

Synergy Pharmaceuticals, Inc.
Form 10-Q
May 20, 2009

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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: MARCH 31, 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):

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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 67,176,195 as of May 18, 2009.

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. 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**

| | March 31, 2009 | December 31, 2008 |
|---|-------------------|----------------------|
| | (unaudited) | |
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 7 | \$ 216,007 |
| Cash in escrow | 191,000 | |
| Due from majority shareholder | 697,731 | 690,333 |
| Total Current Assets | 888,738 | 906,340 |
| Property and equipment, net | 11,207 | 11,701 |
| Security deposits | 4,400 | 4,400 |
| | \$ 904,345 | \$ 922,441 |
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| Current Liabilities: | | |
| Accounts payable | \$ 2,154,212 | \$ 2,000,220 |
| Accrued expenses | 334,958 | 78,013 |
| Total Current Liabilities | 2,489,170 | 2,078,233 |
| Stockholders' Deficit: | | |
| Common stock, par value of \$.0001 authorized 150,000,000 shares at March 31, 2009 and December 31, 2008, outstanding 66,172,148 and 65,606,434 shares at March 31, 2009 and December 31, 2008, respectively. | 6,617 | 6,560 |
| Preferred stock, Authorized 20,000,000 shares and 0 shares outstanding at March 31, 2009 and December 31, 2008, respectively | | |
| Additional paid-in capital | 31,200,528 | 30,633,089 |
| Deficit accumulated during development stage | (32,791,970) | (31,795,441) |
| Total Stockholders' Deficit | (1,584,825) | (1,155,792) |
| | \$ 904,345 | \$ 922,441 |

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 March 31, | | November 15, 2005 |
|---|------------------------------|-------------|----------------------------------|
| | 2009 | 2008 | (inception) to March 31, 2009 |
| | \$ | \$ | \$ |
| Revenues | | | |
| Costs and Expenses: | | | |
| Research and development | 333,147 | | 2,242,373 |
| Purchased in-process research and development | | | 28,156,502 |
| General and administrative | 663,512 | | 2,326,397 |
| Loss from Operations | (996,659) | | (32,725,272) |
| Interest and investment income | 130 | | 5,123 |
| Loss from Continuing Operations | (996,529) | | (32,720,149) |
| Loss from discontinued operations | | (6,874) | (71,821) |
| Net Loss | \$ (996,529) | \$ (6,874) | \$ (32,791,970) |
| Weighted Average Common Shares Outstanding | | | |
| Basic and Diluted | 65,742,879 | 165,081,215 | |
| Net Loss per Common Share, Basic and Diluted | | | |
| Net Loss from Continuing Operations | \$ (0.02) | \$ | |
| Discontinued Operations: | | | |
| Loss from discontinued operations | | | |
| Net Loss per Common Share, Basic and Diluted | \$ (0.02) | \$ | |

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 period | | | | (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 | 565,714 | 57 | 390,943 | | 391,000 |

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| | | | | | | |
|----------------------------------|--|--|---------|-----------|--|-----------|
| Stock based compensation expense | | | 176,496 | | | 176,496 |
| Net loss for the period | | | | (996,529) | | (996,529) |

Balance, March 31, 2009 66,172,148 \$ 6,617 \$31,200,528 \$ (32,791,970) \$ (1,584,825)

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)

| | Three Months Ended March 31, 2009 | Three Months Ended March 31, 2008 | Period from November 15, 2005 (Inception) to March 31, 2009 |
|---|--|--|---|
| Cash Flows From Operating Activities: | | | |
| Net loss | \$ (996,529) | \$ (6,874) | \$ (32,791,970) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 494 | 168 | 1,716 |
| Stock-based compensation expense | 176,496 | | 556,379 |
| Purchased in-process research and development | | | 28,156,502 |
| Changes in operating assets and liabilities: | | | |
| Security deposit | | | (4,400) |
| Accounts payable and accrued expenses | 410,937 | 6,417 | 1,766,127 |
| Total Adjustments | 587,927 | 6,585 | 30,476,324 |
| Net Cash Used in Operating Activities | (408,602) | (289) | (2,315,646) |
| Cash Flows From Investing Activities: | | | |
| Net cash paid on Exchange Transaction | | | (155,326) |
| Loans and cash advances from (to) related parties | (7,398) | | (697,731) |
| Additions to property and equipment | | | (12,195) |
| Net Cash used in Investing Activities | (7,398) | | (865,252) |
| Cash Flows From Financing Activities: | | | |
| Capital contribution by shareholders | | | 8,893 |
| Issuance of common stock | | | 2,000 |
| Proceeds of private placement of common stock | 200,000 | | 3,151,912 |
| Proceeds from sale of unregistered common stock to founders | | | 18,100 |
| Net Cash Provided by Financing Activities | 200,000 | | 3,180,905 |
| Net increase (decrease) in cash and cash equivalents | (216,000) | (289) | 7 |
| Cash and cash equivalents at beginning of period | 216,007 | 1,807 | |
| Cash and cash equivalents at end of period | \$ 7 | \$ 1,518 | \$ 7 |
| Supplementary disclosure of cash flow information: | | | |
| Cash paid for taxes | \$ 1,674 | \$ | \$ 2,306 |
| Cash paid for interest | \$ | \$ | \$ |
| Cash received in escrow for private placement of common stock. | \$ 191,000 | \$ | \$ 191,000 |

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Value of common stock issued via Exchange

Transaction

\$

\$

\$ 27,278,861

Cash flow activities for the three months ended March 31, 2008 represent the discontinued operations of Synergy's pet food business.

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

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"), under the terms of an Exchange Agreement among Pawfect, Callisto Pharmaceuticals, Inc. ("Callisto"), Synergy-DE, and certain other holders of Synergy-DE common stock ("Exchange Transaction").

On July 14, 2008, Pawfect discontinued its pet food business and is now exclusively focused on the development of drugs to treat gastrointestinal ("GI") disorders and diseases. Pawfect acquired the GI drugs and related technology in connection with the Exchange Transaction.

On July 21, 2008, Pawfect amended its articles of incorporation to effect the actions necessary to complete the transactions contemplated by the Exchange Transaction and changed its 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 data from the trial were included in an abstract accepted for presentation at the Digestive Disease Week conference that meets in Chicago in June 2009. Synergy plans to initiate a Phase Ib 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 the GC-C receptor 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 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 a contract research organization. At present, the Company has multiple 100 gram-scale lots of SP-304, produced under current good manufacturing practices ("cGMP"), which may be used for non-clinical work to support further human studies.

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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. Recent results from his laboratory also 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 and initiate a Phase I clinical trial in 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 forward. 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 three months ended March 31, 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.

These condensed consolidated financial statements as of March 31, 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 March 31, 2009, Synergy had an accumulated deficit of \$32,791,970, resulting primarily from acquired in-process research and development valued at \$28,156,502 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 trials of SP-304 for the treatment of GI disorders, acquires or licenses technologies, advances other product candidates

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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)

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 \$408,602 for the three months ended March 31, 2009. As of March 31, 2009 Synergy has \$7 of cash. During the three months ended March 31, 2009, Synergy incurred net losses from continuing operations of \$996,529. 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 three months ended March 31, 2009 was \$200,000, which excludes \$191,000 of cash held in escrow at March 31, 2009 which was released to the Company on April 2 and 13, 2009.

As of March 31, 2009 Synergy had a working capital deficit of \$1,600,432. On April 15, 2009 Synergy sold 1,045,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$732,000. 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. These actions may not be sufficient to allow the Company time to raise additional capital.

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.

3. Recent Accounting Pronouncements

In October 2008, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position ("FSP") No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, ("FSP No. 157-3"). This FSP applies to financial assets within the scope of accounting pronouncements that require or permit fair value measurements in accordance with SFAS No. 157. This FSP clarifies the application of SFAS No. 157 in determining the fair values of assets or liabilities in a market that is not active. This FSP is effective upon issuance, including prior periods for which financial statements have not been issued. The adoption of this FSP did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Recent Accounting Pronouncements (Continued)

In April 2009, the FASB issued FSP 107-1 and Accounting Principles Board ("APB") 28-1, *Interim Disclosures about Fair Value of Financial Instruments* ("FSP 107-1"). FSP 107-1 amends SFAS No. 107, *Disclosures About Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FSP 107-1 also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods. FSP 107-1 is effective for interim reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. FSP 107-1 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP 107-1 requires comparative disclosures only for periods ending after initial adoption. Synergy is currently evaluating the potential impact of the provisions of FSP FAS 107-1 and APB 28-1.

In April 2009, the FASB issued FSP 115-2 and 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments* ("FSP 115-2 and 124-2"). FSP 115-2 and 124-2 amends the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. FSP 115-2 and 124-2 does not amend existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. FSP 115-2 and 124-2 is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. FSP 115-2 and 124-2 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP 115-2 and 124-2 requires comparative disclosures only for periods ending after initial adoption. Synergy is currently evaluating the potential impact of the provisions of FSP FAS 115-2 and FAS 124-2.

In April 2009, the FASB issued FSP 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* (FSP 157-4"). FSP 157-4 provides additional guidance for estimating fair value in accordance with SFAS 157 when the volume and level of activity for the asset or liability have significantly decreased. FSP 157-4 also includes guidance on identifying circumstances that indicate a transaction is not orderly. FSP 157-4 is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. FSP 157-4 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP 157-4 requires comparative disclosures only for periods ending after initial adoption. Synergy is currently evaluating the potential impact of the provisions of FSP FAS 157-4.

In June 2008, the FASB ratified the consensus reached on Emerging Issues Task Force ("EITF") Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* ("EITF No. 07-05"). EITF No. 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. The Company adopted EITF No. 07-05 on January 1, 2009 and the adoption did not have a material effect on its consolidated financial position, results of operations or cash flows.

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Recent Accounting Pronouncements (Continued)

In February 2008, the FASB issued FSP No. FAS No. 157-2, *Partial Deferral of the Effective Date of Statement 157*, ("FSP No. 157-2"). FSP No. 157-2 delays the effective date of SFAS No. 157, *Fair Value Measurements* ("SFAS No. 157") for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually) to fiscal years beginning after November 15, 2008. The Company adopted SFAS No. 157 for nonfinancial assets and nonfinancial liabilities on January 1, 2009 and the adoption did not have a material impact on its consolidated financial position, results of operations or cash flows.

In December 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, ("EITF No. 07-1"), which provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure requirements. EITF No. 07-1 is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company adopted the provisions of EITF No. 07-1 on January 1, 2009; however, the adoption did not have a material effect on its consolidated financial position, results of operations or cash flows.

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 SFAS No. 123R 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 EITF No. 96-18: *"Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services"* and EITF No. 00-18 *"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

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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)

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 March 31, | | November 15, 2005 (inception) to March 31, 2009 |
|--|------------------------------------|------------|---|
| | 2009 | 2008 | |
| Employees included in research and development | \$ 43,241 | n/a | \$ 122,771 |
| Employees included in general and administrative | 56,073 | n/a | 168,801 |
| Non-employees included in research and development | 8,362 | n/a | 16,910 |
| Non-employees included in general and administrative | 68,820 | n/a | 247,897 |
| Total stock-based compensation expense | \$ 176,496 | n/a | \$ 556,379 |

The unrecognized compensation cost related to non-vested employee stock options outstanding at March 31, 2009, net of expected forfeitures, was \$1,162,156, to be recognized over a weighted-average remaining vesting period of approximately 2.3 years.

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 as of March 31, 2009 |
|--|----------------------|-----------------------------|---|--|
| Balance outstanding, December 31, 2008 | 4,080,016 | \$ 0.25 - 0.95 | \$ 0.29 | \$ 8,933,935 |
| Granted | | | | |
| Exercised | | | | |
| Forfeited | | | | |
| Balance outstanding, March 31, 2009 | 4,080,016 | \$ 0.25 - 0.95 | \$ 0.29 | \$ 9,627,538 |
| Exercisable at March 31, 2009 | 74,871 | \$ 0.25 | \$ 0.25 | \$ 179,690 |

Synergy Restricted Stock Units

Restricted Stock Units, which entitle the holder to receive, 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 SFAS No. 123R in the same manner as stock options using fair value at the date of grant. Subject to a repurchase agreement assumed by Synergy pursuant to the Exchange Transaction, 50% of the units vest after 1 year of continuous service and the remaining 50% vest after 2 years of continuous service from the grant date. The total fair value is being expensed ratably by month over the 2 year service period.

On July 3, 2008, 874,760 restricted stock units were granted 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

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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)

shareholders participating in Synergy's July 14, 2008 private placement. As of March 31, 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 \$48,530 was recorded as stock-based compensation expense during the three months ended March 31, 2009.

SFAS No. 123R 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

On February 13, 2009, Synergy sold 285,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$200,000. On March 31, 2009 Synergy sold 280,000 shares of unregistered common stock at \$0.70 per share to two private investors for aggregate proceeds of \$196,000. There were no warrants issued or finder's fees associated with these transactions, although the Company incurred \$5,000 in legal fees. Net proceeds during the three month ended March 31, 2009 was \$200,000. The proceeds from the 280,000 shares sold on March 31, 2009 were included in cash in escrow at March 31, 2009 and were deposited into the Company's cash account April 2 and 13, 2009.

Synergy's majority shareholder, Callisto, owns 68% of its outstanding shares.

6. Loss Per Share

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, *Earnings per Share*, ("SFAS No. 128") for all periods presented. In accordance with SFAS No. 128, 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 months ended March 31, 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 March 31, 2008, there were no outstanding stock options and other common stock equivalents.

7. Commitments and Contingencies

Employment and Consulting Agreements

Gary S. Jacob, Ph.D.

On March 11, 2009, Dr. Gary S. Jacob entered into an employment agreement with Synergy in which he agreed to serve as Acting Chief Executive Officer and President. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2011 and is automatically renewed for successive one year periods at the end of each term. Dr. Jacob's salary is \$300,000 per year of which 75% is to be allocated to Synergy and 25% is to be allocated to Callisto. Dr. Jacob is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

7. Commitments and Contingencies (Continued)

objectives and bonus criteria. Such performance objectives and bonus criteria had not been determined as of March 31, 2009 and therefore not met or earned. Dr. Jacob is also eligible to receive a realization bonus in the event that Synergy enters into an out-license agreement for its technology or engages in a merger or sale of substantially all its assets where the enterprise value equals or exceeds a minimum of \$150 million, \$200 million and \$250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, or the license fees Synergy contracts to receive equals or exceeds \$50 million. The realization bonus will be equal to the enterprise value in the case of a merger or sale or the sum of the license fees actually received multiplied by 0.5%.

If the employment agreement is terminated by Synergy other than for cause or as a result of Dr. Jacob's death or permanent disability or if Dr. Jacob terminates his employment for good reason which includes a change of control, Dr. Jacob shall receive (i) a severance payment equal to the higher of the aggregate amount of his base salary for the then remaining term of the agreement or twelve times the average monthly base salary paid or accrued during the three full calendar months preceding the termination, (ii) expense compensation in an amount equal to twelve times the sum of his average base salary during the three full months preceding the termination, (iii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iv) payment in respect of compensation earned but not yet paid and (v) payment of the cost of medical insurance for a period of twelve months following termination.

Gabriele M. Cerrone.

On March 11, 2009, Gabriele M. Cerrone, Chairman of the Board, entered into a consulting agreement with Synergy. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2011 and is automatically renewed for successive one year periods at the end of each term. Pursuant to the agreement, Mr. Cerrone's compensation is \$295,000 per year of which 75% is to be allocated to Synergy and 25% is to be allocated to Callisto. Mr. Cerrone is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Such performance objectives and bonus criteria had not been determined as of March 31, 2009 and therefore not met or earned. Mr. Cerrone is also eligible to receive a realization bonus in the event that Synergy enters into an out-license agreement for its technology or engages in a merger or sale of substantially all its assets where the enterprise value equals or exceeds a minimum of \$150 million, \$200 million and \$250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, and in the case of a financing transaction, Synergy receives not less than \$20 million of gross proceeds; or the license fees Synergy contracts to receive equals or exceeds \$50 million. The realization bonus will be equal to the enterprise value in the case of a merger, sale or financing or the sum of the license fees actually received multiplied by 0.5%.

If the consulting agreement is terminated by Synergy other than for cause or as a result of Mr. Cerrone's death or permanent disability or if Mr. Cerrone terminates the agreement for good reason which includes a change of control, Mr. Cerrone shall receive (i) a severance payment equal to

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

7. Commitments and Contingencies (Continued)

the higher of the aggregate amount of his base compensation for the then remaining term of the agreement or twelve times the average monthly base compensation paid or accrued during the three full calendar months preceding the termination, (ii) expense compensation in an amount equal to twelve times the sum of his average base compensation during the three full months preceding the termination, (iii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iv) payment in respect of compensation earned but not yet paid and (v) payment of the cost of medical insurance for a period of twelve months following termination.

8. Subsequent Events

On April 15, 2009, Synergy sold 1,045,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$732,000. There were no warrants issued or finder's fees associated with this transaction.

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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 months ended March 31, 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 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. and its wholly-owned subsidiary, Synergy Advanced Pharmaceuticals, Inc. (collectively "Synergy-DE"), a Delaware corporation incorporated on September 11, 1992, under the terms of an Exchange Transaction among Pawfect, Callisto Pharmaceuticals, Inc. ("Callisto"), Synergy-DE, and certain other holders of Synergy-DE common stock ("Exchange Transaction").

On July 14, 2008, Synergy discontinued its pet food business and is now exclusively focused on the development of drugs to treat gastrointestinal ("GI") disorders and diseases. Synergy acquired the GI drugs and related technology in connection with the Exchange Transaction.

On July 21, 2008, Pawfect amended its articles of incorporation to effect the actions necessary to complete the transactions contemplated by the Exchange Transaction and changed its 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. The purpose of the initial Phase I trial was to establish the safety of the drug. This first trial was a single-dose, dose-escalation, placebo-controlled trial in volunteers. Synergy plans to open a Phase Ib repeated-dose trial of SP-304 in CC 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

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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 the GC-C receptor 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 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 a contract research organization. At present, we have multiple 100 gram-scale lots of SP-304, produced under current good manufacturing practices ("cGMP"), which may be used for non-clinical work to support further human studies.

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. Recent results from his laboratory also 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 and initiate a Phase I clinical trial in UC patients in early 2010.

FINANCIAL OPERATIONS OVERVIEW

From inception through March 31, 2009, we have sustained cumulative net losses of \$32,791,970, resulting primarily from acquired in-process research and development valued at \$28,156,502 which was expensed upon the acquisition of Synergy on July 14, 2008. From inception through March 31, 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 Note 3*Summary of Significant Accounting Policies and New Accounting Pronouncements*, included in our 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.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

For a discussion of changes in contractual obligations since December 31, 2008, see Item 1. Financial Statements and Notes to Condensed Consolidated Financial Statements Note 6*Commitments and Contingencies*, included elsewhere in this Report on Form 10-Q for the three months ended March 31, 2009.

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OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of March 31, 2009.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 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 March 31, 2009. 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.

We had no revenues during the three months ended March 31, 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.

For the three months ended March 31, 2009, research and development expenses totaled \$333,147. These research and development expenses were primarily attributable to our SP-304 product candidate. These expenses included clinical program expenses of approximately \$60,000, scientific and regulatory advisory fees and expenses of approximately \$68,000, in-house staff compensation and employee benefits of approximately \$145,000 and patent related legal fees of approximately \$59,000. There were no such expenses during the three months ended March 31, 2008 because the SP-304 product was acquired in connection with the July 14, 2008 Exchange Transaction discussed above.

For the three months ended March 31, 2009, general and administrative expenses were \$663,512. These expenses primarily include non-scientific salaries and related employee benefits of approximately \$353,000, facilities cost of approximately \$93,000, accounting, legal and tax services of approximately \$68,000 and consultants and advisors, including Board fees, of approximately \$115,000. Such expenses during the three months ended March 31, 2008 were exclusively devoted to our pet food business which was discontinued on July 14, 2008 and reported as \$6,874 "loss from discontinued operations" in the accompanying financial statements.

Net loss for the three months ended March 31, 2009 was \$996,529 compared to a net loss (from discontinued operations) of \$6,874 incurred for the three months ended March 31, 2008.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2009 we had \$7 in cash and cash equivalents, compared to \$216,007 as of December 31, 2008. Net cash used in operating activities was \$408,602 for the three months ended March 31, 2009. Net cash provided by financing activities for the three months ended March 31, 2009 was \$200,000. On February 13, 2009, we sold 285,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$200,000. On March 31, 2009, we sold 280,000 shares of unregistered common stock at \$0.70 per share to two private investors for aggregate proceeds of \$196,000. There were no warrants issued or finder's fees associated with these transactions, although we incurred \$5,000 in legal fees. The proceeds from the 280,000 shares sold on March 31, 2009 were included in cash in escrow at March 31, 2009 and were deposited into our cash account on April 2 and 13, 2009.

As of March 31, 2009 we had a working capital deficit of \$1,600,432. On April 15, 2009, we sold 1,045,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$732,000. Recent worldwide economic conditions and the international equity and credit

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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. These actions may not be sufficient to allow the Company time to raise additional capital.

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of pharmaceutical research and development programs. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at our current cash expenditure levels. To date, our sources of cash have been primarily limited to the sale of equity securities. 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 of 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.

Our consolidated financial statements as of March 31, 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 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 March 31, 2009, we had no 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 March 31, 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

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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.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As of March 31, 2009 we are in the process of remediating the material weaknesses which existed at December 31, 2008. In connection with the Exchange Transaction described above in Item 1. Financial Statements and Notes to Condensed Consolidated Financial Statements, we plan to add financial staff resources to our accounting and finance department when funding becomes available and implemented certain other controls and procedures which management believes will prevent the recurrence of the material weakness described above. However, it will require a period of time to determine the operating effectiveness of these newly implemented internal controls over financial reporting. We plan to test and re-evaluate our controls as of December 31, 2009.

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 March 31, 2009.

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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, 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 February 13, 2009 we sold 285,714 shares of common stock at \$0.70 per share to a private investor for gross proceeds of \$200,000. On March 31, 2009 we sold 100,000 shares of common stock at \$0.70 per share to a private investor for gross proceeds of \$70,000. On March 31, 2009 we sold 180,000 shares of common stock at \$0.70 per share to a private investor for gross proceeds of \$126,000 and on April 15, 2009 we sold 1,045,714 shares of common stock at \$0.70 per share to a private investor for gross proceeds of \$732,000. 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.

