Synergy Pharmaceuticals, Inc.
Form 10-Q
November 19, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: SEPTEMBER 30, 2008

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

For the transition period from to
Commission File Number: 333-131722

SYNERGY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Florida	**20-3823853**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
420 Lexington Avenue, Suite 1609, New York, New York	**10170**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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

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 o No ý

The number of the registrant's shares of common stock outstanding was 65,606,434 as of November 19, 2008.

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(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 under "Risk Factors" included in this Report on Form 10-Q and other periodic filings with the Securities Exchange Committee. 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.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2008 (Unaudited)	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,633,700	$ 1,807
Other current assets	25	
Total Current Assets	1,633,725	1,807
Property and equipment, net	12,195	2,658
Total Assets	$ 1,645,920	$ 4,465
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 938,621	$ 5,000
Accrued expenses	126,667	6,233
Loans payable related parties		4,500
Total Current Liabilities	1,065,288	15,733
Commitments and contingencies (Note 6)		
Stockholders' Equity (Deficit):		
Common stock, par value of $.0001 and $.001 per share as of September 30, 2008 and December 31, 2007, respectively; Authorized 150,000,000 and 50,000,000 shares at September 30, 2008 and December 31, 2007, respectively; Outstanding 65,606,434 and 165,081,215 shares at September 30, 2008 and December 31, 2007, respectively	6,560	16,508
Preferred stock, authorized 20,000,000 shares and 0 shares outstanding at September 30, 2008 and December 31, 2007		
Additional paid-in capital	30,454,348	12,485
Deficit accumulated during development stage	(29,880,276)	(40,261)
Total Stockholders' Equity (Deficit)	580,632	(11,268)
Total Liabilities and Stockholders' Equity (Deficit)	$ 1,645,920	$ 4,465

Balances as of December 31, 2007 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)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		November 15, 2005 (inception) to September 30,
	2008	2007	2008	2007	2008
Revenues	$	$	$	$	$
Costs and Expenses:					
Research and development	708,836		708,836		708,836
Purchased in-process research and development	28,156,503		28,156,503		28,156,503
General and administrative	940,269		940,269		940,269
Loss from Operations	(29,805,608)		(29,805,608)		(29,805,608)
Interest and investment income	(2,847)		(2,847)		(2,847)
Loss from Continuing Operations	(29,808,455)		(29,808,455)		(29,808,455)
Loss from discontinued operations		(5,088)	(31,560)	(10,288)	(71,821)
Net Loss	$ (29,808,455)	$ (5,088)	$ (29,840,015)	$ (10,288)	$ (29,880,276)
Weighted Average Common Shares Outstanding					
Basic and Diluted	79,643,602	165,081,215	136,394,134	165,081,215	
Net Loss per Common Share, Basic and Diluted					
Net Loss from Continuing Operations	(0.37)	.00	(0.22)	.00	
Discontinued Operations:					
Loss from discontinued operations	.00	.00	.00	.00	
Net Loss per Common Share, Basic and Diluted	$ (0.37)	$ .00	$ (0.22)	$ .00	

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	27,274,310		27,278,856
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			(73,087)		(73,087)
Stock based compensation expense			201,146		201,146
Net loss for the period				(29,840,015)	(29,840,015)
	65,606,434	$ 6,560	$30,454,348	$ (29,880,276)	$ 580,632

Balance, September 30, 2008

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

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,		November 15, 2005 (inception) to September 30,
	2008	**2007**	**2008**
Cash Flows From Operating Activities:			
Net loss	$ (29,840,015)	$ (10,288)	$ (29,880,276)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation		504	728
Stock-based compensation expense	201,146		201,146
Purchased in-process research and development	28,156,503		28,156,503
Changes in operating assets and liabilities:			
Other current assets	(25)		(25)
Accounts payable	246,778	2,498	251,777
Accrued expenses	87,614	(2,837)	93,847
Total Adjustments	28,692,016	165	28,703,976
Net Cash Used in Operating Activities	(1,147,999)	(10,123)	(1,176,299)
Cash Flows From Investing Activities:			
Cash received in Exchange Transaction less repayment of Callisto debt	(155,326)		(155,326)
Additions to property and equipment	(12,195)		(15,581)
Net Cash Used in Investing Activities	(167,521)		(170,907)
Cash Flows From Financing Activities:			
Capital contribution by shareholders		8,893	8,893
Issuance of common stock			18,100
Proceeds from private placements of common stock	2,951,913		2,951,913
Repayments of loans payable- related parties	(4,500)		
Proceeds from sale of unregistered common stock to founder			2,000
Net Cash Provided by Financing Activities	2,947,413	8,893	2,980,906
Net (decrease) increase in cash and cash equivalents	1,631,893	(1,230)	
Cash and cash equivalents at beginning of period	1,807	1,552	1,633,700
Cash and cash equivalents at end of period	$ 1,633,700	$ 322	$ 1,633,700
Supplementary disclosure of cash flow information:			

Cash paid for taxes	$ 632	$	$ (35)
Cash paid for interest	$	$	$
Value of common stock issued via the exchange transaction	$ 27,278,856	$	$ 27,278,856

Cash flow activities for the nine months ended September 30, 2007 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"). For a more detailed discussion of this Exchange Transaction, see Note 8, *Acquisition and Stockholders' Equity (Deficit)* below.

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").

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.

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 during 2009.

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 developed 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"), that are being 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 2009.

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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

As discussed above on July 14, 2008, Pawfect 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 unaudited condensed consolidated financial statements from July 14, 2008 to September 30, 2008. As a result of the acquisition of Synergy-DE on July 14, 2008, the Company decided to discontinue Pawfect's pet food business and accordingly, amounts in the condensed consolidated statements of operations and related notes for all historical periods have been restated to reflect these operations as discontinued. The condensed consolidated balance sheet as of December 31, 2007 has not been restated due to being immaterial. For a more detailed discussion of this acquisition, see Note 8, *Acquisition and Stockholders' Equity (Deficit)* below.

All intercompany balances and transactions have been eliminated. 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 and the adjustments relating to the acquisition of Synergy-DE, 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, 2008 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2008. The accompanying condensed consolidated financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2007 contained in the Company's Annual Report on Form 10-KSB filed with the Securities Exchange Commission ("SEC").

These condensed consolidated financial statements as of September 30, 2008 and December 31, 2007 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, 2008, Synergy had an accumulated deficit of $29,880,276, 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 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 $1,147,999 for the nine months ended September 30, 2008. As of September 30, 2008 Synergy has $1,633,700 of cash and cash equivalents. During the nine months ended September 30, 2008, Synergy incurred net losses from continuing operations of

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SYNERGY PHARMACEUTICALS, INC.
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

2. Basis of Presentation and Going Concern (Continued)

$29,808,455. 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, 2008 was $2,947,413.

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. Summary of Significant Accounting Policies and New Accounting Pronouncements

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of checking accounts and short-term money market funds as of September 30, 2008 and December 31, 2007 on deposit with U.S. commercial banks, which at any point in time, may exceed federally insured limits.

Fair Value of Financial Instruments

Financial instruments consist of cash and accounts payable. These financial instruments are stated at their respective historical carrying amounts which are equivalent to fair value due to their short term nature.

Capital Assets and Depreciation

Expenditures for additions, renewals and improvements are capitalized at cost. Depreciation is generally computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of the major classes of depreciable assets are 2 to 5 years for equipment, furniture and fixtures. Synergy periodically evaluates whether current events or circumstances indicate that the carrying value of its depreciable assets may not be recoverable.

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Summary of Significant Accounting Policies and New Accounting Pronouncements (Continued)

Income Taxes

Income taxes have been determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes result from differences between the financial and tax bases of Synergy's assets and liabilities and are adjusted for changes in tax rates and tax laws when changes are enacted. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required often requires significant judgments.

Contingencies

In the normal course of business, Synergy is subject to loss contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters, including, among others, government investigations, shareholder lawsuits, product and environmental liability, and tax matters. In accordance with Statement of Financial Accounting Standards ("SFAS") No. 5, *Accounting for Contingencies*, ("SFAS No. 5), Synergy records accruals for such loss contingencies when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. Synergy, in accordance with SFAS No. 5, does not recognize gain contingencies until realized. For a discussion of contingencies, see Note 6. *Commitments and Contingencies* below.

Research and Development

Synergy has never had any commercial biopharmaceutical products, and does not expect to have such for several years, if at all. Therefore, because the future benefits of current research and development expenditures are highly uncertain, research and development costs are expensed as incurred. These costs include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, patent filing and maintenance expenses, purchased in-process research and development, regulatory and scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring, insurance and FDA consultants.

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.

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*

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SYNERGY PHARMACEUTICALS, INC.
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Summary of Significant Accounting Policies and New Accounting Pronouncements (Continued)

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 our consolidated financial statements.

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*. EITF No. 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. The Company is currently evaluating the impact of the pending adoption of EITF No. 07-05 and does not anticipate the adoption will have a material effect on its consolidated financial statements.

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 is currently evaluating the impact of SFAS No. 157 on nonfinancial assets and nonfinancial liabilities, but does not expect the adoption to 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 is continuing to evaluate the impact of adopting the provisions of EITF No. 07-1; however, it does not anticipate that adoption will have a material effect on its consolidated results of operations or financial position.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51*, ("SFAS No. 160"). SFAS No. 160 establishes accounting and reporting standards that require the ownership interests in subsidiaries held by parties other than the parent to be clearly identified, labeled and presented in the consolidated statement of financial position within equity, but separate from the parent's equity. This statement also requires the amount of consolidated net income attributable to the parent and to the noncontrolling interest to be clearly identified and presented on the face of the consolidated statement of income. Its intention is to eliminate the diversity in practice regarding the accounting for transactions between an entity and

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Summary of Significant Accounting Policies and New Accounting Pronouncements (Continued)

noncontrolling interests. This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. The Company is continuing to evaluate the impact of adopting the provisions of SFAS No. 160 and does not anticipate that adoption will have a material effect on its consolidated financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141(R), a revised version of SFAS No. 141, *Business Combinations* ("SFAS No. 141(R)"). The revision is intended to simplify existing guidance and converge rulemaking under GAAP with international accounting rules. This statement applies prospectively to business combinations where the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. The Company is continuing to evaluate the impact of adopting the provisions of SFAS No. 141(R) and does not anticipate that adoption of this Statement will have a material effect on its consolidated financial position or results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an Amendment to SFAS No. 115* ("SFAS No. 159"). The fair value option established by SFAS No. 159 permits all entities to measure all eligible items at fair value at specified election dates. A business entity shall report all unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. The provisions of SFAS No. 159 are effective for fiscal years beginning after November 15, 2007. The Company adopted SFAS No. 159 on January 1, 2008 and such adoption did not have a material effect on Synergy's financial statements, as Synergy did not elect this fair value option on any financial assets or liabilities.

In September 2006, the FASB issued SFAS No.157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with GAAP and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements. SFAS No. 157 emphasizes a "market-based" as opposed to an "entity-specific" measurement perspective, establishes a hierarchy of fair value measurement methods and expands disclosure requirements about fair value measurements including methods and assumptions and the impact on earnings. This Statement is effective for fiscal years beginning after November 15, 2007. The Company adopted SFAS No. 157 on January 1, 2008 and such adoption did not did not have a material effect on Synergy's financial statements.

4. Accounting for Shared-Based Payments

Stock Options

In December 2004, the FASB issued SFAS No. 123 (Revised 2004), *Share-Based Payments* ("SFAS No. 123R"). SFAS No. 123R requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS No. 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. Synergy did not issue stock options until the quarter ended September 30, 2008.

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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)

During the quarter ended September 30, 2008 Synergy adopted The 2008 Equity Compensation Incentive Plan (the "Plan") which is intended to promote the best interests of its stockholders by (i) assisting the Company and its Subsidiaries in the recruitment and retention of persons with ability and initiative, (ii) providing an incentive to such persons to contribute to the growth and success of the Company's businesses by affording such persons equity participation in the Company and (iii) associating the interests of such persons with those of the Company and its Subsidiaries and stockholders. 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. In connection with the Exchange Transaction, all outstanding options of Synergy-DE were assumed by Synergy and continued to have the same terms and conditions as they did prior to the Exchange Transaction.

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

	Three and Nine Months Ended September 30,		November 15, 2005 (inception) to September 30, 2008
	2008	2007	
Employees included in research and development	$ 37,009		$ 37,009
Employees included in general and administrative	55,409		55,409
Subtotal employee stock option grants	92,418		92,418
Non-employee stock option grants included in general and administrative	108,728		108,728
Total stock-based compensation expense	$ 201,146		$ 201,146

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the three and nine months ended September 30, 2008 and 2007.

	Three and Nine Months Ended September 30,	
	2008	2007
Risk-free interest rate	3.08 3.28%	N/A
Dividend yield		N/A
Expected volatility	90%	N/A
Expected term (in years)	6.0 yrs	N/A

Risk-free interest rate Based upon observed interest rates appropriate for the expected term of Synergy's employee stock options.

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

Expected volatility Based on the historical volatility of comparable publicly traded stocks.

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for Shared-Based Payments (Continued)

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

In December 2007, the SEC issued SAB No. 110, *Share-Based Payment*, ("SAB No. 110"). SAB No. 110 was effective January 1, 2008 and expresses the views of the Staff of the SEC with respect to extending the use of the simplified method, as discussed in SAB No. 107, in developing an estimate of the expected term of "plain vanilla" share options in accordance with SFAS No. 123R. The Company will continue to use the simplified method until it has the historical data necessary to provide a reasonable estimate of expected life in accordance with SAB No. 107, as amended by SAB No. 110. For the expected term, the Company has "plain-vanilla" stock options, and therefore used a simple average of the vesting period and the contractual term for options granted subsequent to January 1, 2006 as permitted by SAB No. 107.

Forfeitures SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Synergy estimated future unvested option forfeitures based on historical experience of its majority-owned shareholder, Callisto (See Note 8).

The weighted-average fair value per share of all options granted during the nine months ended September 30, 2008 estimated as of the grant date using the Black-Scholes option valuation model was $0.51 per share.

The unrecognized compensation cost related to non-vested employee stock options outstanding at September 30, 2008 was $1,719,446, to be recognized over a weighted-average remaining vesting period of approximately 2.3 years. The weighted-average remaining term of all options outstanding at September 30, 2008 was 9.8 years. There were no options outstanding at December 31, 2007.

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for Shared-Based Payments (Continued)

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

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value as of September 30, 2008
Balance outstanding, December 31, 2007				
Granted	3,999,988	$ 0.25 0.60	$ 0.28	
Exercised				
Forfeited	(4,972)	$ 0.25	$ 0.25	
Balance outstanding, September 30, 2008	3,995,016	$ 0.25 0.60	$ 0.28	$ 2,691,512
Exercisable at September 30, 2008	74,871	$ 0.25	$ 0.25	$ 52,410

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.

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 in accordance with SFAS No. 123R in the same manner as stock options at 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 expensed ratably over the service period of the employees receiving the rewards.

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 current officers and a consultant by Synergy. The fair value of each restricted stock unit is estimated on the grant date based on the price paid by shareholders participating in the Company's July 14, 2008 private placement. Accordingly, the weighted-average grant date fair value per share of the 874,760 shares issued during the three and nine months ended September 30, 2008 was determined to be $0.60. As of September 30, 2008 and 2007 there were 874,760 and zero restricted stock units outstanding, respectively, included in shares outstanding. The fair value of the 874,760 restricted stock units on the date of grant was $524,856 of which $47,992 was recorded as stock-based compensation expense during the three and nine months ended September 30, 2008.

5. Income Taxes

The provisions of FASB Interpretation ("FIN") No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of SFAS No. 109,* ("FIN No. 48"), were adopted by Synergy on January 1, 2007 and had no effect on Synergy's financial position, cash flows or results of operations upon adoption, as

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

5. Income Taxes (Continued)

Synergy did not have any unrecognized tax benefits. Synergy also evaluated its tax positions as of September 30, 2008 and reached the same conclusion. Synergy does not currently expect any significant changes to unrecognized tax benefits during the fiscal year ended December 31, 2008. Synergy's practice is to recognize interest and/or penalties related to income tax matters in income tax expense and none have been incurred to date. Synergy has no uncertain tax positions subject to examination by the relevant tax authorities as of December 31, 2007. Synergy files U.S. and state income tax returns in jurisdictions with varying statutes of limitations. The 2004 through 2007 tax years generally remain subject to examination by federal and most state tax authorities.

On July 14, 2008, Synergy engaged in a tax-free reorganization pursuant to the Internal Revenue Code Section 368(a)(1)(B) thereby acquiring 100% of shares in Synergy-DE, from Callisto, a Delaware corporation, and other restricted holders of shares in Synergy-DE in exchange for 45,464,760 shares of the Company's common stock (or approximately 70% of the Company's outstanding common stock). The transaction was characterized as a tax-fee type "B" reorganization resulting in no gain or loss recognition to the Company, for federal tax purposes.

At September 30, 2008, Synergy-DE has net operating loss carryforwards ("NOLs") acquired in the Exchange Transaction aggregating approximately $21.3 million, which, if not used, expire through 2028. The utilization of these NOLs may be subject to limitations based on past and future changes in ownership of Synergy pursuant to Internal Revenue Code Section 382. Synergy records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Due to the significant doubt related to Synergy's ability to continue as a going concern and utilize its deferred tax assets, a valuation allowance for the full amount of the deferred tax assets has been established at September 30, 2008. As a result of this valuation allowance there are no income tax benefits reflected in the accompanying condensed consolidated statements of operations to offset pre-tax losses.

6. Commitments and Contingencies

Employment and Consulting Agreements

Melvin K. Spigelman

On August 21, 2008, the Board of Directors ("the Board") of Synergy appointed Melvin K. Spigelman, M.D. as a Director of the Company. In addition, the Board of Directors appointed Dr. Spigelman Chairman of Synergy's Clinical Oversight Committee ("the Committee") as well as a member of the Compensation and Audit Committees. In connection therewith, the Board of Directors approved the payment of an annual fee of $90,000 to Dr. Spigelman for his service on the Board and the Committees. Additionally, the Board approved a grant of 300,000 stock options to Dr. Spigelman with an exercise price of $0.60 per share. Such options vest in 100,000 increments over a period of 3 years. The fair value of the 300,000 options on the date of grant was $135,655 of which $3,717 was recorded as stock-based compensation expense during the three and nine months ended September 30, 2008.

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SYNERGY PHARMACEUTICALS, INC.
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

6. Commitments and Contingencies (Continued)

Kunwar Shailubhai, Ph.D

On April 6, 2004, Kunwar Shailubhai, Ph.D. entered into an employment agreement with Synergy-DE in which he agreed to serve as Senior Vice President, Drug Discovery. Dr. Shailubhai's employment agreement was for a term of 12 months beginning April 6, 2004 and was automatically renewed for successive one year periods at the end of each term. On July 9, 2008, Dr. Shailubhai was appointed Chief Scientific Officer of Synergy, his salary is currently $190,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year.

Capebio, LLC

On September 25, 2007, Synergy Advanced Pharmaceuticals, Inc. entered into a Service Agreement with Capebio, LLC ("Capebio") to provide research and development services for the commercialization of non-oncology related gastrointestinal pharmaceutical products under the SP-304 patent (the "Service Agreement"). The Service Agreement was for a minimum term of eleven months starting October 1, 2007 during which period Synergy Advanced Pharmaceuticals, Inc. paid an initial fee of $55,000 and was obligated to pay $26,000 per month through August 31, 2008. This Service Agreement was terminated during the quarter ended September 30, 2008 and all amounts due thereunder were paid.

Lease agreements

The Company occupies a small laboratory and several offices on a month-to-month basis in the Bucks County Biotechnology Center, in Doylestown, Pennsylvania at the rate of $200 per month. Synergy is currently in negotiations to establish an annual rental agreement and expand this space.

Synergy is provided the use of office space on a month-to-month basis in New York, New York by Callisto. Synergy paid approximately $48,000 for this space during the three and nine months ended September 30, 2008 and has no long term obligations to Callisto for use of this space.

Commitments Prior to Exchange Transaction

The Company had retained Mr. Pietro Gattini as President, Chairman and Chief Executive Officer. Prior to the Exchange Transaction, Mr. Gattini was the only director, officer and employee of the Company. Compensation has been accrued at a rate of $500 per month. On July 14, 2008, Mr. Gattini resigned as Chief Executive Officer and sole director of the Company and all compensation due him was paid from the net proceeds of the private placement. For a more detailed discussion of the private placement, see Note 8, *Acquisition and Stockholders' Equity (Deficit)* below.

The Company leased approximately 70 square feet of office space on a month-to-month basis from Steinway Group, LLC in Long Island City, New York. This facility served as the Company's principal executive and administrative office. Rent for the facility was $2,400 per annum payable in equal monthly installments. On August 5, 2008, the Company terminated the lease with Steinway Group, LLC. For a more detailed discussion of the private placement, see Note 8, *Acquisition and Stockholders' Equity (Deficit)* below.

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SYNERGY PHARMACEUTICALS, INC.
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

7. Property and Equipment

The major categories of property and equipment were as follows:

	September 30, 2008	December 31, 2007
Furniture and fixtures	$ 38,343	$
Machinery and equipment	12,195	3,386
Less accumulated depreciation	(38,343)	(728)
Property and equipment, net	$ 12,195	$ 2,658

Depreciation expense for the nine months ended September 30, 2008 was $0 and $38,343 for the period November 15, 2005 (inception) to December 31, 2007.

8. Acquisition and Stockholders' Equity (Deficit)

On July 14, 2008, Pawfect acquired 100% of the common stock of Synergy-DE from Callisto and certain other holders of Synergy-DE shares, in exchange for 45,464,760 unregistered shares of Pawfect's common stock. This represented approximately 70% of Pawfect's outstanding common stock after giving effect to (i) a 75.69060773 for one stock split, (ii) cancellation of 149,981,208 of 151,381,215 unregistered shares owned by Pawfect's principal stockholder and (iii) a $3,000,000 private placement of 5,000,000 unregistered shares of Pawfect's common stock to private investors. Fees and expenses directly related to the closing of this private placement totaled $73,087, yielding net proceeds of $2,926,913. The stock split and change in par value, from $0.001 to $0.0001, resulted in the restatement of all historical common stock and additional paid-in capital amounts presented in the accompanying financial statements.

These transactions were completed under the terms of an Exchange Agreement dated as of July 11, 2008, as amended and effective on July 14, 2008 among Pawfect, Callisto, Synergy-DE, and certain other holders of Synergy-DE common stock. Callisto received 44,590,000 of the 45,464,760 shares of Pawfect's common stock exchanged for ownership of Synergy-DE, and Callisto is now the holder of 68% of Pawfect's outstanding common stock (see Note 4 for shares issued to other holders).

The Exchange Transaction was treated as an asset acquisition by Pawfect for accounting purposes. Under this method of accounting, Pawfect is treated as the acquiring entity, issuing stock for the assets and liabilities of Synergy-DE. The assets and liabilities of Synergy-DE, primarily cash and accounts payable, were stated at their fair value. Net liabilities acquired totaled $877,647. The fair value of the 45,464,760 shares issued in connection with the Exchange Transaction, totaled $27,278,856 on July 14, 2008, based on a per share value of $0.60, which was the per share price the Company's 5,000,000 common shares sold for in a private placement on that date. The total consideration of $28,156,503 was allocated in full to the Synergy research and development projects which had not yet reached technological feasibility and, having no alternative use, this amount was charged to purchased in-process research and development ("IPRD") expense during the three months ended September 30, 2008.

In addition to purchased IPRD, the Company retained four full time employees and acquired a patent related to the technologies acquired. There were no other intangible assets acquired which

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SYNERGY PHARMACEUTICALS, INC.
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

8. Acquisition and Stockholders' Equity (Deficit) (Continued)

required allocation of the purchase price. The Company did not assign a value to the acquired employees as all continuing research and development is being performed under the supervision of other Company employees, nor the patent since the technology is still in an early stage. Therefore, the full purchase price accordingly allocated to purchased in-process research and development and there was no value assigned to goodwill. The value of the IPR&D was based on the fair value of the consideration given which was the value most reliably measurable.

Net assumed liabilities in excess of Synergy-DE assets acquired in connection with the Exchange Transaction on July 14, 2008 were as follows:

Assets	
Cash	$ 194,673
Total assets acquired	194,673
Liabilities	
Accounts payable and other liabilities	(722,320)
Due to Callisto	(350,000)
Total liabilities assumed	(1,072,320)
Net liabilities assumed in excess of assets acquired	(877,647)
Fair value of shares issued to Synergy-DE shareholders	(27,278,856)
Total consideration paid by Pawfect to acquire Synergy-DE	$(28,156,503)

On July 14, 2008, Synergy discontinued its pet food business and is now exclusively focused on continuing the development of drugs to treat gastrointestinal disorders and diseases acquired 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, including: (i) an increase in the authorized number of common shares from 50,000,000 to 150,000,000 (ii) authorized 20,000,000 shares of preferred stock (iii) changed the common stock par value per share from $0.001 to $0.0001 and (iv) changed its name to Synergy Pharmaceuticals, Inc. ("Synergy" or "the Company").

9. Related Parties

Synergy's majority shareholder, Callisto, owns 68% of its outstanding shares. Synergy occupies corporate office space in New York City under a month to month sharing arrangement with Callisto, its majority shareholder. Facilities costs are allocated from Callisto monthly based on the square footage of office space occupied by Synergy. Such costs include rent, telecommunications and information technology services, property and casualty insurance, postage and other office related expenses. These expenses are principally general and administrative in nature and totaled approximately $190,000 during the period from July 14, 2008 through September 30, 2008. Synergy currently has no facilities independent of Callisto other than a small (approximately 500 square feet) laboratory in Doylestown, PA where four employees are currently located.

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SYNERGY PHARMACEUTICALS, INC.
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

9. Related Parties (Continued)

As part of the Exchange Transaction, Callisto cancelled all Synergy-DE and Synergy Advanced Pharmaceuticals, Inc. intercompany obligations due to Callisto, with the exception of $350,000, which was paid by Pawfect, on behalf of Synergy Advanced Pharmaceuticals, Inc., from the proceeds from the private placement on July 14, 2008. For a more detailed discussion of this private placement, see Note 8, *Acquisition and Stockholders' Equity (Deficit)* above.

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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 nine months ended September 30, 2008 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"). For a more detailed discussion of this exchange transaction, see Item 1. Financial Statements and Notes to Condensed Consolidated Financial Statements Note 8*Acquisition and Stockholders' Equity (Deficit).*

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").

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.

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 during 2009.

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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 developed 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"), that are being 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 2009.

FINANCIAL OPERATIONS OVERVIEW

Since inception in November 2005, we have been a development stage company. Prior to the Exchange Transaction described above, our primary focus was on offering an online marketplace for premium and holistic pet food, which was not readily available in the traditional retail stores. Subsequent to the Exchange Transaction, we discontinued the pet food business and are now exclusively a development stage biopharmaceutical company, whose primary focus is on the development of drugs to treat gastrointestinal disorders and diseases acquired in connection with the Exchange Transaction.

From inception through September 30, 2008, we have sustained cumulative net losses available to common stockholders of $29,880,276, 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. From inception through September 30, 2008, 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, the nature and timing of costs and competing technologies being developed by organizations with significantly greater resources.

Our research and development expenses consist primarily of costs associated with clinical development team salaries and staff costs, application and filing for regulatory approval of our proposed products, regulatory and scientific consulting fees, clinical and patient costs for product candidates in on-going trials, sponsored pre-clinical research, as well as legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products. We expense all research and development costs as they are incurred. We expect our research and development expenses to increase significantly in the future as we develop our product candidates.

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Our general and administrative expenses primarily include personnel and related costs, rent and professional accounting and corporate legal fees. We expect our general and administrative expenses to increase significantly over the next few years as we continue to build our operations to support our product candidates and as we incur costs associated with being a publicly traded company.

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 1. Financial Statements and Notes to Condensed Consolidated Financial Statements Note 3*Summary of Significant Accounting Policies and New Accounting Pronouncements* of the notes to our condensed consolidated financial statements included in this Report on Form 10-Q as of and for the nine months ended September 30, 2008. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. We believe that the following discussion represents our critical accounting policies.

Research and Development

We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all and therefore our research and development costs are expensed as incurred. These include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of our proposed products, purchase of in-process research and development, regulatory and scientific consulting fees, contract research payments to outside suppliers, facilities and universities as well as legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products. While certain of our research and development costs may have future benefits, our policy of expensing all research and development expenditures is predicated on the fact that we have no history of successful commercialization of biopharmaceutical products to base any estimate of the number of future periods that would be benefited.

Stock-Based Compensation

We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options and restricted stock units is designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage. Since inception through September 30, 2008 stock-based compensation expense has totaled $201,146.

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") No. 123 (Revised 2004), *Share-Based Payments* ("SFAS No. 123R"). SFAS No. 123R requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS No. 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. Synergy did not issue stock options until the quarter ended September 30, 2008.

Upon adoption of SFAS No. 123R, we selected the Black-Scholes option pricing model as the most appropriate model for determining the estimated fair value for stock-based awards. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Expected volatility was calculated based on the historical volatility of similar public entities. The expected term was also determined based on a sampling of comparable public entities. The risk-free

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interest rate is based on observed interest rate appropriate for the expected term of the Company's employee stock options. Forfeitures are estimated, based on Callisto's historical experience, at the time of grant.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

For a discussion of contractual obligations, see Item 1. Financial Statements and Notes to Condensed Consolidated Financial Statements Note 3*Summary of Significant Accounting Policies and New Accounting Pronouncements*.

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 of this FSP did not have a material impact on our consolidated financial statements.

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*. EITF No. 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. The Company is currently evaluating the impact of the pending adoption of EITF No. 07-05 and does not expect adoption to have a material effect on its consolidated financial statements.

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 is currently evaluating the impact of SFAS No. 157 on nonfinancial assets and nonfinancial liabilities, but does not expect the adoption to 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 is continuing to evaluate the impact of adopting the provisions of EITF No. 07-1; however, it does not anticipate that adoption will have a material effect on its consolidated results of operations or financial position.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51*, ("SFAS No. 160"). SFAS No. 160 establishes accounting and reporting standards that require the ownership interests in subsidiaries held by parties other than the parent to be clearly identified, labeled and presented in the consolidated statement of

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financial position within equity, but separate from the parent's equity. This statement also requires the amount of consolidated net income attributable to the parent and to the noncontrolling interest to be clearly identified and presented on the face of the consolidated statement of income. Its intention is to eliminate the diversity in practice regarding the accounting for transactions between an entity and noncontrolling interests. This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. The Company is continuing to evaluate the impact of adopting the provisions of SFAS No. 160 and does not anticipate that adoption will have a material effect on its consolidated financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141(R), a revised version of SFAS No. 141, *Business Combinations* ("SFAS No. 141(R)"). The revision is intended to simplify existing guidance and converge rulemaking under GAAP with international accounting rules. This statement applies prospectively to business combinations where the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. The Company is continuing to evaluate the impact of adopting the provisions of SFAS No. 141 (R) and does not anticipate that adoption of this Statement will have a material effect on its consolidated financial position or results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an Amendment to SFAS No. 115* ("SFAS No. 159"). The fair value option established by SFAS No. 159 permits all entities to measure all eligible items at fair value at specified election dates. A business entity shall report all unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. The provisions of SFAS No. 159 are effective for fiscal years beginning after November 15, 2007. The Company adopted SFAS No. 159 on January 1, 2008 and such adoption did not have a material effect on Synergy's financial statements, as Synergy did not elect this fair value option on any financial assets or liabilities.

In September 2006, the FASB issued SFAS No.157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with GAAP and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements. SFAS No. 157 emphasizes a "market-based" as opposed to an "entity-specific" measurement perspective, establishes a hierarchy of fair value measurement methods and expands disclosure requirements about fair value measurements including methods and assumptions and the impact on earnings. This Statement is effective for fiscal years beginning after November 15, 2007. The Company adopted SFAS No. 157 on January 1, 2008 and such adoption did not did not have a material effect on Synergy's financial statements.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2008.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

We had no revenues during the three months ended September 30, 2008 and 2007 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, 2008, research and development expenses totaled $708,836. These research and development expenses were primarily attributable to our newly acquired SP-304 product candidate. These expenses include pre-clinical animal testing, drug formulation, tableting, hospital patient costs, blood testing, data collection, clinical monitoring and FDA consultants. Also included in research and development expense are in-house staff salaries and wages, scientific advisory fees and patent prosecution costs. There were no such expenses during the three months ended September 30, 2007 because the SP-304 product was acquired

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as a result of the July 14, 2008 Exchange Transaction discussed above and our pet food business was discontinued on July 14, 2008.

Purchased in-process research and development The fair value of the 45,464,760 shares issued in connection with the Exchange Transaction, totaled $27,278,856 on July 14, 2008, based on a per share value of $0.60, which was the per share price of the Company's 5,000,000 common shares sold in a private placement on that date. In addition, the assets and liabilities of Synergy-DE, primarily cash and accounts payable, were stated at their fair value, which net liabilities acquired totaled $877,647. The total remaining consideration was allocated to the Synergy research and development projects which had not yet reached technological feasibility and, having no alternative use, this total amount of $28,156,503 was charged to purchased in-process research and development expense during the three months ended September 30, 2008. There were no such expenses during the three months ended September 30, 2007. In addition, the acquisition of all the assets and liabilities of Synergy-DE was treated as an asset acquisition.

In addition to purchased in-process research and development ("IPR&D"), the Company acquired four full time employees and a patent related to the technologies acquired. There were no other intangible assets acquired which required allocation of the purchase price. The Company did not assign a value to the acquired employees as all continuing research and development is being performed under the supervision of other Company employees, nor the patent since the technology is still in an early stage. Therefore, the full purchase price accordingly was allocated to purchased IPR&D and there was no value assigned to goodwill. The value of the IPR&D was based on the fair value of the consideration given which was the value most reliably measurable.

General and administrative expenses For the three months ended September 30, 2008, general and administrative expenses were $940,269. These expenses primarily include non-scientific personnel and related costs, rent and professional accounting and corporate legal fees. Such expenses during the three months ended September 30, 2007 were exclusively devoted to our pet food business which was discontinued on July 14, 2008 and reported as "loss from discontinued operations" in the accompanying financial statements.

Net loss for the three months ended September 30, 2008 was $29,808,455 compared to a net loss of $5,088 incurred for the three months ended September 30, 2007.

NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

We had no revenues during the nine months ended September 30, 2008 and 2007 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses For the nine months ended September 30, 2008, research and development expenses totaled $708,836. These research and development expenses were primarily attributable to our newly acquired SP-304 product candidate. These expenses include pre-clinical animal testing, drug formulation, tableting, hospital patient costs, blood testing, data collection, clinical monitoring and FDA consultants. Also included in research and development expense are in-house staff salaries and wages, scientific advisory fees and patent prosecution costs. There were no such expenses during the nine months ended September 30, 2007 because the SP-304 product was acquired as a result of the July 14, 2008 Exchange Transaction discussed above and our pet food business was discontinued on July 14, 2008.

Purchased in-process research and development The fair value of the 45,464,760 shares issued in connection with the Exchange Transaction, totaled $27,278,856 on July 14, 2008, based on a per share value of $0.60, which was the per share price of the Company's 5,000,000 common shares sold in a private placement on that date. In addition, the assets and liabilities of Synergy-DE, primarily cash and accounts payable, were stated at their fair value, which net liabilities acquired totaled $877,647. The

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total remaining consideration was allocated to the Synergy research and development projects which had not yet reached technological feasibility and, having no alternative use, this total amount of $28,156,503 was charged to purchased in-process research and development expense during the nine months ended September 30, 2008. There were no such expenses during the nine months ended September 30, 2007. In addition, the acquisition of all the assets and liabilities of Synergy-DE was treated as an asset acquisition.

In addition to purchased IPR&D, the Company acquired four full time employees and a patent related to the technologies acquired. There were no other intangible assets acquired which required allocation of the purchase price. The Company did not assign a value to the acquired employees as all continuing research and development is being performed under the supervision of other Company employees, nor the patent since the technology is still in an early stage. Therefore, the full purchase price was accordingly allocated to purchased IPR&D and there was no value assigned to goodwill. The value of the IPR&D was based on the fair value of the consideration given which was the value most reliably measurable.

General and administrative expenses For the nine months ended September 30, 2008, general and administrative expenses were $940,269. These expenses primarily include non-scientific personnel and related costs, rent and professional accounting and corporate legal fees. Such expenses during the nine months ended September 30, 2007 were exclusively devoted to our pet food business which was discontinued on July 14, 2008 and reported as "loss from discontinued operations" in the accompanying financial statements.

Net loss for the nine months ended September 30, 2008 was $29,840,015 compared to a net loss of $10,288 incurred for the nine months ended September 30, 2007.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2008 we had $1,633,700 in cash and cash equivalents, compared to $1,807 as of December 31, 2007. Net cash used in operating activities was $1,147,999 for the nine months ended September 30, 2008. Net cash provided by financing activities for the nine months ended September 30, 2008 was $2,947,413, principally the result of closing a private placement of 5,000,000 shares of our common stock at $0.60 per share, yielding aggregate gross proceeds of $3,000,000 on July 14, 2008.

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 September 30, 2008 and December 31, 2007 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.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk on the fair values of certain assets is related to credit risk associated with securities held in money market accounts and the FDIC insurance limit on our bank balances. At September 30, 2008, our money market balances totaled approximately $1,600,000.

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, 2008, 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, 2007. 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, 2007, 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, 2007, 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.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As of September 30, 2008 we are in the process of remediating the material weaknesses which existed at December 31, 2007. In connection with the Exchange Transaction described above in Item 1. Financial Statements and Notes to Condensed Consolidated Financial Statements, we have added financial staff resources to our accounting and finance department 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, 2008.

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, 2008.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors and the other information included herein, as well as the information included in other reports and filings made with the SEC before investing in our common stock. If any of the following risks actually occurs, our business, financial condition or results of operations could be harmed. The trading price of our common stock could decline due to any of these risks, and you may lose part or all of your investment.

WE ARE AT AN EARLY STAGE OF DEVELOPMENT AS A COMPANY, CURRENTLY HAVE NO SOURCE OF REVENUE AND MAY NEVER BECOME PROFITABLE.

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

- demonstration in Phase I clinical trials that our product candidate, SP-304 for the treatment of GI disorders, is safe and effective;
- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;
- the successful commercialization of our product candidates; and
- market acceptance of our products.

All of our existing product candidates will require extensive additional clinical evaluation, regulatory review, significant marketing efforts and substantial investment before they could provide us with any revenue. As a result, if we do not successfully develop and commercialize SP-304, we will be unable to generate any revenue for many years, if at all. We do not anticipate that we will generate revenue for several years, at the earliest, or that we will achieve profitability for at least several years after generating material revenue, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

WE HAVE INCURRED SIGNIFICANT LOSSES SINCE INCEPTION AND ANTICIPATE THAT WE WILL INCUR CONTINUED LOSSES FOR THE FORESEEABLE FUTURE.

As of September 30, 2008, we had an accumulated deficit of $29,880,276. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development, continue our clinical trials of SP-304 for the treatment of GI disorders, acquire or license technologies, advance our other product candidates into clinical development, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock will likely decline.

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WE WILL NEED TO RAISE SUBSTANTIAL ADDITIONAL CAPITAL WITHIN THE NEXT YEAR TO FUND OUR OPERATIONS, AND OUR FAILURE TO OBTAIN FUNDING WHEN NEEDED MAY FORCE US TO DELAY, REDUCE OR ELIMINATE OUR PRODUCT DEVELOPMENT PROGRAMS OR COLLABORATION EFFORTS.

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

- continue clinical development of SP-304 to treat GI disorders;
- continue development of our other product candidates;
- finance our general and administrative expenses;
- prepare regulatory approval applications and seek approvals for SP-304 and our other product candidates;
- license or acquire additional technologies;
- launch and commercialize our product candidates, if any such product candidates receive regulatory approval; and
- develop and implement production, sales, marketing and distribution capabilities.

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

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

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

We cannot be certain that funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms,

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we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

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

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

CLINICAL TRIALS INVOLVE A LENGTHY AND EXPENSIVE PROCESS WITH AN UNCERTAIN OUTCOME, AND RESULTS OF EARLIER STUDIES AND TRIALS MAY NOT BE PREDICTIVE OF FUTURE TRIAL RESULTS.

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

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

DELAYS IN CLINICAL TESTING COULD RESULT IN INCREASED COSTS TO US AND DELAY OUR ABILITY TO GENERATE REVENUE.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval to conduct a trial at a prospective site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new drugs approved for the conditions we are investigating. Prescribing physicians will also have to decide to use our product candidates over existing drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and delay our ability to generate revenue.

WE MAY BE REQUIRED TO SUSPEND OR DISCONTINUE CLINICAL TRIALS DUE TO UNEXPECTED SIDE EFFECTS OR OTHER SAFETY RISKS THAT COULD PRECLUDE APPROVAL OF OUR PRODUCT CANDIDATES.

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

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

IF WE ARE UNABLE TO SATISFY REGULATORY REQUIREMENTS, WE MAY NOT BE ABLE TO COMMERCIALIZE OUR PRODUCT CANDIDATES.

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

This regulatory review and approval process, which includes evaluation of preclinical studies and clinical trials of a product candidate as well as the evaluation of our manufacturing process and our contract manufacturers' facilities, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that the product candidate is both safe and effective for each indication where approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might submit for regulatory review any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use.

The FDA has substantial discretion in the approval process and may either refuse to file our application for substantive review or may form the opinion after review of our data that our application is insufficient to allow approval of our product candidates. If the FDA does not file or approve our application, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to abandon our applications for approval, which might cause us to cease operations.

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

IF OUR PRODUCT CANDIDATES ARE UNABLE TO COMPETE EFFECTIVELY WITH MARKETED DRUGS TARGETING SIMILAR INDICATIONS AS OUR PRODUCT CANDIDATES, OUR COMMERCIAL OPPORTUNITY WILL BE REDUCED OR ELIMINATED.

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of

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

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

- successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our products and manufacturing processes and other related product technology;
- attract and retain key personnel;
- develop relationships with physicians prescribing these products; and
- build an adequate production, sales and marketing infrastructure for our product candidates.

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

WE CURRENTLY HAVE NO SALES AND MARKETING ORGANIZATION. IF WE ARE UNABLE TO ESTABLISH A DIRECT SALES FORCE IN THE UNITED STATES TO PROMOTE OUR PRODUCTS, THE COMMERCIAL OPPORTUNITY FOR OUR PRODUCTS MAY BE DIMINISHED.

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

WE MAY NEED OTHERS TO MARKET AND COMMERCIALIZE OUR PRODUCT CANDIDATES IN INTERNATIONAL MARKETS.

In the future, if appropriate regulatory approvals are obtained, we intend to commercialize our product candidates in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. Currently, we do not have any plans to enter international markets. If we decide

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to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

IF THE FDA DOES NOT APPROVE OUR CONTRACT MANUFACTURERS' FACILITIES, WE MAY BE UNABLE TO DEVELOP OR COMMERCIALIZE OUR PRODUCT CANDIDATES.

We rely on third-party contract manufacturers to manufacture our product candidates, and currently have no plans to develop our own manufacturing facility. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA. If the FDA does not approve these facilities for the manufacture of our product, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for and manufacturing of our product candidates. In addition, our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies for compliance with good manufacturing practices regulations, or cGMPs, and similar foreign standards. These regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. We do not have control over our contract manufacturers' compliance with these regulations and standards. Failure by our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant market approval of drugs, delays, suspension or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we have no control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect the development of our product candidates and our business.

IF PRODUCT LIABILITY LAWSUITS ARE SUCCESSFULLY BROUGHT AGAINST US, WE MAY INCUR SUBSTANTIAL LIABILITIES AND MAY BE REQUIRED TO LIMIT COMMERCIALIZATION OF OUR PRODUCT CANDIDATES.

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

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients;

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product recalls;

loss of revenue; and

the inability to commercialize our product candidates.

We have clinical trial liability insurance with a $5,000,000 annual aggregate limit for up to 75 patients participating at the same time in our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

EVEN IF WE RECEIVE REGULATORY APPROVAL FOR OUR PRODUCT CANDIDATES, WE WILL BE SUBJECT TO ONGOING SIGNIFICANT REGULATORY OBLIGATIONS AND OVERSIGHT.

If we receive regulatory approval to sell our product candidates, the FDA and foreign regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses or marketing of such products, or impose ongoing requirements for post-approval studies. Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations, such as safety reporting requirements, and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. If we become aware of previously unknown problems with any of our product candidates here or overseas or our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to or obtain re-approvals of our contract manufacturers' facilities or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class action suits. Moreover, if we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing and marketing these products.

WE RELY ON THIRD PARTIES TO CONDUCT OUR CLINICAL TRIALS. IF THESE THIRD PARTIES DO NOT SUCCESSFULLY CARRY OUT THEIR CONTRACTUAL DUTIES OR MEET EXPECTED DEADLINES, WE MAY NOT BE ABLE TO SEEK OR OBTAIN REGULATORY APPROVAL FOR OR COMMERCIALIZE OUR PRODUCT CANDIDATES.

We have agreements with third-party contract research organizations, ("CRO" or "CROs"), to provide monitors and to manage our clinical programs. We and our CROs are required to comply with current Good Clinical Practices, ("GCP" or "GCPs"), regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. In the future, if we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials for products in clinical development comply with GCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

IF WE FAIL TO ATTRACT AND KEEP SENIOR MANAGEMENT AND KEY SCIENTIFIC PERSONNEL, WE MAY BE UNABLE TO SUCCESSFULLY DEVELOP OUR PRODUCT CANDIDATES, CONDUCT OUR CLINICAL TRIALS AND COMMERCIALIZE OUR PRODUCT CANDIDATES.

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

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

WE WILL NEED TO INCREASE THE SIZE OF OUR ORGANIZATION, AND WE MAY EXPERIENCE DIFFICULTIES IN MANAGING GROWTH.

We are a small company with 8 full-time and 2 part-time employees as of November 19, 2008. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Over the next 12 months depending on the progress of our planned clinical trials, we plan to add additional employees to assist us with our clinical programs. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

manage our development efforts effectively;

manage our clinical trials effectively;

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

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

hire and train additional qualified personnel.

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

REIMBURSEMENT MAY NOT BE AVAILABLE FOR OUR PRODUCT CANDIDATES, WHICH WOULD IMPEDE SALES.

Market acceptance and sales of our product candidates may depend on reimbursement policies and health care reform measures. The levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of these products. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidates reimbursed by government or third party payors. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our products.

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

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

LEGISLATIVE OR REGULATORY REFORM OF THE HEALTHCARE SYSTEM MAY AFFECT OUR ABILITY TO SELL OUR PRODUCTS PROFITABLY.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact upon our ability to sell our products profitably. In recent years, new legislation has been proposed in the United States at the federal and state levels that would effect major changes in the healthcare system, either nationally or at the state level.

These proposals have included prescription drug benefit proposals for Medicare beneficiaries introduced in Congress. Legislation creating a prescription drug benefit and making certain changes in Medicaid reimbursement has recently been enacted by Congress and signed by the President. Given this legislation's recent enactment, it is still too early to determine its impact on the pharmaceutical industry and our business. Further federal and state proposals are likely. The potential for adoption of these proposals affects or will affect our ability to raise capital, obtain additional collaborators and market our products. We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. Our results of operations could be adversely affected by future healthcare reforms.

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IT IS DIFFICULT AND COSTLY TO PROTECT OUR PROPRIETARY RIGHTS, AND WE MAY NOT BE ABLE TO ENSURE THEIR PROTECTION.

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

As of November 19, 2008, we own one issued United States patent and one issued foreign patent. We have five pending United States patent applications and four pending foreign patent applications. We may file additional patent applications and extensions. Our issued patents and patent applications primarily deal with composition of matter and use related to SP-304; and composition of matter and use of other analogs of the class of GC-C receptor agonists.

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

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

- others may be able to make compounds that are competitive with our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent application;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent application will not result in issued patents;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

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

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WE MAY INCUR SUBSTANTIAL COSTS AS A RESULT OF LITIGATION OR OTHER PROCEEDINGS RELATING TO PATENT AND OTHER INTELLECTUAL PROPERTY RIGHTS AND WE MAY BE UNABLE TO PROTECT OUR RIGHTS TO, OR USE, OUR TECHNOLOGY.

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

Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

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

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

THERE IS NO EXISTING MARKET FOR THE COMPANY'S COMMON STOCK.

Our Common Stock is quoted on the Over the Counter Bulletin Board under the symbol "SGYP.OB." There is no active trading market for any of the Company's securities. Accordingly, there can be no assurance as to the liquidity of any markets that may develop for the securities, the ability of

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holders of the securities to sell their securities, or the prices at which holders may be able to sell their securities.

THE MARKET PRICE OF THE COMMON STOCK MAY BE ADVERSELY AFFECTED BY SEVERAL FACTORS.

The market price of the Common Stock could fluctuate significantly in response to various factors and events, including:

our ability to integrate operations, technology, products and services;

our ability to execute our business plan;

operating results below expectations;

announcements of technological innovations or new products by us or our competitors;

loss of any strategic relationship;

industry developments;

economic and other external factors; and

period-to-period fluctuations in our financial results.

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

WE HAVE NOT PAID DIVIDENDS IN THE PAST AND DO NOT EXPECT TO PAY DIVIDENDS IN THE FUTURE. ANY RETURN ON INVESTMENT MAY BE LIMITED TO THE VALUE OF OUR COMMON STOCK.

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

A SALE OF A SUBSTANTIAL NUMBER OF SHARES OF THE COMMON STOCK MAY CAUSE THE PRICE OF THE COMMON STOCK TO DECLINE.

If our stockholders sell substantial amounts of the Common Stock in the public market, including shares issued upon the exercise of outstanding options, the market price of the Common Stock could fall. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

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WE HAVE IDENTIFIED MATERIAL WEAKNESSES IN OUR DISCLOSURE CONTROLS AND PROCEDURES AND HAVE CONCLUDED THAT INTERNAL CONTROL OVER FINANCIAL REPORTING IS NOT EFFECTIVE AS OF SEPTEMBER 30, 2008. IN ADDITION, WE MAY EXPERIENCE ADDITIONAL MATERIAL WEAKNESSES IN THE FUTURE. ANY MATERIAL WEAKNESSES IN OUR DISCLOSURE CONTROLS AND PROCEDURES OR OUR FAILURE TO REMEDIATE SUCH MATERIAL WEAKNESSES COULD RESULT IN A MATERIAL MISSTATEMENT IN OUR FINANCIAL STATEMENTS NOT BEING PREVENTED OR DETECTED AND COULD AFFECT INVESTOR CONFIDENCE IN THE ACCURACY AND COMPLETENESS OF OUR FINANCIAL STATEMENTS, AS WELL AS OUR STOCK PRICE.

We have identified material weaknesses in our disclosure controls and procedures relating to our lack of sufficient internal accounting personnel and segregation of duties necessary to ensure that adequate review of our financial statements and notes thereto is performed and have concluded that our internal control over financial reporting is not effective as of September 30, 2008. These material weaknesses and our remediation plans are described further in "ITEM 4.T. CONTROLS AND PROCEDURES" of this report. Material weaknesses in our disclosure controls and procedures could result in material misstatements in our financial statements not being prevented or detected. We may experience difficulties or delays in completing remediation or may not be able to successfully remediate material weaknesses at all. Any material weakness or unsuccessful remediation could affect investor confidence in the accuracy and completeness of our financial statements, which in turn could harm our business and have an adverse effect on our stock price and our ability to raise additional funds.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

On July 9, 2008, our majority shareholder approved the following resolutions:

1. Amendment of the Company's By-laws to change the prospective date of our annual meeting of shareholders, correct certain typographical errors, enlarge number of directors on the board and certain other matters.

2. Approve Exchange Agreement among Callisto, Synergy-DE and certain holders of Synergy-DE securities.

3. Approve Share Contribution Agreement, certain restricted stock purchase agreements, option agreements and grid note assignment and release agreement.

4. Approve share contribution by our majority stockholder.

5. Approve private placement of up to 5,000,000 shares of our common stock for $3,000,000.

6. Approve 75.69060773 for one stock split.

7. Approve increase in authorized capital stock to 170,000,000 shares consisting of 150,000,000 shares of common stock and 20,000,000 shares of preferred stock.

8. Approve name change to Synergy Pharmaceuticals, Inc.

9. Approve appointment of Gabriele M. Cerrone, Gary S. Jacob, Chris McGuigan, Tom Adams and John P. Brancaccio as directors.

10. Approve appointment of Gary S. Jacob as President and Acting CEO, Kunwar Shailubhai as Chief Scientific Officer and Bernard Denoyer as Senior VP Finance.

11. Approve the adoption and ratification of our Equity Compensation Plan.

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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.

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SIGNATURES

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

SYNERGY PHARMACEUTICALS, INC.
(Registrant)

Date: November 19, 2008 By: /s/ GARY S. JACOB

Gary S. Jacob
President and Acting Chief Executive Officer

Date: November 19, 2008 By: /s/ BERNARD F. DENOYER

Bernard F. Denoyer
Senior Vice President, Finance