

SYNERGY PHARMACEUTICALS, INC.
Form 10-Q
November 16, 2009

Table of Contents

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: SEPTEMBER 30, 2009

**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
(State or Other Jurisdiction of
Incorporation or Organization)

20-3823853
(I.R.S. Employer Identification No.)

420 Lexington Avenue, Suite 1609,
New York, New York
(Address of principal executive offices)

10170
(Zip Code)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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):

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a 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 88,106,575 as of November 11, 2009.

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

FORM 10-Q

TABLE OF CONTENTS

| | Page |
|---|-------------|
| <u>PART I FINANCIAL INFORMATION</u> | |
| <u>Item 1.</u> <u>Financial Statements</u> | <u>4</u> |
| <u>Condensed Consolidated Balance Sheets as of September 30, 2009 (unaudited) and December 31, 2008</u> | <u>4</u> |
| <u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2009 and 2008 (unaudited) and the period November 15, 2005 (Inception) to September 30, 2009 (unaudited)</u> | <u>5</u> |
| <u>Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period November 15, 2005 (Inception) to September 30, 2009 (unaudited)</u> | <u>6</u> |
| <u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2009 and 2008 (unaudited) and for the period November 15, 2005 (Inception) to September 30, 2009 (unaudited)</u> | <u>7</u> |
| <u>Notes to Condensed Consolidated Financial Statements (unaudited)</u> | <u>8</u> |
| <u>Item 2.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | <u>15</u> |
| <u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u> | <u>19</u> |
| <u>Item 4T.</u> <u>Controls and Procedures</u> | <u>19</u> |
| <u>PART II OTHER INFORMATION</u> | |
| <u>Item 1.</u> <u>Legal Proceedings</u> | <u>21</u> |
| <u>Item 1A.</u> <u>Risk Factors</u> | <u>21</u> |
| <u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u> | <u>21</u> |
| <u>Item 6.</u> <u>Exhibits</u> | <u>21</u> |
| <u>SIGNATURES</u> | <u>22</u> |

Table of Contents

INTRODUCTORY NOTE

This Report on Form 10-Q for Synergy Pharmaceuticals, Inc. ("Synergy" or the "Company") may contain forward-looking statements. You can identify these statements by forward-looking words such as "may," "will," "expect," "intend," "anticipate," "believe," "estimate" and "continue" or similar words. Forward-looking statements include information concerning possible or assumed future business success or financial results. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Accordingly, we do not undertake any obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth in this Report on Form 10-Q and other periodic filings with the Securities Exchange Commission. Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of the Company, please be advised that Synergy's actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements.

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****SYNERGY PHARMACEUTICALS, INC.**
(A development stage company)**CONDENSED CONSOLIDATED BALANCE SHEETS**

| | September 30, 2009 | December 31, 2008 |
|--|-----------------------|----------------------|
| | (unaudited) | |
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 3,086,171 | \$ 216,007 |
| Prepaid Insurance | 89,810 | |
| Due from majority shareholder | | 690,333 |
| Total Current Assets | 3,175,981 | 906,340 |
| Property and equipment, net | 10,713 | 11,701 |
| Security deposits | 14,025 | 4,400 |
| Due from majority shareholder | 821,720 | |
| | \$ 4,022,439 | \$ 922,441 |
| LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | | |
| Current Liabilities: | | |
| Accounts payable | \$ 1,995,802 | \$ 2,000,220 |
| Accrued expenses | 517,272 | 78,013 |
| Total Current Liabilities | 2,513,074 | 2,078,233 |
| Stockholders' Equity (Deficit): | | |
| Common stock, par value of \$.0001 authorized 150,000,000 shares at September 30, 2009 and December 31, 2008, outstanding 75,938,578 and 65,606,434 shares at September 30, 2009 and December 31, 2008, respectively | 7,593 | 6,560 |
| Preferred stock, Authorized 20,000,000 shares and 0 shares outstanding at September 30, 2009 and December 31, 2008, respectively | | |
| Additional paid-in capital | 38,479,984 | 30,633,089 |
| Deficit accumulated during development stage | (36,978,212) | (31,795,441) |
| Total Stockholders' Equity (Deficit) | 1,509,365 | (1,155,792) |
| | \$ 4,022,439 | \$ 922,441 |

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | November 15, 2005 |
|---|----------------------------------|--------------|---------------------------------|--------------|--------------------------------------|
| | 2009 | 2008 | 2009 | 2008 | (inception) to September 30, 2009 |
| Revenues | \$ | \$ | \$ | \$ | \$ |
| Costs and Expenses: | | | | | |
| Research and development | 1,163,643 | 708,836 | 2,611,666 | 708,836 | 4,520,892 |
| Purchased in-process research and development | | 28,156,503 | | 28,156,503 | 28,156,503 |
| General and administrative | 1,058,928 | 940,269 | 2,582,113 | 940,269 | 4,244,995 |
| Loss from Operations | (2,222,571) | (29,805,608) | (5,193,779) | (29,805,608) | (36,922,390) |
| Interest and investment income | 10,862 | (2,847) | 11,008 | (2,847) | 15,999 |
| Loss from Continuing Operations | (2,211,709) | (29,808,455) | (5,182,771) | (29,808,455) | (36,906,391) |
| Loss from discontinued operations | | | | (31,560) | (71,821) |
| Net Loss | \$ (2,211,709) | (29,808,455) | (5,182,771) | (29,840,015) | (36,978,212) |
| Weighted Average Common Shares Outstanding | | | | | |
| Basic and Diluted | 75,769,105 | 79,643,602 | 69,646,019 | 136,394,134 | |
| Net Loss per Common Share, Basic and Diluted | | | | | |
| Net Loss from Continuing Operations | \$ (0.03) | (0.37) | (0.07) | (0.22) | |
| Discontinued Operations: | | | | | |
| Loss from discontinued operations | | | | | |
| Net Loss per Common Share, Basic and Diluted | \$ (0.03) | (0.37) | (0.07) | (0.22) | |

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

(Unaudited)

| | Common Shares | Common Stock, Par Value | Additional Paid in Capital | Deficit Accumulated during the Development Stage | Total Stockholders' Equity (Deficit) |
|---|------------------|-------------------------------|----------------------------------|--|--|
| Balance at inception, November 15, 2005 | | | | | |
| Sale of unregistered common stock to founder | 151,381,215 | \$ 15,138 | \$ (13,138) | | \$ 2,000 |
| Sale of common stock | 13,700,000 | 1,370 | 16,730 | | 18,100 |
| Net loss for the year | | | | (16) | (16) |
| Balance, December 31, 2005 | 165,081,215 | 16,508 | 3,592 | (16) | 20,084 |
| Net loss for the year | | | | (20,202) | (20,202) |
| Balance, December 31, 2006 | 165,081,215 | 16,508 | 3,592 | (20,218) | (118) |
| Capital contribution by shareholders | | | 8,893 | | 8,893 |
| Net loss for the year | | | | (20,043) | (20,043) |
| Balance, December 31, 2007 | 165,081,215 | 16,508 | 12,485 | (40,261) | (11,268) |
| Cancellation of unregistered founder shares | (149,981,208) | (14,998) | 14,998 | | |
| Common stock issued via Exchange Transaction | 45,464,760 | 4,546 | 27,274,315 | | 27,278,861 |
| Common stock issued via private placement July 14, 2008 | 5,000,000 | 500 | 2,999,500 | | 3,000,000 |
| Common stock issued via private placement August 25, 2008 | 41,667 | 4 | 24,996 | | 25,000 |
| Fees and expenses related to private placements | | | (73,088) | | (73,088) |
| Stock based compensation expense | | | 379,883 | | 379,883 |
| Net loss for the year | | | | (31,755,180) | (31,755,180) |
| Balance, December 31, 2008 | 65,606,434 | 6,560 | 30,633,089 | (31,795,441) | (1,155,792) |
| Common stock issued via private placements | 10,332,144 | 1,033 | 7,231,467 | | 7,232,500 |
| Fees and expenses related to private placements | | | (245,000) | | (245,000) |
| Stock based compensation expense | | | 860,428 | | 860,428 |
| Net loss for the period | | | | (5,182,771) | (5,182,771) |
| Balance, September 30, 2009 | 75,938,578 | \$ 7,593 | \$ 38,479,984 | \$ (36,978,212) | \$ 1,509,365 |

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

| | Nine Months Ended September 30, 2009 | Nine Months Ended September 30, 2008 | Period from November 15, 2005 (Inception) to September 30, 2009 |
|---|--|--|--|
| Cash Flows From Operating Activities: | | | |
| Net loss | \$ (5,182,771) | \$ (29,840,015) | \$ (36,978,212) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 988 | | 2,210 |
| Stock-based compensation expense | 860,428 | 201,146 | 1,240,311 |
| Purchased in-process research and development | | 28,156,503 | 28,156,503 |
| Changes in operating assets and liabilities: | | | |
| Security deposit | (9,625) | (25) | (14,025) |
| Accounts payable and accrued expenses | 434,841 | 329,893 | 1,790,030 |
| Prepaid Insurance | (89,810) | | (89,810) |
| Total Adjustments | 1,196,822 | 28,687,517 | 31,085,219 |
| Net Cash Used in Operating Activities | (3,985,949) | (1,152,498) | (5,892,993) |
| Cash Flows From Investing Activities: | | | |
| Net cash paid on Exchange Transaction | | (155,326) | (155,326) |
| Loans from (to) related parties | (131,387) | | (821,720) |
| Additions to property and equipment | | (12,195) | (12,195) |
| Net Cash Used in Investing Activities | (131,387) | (167,521) | (989,241) |
| Cash Flows From Financing Activities: | | | |
| Capital contribution by shareholders | | | 8,893 |
| Issuance of common stock | | | 2,000 |
| Proceeds from sale of common stock | 7,232,500 | 3,025,000 | 10,257,500 |
| Fees and expenses related to private placements | (245,000) | (73,088) | (318,088) |
| Proceeds from sale of unregistered common stock to founders | | | 18,100 |
| Net Cash Provided by Financing Activities | 6,987,500 | 2,951,912 | 9,968,405 |
| Net increase in cash and cash equivalents | 2,870,164 | 1,631,893 | 3,086,171 |
| Cash and cash equivalents at beginning of period | 216,007 | 1,807 | |
| Cash and cash equivalents at end of period | \$ 3,086,171 | \$ 1,633,700 | \$ 3,086,171 |
| Supplementary disclosure of cash flow information: | | | |
| Cash paid for taxes | \$ 2,473 | \$ 632 | \$ 3,105 |
| Cash paid for interest | \$ | \$ | \$ |
| Value of common stock issued via Exchange Transaction | \$ | \$ 27,278,861 | \$ 27,278,861 |

Cash flow activities for the nine months ended September 30, 2008 include discontinued pet food operations prior to July 14, 2008.

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Business Overview

On July 14, 2008, Pawfect Foods, Inc. ("Pawfect"), A Florida corporation incorporated on November 15, 2005, acquired 100% of the common stock of Synergy Pharmaceuticals, Inc., a Delaware corporation incorporated on September 11, 1992, and its wholly-owned subsidiary, Synergy Advanced Pharmaceuticals, Inc., (collectively "Synergy-DE"), from Callisto Pharmaceuticals, Inc. ("Callisto") and certain other holders of Synergy-DE common stock. Simultaneously Pawfect discontinued its pet food business and is now exclusively focused on the development of drugs to treat gastrointestinal ("GI") disorders and diseases. On July 21, 2008, Pawfect amended its articles of incorporation to effect the acquisition of Synergy-DE and changed our name to Synergy Pharmaceuticals, Inc. ("Synergy" or "the Company").

Synergy's lead drug candidate is SP-304, a guanylyl cyclase C ("GC-C") receptor agonist to treat GI disorders, primarily chronic constipation ("CC") and constipation-predominant irritable bowel syndrome ("IBS-C"). On April 2, 2008, Synergy-DE filed an investigational new drug ("IND") application with the United States Food and Drug Administration ("FDA"). On May 2, 2008, Synergy-DE received notice from the FDA that the proposed study was deemed safe to proceed and Synergy-DE initiated a Phase I clinical trial in volunteers on June 4, 2008.

On December 9, 2008, Synergy announced the completion of the Phase I clinical trial of SP-304 in healthy volunteers that was initiated in June 2008. This first study was a double-blind, placebo-controlled, randomized single, oral, ascending dose trial performed in 71 healthy male and female volunteers. The primary objective of the Phase I clinical trial with SP-304 was to characterize the safety, tolerability, pharmacokinetic and pharmacodynamic effects of the drug in healthy volunteers. The clinical data from the Phase I healthy volunteer study was included in an abstract presented at the Digestive Disease Week conference held in Chicago IL from May 30 through June 4, 2009. Synergy plans to initiate a Phase IIa 14-day, repeated-oral-dose trial of SP-304 in chronic constipation patients in early 2010.

SP-304 was developed by Synergy scientists based on structure-function studies performed in-house. A patent covering composition of matter and therapeutic applications of SP-304 was granted by the U.S. Patent and Trademark Office on May 9, 2006. SP-304 is an analog of uroguanylin, a natural GI hormone produced in the gut that is a key regulator of intestinal function. Uroguanylin works by activating GC-C receptors on intestinal cells. The GC-C receptor, promotes fluid and ion transport in the GI tract. Under normal conditions, the receptor is activated by the natural hormones uroguanylin and guanylin. Activation of the receptor leads to the transport of chloride and bicarbonate into the intestine, and water is carried with these ions into the lumen of the intestine, thereby softening stool, and producing other pharmacologic, beneficial effects that could potentially benefit patients with CC and IBS-C.

A practical, efficient and cost effective method for producing SP-304 on a commercial scale is currently being investigated in concert with multiple manufacturing contract research organizations (CRO's). At present, the Company's CROs have produced over 650 grams of SP-304, under current good manufacturing practices ("cGMP"), which have been primarily used for non-clinical work to support further human clinical trials.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

1. Business Overview (Continued)

SP-304 has also undergone pre-clinical animal studies as a treatment for GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of North Carolina, Chapel Hill, NC. Results from his laboratory and from separate CRO's who conducted animal model studies for us showed that SP-304 was efficacious in animal models of ulcerative colitis ("UC"). A second generation GC-C receptor analog, SP-333, is now in pre-clinical development and Synergy plans to file an IND to treat UC patients in 2010.

2. Basis of Presentation and Going Concern

As discussed above, on July 14, 2008, Synergy completed the acquisition of Synergy-DE. The acquisition of Synergy-DE was treated as an asset acquisition, since Synergy-DE is a development stage company and does not have the necessary inputs and outputs to meet the definition of a business. The results of operations of Synergy-DE are included in the accompanying consolidated financial statements from July 14, 2008 to date. As a result of the acquisition of Synergy-DE on July 14, 2008, the Company decided to discontinue its pet food business and accordingly, amounts in the consolidated statements of operations and related notes for all historical periods have been restated to reflect these operations as discontinued.

All intercompany balances and transactions have been eliminated. These unaudited condensed consolidated financial statements include Synergy and its wholly-owned subsidiaries: (1) Synergy-DE, (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 results of operations for the nine months ended September 30, 2009 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2009. 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, 2008 contained in the Company's Annual Report on Form 10-K filed with the Securities Exchange Commission ("SEC") on April 15, 2009. Certain items in the prior year's financial statements have been reclassified to conform to the current year's presentation.

These condensed consolidated financial statements as of September 30, 2009 and December 31, 2008 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. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As of September 30, 2009, Synergy had an accumulated deficit of \$36,978,212 resulting primarily from acquired in-process research and development valued at \$28,156,503 and expensed upon the acquisition of Synergy on July 14, 2008. Synergy expects to incur significant and increasing operating losses for the next several years as Synergy expands its research and development, continues clinical

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

2. Basis of Presentation and Going Concern (Continued)

trials of SP-304 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 \$3,985,949 for the nine months ended September 30, 2009. As of September 30, 2009 Synergy has \$3,086,171 of cash. During the nine months ended September 30, 2009, Synergy incurred net losses from continuing operations of \$5,182,771. To date, Synergy's sources of cash have been primarily limited to private placements of common stock. Net cash provided by financing activities for the nine months ended September 30, 2009 was \$6,987,500.

As of September 30, 2009 Synergy had working capital of \$662,907 as compared to a working capital deficit of \$1,171,893 as of December 31, 2008. During the nine months ended September 30, 2009 Synergy sold 10,332,144 shares of unregistered common stock at \$0.70 per share to a private investors for aggregate proceeds of \$7,232,500 and Synergy paid an aggregate \$235,000 to selling agents and \$10,000 in legal fees in connection with certain of its private placements.

Synergy 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. 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.

Recent worldwide economic conditions and the 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. Synergy has accordingly taken steps to conserve cash which include extending payment terms to our suppliers as well as substantial management and staff salary cuts and deferrals.

3. Recent Accounting Pronouncements

In August 2009, the FASB issued Accounting Standards Update No. 2009-05, "Measuring Liabilities at Fair Value" ("ASU 2009-05"). ASU 2009-05 amends ASC Topic 820 and clarifies that, where a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: 1) a valuation technique that uses a) the quoted price of the identical liability when traded as an asset or b) quoted prices for similar liabilities or similar liabilities when traded as assets and/or 2) a valuation technique that is

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Recent Accounting Pronouncements (Continued)

consistent with the principles of ASC Topic 820. ASU 2009-05 also clarifies that, when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability. The adoption of ASU 2009-05 did not have a material impact on the Company's financial statements.

In June 2009, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2009-01, "Generally Accepted Accounting Principles" (ASC Topic 105), by the Codification which establishes the FASB Accounting Standards Codification (the "Codification" or "ASC") as the single source of authoritative GAAP. All existing accounting standards in effect prior to the Codification were superseded. All other accounting guidance not included in the Codification will be considered non-authoritative. The Codification also includes all relevant SEC guidance organized using the same topical structure in separate sections within the Codification. The Codification does not change GAAP and does not impact the Company's financial statements. Beginning with the financial statements and the notes thereto included in this quarterly report, all references to authoritative accounting literature (including references related to periods prior to the establishment of the Codification) will be referenced in accordance with the Codification.

In May 2009, the FASB issued guidance within ASC Topic 855, "Subsequent Events," relating to subsequent events. This guidance establishes principles and requirements for subsequent events. This guidance defines the period after the balance sheet date during which events or transactions that may occur would be required to be disclosed in a company's financial statements. Public entities are required to evaluate subsequent events through the date that financial statements are issued. This guidance also provides guidelines for evaluating whether or not events or transactions occurring after the balance sheet date should be recognized in the financial statements. This guidance requires disclosure of the date through which subsequent events have been evaluated. The Company has evaluated subsequent events immediately prior to the date of issuance of this report.

In April 2009, the FASB issued guidance within ASC Topic 825, "Financial Instruments - Overall," concerning interim disclosures about fair value instruments. This guidance requires that disclosures about the fair value of a company's financial instruments be made whenever summarized financial information for interim reporting periods is made. The provisions of this guidance are effective for interim periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's financial statements.

4. Accounting for Shared-Based Payments

Stock Options

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 did not issue stock options prior to the quarter ended September 30, 2008. Synergy periodically issues stock options to employees and non-employees and has adopted ASC Topic 718 for employee awards on July 3, 2008 concurrently with adoption of the Plan. Prior to that date Synergy had not issued any stock options. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505:

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for Shared-Based Payments (Continued)

"Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and ASC Topic 505 "Accounting Recognition for Certain Transactions involving Equity Instruments Granted to Other Than 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.

Stock-based compensation expense, including all options 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, 2009 |
|--|-------------------------------------|-------------------|-----------------------------------|-------------------|---|
| | 2009 | 2008 | 2009 | 2008 | |
| Employees included in research and development | \$ 115,615 | \$ 37,009 | \$ 201,911 | \$ 37,009 | 281,440 |
| Employees included in general and administrative | 185,133 | 55,409 | 297,902 | 55,409 | 410,629 |
| Non-employees included in research and development | 8,548 | | 25,366 | | 33,914 |
| Non-employees included in general and administrative | 196,847 | 108,728 | 335,249 | 108,728 | 514,328 |
| Total stock-based compensation expense | \$ 506,143 | \$ 201,146 | \$ 860,428 | \$ 201,146 | \$ 1,240,311 |

The unrecognized compensation cost related to non-vested employee stock options outstanding at September 30, 2009, net of expected forfeitures, was \$1,104,724, to be recognized over a weighted-average remaining vesting period of approximately one year.

A summary of stock option activity and of changes in stock options outstanding under Synergy's plans is presented below:

| | Number of Options | Exercise Price Per Share | Weighted Average Exercise Price Per Share | Intrinsic Value |
|---|----------------------|-----------------------------|---|--------------------|
| Balance outstanding, December 31, 2008 | 4,080,016 | \$ 0.25 - 0.95 | \$ 0.29 | \$ 8,933,935 |
| Granted | | | | |
| Exercised | | | | |
| Forfeited | | | | |
| Balance outstanding, September 30, 2009 | 4,080,016 | \$ 0.25 - 0.95 | \$ 0.29 | \$ 11,300,344 |

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

Exercisable at
September 30,
2009

1,381,587 \$ 0.25 - 0.60 \$ 0.28 \$ 3,847,259

12

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for Shared-Based Payments (Continued)

Synergy Restricted Stock Units

Restricted Stock Units, which issue to the holder 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 grant. The units are subject to a repurchase agreement, according to which, 50% of the units are released after 1 year of continuous service and the remaining 50% are released after 2 years of continuous service from the grant date.

On July 3, 2008, 874,760 restricted stock units were issued by Synergy-DE and assumed by Synergy as part of the Exchange Transaction and are subject to a repurchase agreement, as defined. These restricted stock units were issued to certain officers and a consultant of Synergy. The fair value of each Synergy restricted stock unit is estimated on the grant date based on the price paid by shareholders participating in Synergy's July 14, 2008 private placement. As of September 30, 2009 there were 874,760 Synergy restricted stock units outstanding. The fair value of the 874,760 Synergy restricted stock units on the date of grant was \$524,856 of which \$230,361 and \$327,960 was recorded as stock-based compensation expense during the three and nine months ended September 30, 2009. As of September 30, 2009 the unrecognized fair value of the 165,485 unvested stock units was \$99,290 to be amortized over 9 months. The intrinsic value of the 874,760 outstanding restricted stock units was \$2,676,766 as of September 30, 2009, measured using the closing stock price of \$3.06 per share as of that date.

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.

5. Stockholder's equity

During the nine months ended September 30, 2009 Synergy sold 10,332,144 shares of unregistered common stock at \$0.70 per share to private investors, pursuant to a Securities Purchase Agreement, for aggregate proceeds of \$7,232,500. There were no warrants issued in connection with these transactions. Synergy incurred \$235,000 in fees to selling agents and \$10,000 in legal fees in connection with these transactions. Pursuant to the Securities Purchase Agreement the investors agreed to be subject to a lock-up until August 15, 2010 and Synergy agreed to price protection for the investors in the event of subsequent sales of equity securities as defined, until February 15, 2011. In accordance with the guidance contained in ASC Topic 815-40, the Company has determined that the price protection provisions are embedded derivatives that require bifurcation and recognition at fair value in the company's financial statements. The Company has determined that the fair value of the derivatives is immaterial.

As of September 30, 2009 Synergy's majority shareholder, Callisto, owns approximately 59% of its outstanding shares. As of September 30, 2009, the balance due from majority shareholder amounted to \$821,720, which is Callisto's share of Synergy payments for common operating costs since the inception. 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 it as a long term asset.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

6. 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 nine months ended September 30, 2009 the effect of 4,080,016 outstanding stock options were excluded from the calculation of diluted loss per share because the effect was antidilutive. As of September 30, 2008 there were no outstanding stock options and other common stock equivalents.

7. Subsequent Events

On October 30, 2009, Synergy closed a private placement of 9,389,428 shares of unregistered common stock to certain investors at a per share price of \$0.70 for aggregate gross proceeds of \$6,572,600 pursuant to a Securities Purchase Agreement dated as of October 30, 2009. On November 5, 2009, Synergy sold 1,114,286 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$780,000, pursuant to a Securities Purchase Agreement dated as of November 5, 2009. On November 12, 2009, Synergy sold 1,664,284 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$1,165,000, pursuant to a Securities Purchase Agreement dated as of November 12, 2009. Had these private placements closed on September 30, 2009 pro-forma selected balance sheet items would have been as follows:

| | As Reported | Private Placements | |
|---------------------------|---------------------------|---------------------------|---------------------------|
| | September 30, 2009 | Subsequent to | Pro-forma |
| | | September 30, 2009 | September 30, 2009 |
| Cash and cash equivalents | \$ 3,086,171 | \$ 8,517,599 | \$ 11,603,770 |
| Total assets | 4,022,439 | 8,517,599 | 12,540,038 |
| Total liabilities | 2,513,074 | | 2,513,074 |
| Stockholders equity | \$ 1,509,365 | \$ 8,517,599 | \$ 10,026,964 |
| Common shares outstanding | 75,938,577 | 12,167,998 | 88,106,575 |

14

Table of Contents

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and other financial information appearing elsewhere in this quarterly report. In addition to historical information, the following discussion and other parts of this quarterly report contain forward-looking statements. You can identify these statements by forward-looking words such as "may," "will," "expect," "intend," "anticipate," "believe," "estimate" and "continue" or similar words. Forward-looking statements include information concerning possible or assumed future business success or financial results. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Accordingly, we do not undertake any obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under "Risk Factors" in this Report on Form 10-Q as of and for the three and nine months ended September 30, 2009 and other periodic reports filed with the United States Securities and Exchange Commission ("SEC"). Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of the Company, please be advised that the Company's actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements.

RECENT DEVELOPMENTS

On October 30, 2009, we closed a private placement of 9,389,428 unregistered shares of our common stock to certain investors at a per share price of \$0.70 for aggregate gross proceeds of \$6,572,600 pursuant to a Securities Purchase Agreement dated as of October 30, 2009. On November 5, 2009, Synergy sold 1,114,286 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$780,000, pursuant to a Securities Purchase Agreement dated as of November 5, 2009. On November 12, 2009, Synergy sold 1,664,284 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$1,165,000, pursuant to a Securities Purchase Agreement dated as of November 12, 2009.

Synergy's lead drug candidate is SP-304, a guanylyl cyclase C ("GC-C") receptor agonist to treat GI disorders, primarily chronic constipation ("CC") and constipation-predominant irritable bowel syndrome ("IBS-C"). On April 2, 2008, Synergy-DE filed an investigational new drug ("IND") application with the United States Food and Drug Administration ("FDA"). On May 2, 2008, Synergy-DE received notice from the FDA that the proposed study was deemed safe to proceed and Synergy-DE initiated a Phase I clinical trial in volunteers on June 4, 2008.

On December 9, 2008, Synergy announced the completion of the Phase I clinical trial of SP-304 in healthy volunteers that was initiated in June 2008. This first study was a double-blind, placebo-controlled, randomized single, oral, ascending dose trial performed in 71 healthy male and female volunteers. The primary objective of the Phase I clinical trial with SP-304 was to characterize the safety, tolerability, pharmacokinetic and pharmacodynamic effects of the drug in healthy volunteers. The clinical data from the SP-304 Phase I healthy volunteer study was included in an abstract presented at the Digestive Disease Week conference held in Chicago IL from May 30 through June 4, 2009. SP-304 was well tolerated at all doses studied (0.1 mg to 48.6 mg) and exhibited pharmacodynamic activity in healthy volunteers with no detectable systemic absorption. These data clearly supported advancing

Table of Contents

SP-304 for further clinical studies in patients with CC and IBS-C. Synergy plans to initiate a Phase IIa 14-day, repeated-oral-dose trial of SP-304 in chronic constipation patients in early 2010.

SP-304 was developed by Synergy scientists based on structure-function studies performed in-house. A patent covering composition of matter and therapeutic applications of SP-304 was granted by the U.S. Patent and Trademark Office on May 9, 2006. SP-304 is an analog of uroguanylin, a natural GI hormone produced in the gut that is a key regulator of intestinal function. Uroguanylin works by activating GC-C receptors on intestinal cells. The GC-C receptor, promotes fluid and ion transport in the GI tract. Under normal conditions, the receptor is activated by the natural hormones uroguanylin and guanylin. Activation of the receptor leads to the transport of chloride and bicarbonate into the intestine, and water is carried with these ions into the lumen of the intestine, thereby softening stool, and producing other pharmacologic, beneficial effects that could potentially benefit patients with CC and IBS-C.

A practical, efficient and cost effective method for producing SP-304 on a commercial scale is currently being investigated in concert with multiple manufacturing contract research organizations (CRO's). At present, Synergy's CROs have produced over 650 grams of SP-304, under current good manufacturing practices ("cGMP"), which have been primarily used for non-clinical work to support further human clinical trials.

SP-304 has also undergone pre-clinical animal studies as a treatment for GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of North Carolina, Chapel Hill, NC. Results from his laboratory and from separate CRO's who conducted animal model studies for us showed that SP-304 was efficacious in animal models of ulcerative colitis ("UC"). A second generation GC-C receptor analog, SP-333, is now in pre-clinical development and Synergy plans to file an IND to treat UC patients in 2010.

FINANCIAL OPERATIONS OVERVIEW

From inception through September 30, 2009, we have sustained cumulative net losses of \$36,978,212, resulting primarily from acquired in-process research and development valued at \$28,156,503 which was expensed upon the acquisition of Synergy on July 14, 2008. From inception through September 30, 2009, 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 thus 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 years ended December 31, 2008 and 2007, filed with the SEC on April 15, 2009. There have been no changes to our critical accounting policies since December 31, 2008.

Table of Contents

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, 2008. There have been no changes in our contractual obligations and commitments during the three and nine months ended September 30, 2009.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2009.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008

As discussed above, on July 14, 2008, Synergy completed the acquisition of Synergy-DE. The acquisition of Synergy-DE was treated as an asset acquisition, since Synergy-DE is a development stage company and does not have the necessary inputs and outputs to meet the definition of a business. The results of operations of Synergy-DE are included in the accompanying consolidated financial statements from July 14, 2008 to September 30, 2009. As a result of the acquisition of Synergy-DE on July 14, 2008, we decided to discontinue our pet food business and accordingly, amounts in the consolidated statements of operations and related notes for all historical periods have been restated to reflect these operations as discontinued.

We had no revenues during the three months ended September 30, 2009 and 2008 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the three months ended September 30, 2009 increased \$454,807 or 64%, to \$1,163,643 for the three months ended September 30, 2009 from \$708,836 for the three months ended September 30, 2008. This increase was primarily due to higher development expenses, related to our SP-304 candidate, including analytical testing, animal studies and clinical trial insurance which increased by approximately \$470,000 to approximately \$770,000 during the three months ended September 30, 2009.

For the three months ended September 30, 2009, general and administrative expenses increased \$118,659 or 13%, to \$1,058,928 for three months ended September 30, 2009 from \$940,269 for the three months ended September 31, 2008. This increase was primarily due to higher stock based compensation expense which increased by approximately \$218,000 to approximately \$382,000 during the three months ended September 30, 2009, partially offset by legal and accounting fees which decreased by approximately \$83,000 as compared to the three months ended September 30, 2008.

Net loss for the three months ended September 30, 2009 was \$2,211,709 compared to a net loss of \$29,840,015 incurred for the three months ended September 30, 2008 which was primarily due to the operating expense items discussed above and from acquired purchased in-processes research and development of \$28,156,503 which was expensed upon the acquisition of Synergy on July 14, 2008.

NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008

We had no revenues during the nine months ended September 30, 2009 and 2008 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Table of Contents

For the nine months ended September 30, 2009, research and development expenses totaled \$2,611,666. These research and development expenses were entirely attributable to continuing the development of our SP-304 product candidate. These expenses included (i) procurement of drug substance, totaling approximately \$880,000, to move our clinical trials into Phase II a , (ii) program expenses including animal studies analytical testing and clinical trial insurance of approximately \$815,000 (iii) scientific and regulatory advisory fees and expenses of approximately \$162,000, (iv) in-house staff salaries and wages, stock based compensation and employee benefits of approximately \$483,000 and (v) patent related legal fees of approximately \$208,000. Such expenses during the nine months ended September 30, 2008 are addressed above in our three month discussion because the SP-304 product was acquired in connection with the July 14, 2008 Exchange Transaction.

For the nine months ended September 30, 2009, general and administrative expenses were \$2,582,113. These expenses primarily include (i) non-scientific salaries and wages, stock based compensation and related employee benefits of approximately \$1,350,000, (ii) facilities cost of approximately \$443,000, (iii) independent public accounting, corporate legal and tax services of approximately \$277,000 (iv) consultants and advisors of approximately \$410,000 and (v) travel of approximately \$70,000. Such expenses during the nine months ended September 30, 2008 were related to the SP-304 product was acquired in connection with the July 14, 2008 Exchange Transaction.

Net loss for the nine months ended September 30, 2009 was \$5,182,771 compared to a net loss of \$29,840,015 incurred for the nine months ended September 30, 2008 which was resulted primarily from acquired purchased in-processes research and development valued at \$28,156,503 and expensed upon the acquisition of Synergy on July 14, 2008.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2009 we had \$3,086,171 in cash and cash equivalents, compared to \$216,007 as of December 31, 2008. Net cash used in operating activities was \$3,985,949 for the nine months ended September 30, 2009. During the nine months ended September 30, 2009, we incurred net losses from continuing operations of \$5,182,771. To date, our sources of cash have been primarily limited to private placements of common stock. Net cash provided by financing activities for the nine months ended September 30, 2009 was \$6,987,500. As of September 30, 2009 we had working capital of \$662,907 as compared to a working capital deficit of \$1,171,893 as of December 31, 2008.

During the nine months ended September 30, 2009 Synergy sold 10,332,144 shares of unregistered common stock at \$0.70 per share to private investors for aggregate proceeds of \$7,232,500. On October 30, 2009, we closed a private placement of 9,389,428 shares of our common stock to certain investors at a per share price of \$0.70 for aggregate gross proceeds of \$6,572,600 pursuant to a Securities Purchase Agreement dated as of October 30, 2009. On November 5, 2009, Synergy sold 1,114,286 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$780,000, pursuant to a Securities Purchase Agreement dated as of November 5, 2009. On November 12, 2009, Synergy sold 1,664,284 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$1,165,000, pursuant to a Securities Purchase Agreement dated as of November 12, 2009.

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

Table of Contents

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 and the 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. We have accordingly taken steps to conserve cash which include extending payment terms to our suppliers as well as substantial management and staff salary cuts and deferrals.

Our condensed consolidated financial statements as of September 30, 2009 and December 31, 2008 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the negative outcome of this uncertainty.

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, 2009, we had approximately \$3,100,000 in money market balances.

ITEM 4.T. 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, 2009, 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, 2008. 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, 2008, 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, 2008, 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.

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.

Table of Contents

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As of September 30, 2009 we have added financial staff resources to our accounting and finance department to improve controls surrounding both the segregations of duties and accounting expertise. Management believes this will substantially reduce the risk of a material misstatement resulting from the material weaknesses described above. However, it will require a period of time to determine the operating effectiveness of these newly implemented internal controls over financial reporting.

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, 2009.

Table of Contents

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

There have been no material changes from the legal proceedings disclosed in our Form 10-K for the year ended December 31, 2008. We are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2008.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

On September 3, 2009, we closed a private placement of 200,000 shares of common stock to certain investors at a per share price of \$0.70, for aggregate proceeds of \$140,000, pursuant to a Securities Purchase Agreement. On October 30, 2009, we closed a private placement of 9,389,428 shares of our common stock to certain investors at a per share price of \$0.70 for aggregate gross proceeds of \$6,572,600 pursuant to a Securities Purchase Agreement dated as of October 30, 2009. On November 5, 2009, we closed a private placement 1,114,286 shares of common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$780,000, pursuant to a Securities Purchase Agreement dated as of November 5, 2009. On November 12, 2009, we closed a private placement of 1,664,284 shares of common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$1,165,000, pursuant to a Securities Purchase Agreement dated as of November 12, 2009.

All such shares were sold in reliance on Section 4(2) of the Securities Act of 1933 for transactions by us not involving a public offering.

ITEM 6. EXHIBITS

(a) Exhibits

- 31.1 Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
- 31.2 Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

