evidence of clinical experience, or upon other new information. If the FDA does not file or approve our NDA, or withdraws approval of our NDA it may require that we conduct additional clinical trials, preclinical or manufacturing studies and submit that data before it will reconsider our application. Depending on the extent of these or any other requested studies, approval of any applications that we submit may be delayed by several years, may require us to expend more resources than we have available, or may never be obtained at all.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product in those countries. The approval process varies and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere.

If our product candidates are unable to compete effectively with marketed drugs targeting similar indications as our product candidates, our commercial opportunity will be reduced or eliminated.

We face competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize GI drugs that are safer, more effective, have fewer side effects or are less expensive than our product candidates. These potential competitors compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

If approved and commercialized, plecanatide will compete with at least one currently approved prescription therapy for the treatment of CC and IBS-C, Amitiza. In addition, over-the-counter products are also used to treat certain symptoms of CC and IBS-C. We believe other companies are developing products that could compete with plecanatide should they be approved by the FDA. For example, linaclotide is being developed by Ironwood Pharmaceuticals, Inc. This compound is being co-developed with Forest Laboratories, Inc. and has completed Phase 3 clinical trials for CC and is expecting to have data from Phase 3 clinical trials for IBS-C in the second half of 2010. Another compound, velusetrag, is being developed by Theravance, Inc. and has completed Phase 2 clinical trials for CC. To our knowledge, other potential competitors are in earlier stages of development. If our potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for plecanatide.

In addition, we have brought legal action against Per Lindell, a former consultant, and certain entities he controls in which we allege that the defendants intentionally breached certain non-disclosure and non-compete provisions of consulting agreements previously entered into with us and has used, or tried to use, certain confidential information he gained during his consultancy period in an attempt to secure financing to create his own competing product. Thus far, he has been unsuccessful in this endeavor. We are requesting that the defendants be permanently restrained and enjoined from creating a competing product and further breaching these agreements. This action further seeks disgorgement of all compensation and any and all profits earned in the event a competing product is actually created in the future and marketed. In addition, we are requesting an assignment of any intellectual property rights defendants may acquire relating to any inventions learned of or created in breach of the agreements, as well as compensatory, consequential and punitive damages. Defendants have opposed our patent in Europe in an effort to compete with our product. Although the final outcome of the legal action against defendants is unclear at this time, if we are not granted an injunction or our European patent is invalidated, defendants or others may develop a competing product which may materially harm our business.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;

- maintain a proprietary position for our products and manufacturing processes and other related product technology;

- attract and retain key personnel;

- develop relationships with physicians prescribing these products; and

25

Table of Contents

- build an adequate sales and marketing infrastructure for our product candidates.

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to existing GI drugs. If we are unable to compete effectively in the GI drug market and differentiate our products from other marketed GI drugs, we may never generate meaningful revenue.

We currently have no sales and marketing organization. If we are unable to establish a direct sales force in the United States to promote our products, the commercial opportunity for our products may be diminished.

We currently have no sales and marketing organization. If any of our product candidates are approved by the FDA, we intend to market that product through our own sales force. We will incur significant additional expenses and commit significant additional management resources to establish this sales force. We may not be able to establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If we elect to rely on third parties to sell our product candidates in the United States, we may receive less revenue than if we sold our products directly. In addition, although we would intend to use diligence in monitoring their activities, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third party to sell our product candidates, we may not be able to commercialize our product candidates which would negatively impact our ability to generate revenue.

We may need others to market and commercialize our product candidates in international markets.

In the future, if appropriate regulatory approvals are obtained, we intend to commercialize our product candidates in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. Currently, we do not have any plans to enter international markets. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

If the manufacturers upon whom we rely fail to produce plecanatide and our product candidates, including SP-333, in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our product candidates.

We do not currently possess internal manufacturing capacity. We currently utilize the services of contract manufacturers to manufacture our clinical supplies. With respect to the manufacturing of plecanatide, we are currently pursuing long-term commercial supply agreements with multiple manufacturers. Any curtailment in the availability of plecanatide could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

We may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions with the contract manufacturers. We may not be able to enter into long-term agreements on commercially reasonable terms, or at all. If we change or add manufacturers, the FDA and comparable foreign regulators may require approval of the changes. Approval of these changes could require new testing by the manufacturer and compliance inspections to ensure the manufacturer is conforming to all applicable laws and regulations, including good manufacturing practices, or GMP. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our product candidates. Peptide manufacturing is a highly specialized manufacturing business. While we believe we will have long term arrangements with a sufficient number of contract manufacturers, if we lose a manufacturer, it would take us a substantial amount of time to identify and develop a relationship and seek regulatory approval, where necessary, for an alternative manufacturer.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

We are responsible for ensuring that each of our contract manufacturers comply with the GMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer s compliance with GMP requirements. We are responsible for regularly assessing a contract manufacturer s compliance with GMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations. Manufacturers of plecanatide and other product candidates, including SP-333, may be unable to comply with these GMP requirements and with other FDA and foreign regulatory requirements, if any. While we will oversee compliance by our contract manufacturers, ultimately we have no control over our manufacturers compliance with these regulations and standards. A failure to comply

Table of Contents

with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of plecanatide or other product candidates is compromised due to a manufacturers failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize plecanatide or other product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of plecanatide or other product candidates, entail higher costs or result in our being unable to effectively commercialize plecanatide or other product candidates. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

To date, our product candidates have been manufactured in small quantities for preclinical studies and clinical trials. If any of our product candidates is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidate in larger quantities. We may not be able to increase successfully the manufacturing capacity for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to increase successfully the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high quality manufacturing. Our failure to achieve and maintain these high quality manufacturing standards in collaboration with our third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.

We rely on the third-party manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce the bulk active pharmaceutical ingredients, or APIs, and product candidates for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the APIs and finished products for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidate would be delayed, which may significantly impact our ability to develop the product candidate. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If one of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of

factors, including:

- demonstration of efficacy;
- changes in the practice guidelines and the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- budget impact of adoption of our product on relevant drug formularies and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners sales and marketing strategies;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In

Table of Contents

addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

Guidelines and recommendations published by various organizations can impact the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our proposed products.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates, and will face an even greater risk if we sell our product candidates commercially. Currently, we are not aware of any anticipated product liability claims with respect to our product candidates. In the future, an individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- initiation of investigations by regulators;

- substantial monetary awards to patients or other claimants;

- distraction of management s attention from our primary business;

- product recalls;

- loss of revenue; and

- the inability to commercialize our product candidates.

We have clinical trial liability insurance with a $5,000,000 aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liabilities that may arise.

Our failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we intend to develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. Failure of this strategy would impair our ability to grow.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;

- disruption of our business and diversion of our management s time and attention to develop acquired products or technologies;

- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;

Table of Contents

- higher than expected acquisition and integration costs;

- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;

- increased amortization expenses;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and

- inability to motivate key employees of any acquired businesses.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Plecanatide and other product candidates, including SP-333, would also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or GMP, regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;

- impose civil or criminal penalties;

- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products or request us to initiate a product recall; or
- pursue and obtain an injunction.

Drugs approved to treat IBS have been subject to considerable post-market scrutiny, with consequences up to and including voluntary withdrawal of approved products from the market. This may heighten FDA scrutiny of our product candidates before or following market approval.

Products approved for the treatment of IBS have been subject to considerable post-market scrutiny. For example, in 2007, Novartis voluntarily discontinued marketing Zelnorm (tegaserod), a product approved for the treatment of women with IBS-C, after the FDA found an increased risk of serious cardiovascular events associated with the use of the drug. Earlier, in 2000, Glaxo Wellcome withdrew Lotronex (alosetron), which was approved for women with severe diarrhea-prominent IBS, after the manufacturer received numerous reports of AEs, including ischemic colitis, severely obstructed or ruptured bowel, or death. In 2002, the FDA approved the manufacturer s application to make Lotronex available again, on the condition that the drug only be made available through a restricted marketing program.

Although plecanatide is being investigated for IBS, plecanatide is from a different pharmacologic class than Zelnorm or Lotronex, and would not be expected to share the same clinical risk profile as those agents. Nevertheless, because these products are in the same or related therapeutic classes, it is possible that the FDA will have heightened scrutiny of plecanatide or any other agent under development for IBS. This could delay product approval, increase the cost of our clinical development program, or increase the cost of post-market study commitments for our IBS product candidates, including plecanatide.

Even if our product candidates receive regulatory approval in the United States, we may never receive approval to commercialize them outside of the United States.

In the future, we may seek to commercialize plecanatide and/or other product candidates, including SP-333, in foreign countries outside of the United States. In order to market any products outside of the United States, we must establish and comply with numerous and varying

regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the United States. The time required to obtain approval in other jurisdictions might differ from that required to obtain FDA approval. The regulatory approval process in other jurisdictions

Table of Contents

may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that plecanatide or other product candidates may not be approved for all indications for use included in proposed labeling or for any indications at all, which could limit the uses of plecanatide or other product candidates and have an adverse effect on our products commercial potential or require costly post-marketing studies.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product candidates.

We have agreements with third-party contract research organizations, or CROs, under which we have delegated to the CROs the responsibility to coordinate and monitor the conduct of our clinical trials and to manage data for our clinical programs. We, our CROs and our clinical sites are required to comply with current Good Clinical Practices, or GCPs, regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our CROs and at our clinical sites to confirm compliance with these requirements. In the future, if we, our CROs or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly Gary S. Jacob, Ph.D., our President and Chief Executive Officer and Kunwar Shailubhai, Ph.D., our Chief Scientific Officer. The loss of services of Dr. Jacob or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidates.

The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with 7 full-time and 3 part-time employees as of November 8, 2010. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Over the next 12 months depending on the progress of our planned clinical trials, we plan to add additional employees to assist us with our clinical programs. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage development efforts effectively;

- manage our clinical trials effectively;

- integrate additional management, administrative, manufacturing and sales and marketing personnel;

- maintain sufficient administrative, accounting and management information systems and controls; and

- hire and train additional qualified personnel.

- We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results and impact our ability to achieve development milestones.

Reimbursement may not be available for our product candidates, which would impede sales.

Market acceptance and sales of our product candidates may depend on reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products as well as levels at which these payers pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will

Table of Contents

be available for any of these products. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidates reimbursed by government or third party payors. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our products.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subject the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products.

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse patients for their use of newly-approved drugs, which in turn will put pressure on the pricing of drugs.

Healthcare reform measures could hinder or prevent our product candidates commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

For example, in March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the PPACA. This law will substantially change the way health care is financed by both government health plans and private insurers, and significantly impact the pharmaceutical industry. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the PPACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which we believe will increase the cost of our products. In addition, as part of the PPACA s provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the donut hole), we will be required to provide a 50% discount on branded prescription drugs sold to beneficiaries who fall within the donut hole. Similarly PPACA increases the level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% and requires collection of rebates for drugs paid by

Medicaid managed care organizations. The PPACA also included significant changes to the 340B Drug Pricing Program including expansion of the list of eligible covered entities that may purchase drugs under the program. At the same time, the expansion in eligibility for health insurance benefits created under PPACA is expected to increase the number of patients with insurance coverage who may receive our products. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

In addition, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reformed the way Medicare covers and reimburses for pharmaceutical products. This legislation could decrease the coverage and price that we may receive for our proposed products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our proposed products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA s exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

Table of Contents

Our ability to use our net operating loss carryforwards may be subject to limitation.

Generally, a change of more than 50% in the ownership of a company s stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit a company s ability to use its net operating loss carryforwards attributable to the period prior to the change. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability for us. At December 31, 2009, we had net operating loss carryforwards aggregating approximately $30 million. We have determined that an ownership change occurred as of April 30, 2003 pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. In addition, the shares of our common stock that we issued since December 31, 2009 have resulted in an additional ownership change. As a result of these events, our ability to utilize our net operating loss carry forwards is limited.

In preparing our consolidated financial statements, we identified material weaknesses in our internal control over financial reporting, and our failure to remedy the material weaknesses identified as of December 31, 2009 and our ineffective disclosure controls and procedures could result in material misstatements in our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our management identified five material weaknesses in our internal control over financial reporting as of December 31, 2009. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified by management as of December 31, 2009 consisted of:

- Ineffective control environment;
- Ineffective monitoring of internal control over financial reporting;
- Ineffective controls over period end financial close and reporting;
- Ineffective controls to ensure the correct application of GAAP related to equity transactions; and
- Ineffective controls to adequately segregate the duties over cash management.

As a result of these material weaknesses, our management concluded as of December 31, 2009 that our internal control over financial reporting was not effective based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control An Integrated Framework (September 1992).

In addition, based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of September 30, 2010, our management has concluded that our disclosure controls and procedures were not 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 required time periods.

We have begun to implement and continue to implement remedial measures designed to address these material weaknesses and the ineffectiveness of our disclosure controls and procedures. If these remedial measures are insufficient to address these material weaknesses and the ineffectiveness of our disclosure controls and procedures, or if additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future and the ineffectiveness of our disclosure controls and procedures continues, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements may contain material misstatements, we could be required to restate our prior period financial results, our operating results may be harmed, we may be subject to class action litigation, and if we gain a listing on the NYSE Amex, our common stock could be delisted from that exchange. Any failure to address the identified material weaknesses or any additional material weaknesses in our internal control or the ineffectiveness of our disclosure controls and procedures could also adversely affect the results of the periodic management evaluations regarding the effectiveness of our internal control over financial reporting and our disclosure controls and procedures that are required to be included in our annual report on Form 10-K. Internal control deficiencies and ineffective disclosure controls and procedures could also cause investors to lose confidence in our reported financial information. We can give no assurance that the measures we plan to take in the future will remediate the material weaknesses identified or the ineffectiveness of our disclosure controls and procedures or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or adequate disclosure controls and procedures or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures, if we fail to remedy the material weaknesses and other deficiencies in our internal control and accounting procedures, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, if we fail to remedy the material weaknesses and other deficiencies in our internal control and accounting procedures, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent auditors addressing these assessments. We have documented and tested our internal control procedures, and we have identified material weaknesses in our internal control over financial reporting and other deficiencies. These material weaknesses and deficiencies could cause investors to lose confidence in our Company and result in a decline in our stock price and consequently affect our financial condition. We have begun to implement and continue to implement remedial measures designed to address these material weaknesses. In addition, if these remedial measures are insufficient to address these material weaknesses, if additional material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls, particularly those related to revenue recognition, are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot

Table of Contents

provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our Common Stock could drop significantly. In addition, we cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. We will only be able to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties to the extent that we have rights under valid and enforceable patents or trade secrets that cover these activities.

As of November 8, 2010, we have two issued United States patents which cover composition of matter of plecanatide and expire in 2022 and 2023. In addition, we have three issued foreign patents which cover composition-of-matter of plecanatide and expire in 2022. These foreign patents cover Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Sweden, Turkey, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyz Republic, Moldova, Russian Federation, Tajikistan, Turkmenistan, and Japan. Additionally as of November 8, 2010, we have 10 pending United States patent applications (seven utility and three provisional) and 20 pending foreign patent applications covering various derivatives and analogs of plecanatide and SP-333. We may file additional patent applications and extensions. In April 2010, two parties filed an opposition to our granted European patent with the European Patent Office. We cannot predict the final outcome of the opposition, which is likely to take several years to complete.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The biotechnology patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our issued patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are competitive with our product candidates but that are not covered by the claims of our patents;

- we might not have been the first to make the inventions covered by our pending patent applications;

- we might not have been the first to file patent applications for these inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies;

- it is possible that our pending patent applications will not result in issued patents;

- we may not develop additional proprietary technologies that are patentable; or

- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party s activities do not infringe our rights to these patents.

Furthermore, a third party may claim that we are using inventions covered by the third party s patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we

Table of Contents

are infringing the third party s patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party s patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO, to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We have not yet registered trademarks for plecanatide in our potential markets, and failure to secure those registrations could adversely affect our ability to market our product candidate and our business.

We have not yet registered trademarks for plecanatide in any jurisdiction. Our trademark applications in the United States, when filed, and any other jurisdictions where we may file may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the PTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our ability to market our product candidates and our business.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party s relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Table of Contents

The market price of the common stock may be volatile and adversely affected by several factors.

The market price of our common stock could fluctuate significantly in response to various factors and events, including:

- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- our issuance of additional securities, including debt or equity or a combination thereof, which will be necessary to fund our operating expenses;
- announcements of technological innovations or new products by us or our competitors;
- loss of any strategic relationship;
- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;
- economic and other external factors;
- period-to-period fluctuations in our financial results; and
- whether an active trading market in our common stock develops and is maintained.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our

common stock.

We have not paid cash dividends in the past and do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our capital stock and do not anticipate paying cash dividends on our capital stock in the foreseeable future. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the common stock price appreciates.

A sale of a substantial number of shares of the common stock may cause the price of our common stock to decline.

If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, including the ending of restriction on resale or the expiration of lock-up agreements, substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants and 98,765 shares and warrants to purchase 98,765 shares issued as part of a private placement to an investor in August 2010, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. We may become involved in securities class action litigation that could divert management s attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and biopharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management s attention and resources, which could adversely affect our business.

Except for the above, there have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2009.

Table of Contents

6. EXHIBITS

(a) Exhibits

10.1	Master Services Agreement dated July 20, 2010*
10.2	Master Services Agreement dated August 5, 2010*
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.

* Portions of this exhibit were omitted and filed separately with the U.S. Securities and Exchange Commission pursuant to a request for confidential treatment.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SYNERGY PHARMACEUTICALS, INC.
(Registrant)

Date: November 9, 2010	By:	/s/ GARY S. JACOB Gary S. Jacob *President and Chief Executive Officer*
Date: November 9, 2010	By:	/s/ BERNARD F. DENOYER Bernard F. Denoyer *Senior Vice President, Finance*