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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: September 30, 2010

☐ **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	**10170**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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

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

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

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

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

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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," "believes," "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.

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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.

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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.

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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.

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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.

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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.

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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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.

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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.

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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.

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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.

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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.

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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:

	Derivative Instrument

Date	Description	New Warrants	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

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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:

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	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.

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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.

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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.

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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.

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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.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

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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.

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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

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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.

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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

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- 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

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

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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;

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- 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

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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

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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.

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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

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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

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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.

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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.

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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.

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SIGNATURES

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

SYNERGY PHARMACEUTICALS, INC.
(Registrant)

Date: November 9, 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

Exhibit 10.1

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as *. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

MASTER SERVICES AGREEMENT
(CMC Services)

This MASTER SERVICES AGREEMENT (this "Agreement") is made as of July 20, 2010 by and between Synergy Pharmaceuticals, Inc., a Florida corporation with an address of 420 Lexington Avenue, New York, NY 10170 ("Synergy"), and *, a corporation with offices at * ("Contractor"). Terms not otherwise defined herein shall have their respective meanings in Section 1 of this Agreement.

R E C I T A L S

A. WHEREAS, Synergy and its Affiliates are in the business of discovering, developing and commercializing pharmaceutical products;

B. WHEREAS, Contractor is in the business of providing pharmaceutical development, analytical, and/or manufacturing services; and

C. WHEREAS, Synergy wishes to retain Contractor to provide certain services associated with the development, analysis, and/or manufacturing and/or supply of certain quantities of specific products for use in IND-enabling studies and/or clinical trials, as more fully set forth below.

NOW, THEREFORE, in consideration of the premises and of the covenants herein contained, the parties hereto mutually agree as follows:

A G R E E M E N T

1. Definitions. In addition to the terms defined elsewhere in this Agreement (including the Statement(s) of Work), the following terms shall have their respective meanings set forth below:

1.1. "API" means the active pharmaceutical ingredient.

1.2. "Agreement" means this Master Services Agreement for Development and Manufacturing Services.

1.3. "Affiliate" means any corporation, company, partnership, joint venture and/or firm that controls, is controlled by or is under common control with a party to this Agreement. For purposes hereof, "control" means (a) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares entitled to vote for the election of directors; and (b) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities.

1.4. "cGMP" means current Good Manufacturing Practices as promulgated under each of the following as in effect on the date of this Agreement and as amended or revised thereafter:

(a) the FDA Act, including 21 CFR (parts 11, 210 and 211) and other FDA regulations, policies and guidelines in effect from time to time governing the manufacture, testing and quality control of investigational drugs; and

(b) all ICH guidance documents as appropriate, including ICH guidance Q7a, "ICH Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients," as applied to investigational drugs (Section 19) specifically for manufacturing activities of API.

1.5. "Change Order" means an agreement signed by both parties that amends a Work Order. Each Change Order shall refer to the specific Work Order it amends, and shall be sequentially numbered with respect to multiple amendments to the same Work Order.

1.6. "CMC" means chemistry manufacturing and control information required by the FDA for filing of an IND or NDA.

1.7. "Confidential Information" means all information, whether in tangible form or not, (a) provided by either party and/or its Affiliates hereunder to the other, or (b) generated by Contractor in the performance of any Project, including but not limited to: any information about manufacturing, testing/analysis methods or processes; any Products or products (whether investigational or not), Synergy Materials, samples, specimens, and other materials or compounds, sub-samples, and retention samples; analyses and the results of such analyses, information on research and development compounds, technical know-how; formulas; studies; regulatory submissions and records; research data and information; financial information; sales and marketing information (including, without limitation, service proposals, price quotations and customer lists); inventions; patent applications and other trade secrets;

information relating to potential new transactions and business between the parties; and all information developed or prepared by either party pursuant to the terms and conditions of this Agreement, each in any form (including but not limited to information provided orally, electronically, or in writing). Product Intellectual Property generated by Contractor in the performance of any Project shall be the Confidential Information of Contractor. To avoid misunderstanding, in order to be treated as Confidential Information hereunder, disclosures initially made in tangible form shall be marked as "Confidential Information" or similar legend, and disclosures initially made in non-tangible form shall be identified as confidential information at the time of initial disclosure and subsequently summarized in a writing provided to the recipient within thirty (30) days of the initial disclosure.

1.8. "Debarment Act" means the Generic Drug Enforcement Act of 1992, as amended, 21 U.S.C. §§ 306.

1.9. "Disputed Product" shall have the meaning set forth in Section 5.3(b).

1.10. "Effective Date" means the later of the two dates on the signature page hereto.

1.11. "FDA" means the United States Food and Drug Administration (or its successor agency) and/or the corresponding governmental or other authority in another country, as applicable, such as the European Agency for the Evaluation of Medicinal Products (or "EMEA") in Europe.

1.12. "FDA Act" means the United States Federal Food, Drug and Cosmetic Act (21 U.S.C. 301, *et. seq.*), and the regulations promulgated thereunder, as amended from time to time, and any successor statute(s).

1.13. "IND" means an Investigational New Drug Application filed with the FDA to begin clinical studies of a new drug in humans (pursuant to 21 CFR 312, *et. seq.*, as amended), and/or the corresponding application with a corresponding regulatory agency in a country other than the United States, as applicable, and/or any successor application (s).

1.14. "Indemnified Party" shall have the meaning set forth in Section 13.3.

1.15. "Indemnifying Party" shall have the meaning set forth in Section 13.3.

1.16. "Synergy Materials" means any materials (and derivatives thereof), including API, supplied by Synergy to Contractor, if any, pursuant to a Work Order.

1.17. "Synergy Representative" shall have the meaning set forth in Section 4.

1.18. "Losses" shall have the meaning set forth in Section 13.1.

1.19. "Manufacture and Release Requirements" means those methodologies, analytical tests, process parameters and cGMP requirements necessary to manufacture and release Product to Synergy in conformity with the Specifications. As applicable, all Manufacture and Release Requirements shall be set forth in the Work Order.

1.20. "Product" means the product resulting from the Services to be rendered by Contractor hereunder, as defined in the Work Order, including the product of such Services that does not meet the Specifications but is accepted by Synergy.

1.21. "Product Intellectual Property" means all intellectual property (including non-patentable inventions) generated by Contractor in the performance of the Services hereunder, or intellectual property generated prior to the Effective Date in anticipation of provision of the Services, and which relates to methods, procedures and processes for the synthesis and production of any Product and is necessary to manufacture the Product or which it is necessary or advisable to disclose to any regulatory authority in connection with (i) any request for an approval from such regulatory authority or (ii) any regulatory requirement.

1.22. "Project" means the separate, defined projects described in a Work Order.

1.23. "Project Manager" shall have the meaning set forth in Section 4.

1.24. "Regulatory Audit" shall have the meaning set forth in Section 16.1.

1.25. "Services" means those services, which may include (but not be limited to) formulation development, intermediary and product manufacture, consulting, chemical synthesis, chemical process research, analytical methods development, medicinal chemical synthesis, computational chemistry services, validation or release testing and other related services, that are requested by Synergy and agreed to be provided by Contractor as set forth in a Work Order.

1.26. "Specifications" means the composition, quality, purity, identity and strength of a Product and any chemistry, manufacturing and controls requirements for the manufacture of Product: (a) as appended hereto at Schedule 1,; or (b) as approved and provided by Synergy to Contractor and accepted by Contractor prior to the commencement of the Services and included in the applicable Work Order, as applicable.

1.27. "Third Party Rights" means any invention, discovery, technology, know-how and/or other intellectual property that are incorporated into the Work Product and/or Product Intellectual Property, but which is not owned or otherwise assignable by Contractor or its Affiliates.

1.28. "Work Order" refers to the written statement of work, substantially in the form attached hereto as Schedule A, that specifies the Services to be provided by Contractor for Synergy, including, as may be applicable, a description of the Product, Specifications, quantity of Product, Manufacture and Release Requirements, estimated duration of the Project(s), milestones and all other matters pertinent to design, scheduling and completion of the Project, and the cost and payment terms.

1.29. "Work Product" means all results of Services, including but not limited to the Product and other compounds, data, information, documentation (including, but not limited to, lab notebooks as applicable), reports and any other deliverables listed in the Work Order.

2. Scope of Services.

2.1 Work Order. Services provided by Contractor shall be subject to the terms and conditions of this Agreement. All such Services shall be the subject of a Work Order, substantially in the form of Exhibit A, setting forth the following with respect to the applicable Project: (i) description of Services to be provided, (ii) fee and payment schedule for the Services, (iii) description of deliverables to be delivered by Contractor (each, a "Deliverable") and their intended use, (iv) materials to be provided by each party and (v) a Project timeline. After a work order substantially in the form of Exhibit A is agreed upon and executed by the parties hereto, the same shall be attached to this Agreement as an amendment to Exhibit B (each, a "Work Order") and the Work Order shall then be a part of this Agreement. There will be no limit to the number of Work Orders that may be added to this Agreement. Services shall only be commenced after the execution of a Work Order.

2.2 Change Orders. In the event that Synergy would like Contractor to materially alter the Services under a given Work Order or the assumptions underlying the budget, the parties shall agree upon a written Change Order prior to the provision of said Services. The Change Order constitutes an amendment to the applicable Work Order and the services set forth therein shall be deemed to be Services part of such Work Order. Any unauthorized changes in scope made by Contractor shall be the responsibility of Contractor and Contractor agrees to pay to Synergy any of its losses or added costs related thereto. Contractor has no obligation to perform and Synergy has no obligation to pay for any additional or modified Services absent written agreement by the parties included in a Change Order with respect thereto.

2.3 Subcontracting. With Synergy's prior written consent, Contractor may subcontract the performance of certain of its obligations in a Work Order to qualified third parties; *provided* that (a) Contractor notifies Synergy of the proposed subcontractor and identifies the specific Services to be performed by such subcontractor, and (b) such subcontractor performs such Services in accordance with the terms and conditions of this Agreement (including, without limitation, Sections 9 and 10 hereof). Contractor shall remain liable to Synergy for the performance of any such subcontractor.

2.4 Contractor Employees and Agents. Contractor shall be solely responsible for any and all salaries, fees, state and federal taxes, withholding, FICA, worker's compensation or other

payments due with respect to the compensation paid to Contractor by Synergy or by Contractor to any employee or agent employed by Contractor. Contractor's employees and other agents shall have no right to receive from Synergy any employee benefits (including by not limited to health and accident insurance, sick leave or vacation) that Synergy provides to its own employees.

3. Materials.

3.1. Supply of Synergy Materials. To the extent required by a Work Order, Synergy shall provide Contractor with sufficient amounts of any Synergy Materials (either directly or indirectly, and including API). Synergy shall also provide Contractor with such data as is in its possession, with the right to disclose, and as may be necessary to apprise Contractor, prior to delivery of any Synergy Materials, of the stability, proper storage and safety and other characteristics and requirements of such Synergy Materials. Synergy shall be solely responsible for providing Contractor with any such Synergy Materials in a manner that materially complies with all applicable law, including but not limited to Synergy obtaining any necessary regulatory permits or licenses to ship such Synergy Materials to Contractor and/or satisfying any necessary regulatory labeling requirements on such Synergy Materials. Contractor shall use any such Synergy Materials solely for rendering the Services under the applicable Work Order, and shall not transfer any Synergy Materials to a third party except pursuant to Section 2.2. Any Synergy Materials remaining upon completion of the Services under a Work Order shall be, at Synergy's direction, either returned to Synergy or destroyed. If Synergy does not notify Contractor within sixty (60) days after completion of a Project of its intention hereunder, then Contract shall return the Synergy Materials at Synergy's expense.

3.2. Third Party Materials. The costs of all third party-suppliers' fees and the purchase of Project-specific items (such as raw materials, excipients, packaging, special equipment, tooling, change parts, laboratory columns and reagents) necessary for Contractor to perform the Services shall be purchased by Contractor and charged to Synergy at Contractor's cost, provided that any such costs shall be set forth in the applicable Work Order, or as necessary, agreed to by the parties pursuant to Section 2.1(b), and Contractor shall only use any such Project-specific items to render the Services.

3.3. Importation of Materials. If applicable, Contractor and Synergy will co-operate and provide such assistance to

each other as may be reasonably necessary to permit the import of the API and other Synergy Materials into the country where the Services will be performed.

4. Project Manager. Core Team. Contractor will assign a project manager (the "Project Manager") and other members of the core Project team (including, as relevant, a project director) (the "Core Team") for the duration of each project for which a Work Order has been authorized. Contractor agrees to provide thirty (30) days prior written notice to Company, whenever practicable, of any changes to the Core Team, except as specified below. During any Project, Contractor will employ its commercially reasonable efforts to promote members of the Core Team within the Project. Contractor will provide Project-specific training to replacement Core Team members at its own expense. The Project Manager, or such other Core Team Member agreed by the parties, shall be the primary contact for Company and shall timely address all issues and concerns raised by Company, as well as provide to Company all information requested by Company concerning this Agreement or the Services.

5. Shipping and Inspection of Product.

5.1. Shipping. All Product shipped hereunder shall comply in all material respects

with the applicable Manufacture and Release Requirements and shall be accompanied by a certificate of analysis and cGMP certificate of conformance, each in a form to be agreed upon by the parties. Contractor agrees to work with Synergy to deliver and transfer the Product to such locations and in such manner as directed by Synergy. All Product generated hereunder shall be packaged and shipped to Synergy's designated destination and in accordance with Synergy's written instructions and in compliance with all applicable shipping regulations. All risk to the Product shall pass to Synergy upon delivery to Synergy's carrier. Unless the parties agree in the applicable Work Order or otherwise, Synergy shall designate a shipping company, coordinate with the shipping company for the shipment of the Product, and be billed directly by the shipping company for all related shipping costs.

5.2. Evaluation Period. Synergy shall have one (1) month from the date the Product is delivered to its designated destination to evaluate the Product and reject the acceptance thereof; *provided* that, Synergy may reject any Product only if (a) Contractor fails to deliver the certificate of analysis; (b) the Product does not meet the Specifications in material respect as of (i) the date of delivery to Synergy's carrier if Synergy arranges shipment, or (ii) the date of delivery to Synergy if Contractor arranges shipment ; or (c) the Product was not processed according to the Manufacture and Release Requirements (including cGMP requirements). If Synergy fails to notify Contractor of its rejection within such one month period, Synergy shall be deemed to have accepted such Product. Notwithstanding the foregoing, such one (1)-month period shall be extended to a period of three (3) months from delivery in the event a defect is discovered which comprises a failure of Product to meet applicable regulatory requirements. The right of rejection set forth in this section 5.2 shall not apply to defects in material that does not meet Specifications but which Synergy agrees to accept irrespective of such defects.

5.3. Rejection of Product.

(a) If Synergy rejects any of the Product pursuant to Section 5.2, Synergy shall (i) promptly provide to Contractor written notice of rejection that includes the basis for such rejection and (ii) provide Contractor with the opportunity to conduct its own tests to confirm such basis of rejection, which shall be conducted promptly. Synergy shall return all remaining unused Product to Contractor; *provided* that Synergy may retain a sample of such reject Product that is being used for laboratory testing and to confirm its rights hereunder, but may not use any such sample for any human clinical testing or trials. Contractor shall replace such rejected Product with conforming Product as soon as commercially reasonable, but in no event after a period longer than the original lead time required for shipment of Product as set forth in the applicable Work Order for such Product.

(b) Notwithstanding the foregoing, if Synergy rejects the Product pursuant to Section 5.2(b) or (c) and the Contractor disagrees with the basis for such rejection in writing to Synergy within three (3) weeks of receipt of Synergy's notice (such Product, the "Disputed Product"), then the parties shall resolve such disputed rejection as follows: (i) representatives from both parties shall promptly meet to confirm that the methods of analysis are the same and are being executed in the same manner; (ii) each party shall send samples to the other for analysis; (iii) after such analysis, the parties shall discuss the results and use good faith efforts for a period of ten (10) business days to reach agreement regarding such disputed rejection. In the event the parties cannot resolve the matter, they shall in good faith discuss and choose an independent third party laboratory to perform the same analysis on the Disputed Product. The report of such laboratory shall be in writing, addressed to both parties and shall state whether the Disputed Product

met the requirements of Section 5.2(b) and (c), and shall be binding upon the parties. Synergy and Contractor shall be equally obligated to such laboratory for the costs of such analysis, but upon the issuance to the parties of the report therefor the prevailing party shall be promptly reimbursed by the other party for its share of such costs actually paid (if any).

(c) If Synergy properly rejects any Product pursuant to this Section 5.3 and Contractor cannot replace such rejected Product with conforming Product within the time period set forth in Section 5.3(a), then Contractor shall refund to Synergy all amounts paid for such rejected Product; *provided* that, Contractor shall not wait for such time period to expire if it does not have a reasonable belief that it could not meet such deadline. Nothing in this Section 5 shall permit Contractor to

terminate or otherwise cancel its other obligations under the same or other Work Orders or terminate this Agreement.

(d) Synergy's remedies in the event of a failure of Product to meet the Specifications shall be limited to replacement of the nonconforming Product or the purchase price of the particular Product at issue. CONTRACTOR SHALL NOT BE LIABLE, AND SYNERGY WAIVES ALL CLAIMS AGAINST CONTRACTOR, FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED UPON NEGLIGENCE, BREACH OF WARRANTY, STRICT LIABILITY IN TORT OR ANY OTHER CAUSE OF ACTION.

6. Compliance with Applicable Law; Recalls.

6.1. In addition to Contractor's obligations under Section 2.1, Contractor shall also perform the Services in accordance with (a) Contractor's applicable, standard operating procedures (and shall, upon request, provide access to Synergy on Contractor's site to copies of all Contractor's standard operating procedures relevant to the Services), and (b) subject to Section 6.2, applicable federal, state and local laws and regulations (including, but not limited to, the FDA Act and other applicable rules and regulations of the FDA and federal, state and local environmental and occupational safety and health requirements).

6.2. Should any government regulatory requirement change that is applicable to the Services, Contractor shall make a reasonable effort to satisfy the new requirements. If compliance with such new regulatory requirements necessitates a change in a Work Order, Contractor shall submit to Synergy a revised technical and cost proposal prior to making any changes in such Work Order and shall not proceed until such changes have been agreed upon pursuant to Section 2.1(b). In the event Synergy does not approve such changes, Synergy or Contractor may terminate the applicable Statement(s) of Work with no further obligation to Contractor, and Contractor shall deliver to Synergy all Work Product (including Products) generated by the Services until that point and limit costs incurred, in both cases pursuant to Section 15.

6.3. In the event of a conflict in applicable government regulations, Contractor shall notify Synergy, and at Synergy's request shall contact the relevant governmental authorities to obtain clarification and guidance regarding compliance with the regulations in question. If there is a choice of regulations that may be validly used, the parties shall work in good faith to agree on the designation of which regulations shall be applicable.

6.4. Contractor shall ensure that Projects intended to support INDs or NDAs shall comply with all appropriate regulatory requirements applicable to such applications; *provided* that, it is expressly understood that Synergy or its Affiliate, as applicable, is the Sponsor (as such term is defined in 21 CFR Part 312.3) of any such IND or NDA, and that Synergy shall remain responsible for all legal requirements applicable to Synergy of INDs or NDAs, including but not limited to applicable regulations of the FDA and cGMP requirements, except to the extent that such obligations may be and are expressly transferred to Contractor by the specific terms and conditions of a Work Order. Contractor agrees to provide to Synergy, either directly or through filing such material with FDA and irrevocably and unconditionally providing Synergy with a right of reference to such filing or filings, such information embodied in Product Intellectual Property as Synergy may reasonably require for purposes of applying for and maintaining application for regulatory approval of the Product, including, without limitation, providing Synergy with all reports, authorizations, certificates, methodologies, and other documentation in the possession or under the control of Contractor relating to the synthesis or manufacture of the Product (or any component thereof). Such information, if provided to Synergy, shall be deemed the Confidential Information of Contractor, in accordance with the provisions of Section 1.7, and shall be governed by the provisions of Sections 9 and 10.4, provided that it is expressly understood that Synergy may provide such information to a regulatory authority as necessary to support any application for authorization to conduct clinical trials or regulatory approval of a Product or in response to the requests or requirements of such regulatory authority, except to the extent Synergy is required or strongly encouraged to maintain such information solely at its facility by any relevant regulatory authority. Contractor will provide to Synergy a copy of any correspondence with any regulatory authority related to the Project, a Product or the Services within a reasonable time, not to exceed three days from receipt or transmission of such correspondence.

6.5. In the event that Synergy shall be required or shall voluntarily decide to recall any Product Manufactured by Supplier pursuant to this Agreement, then Contractor shall cooperate with Synergy in implementing such recall.

7. Audits; Progress Review; Records.

7.1. As required by an applicable Work Order, Contractor shall provide Synergy such periodic and final written reports (either in electronic or paper format), as outlined in the Work Order.

7.2. Synergy reserves the right to visit Contractor's laboratories and to inspect Contractor's records during normal business hours and upon reasonable notice (a) to confirm Contractor's performance of this Agreement in accordance with the terms of this Agreement, and/or (b) in the event circumstances arise that would adversely affect the quality of Product, Contractor shall immediately notify Synergy of such circumstances, Contractor shall allow representatives of Synergy prompt access to relevant Contractor areas and records. In addition, during the Term of this Agreement, Synergy shall have the right (either itself or through an agent) during normal business hours and upon reasonable prior notice, to audit, inspect and observe the manufacture, processing, testing, packaging, storage and transportation of materials related to or used in the manufacture of the Product(s), and to review all batch manufacturing records, for purposes of conducting quality control audits required for its internal control or confirming compliance with legal or other requirements as imposed pursuant to this Agreement. A representative of Contractor may be present during such inspections. Such representatives of Synergy shall have no responsibility for or right to supervise Contractor's employees performing the manufacture, processing, testing, packaging, storage or transportation operations or for the

operations themselves. Synergy shall be responsible for all its expenses related to such audits. Observations made during any visit permitted by this Section 7.2 shall be subject to the provisions of Section 9 hereof.

7.3. Contractor shall retain experimental records and laboratory notebooks relating to each Project, and shall maintain suitable CMC support documentation to allow Synergy or its Affiliates to file an IND, IND amendment, NDA or ANDA with the FDA. All such documentation and Work Product in Contractor's possession (not otherwise returned to Synergy) shall be archived in a secure area reasonably protected from fire, theft or destruction by Contractor for a period of ten (10) years following the completion of a given Project or earlier termination thereof. Synergy may elect to have the materials retained in Contractor's archives for an additional period of time for a reasonable storage fee.

7.4. With respect to a filing with the FDA, in the event Synergy intends to (a) include documentation generated by Contractor, at least seven (7) days prior to such filing, Synergy shall provide Contractor with relevant portions of such documents for the sole purpose of Contractor's confirmation of the accuracy of such Contractor-generated data, or (b) incorporate in a narrative fashion information about the Services (e.g., a description process manufacturing in an IND), simultaneously with such filing Synergy shall provide Contractor with a copy of the relevant portions of such documents.

8. Payment. All payments by Synergy shall be made in accordance with the Work Order in U.S. dollars. Payment will be due net thirty (30) days from the date of Contractor's invoice. Contractor shall have the right to seek to collect interest on any payments that are not paid on or before thirty (30) days after the date such payments are at a rate equal to the lesser of (a) one percent (1.0%) per month or (b) the maximum rate allowable by applicable law, calculated on the total number of days payment is delinquent. Upon request of Contractor, Synergy shall provide adequate proof of financial resources prior to acceptance of any Work Order by Contractor. Contractor reserves the right, in its sole discretion, to determine whether to extend credit to Synergy at the time of placement of each Work Order issued under this Agreement, or at any time during the term of this Agreement.

9. Confidential Information.

9.1. Each party hereto shall (a) hold the Confidential Information of the other party (and/or its Affiliates, as applicable) in strict confidence and take reasonable precautions to protect such Confidential Information (including, without limitation, all precautions the receiving party normally employs with respect to its own confidential information), (b) not divulge any such Confidential Information to any third party (other than those parties specifically permitted to receive such Confidential Information pursuant to the terms of this Agreement), (c) not make any use whatsoever at any time of such Confidential Information except to carry out its obligations under this Agreement and the Projects and Work Orders hereunder and to exploit the rights granted to such party hereunder, (d) not derive any commercial benefit (whether direct or indirect) from such Confidential Information (other than pursuant to Services rendered under this Agreement), and (e) not copy (except as may be necessary to accomplish the purposes of this Agreement) or reverse engineer any such Confidential Information.

9.2. Without granting any right or license, a party's obligations under this Article 9 shall not apply to Confidential Information that the other party can demonstrate by reasonable documentary evidence: (a) was in its possession prior to receipt from the disclosing party (or, in the case of Work Product, prior to its generation under this Agreement); (b) was in the public domain at the time of receipt from the disclosing party (or, in the case of Work Product, prior to

its generation under this Agreement); (c) becomes part of the public domain without breach of such party's obligations of confidentiality under this Agreement; or (d) is lawfully received by the receiving party from a third party, where the third party is wholly independent of the receiving party and has no obligation of confidentiality to disclosing party with respect to such information disclosed. Notwithstanding the foregoing, (i) Confidential Information shall not fall within an exception set forth in this Section 9.2 merely because such Information is embraced by more general information in the public domain or in the possession of the receiving party, and (ii) the fact that any Work Product may fall within one or more of the exceptions set forth in this Section 9.2 shall not relieve Contractor or Synergy of its obligations under Sections 9.1(a) or (b).

9.3. In the event a party is required to disclose Confidential Information of the other party pursuant to an order of a court or administrative agency or other governmental body with valid jurisdiction, the receiving party may disclose Confidential Information only after providing the disclosing party with reasonable advance notice thereof to enable the disclosing party to seek a protective order or otherwise prevent such disclosure, but nothing herein shall require a party to take or refrain from taking any action in violation of any such legal process.

9.4. Each party shall limit the disclosure of Confidential Information to its or its Affiliates' directors, employees and agents (and in the case of Contractor, to its permitted subcontractors, if any), in each case with a legitimate "need to know" and who are bound in writing to observe the obligations of nondisclosure and non-use under this Agreement. Information exchanged by and between the parties and any such directors, employees and/or agents shall be deemed the Confidential Information of the party on whose behalf such information was disclosed, and shall be governed by the provisions of Sections 1.8 and 9. For the avoidance of doubt, any information of a party not specifically disclosed but of which any director, employee or agent becomes aware via site visits or otherwise shall be the Confidential Information of such party.

9.5. Except as otherwise specified in this Agreement, each party shall upon the request of the other party, turn over to

the disclosing party all Confidential Information of the disclosing party in the receiving party's possession or control (including any copies or extracts thereof) or destroy such records and certify the destruction thereof, except for any copy legally required to be retained for archive purposes.

9.6. Each party acknowledges and agrees that due to the unique nature of the disclosing party's Confidential Information, there can be no adequate remedy at law for any breach of its obligations hereunder, that any such breach may allow the receiving party or third parties to unfairly compete with the disclosing party, and therefore, that upon any such breach or any threat thereof, the disclosing party shall be entitled to appropriate equitable relief in addition to whatever remedies it might have at law. The receiving party shall notify the disclosing party in writing immediately upon the occurrence of any such unauthorized release or other breach of which it becomes aware.

9.7. The obligations of each party with respect to Confidential Information disclosed in connection with any Project shall continue in effect until completion or other termination of such Project and for ten (10) years thereafter.

10. Ownership, Inventions and Patents; Assignment; License Grants.

10.1. All intellectual property (including, without limitation, Confidential Information) of Synergy in existence as of the Effective Date is and shall remain the exclusive property of

Synergy. Synergy hereby grants to Contractor, on a Project by Project basis and for the duration of such Project, a non-exclusive license (with no right to sublicense) to use such Synergy intellectual property actually disclosed (or transferred, as applicable) to Contractor solely for the purpose of, and only to the extent strictly necessary for, Contractor's performance of the applicable Services.

10.2. All intellectual property (including, without limitation, Third Party Rights and Confidential Information) of Contractor in existence as of the Effective Date is and shall remain the exclusive property of Contractor. Contractor hereby grants to Synergy, on a Project by Project basis, a fully paid-up, royalty free, irrevocable (subject to the provisions of Section 15.2 (a)), worldwide, non-exclusive license to use such Contractor intellectual property solely for the purpose of, and only to the extent strictly necessary for, Synergy's full use and enjoyment (including the commercialization of Products) of the Work Product. For the avoidance of doubt, the foregoing license is not intended to enable Synergy to manufacture, or have manufactured, the Product using any process developed and owned by Contractor as of the Effective Date. This license shall not apply to any Product Intellectual Property embodied in such Contractor intellectual property, for which Section 10.4 shall apply.

10.3. (a) Each Party shall own such data, information, developments, ideas and inventions as its employees or contractors may make in the course of performance under this Agreement. In particular, Contractor shall own all Product Intellectual Property.

(b) Data, information, developments, ideas and inventions made jointly by the parties ("Joint Developments") shall be jointly owned, and each party shall have a permanent, worldwide nonexclusive right to use and authorize others to use such Joint Developments without any obligation to obtain the consent of or account to the other Party. In the event of any patentable Joint Development, the parties shall meet in order to decide (i) whether they will apply for patent protection, and if they decide to do so, (ii) the countries in which they will file the related patent application(s). In the event the Parties decide to file in joint ownership any related patent right, the administration procedure for any such patent right shall be agreed upon between the Parties before any commercial exploitation of the same. All external costs related to the filing, prosecution, maintenance and defense of any related patent right in the countries agreed upon by the parties shall be shared as agreed by the parties.

10.4. Contractor hereby grants to Synergy and its Affiliates a fully paid-up, royalty free, irrevocable, fully transferable, worldwide, non-exclusive license (with the right to sublicense) under Product Intellectual Property to the extent necessary or useful, to use, have used, disclose, modify, reproduce, enhance, sell, make or have made derivative works thereof, and to develop, make, have made, use, sell, offer to sell and import Product. The foregoing right includes the right to disclose Product Intellectual Property comprising Confidential Information of Contractor under an obligation of confidentiality in connection with manufacturing, licensing, or regulatory approval matters or in connection with a potential sale of Synergy's business. Notwithstanding the foregoing, Contractor is not required to disclose Product Intellectual Property to Synergy unless otherwise required to do so under this Agreement. For the avoidance of doubt, the foregoing license is intended to preclude Contractor from asserting any right in Product Intellectual Property against Synergy in a manner which would preclude Synergy from manufacturing Product for itself or having Product manufactured for it, but is not necessarily intended to enable Synergy to manufacture Product using the process developed by Contractor.

10.5. If requested by a party, the other party shall execute any and all documents necessary to assign or perfect the first party's ownership in inventions or discoveries (as determined under this Section 10) at such first party's expense.

10.6. Except as expressly agreed to by the parties in this Agreement or any Work Order, nothing contained herein, nor the delivery of any Confidential Information of one party to the other, shall be deemed to grant any right or license under any patent or patent applications or to any intellectual property of the first party to the other.

11. Insurance.

Contractor agrees, throughout the performance of each Project and for five (5) years thereafter, to keep in full force and effect and maintain at its sole cost and expense insurance coverage in types and amounts commensurate in its industry for the performance of services substantially similar to the Services by similarly sized service providers and as otherwise prudent or required by law, which coverage will be placed with a first class insurer with at least an A+:X rating by AM Best. Contractor agrees to provide Synergy with certificates of insurance if requested to do so by Synergy.

12. Representations, Warranties and Covenants.

12.1. Representations, Warranties and Covenants.

(a) Contractor hereby represents, warrants and covenants to Synergy that it has and shall engage competent employees and consultants with the proper skill, training and background to support its obligation to render the Services hereunder, and shall provide the facilities, supplies and staff necessary to complete each Project as specified in the Work Order for such Project, and in accordance with the other terms of this Agreement.

(b) Contractor and Synergy each represents, warrants and covenants to the other that it has and shall continue to have written agreements with its directors, officers, employees, agents, subcontractors and representatives to effectuate the terms of this Agreement, including without limitation Sections 9 and 10, and shall enforce such agreements to provide the other with the benefits thereof.

(c) Contractor warrants and covenants that each Project shall be performed in all material respects in accordance with the terms of this Agreement and the applicable Work Order and all Product will conform in all respects to the Specifications and Manufacture and Release Requirements set forth in the applicable Work Order at the time of delivery to Synergy's carrier if Synergy arranges for shipment, or time of delivery to Synergy if Contractor arranges shipment; provided that should Synergy agree to accept Product with actual knowledge that is fails to meet Specifications, the warranty that the Product meets Specifications will be deemed waived with respect to a defect known to Synergy at the time of acceptance.

(d) Contractor is under no contractual or other obligation or restriction that is inconsistent with Contractor's execution of its obligations under this Agreement, including the performance of the Services. During the term of this Agreement, Contractor will not enter into any agreement, either written or oral, in conflict with its obligations hereunder. Contractor shall provide the Services in a manner that the

provision thereof will not conflict with its responsibilities under any other agreement, arrangement or understanding, including any employment relationship.

(e) Contractor shall not knowingly use any Third Party Rights in the rendition of the Services without the prior written consent of Synergy.

12.2. Mutual Representation and Warranties. Each of Synergy and Contractor hereby represent and warrant that:

(a) such party is, and at all times during the term of the Agreement shall remain, a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization; and

(b) the execution and delivery of this Agreement has been duly authorized by all requisite corporate action. This Agreement is, and shall remain, a valid and binding obligation of such party, enforceable pursuant to its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.

12.3. THE WARRANTIES EXPRESSLY MADE IN THIS AGREEMENT ARE THE SOLE WARRANTIES PROVIDED BY THE PARTIES AND ARE EXPRESSLY IN LIEU OF ALL IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Except as provided elsewhere in this Agreement, Contractor does not warrant that any Project design(s) and/or the results of such Project(s) shall necessarily satisfy the requirements of the FDA at the time of submission.

13. Indemnification. Notwithstanding any other provisions of this Agreement;

13.1. Synergy shall indemnify, defend and hold harmless Contractor, its Affiliates and its and their respective agents, directors and employees, from and against any and all losses, costs, expenses, liabilities, claims, actions and damages (including without limitation reasonable attorney's fees, and arbitration and/or litigation costs) ("Losses") actually incurred and resulting from a claim brought by a third party arising out of or related to: (a) the development, manufacture, use or commercialization of a Product (or any product derived from a Product) by Synergy or its Product (or product) licensee; or (b) any breach of its representations, warranties or obligations in this Agreement, except in each case to the extent caused by the gross negligence or willful misconduct of Contractor, its Affiliates and its and their agents or employees.

13.2. Contractor shall indemnify, defend and hold harmless Synergy, its Affiliates and its and their respective agents,

officers and employees, from and against any and all Losses actually incurred and resulting from a claim brought by a third party arising out of or related to: (a) the failure to implement the Project and any Work Order pursuant to their terms and the other terms of this Agreement, or (b) any breach of its representations, warranties or obligations in this Agreement, except in each case to the extent caused by the gross negligence or willful misconduct of Synergy, its Affiliates and its and their agents or employees.

13.3. If a party is entitled to indemnification hereunder (the "Indemnified Party"), it shall promptly notify the other party (the "Indemnifying Party") and the Indemnifying Party shall undertake the defense or settlement of any third party claim or action to which its indemnification may be applicable. If the Indemnifying Party fails to undertake such defense within a reasonable time, the Indemnified Party may defend or settle the matter in its sole discretion and seek the

appropriate remedy from the Indemnifying Party. However, the Indemnifying Party may not settle a claim without the Indemnified Party's prior written consent if such settlement would impose on Indemnified Party any liability or obligation, and such consent shall not be unreasonably withheld or delayed.

14. Debarment.

14.1. Contractor represents and warrants that it has not been debarred, and has not been convicted of a crime which could lead to debarment, under the Debarment Act. In the event that Contractor or any of its officers, directors, or employees becomes debarred or receives notice of action or threat of action with respect to its debarment, Contractor shall notify Synergy immediately in writing.

14.2. Contractor represents and warrants that it has not utilized, and shall use its reasonable best efforts not to utilize, the services of any individual or entity in the performance of services under this Agreement that has been debarred or that has been convicted of a crime which could lead to debarment under the Debarment Act. In the event that Contractor receives notice of the debarment or threatened debarment of any such individual or entity, Contractor shall notify Synergy immediately.

15. Term and Termination.

15.1. This Agreement shall be in effect from the Effective Date and for a period of five years, unless terminated by either party as expressly permitted in this Agreement; *provided* that, in the event either party delivers a termination notice pursuant to this Section 15, the parties shall fulfill their respective obligations under any outstanding Work Order(s).

15.2. In addition to the provisions of Section 15.1:

(a) either party may terminate this Agreement or any Work Order in the event of a material misrepresentation or breach of a material obligation of the other party, if such misrepresentation or breach remains uncured, or in the case of a breach that cannot reasonably by cured within such time period, the breaching party fails to take significant measures to achieve a cure, to the reasonable satisfaction of the non-defaulting party for thirty (30) days after delivery of written notice of such breach by the non-defaulting party to the defaulting party. In the event Contractor delivers a termination notice pursuant to this Section 15.2 and does not indicate in such notice that it shall cease the rendition of the Services to which such material misrepresentation or breach relates, Contractor shall complete all existing Projects pursuant to their terms. In the event Synergy delivers a termination notice pursuant to this Section 15.2, Contractor shall promptly comply with the terms of such notice(s) to terminate work on the Project(s) or Work Orders (as applicable) and use its best efforts to limit any further cost to Synergy, and Synergy shall pay Contractor all of its costs incurred or irrevocably obligated as of the date of termination, in each case pursuant to this Agreement.

(b) Synergy may terminate any Project or Work Order (or a portion thereof) at any time prior to completion by giving written notice to Contractor. Synergy may, on termination of all Projects and Work Orders, terminate this Agreement. Contractor shall promptly comply with the terms of such notice(s) to terminate work on the Project(s) or Work Order(s) (as applicable) and use its best efforts to limit any further cost to Synergy, and

Synergy shall pay Contractor all of its costs incurred or irrevocably obligated as of the date of termination and any applicable fees, in each case pursuant to this Agreement.

(c) this Agreement may be terminated in whole or in part as set forth in Section 2.5.

(d) notwithstanding the provisions of Section 15(a), Contractor may terminate this Agreement or suspend further deliveries immediately upon written notice to Synergy if Synergy fails to make timely payment of amounts due hereunder if such nonpayment remains uncured for ten (10) days following delivery of written notice thereof from Contractor to Synergy.

15.3. Except as set forth in Section 15(d), upon delivery of a notice to terminate the Agreement pursuant to this Section 15, the Agreement shall terminate contemporaneously with the later of the termination date set forth in such notice and the completion of any final Work Order(s).

15.4. Upon termination of the Agreement or any Work Order by either party, Contractor shall promptly deliver to Synergy all Product, reports, data, records and other Work Product generated by Contractor for the Project(s) and Statement(s) of Work and return all remaining Synergy Materials to Synergy, in each case as applicable. Notwithstanding the foregoing, Contractor shall not provide batch records or process information, except as set forth in Section 6 of this agreement.

15.5. The termination of this Agreement for any reason shall not relieve the parties of any obligation accruing prior to such termination. In no way limiting the generality of the foregoing, Sections 1, 6, 7, 9, 10, 11, 12, 13, 16 and 17 shall survive the termination of this Agreement.

16. Regulatory Filings and Contacts; Audits.

16.1. Contractor shall give Synergy reasonably prompt notice in the event of any changes, additions or corrections to any Drug Master File that it owns, controls or otherwise maintains, in each case as related to Product.

16.2. Synergy shall be solely responsible for all contacts and communications with any regulatory authority regarding the provision of Services hereunder. Unless required by applicable law, Contractor shall have no contact or communication with any regulatory authority regarding the provision of the Services hereunder without the prior written consent of Synergy, which shall not be unreasonably withheld or delayed. Contractor shall: (a) promptly notify Synergy in writing of any FDA or other governmental inspection or inquiry concerning any Project or Work Order, including, but not limited to, inspections of investigational sites or laboratories (a "Regulatory Audit"); (b) promptly forward to Synergy copies of any correspondence from any regulatory or governmental agency relating to such Regulatory Audit, including, but not limited to, FDA Form 483 notices and FDA refusal to file, rejection or warning letters; and (c) obtain the written consent of Synergy, which will not unreasonably be withheld or delayed, before referring to Synergy or any of its affiliates in any Regulatory Audit correspondence. Synergy may, in its reasonable discretion, have a representative present during a Regulatory Audit inspection. In the event such a representative is present, Synergy acknowledges that it may not direct the manner in which Contractor fulfills its obligations to permit inspection by governmental entities.

16.3. Should any Regulatory Audit or other inspection or audit by a regulatory authority require any process changes, Contractor shall notify Synergy immediately and the

parties shall discuss the means for implementing such changes. For the avoidance of doubt, Contractor may not implement any such change to a Product-related Process without Synergy's prior, written consent (including pursuant to a Change Order).

16.4. Contractor agrees that, during a Regulatory Audit, it will not disclose information and materials that are not required to be disclosed to such agency without the prior consent of Synergy, which shall not unreasonably be withheld or delayed. For example, such information and materials that a party conventionally would not be required to disclose include, but are not limited to, (a) financial and pricing data (including, but not limited to, the budget and payment sections of a Work Order), (b) sales data (other than shipment data), and (c) personnel data (other than data as to qualification of technical and professional persons performing functions subject to regulatory requirements).

16.5. All information disclosed, revealed to or ascertained by Synergy or Contractor, as the case may be, in connection with any such Regulatory Audit or in connection with any correspondence between Contractor and any regulatory authorities (including the redacted portions of any FDA Form 483 notices) shall be deemed to constitute Confidential Information for purposes of this Agreement.

17. Miscellaneous.

17.1. Independent Contractor. It is expressly agreed that the relationship between Synergy and Contractor shall not constitute a partnership, joint venture or agency. Neither Synergy nor Contractor shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other party to do so.

17.2. Governing Law. This Agreement shall be governed by the laws of the State of New York, U.S.A. without regard to the conflicts of law provisions thereof.

17.3. Publicity; Use of Names. Neither party may publish any articles or make any presentations relating to the Services provided hereunder or referring to data, information or materials generated as part of such Services, in whole or in part, without the prior written consent of the other. In addition, except as required by law or the rules of any stock exchange or market on which securities of a party are listed, neither party shall use the name of the other party or the names of the employees of the other party in any advertising or sales promotional material or in any publication without prior written permission of such party.

17.4. Merger, Consolidation or Sale of Assets; Assignment. Neither party may assign any of its rights or obligations under this Agreement without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed, provided that each party may grant sublicenses as provided in this Agreement and assign its rights and obligations hereunder in connection with a merger, consolidation or the sale of substantially all of the assets to which this Agreement relates. Any permitted assignee shall assume all obligations of its assignor under this Agreement, unless the parties otherwise agree. For purposes of this Agreement, a merger, consolidation or sale of all or substantially all of a party's assets shall not be deemed an assignment; *provided* that such party's rights and obligations under this Agreement shall be assumed by its successor in interest in any such transaction and

shall not be transferred separate from all or substantially all of its other business assets, including those business assets that are the subject of this Agreement.

17.5. Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under present or future state or federal laws or rules and regulations promulgated thereunder effective during the term hereof, such provision shall be fully severable, and this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, and the remaining provisions hereof shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom.

17.6. Notices. Other than payments pursuant to Section 8 or standard communications pursuant to Section 4, any notice to be given to a party under or in connection with this Agreement shall be in writing and shall be delivered (a) personally, (b) by a nationally recognized overnight courier or by certified mail, postage prepaid, return receipt requested, (c) via facsimile, with receipt confirmed, or (d) if actually received, by U.S. mail, addressed to such party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and shall be effective upon receipt by the addressee:

If to Contractor:

[*]
[Admin office address]

Attention:
Phone:
Fax:

If to Synergy:

Synergy Pharmaceuticals Inc.
420 Lexington Avenue, Suite 1609
New York, NY 10170
Attention: Gary S. Jacob, Ph.D.
Telephone: 212-297-0010
FAX: 212-297-0020

With a copy to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, PC
One Financial Center
Boston, MA 02111
Attention: John A. Dellapa
Telephone: (617) 348-1797
Fax: (617) 522-2241
Email: jadellapa@mintz.com

17.7. Dispute Resolution. The parties hereby agree that they shall attempt in good faith to resolve any controversy or claim arising out of or relating to this Agreement promptly by negotiations. If a controversy or claim should arise hereunder, the matter shall be referred to an individual designated by the chief executive officer (or the equivalent position) of Synergy and an individual designated by the chief executive officer (or the equivalent position) of Contractor. If the matter has not been resolved within thirty (30) days of the first meeting of the representatives of the parties (which period may be extended by mutual agreement) concerning such matter, subject to rights to injunctive relief and specific performance, and unless otherwise specifically provided for herein, any controversy or claim arising out of or relating to this Agreement, or the breach thereof, may be brought in any court of competent jurisdiction.

17.8. Waiver. No waiver of any provision of this Agreement, whether by conduct or otherwise, in any one or more instances shall be deemed to be or be construed as a further or

continuing waiver of any such provision in any other instance, or of any other provision or condition of this Agreement.

17.9. Entire Agreement; Modification. This Agreement (including the Work Orders) supersedes all prior discussions and writings and constitutes the entire agreement between the parties with respect to the subject matter hereof. No waiver or modification of this Agreement shall be binding upon either party unless made in writing and signed by a duly authorized representative of such party and no failure or delay in enforcing any right shall be deemed a waiver. In the event of any conflict between this Agreement and any Work Order, the terms of this Agreement shall control.

IN WITNESS WHEREOF, the parties have caused their duly authorized officers to execute and deliver this Master Services Agreement as of the Effective Date.

Synergy: **SYNERGY, INC.**

By: /s/ Kunwar Shailubhai
Name: Kunwar Shailubhai
Title: CSO

Date: July 19, 2010

Contractor: *

By: /s/ *
Name: *, Ph.D.
Title: Vice President & General Manager
Date: July 20, 2010

EXHIBIT A

FORM OF WORK ORDER

Pursuant to Section 2.1 of the Master Services Agreement dated , 200 , by and between Synergy Pharmaceuticals Inc. and * and in consideration of the mutual promises contained therein and for other good and valuable consideration the receipt and adequacy of which each of the parties does hereby acknowledge, the parties hereby agree to amend Exhibit B by adding the attached new Work Order entitled , which is designated Work Order B - . This Work Order is effective as of , 200 .

Work Order B - may contain the following Attachments, each of which is made a part hereof:

Attachment A – Purchase order or Purchase Order Number
Attachment B – Description of Services/Specifications/Description of Deliverables and Intended Use of Deliverables
Attachment C - Quality Requirements
Attachment D – Budgets, Fees, Pass-through Costs, and Payment Schedule
Attachment E – Materials Provided by Either Party
Attachment F – Project Schedule
Attachment G – Key Team Members
Attachment H – Reports and Information Management/Regular Meetings
Attachment I — Special Insurance

Note: A majority of the attachments may be provided in a project proposal provided to Synergy by Contractor

SYNERGY PHARMACEUTICALS, INC. *

By: _____ By: _____
Name: _____ Name: _____
Title: _____ Title: _____
Date: _____ Date: _____

Acknowledged and Agreed:

_____
_____, Project Manager

Exhibit 10.2

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as *. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

MASTER SERVICES AGREEMENT

This Master Services Agreement (this "Agreement") is made as of August 5, 2010 by and between Synergy Pharmaceuticals, Inc., a Florida corporation with an address of 420 Lexington Avenue, New York, NY 10170 ("Synergy"), and *, a corporation with offices at * ("Contractor").

A. Synergy is in the business of discovering, developing and commercializing pharmaceutical products.

B. Contractor is in the business of providing pharmaceutical development and manufacturing services.

C. Synergy wishes to retain Contractor to provide certain services associated with the development, manufacturing and/or supply of certain quantities of specific products for use in IND-enabling studies and/or clinical trials, and Contractor is willing to perform such services, all as more fully set forth below.

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties intending to be legally bound agree as follows:

1. DEFINITIONS

1.1. "Affiliate" means any person or entity that controls, is controlled by or is under common control with a party to this Agreement, where "control" means (a) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares entitled to vote for the election of directors; and (b) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities.

1.2. "API" means bulk quantities of active pharmaceutical ingredients.

1.3. "Applicable Laws" means all laws, statutes, ordinances, codes, rules and regulations which have been enacted by a government authority and are in force as of the Effective Date or come into force during the term of this Agreement (including but not limited to the FDA Act and other applicable rules and regulations of the FDA, and federal, state and local environmental and occupational safety and health requirements, and the United States Export Administration Act of 1979 as amended, the Trading With the Enemy Act, and the regulations of the U.S. Departments of Commerce, Defense, State, Energy and Treasury pursuant thereto.), in each case to the extent the same are applicable to the performance by the parties of their respective obligations under this Agreement.

1.4. "CMC" means chemistry manufacturing and control information required by the FDA for filing of an IND or NDA.

1.5. "Confidential Information" means all information and materials, whether in tangible, electronic, oral or visual form, (a) provided by either party and/or its Affiliates hereunder to the other party, (b) generated by Contractor in the performance of any Project (including but not limited to any information about manufacturing, testing/analysis methods or processes, Products or products (whether investigational or not), Synergy Materials, samples, specimens, and other materials or compounds, sub-samples, and retention samples; analyses and the results of such analyses, information on research and development compounds, technical know-how; formulas; studies; regulatory submissions and records; research data and information; financial information; sales and marketing information (including, without limitation, service proposals, price quotations and customer lists); inventions; patent applications and other trade secrets, (c) information relating to potential new transactions and business between the parties; and (d) all information developed or prepared by either party pursuant to the terms and conditions of this Agreement.

1.6. "Contractor Intellectual Property" means all Intellectual Property owned by or licensed to (other than by Synergy) Contractor as of the Effective Date, including methods and processes developed and owned by Contractor as of the Effective Date. Contractor Intellectual Property constitutes Contractor Confidential Information.

1.7. "Debarment Act" means the Generic Drug Enforcement Act of 1992, as amended, 21 U.S.C. §§ 306.

1.8. "FDA" means the United States Food and Drug Administration (or its successor agency) and/or the corresponding governmental or other authority in another country, as applicable, such as the European Agency for the Evaluation of Medicinal Products (or "EMEA") in Europe.

1.9. "FDA Act" means the United States Federal Food, Drug and Cosmetic Act (21 U.S.C. 301, *et. seq.*), and the regulations promulgated thereunder, as amended from time to time, and any successor statute(s).

1.10. "cGMP" means current Good Manufacturing Practices as promulgated under each of the following as in effect upon the Effective Date and as amended or revised thereafter: (a) the FDA Act, including 21 CFR (parts 11, 210 and 211) and other FDA regulations,

policies and guidelines in effect from time to time governing the manufacture, testing and quality control of investigational drugs; and (b) all International Conference on Harmonisation (ICH) guidance documents as appropriate, including ICH guidance Q7a, "ICH Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients," as applied to investigational drugs (Section 19) specifically for manufacturing activities of API.

1.11. "IND" means an Investigational New Drug Application filed with the FDA to begin clinical studies of a new drug in humans (pursuant to 21 CFR 312, *et. seq.*, as amended),

1.12. "Intellectual Property" means all intellectual property, including (without limitation) patents, supplementary protection certificates, petty patents, utility models, trademarks, database rights, rights in designs, copyrights and topography rights (whether or not any of these rights are registered, and including applications and the right to apply for registration of any such rights) and all inventions, know-how, trade secrets, techniques and confidential information and other proprietary knowledge and information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world, in each case for their full term, and together with any renewals or extensions.

1.13. "Manufacture and Release Requirements" means those methodologies, analytical tests, process parameters and cGMP requirements necessary to manufacture and release Product to Synergy in conformity with the Specifications and as set forth in the Work Order.

1.14. "Product" means the product resulting from the Services to be rendered by Contractor hereunder, as defined in the Work Order, including the product of such Services that does not meet the Specifications but is delivered to Synergy.

1.15. "Project" means the separate, defined project described in a Work Order.

1.16. "Services" means those formulation development, intermediary and product manufacture, consulting, chemical synthesis, chemical process research, analytical methods development, medicinal chemical synthesis, computational chemistry services, validation or release testing and other related services, in each case that are to be provided by Contractor as set forth in a Work Order.

1.17. "Specifications" means the composition, quality, purity, identity and strength of a Product and any chemistry, manufacturing and controls requirements for the manufacture of Product as set forth in the applicable Work Order or as agreed by the parties in writing pursuant to a Work Order.

1.18. "Synergy Intellectual Property" means all Intellectual Property owned by or licensed to Synergy, and all Intellectual Property that relates to methods, procedures and processes for the synthesis and production of Products (including without limitation all hybrid solution solid-phase processes developed and/or performed by Contractor), and all Intellectual Property relating to Synergy Materials. Synergy Intellectual Property constitutes Synergy Confidential Information, and does not include Contractor Intellectual Property.

1.19. "Synergy Materials" means all materials, including the API, provided by or on behalf of Synergy to Contractor under a Work Order.

1.20. "Work Order" means a written statement of work signed by both parties that specifies the Services to be provided by Contractor for Synergy, including, as may be applicable, a description of the Product, Specifications, quantity of Product, Manufacture and Release Requirements, estimated duration of the Project(s), milestones and all other matters as the parties may agree.

1.21. "Work Product" means all results of Services, including but not limited to the Product, Specifications, and compounds, data, information, documentation (including, but not limited to, lab notebooks as applicable), reports and any other deliverables listed in the Work Order and/or developed by Contractor in its performance of a Work Order.

2. Scope of Services.

2.1. Work Order. Services provided by Contractor shall be subject to the terms and conditions of this Agreement and each Work Order. Each Work Order shall a part of this Agreement. If Synergy wishes to amend any Work Order, the parties shall negotiate a change in good faith and, upon their agreement, shall execute a written change order amending such Work Order ("Change Order"). The Change Order constitutes an amendment to the applicable Work Order and the services set forth therein shall be deemed to be Services part of such Work Order.

2.2. Subcontracting. Contractor may not subcontract the performance of any Services without Synergy's prior written consent. Any permitted subcontractor shall be under a written obligation to comply with terms of this Agreement governing Contractor's performance of Services and protection of Synergy's Confidential Information, and Contractor shall remain liable to Synergy for the performance of any such subcontractor.

2.3. Contractor Employees and Agents. Contractor shall be solely responsible for any and all salaries, fees, state and federal taxes, withholding, FICA, worker's compensation or other payments due with respect to the compensation paid to Contractor by Synergy or by Contractor to any employee or agent of Contractor. Contractor's employees and other agents shall have no right to receive from Synergy any employee benefits (including by not limited to health and accident insurance, sick leave or vacation) that Synergy provides to its own employees, and shall indemnify and hold harmless any claims brought against Synergy demanding the same.

2.4. Standards. Contractor will perform Services in accordance with the terms of this Agreement and the relevant Work

Order, with Applicable Laws, and with its standard operating procedures (and shall, upon request, deliver copies of all Contractor's standard operating procedures relevant to the Services).

2.5. Supply of Synergy Materials. To the extent required by a Work Order, Synergy shall provide Contractor with sufficient amounts of any Synergy Materials (either directly or indirectly, and including API). Synergy shall provide Contractor with data regarding the stability, proper storage and safety and other characteristics and requirements of such Synergy Materials. Contractor shall use Synergy Materials solely for rendering the Services under the applicable Work Order, and shall not transfer any Synergy Materials to a third party (except as may be permitted under Section 2.2). Any Synergy Materials remaining upon completion of the Services under a Work Order shall be, at Synergy's direction, either returned to Synergy or destroyed. If Synergy does not notify Contractor within sixty (60) days after completion of a Project of its intention hereunder, then Contract shall return the Synergy Materials to Synergy at Synergy's expense.

2.6. Project Manager. Contractor will assign a project manager (the "Project Manager") and other members of the core Project team (including, as relevant, a project director) (the "Core Team") for the duration of each Project. Contractor shall provide thirty (30) days prior written notice to Synergy, whenever practicable, of any changes to the Core Team, except as specified below. During any Project, Contractor will employ its commercially reasonable efforts to promote members of the Core Team within the Project. Contractor will provide Project-specific training to replacement Core Team members at its own expense. The Project Manager, or such other Core Team Member agreed by the parties, shall be the primary contact for Synergy and shall timely address all issues and concerns raised by Synergy, as well as provide to Synergy all information requested by Synergy concerning this Agreement or the Services.

2.7. Preferred Vendor. For so long as Contractor complies with the terms of this Agreement and for so long as its price for Product is competitive, Synergy shall appoint Contractor as Synergy's preferred and primary supplier of the Product, meaning that Synergy will provide Contractor the first opportunity (taking into account factors regarding Contractor's quality, timing and capacity) to supply up to at least seventy five percent (75%) of Synergy's commercial supply of Products.

2.8. Exclusivity. Contractor shall not, directly or indirectly, develop, manufacture and/or supply any GC-C agonist peptide for or to any third party, where "GC-C agonist peptide" means a peptide that (i) binds and activates a GC-C receptor and (ii) activates the receptor-mediated downstream signalling (including without limitation uroguanylin and structurally similar peptides, and *E. coli* ST peptides and structurally similar peptides.

2.9. Fees. All fees payable by Synergy shall be made in accordance with the Work Order in U.S. dollars. All undisputed payments are due within thirty (30) days from the date of Contractor's invoice.

3. Products and Services.

3.1. Supply. Contractor shall manufacture, store and deliver Products in accordance with cGMP, the Specifications and all Applicable Laws.

3.2. Purchase Orders. When Synergy wishes to purchase the Product, it shall submit a purchase order to Contractor identifying the amount of Product requested, the purchase price, the address for delivery, and the delivery date. If any Product is ordered to be stored for thirty (30) days after Contractor's quality control release, then Synergy may either (a) request Contractor to bill and hold at $25/day for insurance and storage or (b) acquire its own insurance and pay $10/day for storage.

3.3. Shipping. All Product shipped hereunder shall comply in all material respects with the applicable Manufacture and Release Requirements and shall be accompanied by (i) a certificate of analysis; (ii) a cGMP certificate of conformance; and (iii) BSE/TSE certification indicating that no BSE/TSE risk exists from materials-used in production of the batch or came into contact with the batch; each in a form to be agreed upon by the parties. Contractor shall deliver and transfer the Product to such locations and in such manner as directed by Synergy. All Product generated hereunder shall be packaged and shipped to Synergy's designated destination and in accordance with Synergy's written instructions and in compliance with all applicable shipping regulations. Delivery shall be FCA Synergy's facility (Incoterms 2000).

3.4. Pre-Shipment Samples. Contractor shall deliver to Synergy a preshipment sample from each batch of Product prior to full delivery and prior to issuance of the relevant certificate of analysis. Synergy shall test key attributes of the preshipment sample, either itself or through an independent analytical lab, and will inform Contractor whether or not such testing confirms that the sample conforms to the Specifications. If Synergy confirms that the sample conforms to the Specifications, then Contractor will ship the full delivery to Synergy. This process does not relieve Contractor of its obligations to deliver Product that meets the Specifications and that conforms to the relevant certificate of analysis and does not limit Synergy's right to reject product as provided in Section 3.6.

3.5. Evaluation. Synergy shall have three (3) months from the date of its receipt of Product to evaluate the Product (using reasonable analytics) and determine whether or not the Product meets the Specifications. If Synergy fails to notify Contractor of its rejection within such three (3) month period, Synergy shall be deemed to have accepted such Product.

3.6. Rejection of Product. If Synergy rejects any of the Product pursuant to Section 3.5, Synergy shall (i) provide to Contractor written notice of rejection that includes the basis for such rejection and (ii) provide Contractor with the opportunity to conduct its own tests to confirm such basis of rejection, which shall be conducted promptly. Synergy shall return all remaining unused Product to Contractor; *provided* that Synergy may retain a sample of such reject Product that is being used for laboratory testing and to confirm its rights hereunder. Contractor shall replace such rejected Product with conforming Product as soon as commercially reasonable, but in no event after a period longer than the original lead time required for shipment of Product as set forth in the applicable Work Order for such Product.

3.7. Recalls. Contractor shall maintain such traceability records as are sufficient and as may be necessary to permit a recall or field correction of any Product. In the event (a) any applicable regulatory authority should issue

a request, directive or order that a Product be recalled, or (b) a court of competent jurisdiction orders such a recall, or (c) Synergy determines that any Product presents a risk of injury or gross deception or is otherwise defective and that recall of such Product is appropriate ("Recall"), it shall notify Contractor and Contractor shall cooperate with Synergy in implementing any Recall. Synergy shall have sole responsibility for determining all corrective action to be taken and for carrying out a Recall. Synergy shall be responsible for the cost of any Recall (including any direct out-of-pocket expenses incurred by Contractor incurred in implementing Synergy's instructions) except to the extent such Recall is attributable to any negligence on the part of Contractor or any breach by Contractor of its obligations under this Agreement, in which case Contractor will be responsible for the cost of the Recall and shall reimburse Synergy for its related expenses.

3.8. Product Support.

3.8.1. Contractor shall ensure that Projects intended to support INDs or NDAs shall comply with all appropriate regulatory requirements applicable to such applications; *provided* that, Synergy or its Affiliate, as applicable, is the Sponsor (as such term is defined in 21 CFR Part 312.3) of any such IND or NDA, and Synergy shall remain responsible for all legal requirements applicable to Synergy of INDs or NDAs except to the extent that such obligations are transferred to Contractor herein. Contractor shall provide to Synergy directly all information as Synergy may reasonably require for purposes of applying for and maintaining application for regulatory approval of the Product, including, without limitation, providing Synergy with all reports, authorizations, certificates, methodologies, and other documentation in the possession or under the control of Contractor relating to the synthesis or manufacture of the Product (or any component thereof). Such information shall be deemed the Confidential Information of Contractor, and Contractor hereby allows Synergy to provide such information to a regulatory authority as necessary to support any application for authorization to conduct clinical trials or regulatory approval of a Product or in response to the requests or requirements of such regulatory authority. Contractor will provide to Synergy a copy of any correspondence with any regulatory authority related to the Project, a Product or the Services within a reasonable time, not to exceed three (3) days from receipt or transmission of such correspondence.

3.8.2. As between the parties, Synergy shall be solely responsible for all contacts and communications with any regulatory authority regarding Products. Unless required by applicable law, Contractor shall have no contact or communication with any regulatory authority regarding the provision of the Services hereunder without the prior written consent of Synergy, which shall not be unreasonably withheld. Synergy shall have all decision-making authority in every case on whether and how to supplement, amend or otherwise alter the NDAs and any other issues in connection with the NDAs (including, but not limited to, decisions to recall the Products) and on whether and how to communicate with the FDA in connection therewith.

3.8.3. Contractor shall: (a) promptly notify Synergy in writing of any FDA or other governmental inspection or inquiry concerning any Project or Work Order, including, but not limited to, inspections of investigational sites or laboratories ("Regulatory Audit"); (b) promptly forward to Synergy copies of correspondence from any regulatory or governmental agency relating to such Regulatory Audit, including, but not limited to, FDA Form 483 notices and FDA refusal to file, rejection or warning letters; and (c) obtain the written consent of Synergy, which will not unreasonably be withheld, before referring to Synergy or any of its affiliates in any Regulatory Audit correspondence. Contractor shall allow a Synergy representative present during a Regulatory Audit inspection.

3.8.4. Should any Regulatory Audit or other inspection or audit by a regulatory authority require any process changes, Contractor shall notify Synergy immediately and the parties shall discuss the means for implementing such changes. For the avoidance of doubt, Contractor may not implement any such change to a Product-related Process without Synergy's prior, written consent (including pursuant to a Change Order).

3.8.5. Contractor shall not, during a Regulatory Audit, disclose information or materials that are not legally required to be disclosed to such agency without the prior consent of Synergy, which shall not unreasonably be withheld. For example, such information and materials that a party conventionally would not be required to disclose include, but are not limited to, (a) financial and pricing data (including, but not limited to, the budget and payment sections of a Work Order), (b) sales data (other than shipment data), and (c) personnel data (other than data as to qualification of technical and professional persons performing functions subject to regulatory requirements).

3.8.6. All information disclosed, revealed to or ascertained by Synergy or Contractor, as the case may be, in connection with any Regulatory Audit or in connection with any correspondence between Contractor and any regulatory authorities (including the redacted portions of any FDA Form 483 notices) shall be deemed Confidential Information for purposes of this Agreement.

3.9. Audits; Progress Review; Records. Contractor shall provide Synergy such periodic and final written reports (either in electronic or paper format), as outlined in the Work Order or as reasonably requested by Synergy from time to time. Synergy may visit and inspect Contractor's facilities and review and audit Contractor's records during normal business hours and upon reasonable notice (a) to confirm Contractor's performance of this Agreement in accordance with its terms, and/or (b) in the event circumstances arise that may adversely affect the quality of Product. If the event of subsection (b), Contractor shall immediately notify Synergy of such circumstances and shall allow Synergy prompt access to relevant Contractor areas and records. Contractor shall record and maintain all records and data relating to the manufacture, processing, testing, packaging, storage and transportation of Products, including all batch manufacturing records, and Synergy may (either itself or through an agent) during normal business hours and upon reasonable prior notice, audit and inspect such

records and observe the manufacture, processing, testing, packaging, storage and transportation of materials related to or used in the manufacture of Products. Contractor shall retain experimental records and laboratory notebooks relating to each Project, and shall maintain suitable CMC support documentation to allow Synergy or its Affiliates to file an IND, IND amendment, NDA or ANDA with the FDA. All such documentation and Work Product in Contractor's possession (not otherwise returned to Synergy) shall be archived in a secure area reasonably protected from fire, theft or destruction by Contractor for a period of ten (10) years following expiration or termination of this Agreement. Synergy may elect to have the materials retained in Contractor's archives for an additional period of time for a reasonable storage fee.

4. Confidential Information.

4.1. Nondisclosure and Limited Use. Each party shall (a) hold the Confidential Information of the other party in strict confidence and take reasonable precautions to protect such Confidential Information (including, without limitation, all precautions the receiving party normally employs with respect to its own confidential information), (b) not divulge any such Confidential Information to any third party (other than those parties specifically permitted to receive such Confidential Information pursuant to the terms of this Agreement), (c) not make any use whatsoever at any time of such Confidential Information except to carry out its obligations under this Agreement and the Projects and Work Orders hereunder and to exploit the rights granted to such party hereunder, (d) not derive any commercial benefit (whether direct or indirect) from such Confidential Information (other than pursuant to Services rendered under this Agreement), and (e) not copy (except as may be necessary to accomplish the purposes of this Agreement) or reverse engineer any such Confidential Information.

4.2. Exclusions. Without granting any right or license, a party's obligations under Section 4.1 shall not apply to Confidential Information of a disclosing party that: (a) was in the receiving party's possession prior to receipt from the disclosing party; (b) was in the public domain at the time of receipt from the disclosing party; (c) becomes part of the public domain without wrongful act by the receiving party; or (d) the receiving party can demonstrate by written or electronic evidence kept in the ordinary course is lawfully received by the receiving party from a third party, where the third party is wholly independent of the receiving party and has no obligation of confidentiality to disclosing party with respect to such information disclosed. Notwithstanding the foregoing, (i) Confidential Information shall not fall within an exception set forth in this Section merely because such Information is embraced by more general information in the public domain or in the possession of the receiving party, and (ii) the fact that any Work Product may fall within one or more of the exceptions set forth in this Section shall not relieve Contractor or Synergy of its obligations under Section 4.1.

4.3. Permitted Disclosures. If a party is required to disclose Confidential Information of the other party pursuant to an order of a court or administrative agency or other governmental body with valid jurisdiction, the receiving party may disclose Confidential Information only after providing the disclosing party with reasonable advance notice thereof to enable the disclosing party to seek a protective order or otherwise prevent such disclosure, but nothing herein shall require a party to take or refrain from taking any action in violation of any such legal process. Each party shall limit the disclosure of the other party's Confidential Information to its directors, employees and agents, in each case with a legitimate "need to know" and who are bound in writing to observe the obligations of nondisclosure and non-use under this Agreement. Information exchanged by and between the parties

and any such directors, employees and/or agents shall be deemed the Confidential Information of the party on whose behalf such information was disclosed, and shall be governed by the provisions of this Section 4.

4.4. Return of Information. Each party shall, upon the request of the other party, return to the other party all of the other party's Confidential Information in the receiving party's possession or control (including any copies or extracts thereof) or destroy such records and certify the destruction thereof, except for any copy legally required to be retained for archive purposes.

4.5. Injunctive Relief. Each party acknowledges and agrees that due to the unique nature of the disclosing party's Confidential Information, there can be no adequate remedy at law for any breach of its obligations hereunder, that any such breach may allow the receiving party or third parties to unfairly compete with the disclosing party, and therefore, that upon any such breach or any threat thereof, the disclosing party shall be entitled to appropriate equitable relief in addition to whatever remedies it might have at law. The receiving party shall notify the disclosing party in writing immediately upon the occurrence of any such unauthorized release or other breach of which it becomes aware.

4.6. Survival. The obligations of each party with respect to the other party's Confidential Information shall continue in effect for ten (10) years after the expiration or termination of this Agreement.

5. Intellectual Property Rights

5.1. Synergy IP. As between the parties, all Synergy Intellectual Property is and shall remain the exclusive property of Synergy. Synergy hereby grants to Contractor, on a Project by Project basis and solely for the duration of such Project, a limited, non-exclusive license (with no right to sublicense) to use such Synergy Intellectual Property actually disclosed (or transferred, as applicable) to Contractor solely for the purpose of, and only to the extent strictly necessary for, Contractor's performance of the applicable Services. Contractor hereby irrevocably, expressly and automatically assigns, in perpetuity, all right, title and interest in and to Work Product and Synergy Intellectual Property to Synergy. If Contractor has any rights to Work Product and/or Synergy Intellectual Property that cannot (as a matter of law) be assigned to Synergy in accordance with the foregoing, Contractor unconditionally and irrevocably: (i) waives the enforcement of such rights against Synergy or its assignees and licensees; and (ii) grants to Synergy an exclusive, irrevocable, perpetual, worldwide, royalty-free license (a) to reproduce, create derivative works of, distribute, publicly perform, publicly display, digitally perform, and otherwise use and exploit such Work Product and/or Synergy Intellectual Property, (b) to use, make, have made, sell, offer to sell, import, and otherwise exploit any product or service based on, embodying, incorporating, or derived from Work Product and/or Synergy Intellectual Property, and (c) to exercise any and all other present or future rights not yet known in Work Product and/or Synergy Intellectual

Property. Contractor agrees to render all reasonably required assistance to Synergy to protect Synergy's rights under this Section. If Synergy is unable to secure Contractor's signature on any documents deemed necessary by Synergy to carry out the purposes of this Section, Contractor hereby irrevocably designates and appoints Synergy or its designee(s) as Contractor's agent and attorney, which appointment is coupled with an interest, to act for and in Contractor's behalf to execute, verify and file any such documents.

5.2. Contractor IP. As between the parties, all Contractor Intellectual Property is and shall remain the exclusive property of Contractor. Contractor hereby grants to Synergy, on a Project by Project basis, a fully paid-up, royalty free, irrevocable, worldwide, non-exclusive license to use such Contractor Intellectual Property solely for the purpose of, and only to the extent strictly necessary for, Synergy's full use and enjoyment (including the commercialization of Products) of Work Product.

5.3. Reservation of Rights. Except as otherwise expressly agreed to by the parties in this Agreement or any Work Order, nothing contained herein, nor the delivery of any Confidential Information of one party to the other, shall be deemed to grant any right or license under any patent or patent applications or to any intellectual property of the first party to the other. Each party reserves all rights not expressly granted herein, and no right or license is granted hereunder, express or implied or by way of estoppel, to any intellectual property rights or materials other than as expressly set forth herein.

6. Representations, Warranties and Covenants.

6.1. Contractor Representations, Warranties and Covenants. Contractor hereby represents, warrants and covenants to Synergy that:

6.1.1. Contractor has and shall engage competent employees and consultants with the proper skill, training and background to support its obligation to render the Services hereunder, and shall provide the facilities, supplies and staff necessary to complete each Project as specified in the Work Order for such Project, and in accordance with the other terms of this Agreement.

6.1.2. Each Project shall be performed in all material respects in accordance with the terms of this Agreement and the applicable Work Order and all Product will conform in all respects to the Specifications and Manufacture and Release Requirements set forth in the applicable Work Order at the time of delivery to Synergy's carrier if Synergy arranges for shipment, or time of delivery to Synergy if Contractor arranges shipment.

6.1.3. Contractor is under no contractual or other obligation or restriction that is inconsistent with performance of its obligations under this Agreement, and Contractor will not enter into any agreement, either written or oral, in conflict with its obligations hereunder. Contractor shall provide the Services in a manner that the provision thereof will not conflict with its responsibilities under any other agreement, arrangement or understanding, including any employment relationship.

6.1.4. Contractor's performance of Services shall not infringe, violate or misappropriate any third party intellectual property rights except to the extent such performance is based upon Synergy's written instructions or use of Synergy Materials.

6.1.5. Contractor has not been debarred, and has not been convicted of a crime which could lead to debarment, under the Debarment Act. In the event that Contractor or any of its officers, directors, or employees becomes debarred or receives notice of action or threat of action with respect to its debarment, Contractor shall notify Synergy immediately in writing.

6.1.6. Contractor has not utilized and shall not utilize the services of any individual or entity in the performance of Services who has been debarred or who has been convicted of a crime which could lead to debarment under the Debarment Act. In the event that Contractor receives notice of the debarment or threatened debarment of any such individual or entity, Contractor shall notify Synergy immediately.

6.2. Mutual Representation and Warranties. Each of Synergy and Contractor hereby represents, warrants and covenants to the other that:

6.2.1. Such party is, and at all times during the term of the Agreement shall remain, a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.

6.2.2. The execution and delivery of this Agreement has been duly authorized by all requisite corporate action.

6.2.3. This Agreement is, and shall remain, a valid and binding obligation of such party, enforceable pursuant to its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.

6.3. Disclaimer. Contractor makes no warrantees direct or implied about the suitability of the Products for any use by Synergy.

7. Indemnification.

7.1. By Synergy. Synergy, at its own expense, shall: (i) defend, or at its option settle, any claim, suit or proceeding brought by a third party against Contractor and its officers, directors, employees and agents to the extent arising out of: (a) Contractor's use of Synergy Materials to the extent such use is in accordance with this Agreement; (b) Synergy's commercialization of a Product; or (c) Synergy's breach of any representations, warranties or covenants set forth in Section 6.2; and (ii) pay any judgment entered or settlement against Contractor thereon; except in each case to the extent such third party claim is caused by Contractor's or its employee's or agent's breach of this

Agreement, negligence or willful misconduct.

7.2. By Contractor. Contractor, at its own expense, shall: (i) defend, or at its option settle, any claim, suit or proceeding brought by a third party against Synergy and its officers, directors, employees and agents to the

extent arising out of (a) Contractor's use of Synergy Materials other than as expressly permitted by this Agreement; or (B) Contractor's breach of any representations, warranties or covenants set forth in Section 6; and (ii) pay any judgment entered or settlement against Synergy thereon; except in each case to the extent such third party claim is caused by Synergy's or its employee's or agent's breach of this Agreement, negligence or willful misconduct.

7.3. Process. The party indemnifying the other party under this Section 7 shall have no obligation to indemnify the relevant claim unless the indemnified party: (a) gives it prompt written notice of the claim; (b) gives it the right to control and direct the investigation, preparation, defense and settlement of the claim; and (c) fully cooperates with it, at the indemnifying party's expense, in such defense and settlement. The indemnified party may, at its cost, to employ counsel of its choice to participate in the defense of such claim.

8. Insurance.

Contractor shall, during the term of this Agreement and for five (5) years thereafter, maintain comprehensive general liability insurance, with endorsements for contractual liability and product liability with coverage limits of not less than Two Million Dollars ($2,000,000). The minimum level of insurance set forth herein shall not be construed to create a limit on Contractor's liabilities hereunder. Prior to the Effective Date (and each anniversary thereof thereafter), Contractor shall furnish to Synergy a certificate of insurance evidencing such coverage as of the Effective Date (and each anniversary thereof) and upon request by Synergy at any time hereafter. Each such certificate of insurance shall include a provision whereby sixty (60) days' written notice must be received by Synergy prior to coverage modification or cancellation by either Contractor or the insurer.

9. Term and Termination.

9.1. Term. Unless terminated by either party as expressly permitted herein, this Agreement shall be in effect from the Effective Date and for a period of five (5) years, and shall thereafter automatically renew for additional one (1) year terms unless either party notifies the other party of its intent not to renew no later than ninety (90) days prior to expiration of the then-current term, in which case this Agreement shall expire upon expiration of the then-current term.

9.2. Termination.

9.2.1. Each party may terminate this Agreement or any Work Order if the other party materially breaches this Agreement or such Work Order, respectively, and if such breach remains uncured for thirty (30) days from receipt of notice from the other party describing such breach, or in the case of a breach that cannot reasonably by cured within such time period.

9.2.2. Synergy may terminate any Project or Work Order (or a portion thereof) at any time prior to completion by giving written notice to Contractor. Synergy may, on termination of all Projects and Work Orders, terminate this Agreement. Contractor shall promptly comply with the terms of such notice(s) to terminate work on the Project(s) or Work Order(s) (as applicable) and use its best efforts to limit any further cost to Synergy. Synergy shall pay Contractor all fees due in respect of Services property performed as of the date of termination.

9.3. Effect of Termination or Expiration. Upon termination of this Agreement and/or any Work Order by either party, Contractor shall promptly deliver to Synergy all Work Product, reports, data, records and other information and materials generated by Contractor for the Project(s) and Work Orders and return all remaining Synergy Materials to Synergy, in each case as applicable. Termination or expiration of this Agreement for any reason shall not relieve the parties of any obligation accruing prior to such termination. In no way limiting the generality of the foregoing, Sections 3.7, 3.8, 3.9, 4, 5, 6, 7, 8, 9.3 and 10 shall survive termination or expiration of this Agreement.

10. Miscellaneous.

10.1. Independent Contractor. Contractor shall at all times operate as independent contractor of Synergy, and the relationship between Synergy and Contractor shall not constitute a partnership, joint venture or agency. Neither Synergy nor Contractor shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other party to do so.

10.2. Limitation on Damages. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY UNDER OR IN CONNECTION WITH THIS AGREEMENT FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, INCIDENTAL, EXEMPLARY OR PUNITIVE DAMAGES, EVEN IF SUCH PARTY HAS BEEN ADVISED OF OR IS AWARE OF THE LIKELIHOOD OF SUCH DAMAGES, PROVIDED THAT THE FOREGOING SHALL NOT APPLY TO CLAIMS ARISING UNDER SECTION 4 AND/OR SECTION 5, OR TO AMOUNTS OWING TO A THIRD PARTY PURSUANT TO A PARTY'S INDEMNIFICATION OBLIGATIONS IN SECTION 7.

10.3. Governing Law. This Agreement shall be governed by the laws of the State of New York, U.S.A. without regard to any conflict of law provisions or principles.

10.4. Publicity; Use of Names. Neither party may publish any articles or make any presentations relating to the Services provided hereunder or referring to data, information or materials generated as part of such Services, in whole or in part, without the prior written consent of the other. Neither party shall use the name of the other party or the names of the employees of the other party in any advertising or sales promotional material or in any publication without prior written permission of such party.

10.5. Assignment. Neither party may assign any of its rights or obligations under this Agreement without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed, provided that Synergy may this Agreement in its entirety in connection with a merger, consolidation or the sale of substantially all of the assets to which this Agreement relates. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

10.6. Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under present or future state or federal laws or rules and regulations promulgated thereunder effective during the term hereof, such provision shall be fully severable, and this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, and the remaining provisions hereof shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance.

10.7. Cumulative Rights. Except as herein expressly provided, the rights, powers and remedies hereunder shall be in addition to, and not in limitation of, all rights, powers and remedies provided at law or in equity, or under any other agreement between the Parties, and all of such rights, powers and remedies shall be cumulative, and may be exercised successively or cumulatively.

10.8. Notices. Other than standard communications, any notice to be given to a party under or in connection with this Agreement shall be in writing and shall be delivered (a) personally, (b) by a nationally recognized overnight courier or by certified mail, postage prepaid, return receipt requested, (c) via facsimile, with receipt confirmed, or (d) if actually received, by U.S. mail, addressed to such party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and shall be effective upon receipt by the addressee:

If to Contractor:

*
Phone: *
Fax: *

If to Synergy:

Synergy Pharmaceuticals Inc.
420 Lexington Avenue, Suite 1609
New York, NY 10170
Attention: Kunwar Shailubhai
Telephone: 212-297-0010
FAX: 212-297-0020

With a copy to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, PC
One Financial Center
Boston, MA 02111
Attention: John A. Dellapa
Telephone: (617) 348-1797

Fax: (617) 522-2241
Email: jadellapa@mintz.com

10.9. Waiver. No waiver of any provision of this Agreement, whether by conduct or otherwise, in any one or more instances shall be deemed to be or be construed as a further or continuing waiver of any such provision in any other instance, or of any other provision or condition of this Agreement.

10.10. Entire Agreement; Modification. This Agreement (including Work Orders) supersedes all prior discussions and writings and constitutes the entire agreement between the parties with respect to the subject matter hereof. No waiver or modification of this Agreement shall be binding upon either party unless made in writing and signed by a duly authorized representative of such party and no failure or delay in enforcing any right shall be deemed a waiver. In the event of any conflict between this Agreement and any Work Order, the terms of this Agreement shall control.

IN WITNESS WHEREOF, the parties have caused their duly authorized officers to execute and deliver this Master Services Agreement effective as of the Effective Date.

Synergy: **SYNERGY PHARMACEUTICALS, INC.**

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai, Ph.D. & M.B.A.

Title: Chief Scientific Officer

Contractor: *

By: *

Name: *

Title: Executive Vice President, Business Development

EXHIBIT 31.1

CERTIFICATIONS

I, Gary S. Jacob, certify that:

1) I have reviewed this report on Form 10-Q of Synergy Pharmaceuticals, Inc.

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date November 9, 2010

/s/ GARY S. JACOB
Gary S. Jacob
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATIONS

I, Bernard F. Denoyer, certify that:

1) I have reviewed this report on Form 10-Q of Synergy Pharmaceuticals, Inc.

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions);

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2010

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

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
SYNERGY PHARMACEUTICALS, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2010
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I am the Chief Executive Officer of Synergy Pharmaceuticals, Inc., a Florida corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended September 30, 2010 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2010

/s/ GARY S. JACOB
Gary S. Jacob
President and Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION OF SENIOR VICE PRESIDENT, FINANCE
SYNERGY PHARMACEUTICALS, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2010
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I am the Senior Vice President, Finance of Synergy Pharmaceuticals, Inc., a Florida corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended September 30, 2010 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2010

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