

Synergy Pharmaceuticals, Inc.
Form 10-K
April 15, 2009

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.](#)

[Table of Contents](#)

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

FORM 10-K

(Mark One)

**ANNUAL REPORT UNDER SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED: DECEMBER 31, 2008

**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 (I.R.S. Employer Identification No.)
Incorporation or Organization)

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
None	

Securities registered pursuant to section 12(g) of the Act:

Title of class: **None**

Edgar Filing: Synergy Pharmaceuticals, Inc. - Form 10-K

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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 (the "Exchange Act") during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was \$9,060,004 on June 30, 2008 (this valuation was based on \$0.60 per share, the price of 5,000,000 unregistered shares of common stock sold in a private placement on July 11, 2008. The first public trade of the Company's common stock was on September 23, 2008 for 2,500 shares @ \$0.75 per share).

As of April 14, 2009 the registrant had 66,172,148 shares of Common Stock outstanding.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

FORM 10-K

TABLE OF CONTENTS

PART I

<u>Item 1.</u>	<u>Business</u>	<u>1</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>7</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>19</u>
<u>Item 2.</u>	<u>Properties</u>	<u>19</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>19</u>
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Securities Holders</u>	<u>19</u>

PART II

<u>Item 5.</u>	<u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>20</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>21</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>29</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>29</u>
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosures</u>	<u>29</u>
<u>Item 9A(T).</u>	<u>Controls and Procedures</u>	<u>29</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>30</u>

PART III

<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>31</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>34</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>38</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>39</u>
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	<u>40</u>

PART IV

<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	<u>41</u>
-----------------	---	-----------

SIGNATURES

		<u>43</u>
--	--	-----------

Table of Contents

PART I

This Report on Form 10-K for Synergy Pharmaceuticals, Inc. may contain forward-looking statements. Forward-looking statements are characterized by future or conditional verbs such as "may," "will," "expect," "intend," "anticipate," "believe," "estimate" and "continue" or similar words. 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. Such statements are only predictions and our actual results may differ materially from those anticipated in these forward-looking statements. 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. Factors that may cause such differences include, but are not limited to, those discussed under Item 1A. Risk Factors and elsewhere in this Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission, including the uncertainties associated with product development, the risk that products that appeared promising in early clinical trials do not demonstrate safety and efficacy in larger-scale clinical trials, the risk that we will not obtain approval to market our products, the risks associated with dependence upon key personnel and the need for additional financing. We do not assume any obligation to update forward-looking statements as circumstances change.

ITEM 1. BUSINESS.

GENERAL

Synergy Pharmaceuticals, Inc. ("Synergy", "the Company", "we" or "us") was incorporated under the laws of the State of Florida on November 15, 2005 as Pawfect Foods, Inc. Our principal offices are located at 420 Lexington Avenue, Suite 1609, New York, NY 10170.

On July 14, 2008 we acquired 100% of the common stock of Synergy Pharmaceuticals, Inc. a Delaware company incorporated on September 11, 1992 ("Synergy-DE"), under the terms of an Exchange Agreement between us, Callisto Pharmaceuticals, Inc. ("Callisto"), Synergy-DE, and certain other holders of Synergy-DE common stock ("Exchange Transaction").

On July 21, 2008, we amended our articles of incorporation to effect the actions necessary to complete the transactions contemplated by the Exchange Transaction and changed our name from Pawfect Foods, Inc. to Synergy Pharmaceuticals, Inc.

Since inception on November 15, 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. Immediately following 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 ("GI") disorders and diseases. Our lead drug candidates, acquired from Synergy-DE in connection with the Exchange Transaction, are as follows:

- (1) 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")
- (2) SP-333, a second generation GC-C receptor analog, now in pre-clinical development for the treatment of ulcerative colitis ("UC").

From inception through December 31, 2008, we have sustained cumulative net losses of \$31,795,441 resulting primarily from acquired in-process research and development valued at \$28,156,502 which was expensed upon the acquisition of Synergy-DE on July 14, 2008. From inception through December 31, 2008, we have not generated any revenue from operations and expect to incur

Table of Contents

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.

PRODUCTS

SP-304 TO TREAT GASTROINTESTINAL DISORDERS

SP-304 is a new member of a novel class of non-systemic drugs for treatment of chronic constipation (CC), irritable bowel syndrome with constipation (IBS-C) and other GI disorders and diseases. 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 a synthetic analog of uroguanylin, a natural peptide hormone produced in the gut that is a key regulator of intestinal function. Uroguanylin works by activating the GC-C receptor on intestinal cells which promotes fluid and ion transport in the GI tract. Under normal conditions, this receptor is activated by the natural hormone uroguanylin and/or by a similar natural hormone guanylin. Orally administered SP-304 acts in an identical fashion, binding to and activating GC-C expressed on the epithelial cells lining the GI mucosa, resulting in activation of the cystic fibrosis transmembrane conductance regulator (CFTR), and leading to an augmented flow of chloride and water into the lumen of the gut to facilitate bowel movement. In animal models, oral administration of SP-304 promotes intestinal secretion of fluid, thereby softening stool, and producing other pharmacologic effects that could potentially benefit patients with CC and IBS-C.

On April 2, 2008, we filed an investigational new drug ("IND") application with the United States Food and Drug Administration ("FDA") on SP-304 to treat GI disorders and diseases. On May 2, 2008, we received notice from the FDA that the proposed first study in the clinic, a single-dose trial in human volunteers, was deemed safe to proceed.

Preclinical Studies on SP-304

SP-304 has been demonstrated to be superior to uroguanylin in its biological activity, protease stability and pH characteristics. SP-304 acts in an identical manner as the natural hormone as an agonist (i.e. activator) of the GC-C receptor found on the epithelial cells of the colon. Upon activation, the GC-C receptor promotes intracellular synthesis which in turn eventually activates the cystic fibrosis transmembrane conductance regulator (CFTR) within the epithelial cells. Activation of CFTR leads to secretion of salts and water into the intestine, resulting in a liquid and watery intestine content that is more easily transported through the bowel. Recent animal studies performed with SP-304 have demonstrated the drugs potential to enhance intestinal motility.

Clinical Studies of SP-304

On June 4, 2008, we initiated a Phase I clinical trial of SP-304 in volunteers. 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.

On December 9, 2008, we announced the completion of the Phase I clinical trial of SP-304 in healthy volunteers that was initiated in June 2008. This first study was a double-blind,

Table of Contents

placebo-controlled, randomized single, oral, ascending dose trial performed in 71 healthy male and female volunteers. The primary objective of the Phase I clinical trial with SP-304 was to characterize the safety, tolerability, pharmacokinetic and pharmacodynamic effects of the drug in healthy volunteers. The data from the trial were included in an abstract accepted for presentation at the Digestive Disease Week conference that meets in Chicago in June 2009. We plan to initiate a repeated-oral-dose trial of SP-304 in chronic constipation patients in late 2009 or early 2010.

SP-333 TO TREAT ULCERATIVE COLITIS

SP-304 previously was evaluated in animal studies as a treatment for GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of North Carolina, Chapel Hill, NC. Results from his laboratory showed that SP-304 was efficacious in animal models of UC. A second generation GC-C receptor agonist SP-333 with improved stability properties is now in pre-clinical development and Synergy plans to file an IND on SP-333 to treat UC patients, and initiate a Phase I clinical trial in volunteers in late 2009 or early 2010.

Development Plan

Our plan of operations for the next twelve months is to focus primarily on the Phase Ib clinical trial development of SP-304 to treat GI disorders and diseases. During 2008, as discussed above, we completed a Phase I clinical trial in volunteers for SP-304. We are now planning to open a Phase Ib repeated-dose trial of SP-304 for CC patients during late 2009 or early 2010. We also plan to file an IND on SP-333 to treat ulcerative colitis in 2009.

Manufacturing of SP-304 and SP-333

A practical, efficient and cost effective method for producing both SP-304 and SP-333 at commercial scale is currently being developed by two contract research organizations. At present we have multiple 100 gram-scale lots of SP-304 and SP-333, produced under current good manufacturing practices ("cGMP") and good laboratory practices ("GLP"), that are being used for non-clinical work to support further human studies.

We will require additional capital to execute our plan. Worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult 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. 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 our product candidates, (ii) seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available and/or (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.

About Chronic Constipation

Chronic constipation is a very common GI disorder. According to recent studies, by groups such as Giles and Associates and the Mayo Clinic, it is estimated that up to 26 million Americans suffer from the disorder, and of this population about 5 million have a severe condition necessitating relief. The prevalence of the disorder is similar in other developed countries. Patients with chronic constipation often experience hard stools, straining during bowel movements and not enough bowel movements during the week. People with chronic constipation can experience serious discomfort which adversely affects their ability to work and their quality of life.

Table of Contents

About Irritable Bowel Syndrome

Up to one sixth of adults experience irritable bowel syndrome (IBS), a condition marked by disturbed bowel function and abdominal pain. IBS patients can have three different sets of symptoms; diarrhea-predominant (IBS-D), constipation-predominant (IBS-C) and mixed or alternating disorder (IBS-M). The split in prevalence between the forms is about one third each. In addition, most patients suffering from the mixed form of IBS (IBS-M) are believed to mainly have constipation. An estimated 10 million people in the United States and an additional 10 million people in the European Union suffer from IBS-C. IBS (all forms) accounts for 12% of adult visits to primary care physicians in the United States.

GOVERNMENT REGULATION

Regulation by governmental authorities in the United States of America and other countries will be a significant factor in the production and marketing of any products that may be developed by us. The nature and the extent to which such regulation may apply will vary depending on the nature of any such products. Virtually all of our potential products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous pre-clinical and clinical testing and other approval procedures by the FDA and similar health authorities in foreign countries. Various federal statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of such products. The process of obtaining these approvals and the subsequent compliance with appropriate federal and foreign statutes and regulations requires the expenditure of substantial resources. In order to test in human clinical trials, produce and market products for diagnostic or therapeutic use, a company must comply with mandatory procedures and safety standards established by the FDA and comparable agencies in foreign countries. Before beginning human clinical testing of a potential new drug, a company must file an IND and receive clearance to proceed from the FDA. This application is a summary of the pre-clinical studies that were conducted to characterize the drug, including toxicity and safety studies in animals, as well as an in-depth discussion of the human clinical studies that are being proposed.

The pre-marketing program required for approval of a new drug typically involves a time-consuming and costly three-phase process. In Phase I, trials are conducted with a small number of volunteers or patients to determine the early safety profile, the pattern of drug distribution and metabolism. In Phase II, trials are conducted with small groups of patients afflicted with a target disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase III, large scale, multi-center comparative trials are conducted with patients afflicted with a target disease in order to provide enough data for statistical proof of efficacy and safety required by the FDA and others.

The FDA closely monitors the progress of each of the three phases of clinical testing and may, in its discretion, reevaluate, alter, suspend or terminate the testing based on the data that have been accumulated to that point and its assessment of the risk/benefit ratio to the patient. Estimates of the total time required for carrying out such clinical testing vary between two and ten years. Upon completion of such clinical testing, a company typically submits a New Drug Application (NDA) or Product License Application (PLA) to the FDA that summarizes the results and observations of the drug during the clinical testing. Based on its review of the NDA or PLA, the FDA will decide whether or not to approve the drug. This review process can be quite lengthy, and approval for the production and marketing of a new pharmaceutical or medical diagnostic product can require a number of years and substantial funding, and there can be no assurance that any approvals will be granted on a timely basis, if at all.

If the product is approved for sale, FDA regulations govern the production process and marketing activities, and a post-marketing testing and surveillance program may be required to monitor

Table of Contents

continuously a product's usage and effects. Product approvals may be withdrawn if compliance with regulatory standards is not maintained, and other countries, in which any products developed by us are marketed, may impose a similar regulatory process.

COMPETITION

The biopharmaceutical industry is characterized by rapidly evolving technology and intense competition. Our competitors include major pharmaceutical and biotechnology companies focusing on GI such as Ironwood (Microbia), Sucampo/Takeda and Novartis. Most of our competitors have financial, technical and marketing resources significantly greater than our resources. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint venture. We are aware of certain development projects for products to prevent or treat certain diseases targeted by us. The existence of these potential products or other products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect our ability to market the products we develop.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses consist primarily of costs associated with (i) clinical development team salaries and staff costs, (ii) application and filing for regulatory approval of our proposed products, (iii) regulatory and scientific consulting fees, (iv) clinical and patient costs for product candidates in on-going trials, (v) sponsored pre-clinical research, (vi) legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products and (vii) clinical drug substance. We expense all research and development costs as they are incurred and we expect our research and development expenses to increase significantly in the future as we develop our product candidates. Research and development expenses were \$1,909,226 for the twelve months ended December 31, 2008, compared to \$0 for the twelve months ended December 31, 2007 and 2006.

PROPRIETARY RIGHTS

We are able to protect our technology from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents or is effectively maintained as a trade secret. Accordingly, patents or other proprietary rights are an essential element of our business. As of December 31, 2008, we are the assignee or exclusive licensee of 5 pending patent applications, 1 issued patent in the United States and 1 issued foreign patent. We have 4 pending foreign patent applications. We seek patent protection of inventions originating from our ongoing research and development activities that are commercially important to our business. Our United States composition-of-matter and use patent on SP-304 was issued on May 9, 2006.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

While trade secret protection is an essential element of our business and we have taken security measures to protect our proprietary information and trade secrets, we cannot give assurance that our unpatented proprietary technology will afford us significant commercial protection. We seek to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and consultants also sign agreements requiring that they assign to us their interests in intellectual property arising from their work for us. All employees sign an agreement not to engage in any conflicting employment or activity during their employment with us and not to disclose or misuse our confidential information. However, it is possible that these agreements may be breached

Table of Contents

or invalidated, and if so, there may not be an adequate corrective remedy available. Accordingly, we cannot ensure that employees, consultants or third parties will not breach the confidentiality provisions in our contracts, infringe or misappropriate our trade secrets and other proprietary rights or that measures we are taking to protect our proprietary rights will be adequate.

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or us, we may face costly litigation and the diversion of management's attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, or at all.

LICENSE AGREEMENTS

On August 28, 2002, and as amended on May 23, 2003, Synergy-DE entered into a worldwide license agreement (the "Original License") with AnorMED Corporation ("AnorMED") to research, develop, sell and commercially exploit the Atiprimod patent rights. The Original License provided for aggregate milestone payments of up to \$14 million based upon achieving certain regulatory submissions and approvals for an initial indication, and additional payments of up to \$16 million for each additional indication based on achieving certain regulatory submissions and approvals. Commencing on January 1, 2004 and on January 1 of each subsequent year Synergy-DE was obligated to pay AnorMED a maintenance fee of \$200,000 until the first commercial sale of the product. These annual maintenance fee payments under the Original License were made in January 2004, 2005, 2006 and 2007 and recorded as research and development expense.

On December 31, 2007, Callisto and Synergy-DE entered into an Amended and Restated License Agreement with AnorMED, a wholly-owned subsidiary of Genzyme Corporation ("Genzyme"), pursuant to which Callisto and Genzyme amended the Original License agreement for Atiprimod to eliminate all future maintenance fees and milestone payments and reduce future royalties. In return for the reduced future payments to Genzyme, Callisto agreed to pay upfront fees which were recorded as a liability and expensed by Callisto on December 31, 2007. From that point forward Synergy-DE had no further rights to, obligations for or interests in the AnorMED/Atiprimod patent rights.

EMPLOYEES

As of April 14, 2009, we had 6 full-time and 3 part-time employees. We believe our employee relations are satisfactory.

SYNERGY WEBSITE

We maintain a site on the World Wide Web at <http://www.synergybio.net>; however, information found on our website is not incorporated by reference into this report. We make available free of charge through our website our Securities and Exchange Commission, or SEC, filings furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Table of Contents

ITEM 1A. RISK FACTORS.

You should carefully consider the following risk factors and the other information included in this annual report on Form 10-K, 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.

OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM HAS EXPRESSED DOUBT ABOUT OUR ABILITY TO CONTINUE AS A GOING CONCERN, WHICH MAY HINDER OUR ABILITY TO OBTAIN FUTURE FINANCING.

Our consolidated financial statements as of December 31, 2008 were prepared under the assumption that we will continue as a going concern for the next twelve months. Our independent registered public accounting firm has issued a report that included an explanatory paragraph referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 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 December 31, 2008, we had an accumulated deficit of \$31,795,441. 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

Edgar Filing: Synergy Pharmaceuticals, Inc. - Form 10-K

Table of Contents

uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock will likely decline.

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

Edgar Filing: Synergy Pharmaceuticals, Inc. - Form 10-K

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 and/or substantial warrants to purchase our common stock which may be highly dilutive. If we are unable to raise additional capital when required or on acceptable terms, we may

Table of Contents

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.

Table of Contents

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

Table of Contents

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 to sell our product candidates in international markets through a third party, we may not be able to

Table of Contents

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;

product recalls;

Table of Contents

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.

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

Table of Contents

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, Ph.D., our Chief Scientific Officer. The loss of services of Dr. Jacob or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidates.

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

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

We are a small company with 6 full-time and 3 part-time employees as of December 31, 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.

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.

Table of Contents

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

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

Table of Contents

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 December 31, 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.

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

Table of Contents

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 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 our securities. Accordingly, there can be no assurance as to the liquidity of any markets that may develop for the securities, the ability of 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;

Table of Contents

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.

IF WE FAIL TO COMPLY WITH THE RULES UNDER THE SARBANES-OXLEY ACT OF 2002 RELATED TO ACCOUNTING CONTROLS AND PROCEDURES, OR, IF MATERIAL WEAKNESSES OR OTHER DEFICIENCIES ARE DISCOVERED IN OUR INTERNAL ACCOUNTING PROCEDURES, OUR STOCK PRICE COULD DECLINE SIGNIFICANTLY AND RAISING CAPITAL COULD BE MORE DIFFICULT.

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

Table of Contents

reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our Common Stock could drop significantly. In addition, we cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future. See ITEM 9a(T). of this annual report for a more detailed discussion of our internal control weaknesses and deficiencies.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None

ITEM 2. PROPERTIES.

We currently occupy approximately 600 square feet, comprising a small laboratory and several offices in the Bucks County Biotechnology Center, in Doylestown, Pennsylvania under a two year lease expiring November 30, 2010.

We are provided the use of office space on a month-to-month basis at 420 Lexington Avenue, Suite 1609, New York, New York by Callisto, our majority shareholder

ITEM 3. LEGAL PROCEEDINGS.

None

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

No matters were submitted to a vote of our security holders during the fourth quarter of 2008.

Table of Contents**PART II****ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUERS PURCHASES OF EQUITY SECURITIES.****Market Prices**

Our common stock has been quoted on the Over the Counter Bulletin Board under the symbol "SGYP.OB" since September 23, 2008, prior to which date our securities were not traded on any public market. The following table shows the reported high and low closing prices per share for our common stock as reported on the Over the Counter Bulletin Board since that date.

	2008		2007	
	High	Low	High	Low
First Quarter	\$	\$	N/A	N/A
Second Quarter			N/A	N/A
Third Quarter	\$0.95	\$0.75	N/A	N/A
Fourth Quarter	\$2.48	\$0.99	N/A	N/A

Holder of Common Stock

As of April 15, 2009, we had 36 holders of record of our common stock.

Dividends

Historically, we have not declared or paid any cash dividends to the holders of our common stock and we do not expect to pay any such dividends in the foreseeable future as we expect to retain our future earnings for use in the operation and expansion of our business.

Equity Compensation Information

The following table summarizes information about our equity compensation plans as of December 31, 2008.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Stockholders	4,080,016	\$ 0.29	1,545,224
Equity Compensation Plans Not Approved by Stockholders			
Total	4,080,016	\$ 0.29	1,545,224

The maximum aggregate number of shares of Common Stock that may be (i) issued under all equity compensation plans pursuant to the exercise of Options and (ii) issued pursuant to Restricted Stock Awards is 6,500,000 shares of Common Stock. As of December 31, 2008 there were 4,080,016 stock options outstanding under the Plan and 874,760 Restricted Stock Awards issued and outstanding, leaving 1,545,224 shares available for future issuances.

Table of Contents

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our consolidated financial statements and other financial information appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, the following discussion and other parts of this Annual Report contain forward-looking information that involves risks and uncertainties.

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 8. Financial Statements *Note Acquisitions 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").

Immediately following the Exchange Transaction 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.

BUSINESS OVERVIEW

Since inception on November 15, 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. Immediately following 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 GI disorders and diseases. Our lead drug candidates, acquired from Synergy-DE in connection with the Exchange Transaction, are as follows:

- (3) 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")
- (4) SP-333, a second generation GC-C receptor analog, in pre-clinical development for the treatment of ulcerative colitis ("UC").

From inception through December 31, 2008, we have sustained cumulative net losses of \$31,795,441 resulting primarily from acquired in-process research and development valued at \$28,156,502 which was expensed upon the acquisition of Synergy on July 14, 2008. From inception through December 31, 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

Table of Contents

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.

PRODUCTS

SP-304

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.

On April 2, 2008, we filed an investigational new drug ("IND") application with the United States Food and Drug Administration ("FDA"). On May 2, 2008, we received notice from the FDA that the proposed study was deemed safe to proceed and we 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.

On December 9, 2008, we announced the completion of the Phase I clinical trial of SP-304 in healthy volunteers that was initiated in June, 2008. This first study was a double-blind, placebo-controlled, randomized single, oral, ascending dose trial performed in 71 healthy male and female volunteers. The primary objective of the Phase I clinical trial with SP-304 was to characterize the safety, tolerability, pharmacokinetic and pharmacodynamic effects of the drug in healthy volunteers. The data from the trial were included in an abstract accepted for presentation at the Digestive Disease Week conference that meets in Chicago in June, 2009. We plan to initiate a repeated-oral-dose trial of SP-304 in chronic constipation patients in late 2009 or early 2010.

Preclinical Studies

SP-304 has been demonstrated to be superior to uroguanylin in its biological activity, protease stability and pH characteristics. SP-304 acts in an identical manner as the natural hormone as an agonist (i.e. activator) of the GC-C receptor found on the epithelial cells of the colon. Upon activation, the GC-C receptor promotes intracellular synthesis of cGMP, which in turn eventually activates the cystic fibrosis transmembrane conductance regulator (CFTR) within the epithelial cells. Activation of CFTR leads to secretion of salts and water into the intestine, resulting in a liquid and watery intestine content that is more easily transported through the bowel. Recent animal studies performed with SP-304 have demonstrated the drugs potential to enhance intestinal motility.

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 SP-333 is now in pre-clinical development and we plan to file an IND and initiate a Phase I clinical trial in volunteers in 2010.

Table of Contents

Development Plan

Our plan of operations for the next twelve months is to focus primarily on the Phase Ib clinical trial development of SP-304 to treat GI disorders. During 2008, as discussed above, we completed a Phase I clinical trial in volunteers for SP-304. We are now planning to open a Phase Ib repeated-dose trial of SP-304 for CC patients during 2009.

We will require additional capital to execute our plan. Worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult 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. 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 our product candidates, (ii) seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available and/or (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.

Manufacturing of SP-304

A practical, efficient and cost effective method for producing SP-304 on a commercial scale is currently being developed by 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-333

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 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 volunteers during 2010.

FINANCIAL OPERATIONS OVERVIEW

From inception through December 31, 2008, we have sustained cumulative net losses available to common stockholders of \$31,795,441 resulting primarily from acquired in-process research and development valued at \$28,156,502 which was expensed upon the acquisition of Synergy on July 14, 2008. From inception through December 31, 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, our ability to raise additional capital, the nature and timing of research and development expenses and competing technologies being developed by organizations with significantly greater resources.

Table of Contents

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in Item 8. Financial Statements Note *Summary of Significant Accounting Policies and New Accounting Pronouncements*. 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 December 31, 2008 stock-based compensation expense has totaled \$379,883.

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. We did not issue stock options until the year ended December 31, 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 the simplified method provided in Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment*, ("SAB No. 107"). The risk-free interest rate is based on observed interest rate appropriate for the expected term of our employee stock options. Forfeitures are estimated, based on Callisto's historical experience, at the time of grant.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of December 31, 2008.

Table of Contents

RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2008 AND DECEMBER 31, 2007

As discussed above, on July 14, 2008, Synergy completed the acquisition of Synergy-DE. The acquisition of Synergy-DE was treated as an asset acquisition, since Synergy-DE is a development stage company and does not have the necessary inputs and outputs to meet the definition of a business. The results of operations of Synergy-DE are included in the accompanying consolidated financial statements from July 14, 2008 to December 31, 2008. As a result of the acquisition of Synergy-DE on July 14, 2008, the Company decided to discontinue its pet food business and accordingly, amounts in the consolidated statements of operations and related notes for all historical periods have been restated to reflect these operations as discontinued. Pet food business net loss for the six months ended June 30, 2008, pre-acquisition of Synergy-DE, totaled \$31,560.

We had no revenues during the twelve months ended December 31, 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.

For the twelve months ended December 31, 2008, research and development expenses totaled \$1,909,226. These research and development expenses were primarily attributable to our SP-304 product candidate. These expenses include drug formulation of \$523,470, clinical program expenses of \$540,312, scientific and regulatory advisors of \$261,808, in-house staff salaries and employee benefits including stock based compensation expense of \$276,124 and patent prosecution costs of \$137,112. There were no such expenses during the twelve months ended December 31, 2007 because the SP-304 product was acquired in connection with the July 14, 2008 Exchange Transaction discussed above. In addition, our pet food business was discontinued on July 14, 2008 in connection with the Exchange Transaction.

The fair value of the 45,464,760 shares issued in connection with the Exchange Transaction, totaled \$27,278,855 on July 14, 2008, based on a per share value of \$0.60, which was the per share price of our 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 totaled net liabilities acquired of \$877,647. The total remaining consideration was allocated to research and development projects which had not yet reached technological feasibility and, having no alternative use, this total amount of \$28,156,502 was charged to purchased in-process research and development expense during the twelve months ended December 31, 2008. There were no such expenses during the twelve months ended December 31, 2007. In addition, the purchase 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"), we 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. We did not assign a value to the acquired employees as all continuing research and development is being performed under the supervision of Callisto employees, nor to 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.

For the twelve months ended December 31, 2008, general and administrative expenses were \$1,662,885. These expenses primarily include non-scientific salaries and related employee benefits including stock based compensation expense of \$718,002, consultants and advisors of \$253,754, travel and entertainment of \$64,494, facilities cost of \$277,953, accounting and tax services of \$281,250 and corporate legal of \$62,974. Such expenses during the twelve months ended December 31, 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.

Table of Contents

Net loss for the twelve months ended December 31, 2008 was \$31,755,180 compared to a net loss of \$20,043 incurred for the twelve months ended December 31, 2007.

YEARS ENDED DECEMBER 31, 2007 AND DECEMBER 31, 2006

All operating results for the years ended December 31, 2007 and 2006 relate to our discontinued pet food operations which amounts we consider immaterial. Because these operations are not continuing we feel any discussion would not be meaningful to an understanding of our current business.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2008 we had \$216,007 in cash and cash equivalents, compared to \$1,807 as of December 31, 2007. Net cash used in operating activities was \$1,878,744 for the twelve months ended December 31, 2008. Net cash provided by financing activities for the twelve months ended December 31, 2008 was \$2,951,912, principally the net result of closing a private placement of 5,000,000 shares of our common stock at \$0.60 per share, on July 14, 2008.

As of December 31, 2008 we had a working capital deficit of \$1,171,893. On February 13, 2009 Synergy sold 285,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$200,000. On April 2, 2009 Synergy sold 100,000 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$70,000. On April 13, 2009 Synergy sold 180,000 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$126,000. On April 15, 2009 Synergy sold 1,045,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$732,000. As of April 15, 2009 the Company had approximately \$600,000 cash on hand which, at its current reduced cash expenditure rate of approximately \$100,000 per month, allows it to continue its operations for approximately 6 months.

Worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult for us to obtain additional equity or credit financing, when needed. We have accordingly taken steps to conserve our cash which include extending payment terms to our vendors and suppliers as well as management and staff salary cuts and deferrals. These actions may not be sufficient to allow the Company time to raise additional capital.

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of pharmaceutical research and development programs. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates, to fund the existing working capital deficit 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 December 31, 2008 and December 31, 2007 have been prepared under the assumption that we will continue as a going concern. Our independent registered public accounting firm has issued a report dated April 15, 2009 that included an explanatory paragraph

Table of Contents

referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following table is a summary of contractual cash obligations for the periods indicated that existed as of December 31, 2008, and is based on information appearing in the Notes to Consolidated Financial Statements.

	Total	Less than 1 Year	1-2 Years	3-5 Years	More than 5 Years
Operating leases	\$ 48,400	\$ 26,400	\$ 22,000	\$	\$
Purchase obligations principally consulting services	1,338,750	446,250	892,500		
Total obligations	\$ 1,387,150	\$ 472,650	\$ 914,500	\$	\$

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of December 31, 2008.

RECENT ACCOUNTING PRONOUNCEMENTS

In October 2008, the FASB issued FASB Staff Position ("FSP") No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, ("FSP No. 157-3"). This FSP applies to financial assets within the scope of accounting pronouncements that require or permit fair value measurements in accordance with SFAS No. 157. This FSP clarifies the application of SFAS No. 157 in determining the fair values of assets or liabilities in a market that is not active. This FSP is effective upon issuance, including prior periods for which financial statements have not been issued. The adoption of this FSP did not have a material impact on 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. We are currently evaluating the impact of the pending adoption of EITF No. 07-05 on our 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. We are currently evaluating the impact of SFAS No. 157 on nonfinancial assets and nonfinancial liabilities, but do not expect the adoption to have a material impact on our 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

Table of Contents

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. We are continuing to evaluate the impact of adopting the provisions EITF No. 07-1; however, we do not anticipate that adoption will have a material effect on our consolidated financial position, results of operations or cash flows.

In December 2007, the FASB issued SFAS No. 141(R), a revised version of SFAS No. 141, *Business Combinations*. The revision is intended to simplify existing guidance and converge rulemaking under U.S. 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, and may affect the release of our valuation allowance against prior acquisition intangibles. An entity may not apply it before that date. We do not expect that the adoption of this Statement will have a material effect on our consolidated financial condition or results of operations.

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 requires all entities to report noncontrolling (minority) interests in subsidiaries as equity in the consolidated financial statements. 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. We do not expect that the adoption of this Statement will have a material effect on our consolidated financial position, results of operations or cash flows.

In June 2007, the EITF of the FASB reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ("EITF No. 07-3"). EITF No. 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts would be recognized as an expense. We adopted EITF No. 07-3 on January 1, 2008 and the adoption did not have a material effect on our consolidated financial position, results of operations or cash flows.

In February 2007, the FASB issued Statement of Financial Accounting Standards No.159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an Amendment to SFAS 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. We adopted SFAS No. 159 on January 1, 2008 and the adoption did not have a material effect on our consolidated financial position, results of operations or cash flows as we 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 with

Table of Contents

respect to financial assets and financial liabilities on January 1, 2008 and such adoption did not have a material effect on our consolidated financial position, results of operations or cash flows.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

At December 31, 2008 and 2007, a substantial portion of our cash and cash equivalents consists of short term, highly liquid investments in a money market fund managed by a money center bank.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The full text of our audited consolidated financial statements as of December 31, 2008 and 2007 and for the fiscal years ended December 31, 2008, 2007 and 2006 and for the period from November 15, 2005 (inception) to December 31, 2008, begins on page F-1 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A(T). CONTROLS AND PROCEDURES.

Evaluation of disclosure 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 December 31, 2008, our Chief Executive Officer and Principal Financial Officer have concluded that, due to the material weaknesses in our internal control over financial reporting noted below, our disclosure controls and procedures were not effective.

Management's annual report on internal control over financial reporting. We are responsible for establishing and maintaining adequate internal control over our financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements in accordance with accounting principles generally accepted in the United States of America. Our internal control over financial reporting includes those policies and procedures that:

- (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and
- (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Table of Contents

In connection with the preparation of our annual financial statements, we have assessed the effectiveness of internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls. Based on this evaluation, management has determined that as of December 31, 2008, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management's assessment were (i) a lack of sufficient internal accounting expertise to provide reasonable assurance that our financial statements and notes thereto, are prepared in accordance with generally accepted accounting principles (GAAP) and (ii) a lack of segregation of duties to ensure adequate review of financial statement preparation. In light of these material weaknesses, management has concluded that, as of December 31, 2008, we did not maintain effective internal control over financial reporting. As defined by Regulation S-X 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 on a timely basis. In order to ensure the effectiveness of our disclosure controls in the future we will add financial staff resources to our accounting and finance department.

This report does not include an attestation report of our registered public accounting firm regarding our internal controls over financial reporting. The disclosure contained under this Item 9A(T) was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only the disclosure under this Item 9A(T) in this annual report.

Changes in internal control over financial reporting. There were no changes in our internal controls over financial reporting during the fourth quarter of the year ended December 31, 2008 that have materially affected or are reasonably likely to materially affect our internal controls over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

Table of Contents**PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

The following table sets forth certain information regarding the directors and executive officers of Synergy Pharmaceuticals, Inc. as of April 15, 2009:

Name	Age	Position
Gary S. Jacob	62	President, Acting Chief Executive Officer and Director
Kunwar Shailubhai	52	Chief Scientific Officer
Bernard F. Denoyer	61	Senior Vice President, Finance, Secretary
Gabriele M. Cerrone	37	Chairman, Director
Melvin K. Spigelman	59	Director
John P. Brancaccio	62	Director
Thomas H. Adams	65	Director
Christopher McGuigan	49	Director

Gary S. Jacob, Ph.D. has served as our President, Acting Chief Executive Officer and a Director of the Company since July 2008 and as Chairman of Synergy DE from October 2003 until July 2008. Dr. Jacob currently serves as Chief Executive Officer and a director of Callisto Pharmaceuticals, Inc. Dr. Jacob served as Chief Scientific Officer of Synergy DE from 1999 to 2003. Dr. Jacob has over twenty-five years of experience in the pharmaceutical and biotechnology industries across multiple disciplines including research & development, operations and business development. Prior to 1999, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of glycobiology, and from 1997 to 1998 was Director of Functional Genomics, Corporate Science & Technology, at Monsanto Company. Dr. Jacob also served from 1990 to 1997 as Director of Glycobiology at G.D. Searle Pharmaceuticals Inc. During the period of 1986 to 1990, he was Manager of the G.D. Searle Glycobiology Group at Oxford University, England.

Kunwar Shailubhai, Ph.D., has served as our Chief Scientific Officer since July 2008. From March 2004 until July 2008 he served as Senior Vice President, Drug Discovery, of Synergy DE. From May 2003 until March 2004, Dr. Shailubhai served as Executive Vice President, Research and Development. From 2001 to April 2003, Dr. Shailubhai held the position of Vice President, Drug Discovery at Synergy DE where he was chiefly responsible for the preclinical development of our GC-C agonist program for drugs to treat colon cancer and GI inflammation. Between 1993 and 2000, he was with Monsanto Company, serving as Group Leader of the cancer chemoprevention group. Dr. Shailubhai previously served as a Senior Staff Fellow at the National Institutes of Health, and as an Assistant Professor at the University of Maryland. Dr. Shailubhai received his Ph.D. in microbiology in 1984 from the University of Baroda, India, and his M.B.A. in 2001 from the University of Missouri, St. Louis.

Bernard F. Denoyer, CPA has served as our Senior Vice President, Finance and Secretary since July 2008. Since December 2007, Mr. Denoyer has been Senior Vice President, Finance and Secretary of Callisto Pharmaceuticals, Inc. and from January 2004 to November 2007 Mr. Denoyer has served as Callisto's Vice President, Finance and Secretary. From October 2000 to December 2003, Mr. Denoyer was an independent consultant providing interim CFO and other services to emerging technology companies, including Callisto and certain portfolio companies of Marsh & McLennan Capital, LLC. From October 1994 until September 2000, Mr. Denoyer served as Chief Financial Officer and Senior Vice President at META Group, Inc., a public information technology research company, where he was instrumental in their 1995 IPO. From 1990 to 1993 he served as Vice President Finance of Environetics, Inc., a pharmaceutical water diagnostic test business, acquired by IDEXX Laboratories, Inc..

Edgar Filing: Synergy Pharmaceuticals, Inc. - Form 10-K

Table of Contents

Gabriele M. Cerrone has served as our Chairman of the Board of Directors since July 2008. From March 1999 to January 2005 Mr. Cerrone served as a Senior Vice President of Investments of Oppenheimer & Co. Inc., a financial services firm. Prior to such affiliation, Mr. Cerrone held the position of Managing Director of Investments at Barrington Capital, L.P., a merchant bank, between March 1998 and March 1999. Between May 2001 and May 2003, Mr. Cerrone served on the board of directors of SIGA Technologies, Inc. Mr. Cerrone was a founder of FermaVir Pharmaceuticals, Inc., a biotechnology company, and served as Chairman from August 2005 to September 2007, when the company was acquired by Inhibitex, Inc., a biotechnology company. Mr. Cerrone was also a founder of Xenomics, Inc., a diagnostic company, and served as Chairman from July 2004 until November 2006. Mr. Cerrone currently serves as a director of Inhibitex, Inc. and as Chairman of Callisto Pharmaceuticals, Inc. Mr. Cerrone is the managing partner of Panetta Partners Ltd.; a Colorado limited partnership that is a private investor in real estate and public and private companies engaged in biotechnology and other areas.

Melvin K. Spigelman, M.D. has served as a Director of our company since August 2008. Dr. Spigelman has served as Director of Research and Development for the Global Alliance for TB Drug Development, a non-profit organization which seeks to accelerate the discovery and development of faster-acting and affordable drugs to fight tuberculosis, since June 2003. Before joining the Global Alliance for TB Drug Development, Dr. Spigelman was President of Hudson-Douglas Ltd, a consulting company, from June 2001 to June 2003. From 1992 to 2001, Dr. Spigelman served as a Vice President and head of R&D at Knoll Pharmaceuticals, a pharmaceutical unit of BASF Pharma. Dr. Spigelman has been a director of The Medicines Company since 2005. Dr. Spigelman received a B.A. in engineering from Brown University and an M.D. from The Mount Sinai School of Medicine; and is board certified in internal medicine, medical oncology and preventive medicine.

John P. Brancaccio, a retired CPA, has served as a Director of our company since July 2008. Since April 2004, Mr. Brancaccio has been the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. Mr. Brancaccio is currently a director of Alfacell Corporation as well as a director of Xenomics, Inc. and Callisto Pharmaceuticals, Inc.

Thomas H. Adams, Ph.D has served as a Director of our company since July 2008. Since June 2005, Dr. Adams has served as a director of IRIS International, Inc., a diagnostics company, and as Chief Technology Officer of IRIS since April 2006. Dr. Adams served as Chairman and Chief Executive Officer of Leucadia Technologies, a privately held medical-device company, from 1998 to April 2006, when Leucadia was acquired by IRIS. In 1989, Dr. Adams founded Genta, Inc., a publicly held biotechnology company in the field of antisense technology, and served as its Chief Executive Officer until 1997. Dr. Adams founded Gen-Probe, Inc. in 1984 and served as its Chief Executive Officer and Chairman until its acquisition by Chugai Biopharmaceuticals, Inc. in 1989. Before founding Gen-Probe, Dr. Adams held management positions at Technicon Instruments and the Hyland Division of Baxter Travenol. He has significant public-company experience serving as a director of Biosite Diagnostics, Inc., a publicly held medical research firm, from 1989 to 1998 and as a director of Invitrogen, a publicly held company that develops, manufactures and markets research tools and products, from 2000 to 2002. Dr. Adams currently serves as a director of La Jolla Pharmaceutical Co. (NASDAQ: LJPC), a publicly held company that develops and markets novel therapeutics for antibody-mediated autoimmune diseases. Dr. Adams holds a Ph.D. in Biochemistry from the University of California, at Riverside.

Christopher McGuigan, M.Sc., Ph.D. has served as a Director of our company since July 2008. Since 1995, Dr. McGuigan has been Professor, Welsh School of Pharmacy, Chairman of Departmental Research Committee and Director of Research, Head of Medicinal Chemistry. He is the Chemistry Editor for Antiviral Chemistry and Chemotherapy. Professor McGuigan is an Editorial Board Member

Table of Contents

for Journal of Medicinal Chemistry. He is currently the President and Board member of the International Society for Antiviral Research.

Compensation of Directors

Under the 2008 Equity Compensation Incentive Plan, upon election to the Board, each non-employee and non-consultant director receives a grant of stock options vesting over three years and having an exercise price equal to the fair market value of the common stock on the date of grant.

Non-employee and non-consultant directors also receive an annual cash fee of \$15,000 as well as cash compensation for serving on board committees. Chairpersons of the Audit Committee and Compensation Committee receive \$10,000 and \$7,000, respectively and members of such committees receive \$6,000 and \$4,000, respectively.

Audit Committee

The Audit Committee's responsibilities include: (i) reviewing the independence, qualifications, services, fees, and performance of the independent registered public accountants, (ii) appointing, replacing and discharging the independent auditors, (iii) pre-approving the professional services provided by the independent auditors, (iv) reviewing the scope of the annual audit and reports and recommendations submitted by the independent auditors, and (v) reviewing our financial reporting and accounting policies, including any significant changes, with management and the independent auditors. The Audit Committee also prepares the Audit Committee report that is required pursuant to the rules of the Securities Exchange Committee ("SEC").

The Audit Committee currently consists of John P. Brancaccio, chairman of the Audit Committee, Christopher McGuigan and Melvin K. Spigelman. Our board of directors has determined that each of Mr. Brancaccio, Mr. McGuigan and Mr. Spigelman is "independent" as that term is defined under applicable SEC rules. Mr. Brancaccio is our audit committee financial expert. The Board of Directors has adopted a written charter setting forth the authority and responsibilities of the Audit Committee.

Compensation Committee

The Compensation Committee has responsibility for assisting the Board of Directors in, among other things, evaluating and making recommendations regarding the compensation of the executive officers and directors of our company; assuring that the executive officers are compensated effectively in a manner consistent with our stated compensation strategy; producing an annual report on executive compensation in accordance with the rules and regulations promulgated by the SEC; periodically evaluating the terms and administration of our incentive plans and benefit programs and monitoring of compliance with the legal prohibition on loans to our directors and executive officers.

The Compensation Committee currently consists of Thomas H. Adams, chairman of the Compensation Committee, Melvin K. Spigelman and John P. Brancaccio. The Board of Directors has adopted a written charter setting forth the authority and responsibilities of the Compensation Committee.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Table of Contents

Scientific Advisory Board

Michael Camilleri, M.D., Ph.D. is a Professor of Physiology and Medicine at the Mayo Clinic, Minnesota, MN. He has contributed extensively to the fields of enteric neurosciences, motility, and inflammatory bowel diseases (IBD). Dr. Camilleri is on the editorial boards of a number of prestigious journals including Neurogastroenterology and Motility and American Neurogastroenterology. He has been President Elect of the American Neurogastroenterology and Motility Society 2007.

Lin Chang, M.D. is a Professor of Medicine in the Division of Digestive Diseases and Department of Medicine at the David Geffen School of Medicine at UCLA. She is the Co-Director and Head of the Clinical Program at the Center for Neurovisceral Sciences & Women's Health and Director of the Women's Digestive Health Center at UCLA. Dr. Chang is the Co-chair of the Rome III subcommittee on Gender, Age and Cultural Influences on Functional Bowel Disorders. She is currently serving on the FDA GI Advisory Committee.

Douglas Drossman, M.D. is a Professor of Medicine and Psychiatry, UNC School of Medicine, Division of Gastroenterology & Hepatology, and Co-Director of the UNC Center for Functional GI & Motility Disorders. He is President of the Rome Foundation and Scientific Director and member of the Board of the International Foundation for Functional GI Disorders (IFFGD). He has published extensively in the field of gastroenterology, including the textbook Functional GI Disorders (Rome I, Rome II and Rome III)

Scott Plevy, M.D. is an Associate Professor of Medicine, Microbiology and Immunology at the University of North Carolina School of Medicine, Division of Gastroenterology & Hepatology. He is the Core Director of the Immunotechnology Core in the Center for Gastrointestinal Biology and Disease as well as the Director of the University of North Carolina Federation of Clinical Immunology Societies. Dr. Plevy has contributed significantly to the medical literature on Crohn's disease and ulcerative colitis, and has been the principal investigator on numerous ulcerative colitis and Crohn's disease clinical trials.

Code of Business Conduct and Ethics

We have adopted a formal Code of Business Conduct and Ethics applicable to all Board members, executive officers and employees. A copy of our Code of Business Conduct and Ethics will be provided free of charge upon request to: Secretary, Synergy Pharmaceuticals, Inc. 420 Lexington Avenue, Suite 1609, New York, NY 10170.

ITEM 11. EXECUTIVE COMPENSATION.

Summary Compensation Table

The following table provides certain summary information concerning compensation awarded to, earned by or paid to our acting Chief Executive Officer, Principal Financial Officer and two other

Edgar Filing: Synergy Pharmaceuticals, Inc. - Form 10-K

Table of Contents

highest paid executive officers whose total annual salary and bonus exceeded \$100,000 (collectively, the "named executive officers") for fiscal year 2008.

Name & Principal Position(2)	Year	Salary	Bonus	Option Awards(1)	Total
Gary S. Jacob President, Acting Chief Executive Officer and Director	2008	\$ 103,125		\$ 102,006	\$ 205,131
Kunwar Shailubhai Chief Scientific Officer	2008	\$ 121,041	\$ 8,813	\$ 69,363	\$ 199,217

- (1) Amounts represent stock-based compensation expense for fiscal year 2008 for stock options granted in 2008 under SFAS 123R as discussed in Item 8. Financial Statements Note 3 *Summary of Significant Accounting Policies and New Accounting Pronouncements*.
- (2) On July 14, 2008, in conjunction with the Exchange Agreement, Pietro Gattini resigned as President, Secretary and Treasurer of the Company and the management team of Synergy-DE (Messrs. Jacob, Shailubhai and Denoyer) took over management responsibilities. Salary and bonus amounts presented for the above named executive officers are for the period July 14, 2008 through December 31, 2008. For a more detailed discussion of this exchange transaction, see Item 8. Financial Statements Note 4 *Acquisition and Stockholders' Equity (Deficit)*. Mr. Gattini's compensation during fiscal 2008, 2007 and 2006 did not exceed \$6,000 per annum.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information for the named executive officers regarding the number of shares subject to both exercisable and unexercisable stock options and restricted stock, as well as the exercise prices and expiration dates thereof, as of December 31, 2008.

Name	Number of Securities Underlying Unexercised Options	Option Exercise Price	Option Expiration Date
Stock Options			
Gary S. Jacob	949,922(1)	\$ 0.25	July 3, 2018
Kunwar Shailubhai	875,052(1)	\$ 0.25	July 3, 2018
Bernard F. Denoyer	150,034(1)	\$ 0.25	July 3, 2018
Restricted Stock			
Gary S. Jacob	374,939(2)		
Kunwar Shailubhai	124,882(2)		

- (1) The unexercised options vest ratably on July 3, 2009, 2010 and 2011.
- (2) The unexercised restricted stock vest ratably on July 3, 2009 and 2010.

Table of Contents**Director Compensation**

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2008 for services to our company.

Name	Fees Earned or Paid in		Option	Total
	Cash		Awards(1)	
Gabriele M. Cerrone(2)			\$ 100,431	\$ 100,431
Melvin K. Spigelman(3)	\$	30,000	\$ 12,265	\$ 42,265
John P. Brancaccio(4)	\$	14,500	\$ 12,238	\$ 26,738
Thomas H. Adams(5)	\$	11,000	\$ 12,238	\$ 23,238
Christopher McGuigan(6)	\$	10,500	\$ 12,238	\$ 22,738

- (1) Amounts represent the expensed fair value for fiscal year 2008 of stock options granted in 2008 under SFAS 123R as discussed in Item 8. Financial Statements Note *Summary of Significant Accounting Policies and New Accounting Pronouncements*.
- (2) Stock options for the purchase of an aggregate of 925,063 shares were outstanding as of December 31, 2008, with a grant date fair value of \$472,662.
- (3) 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 \$12,265 was recorded as stock-based compensation expense during the twelve months ended December 31, 2008.
- (4) Stock options for the purchase of an aggregate of 200,045 shares were outstanding as of December 31, 2008, with a grant date fair value of \$102,104.
- (5) Stock options for the purchase of an aggregate of 200,045 shares were outstanding as of December 31, 2008, with a grant date fair value of \$102,104.
- (6) Stock options for the purchase of an aggregate of 200,045 shares were outstanding as of December 31, 2008, with a grant date fair value of \$102,045.

Employment Agreements and Change in Control Agreements

On March 11, 2009, Dr. Gary Jacob entered into an employment agreement with us in which he agreed to serve as Acting Chief Executive Officer and President. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2011 and is automatically renewed for successive one year periods at the end of each term. Dr. Jacob's salary is \$300,000 per year of which 75% is to be allocated to us and 25% is to be allocated to Callisto. Dr. Jacob is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Such performance objectives and bonus criteria had not been determined as of December 31, 2008 and therefore not met or earned. Dr. Jacob is also eligible to receive a realization bonus in the event that we enter into an out-license agreement for our technology or engage in a merger or sale of substantially all our assets where the enterprise value equals or exceeds a minimum of \$150 million, \$200 million and \$250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, or the license fees we contract to receive equals or exceeds \$50 million. The realization bonus will be equal to the enterprise

Table of Contents

value in the case of a merger or sale or the sum of the license fees actually received multiplied by 0.5%.

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

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

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

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 \$12,265 was recorded as stock-based compensation expense during the twelve months ended December 31, 2008.

Table of Contents

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 discretionary performance bonus of up to 15% of his salary per year.

Stock Option Plans

We rely on incentive compensation in the form of stock options and restricted stock awards to retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options and restricted stock awards is designed to provide long-term incentives to directors, executive officers, employees and consultants, to encourage them to remain with us and to enable them to develop and maintain an ownership position in our common stock.

We award incentive compensation under the 2008 Equity Compensation Incentive Plan (the "Plan"). The maximum aggregate number of shares of common stock that may be (i) issued under the Plan pursuant to the exercise of stock options and (ii) issued pursuant to restricted stock awards is 6,500,000 shares of common stock. As of December 31, 2008 there were 4,080,016 stock options outstanding under the Plan and 874,760 restricted stock awards issued and outstanding, leaving 1,545,224 shares available for future issuances.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of April xx, 2009 by (i) each person know to beneficially own more than 5% of the outstanding common stock, (ii) each of our directors, (iii) the Named Executive Officers and (iv) all directors and executive officers as a group. Except as otherwise indicated, the persons named in the table have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable. Unless otherwise indicated, the address of each beneficial owner listed below is c/o Synergy Pharmaceuticals, Inc., 420 Lexington Avenue, Suite 1609, New York, N.Y. 10170. Percentage of beneficial ownership is based on 66,172,148 shares of our common stock outstanding as of April 14, 2009.

Name of Beneficial Owner	Number of Shares	Percentage
Executive officers and directors:		
Gabriele M. Cerrone	374,939(1)	*
Gary S. Jacob, Ph.D.	374,939(2)	*
Kunwar Shailubhai, Ph.D.	124,883(3)	*
Bernard Denoyer	0(4)	
John Brancaccio	0(5)	
Christopher McGuigan, M.Sc., Ph.D.	0(6)	
Thomas Adams, Ph.D.	0(7)	
Melvin K. Spigelman, M.D.	0(8)	
All Officers and Directors as a Group (8 persons)	874,761	1.3
5% or greater holders:		
Callisto Pharmaceuticals, Inc. 420 Lexington Avenue, Suite 1609 New York, NY 10170	44,590,000	67.4

*
less than 1%

Table of Contents

- (1) Consists of shares of common stock which are subject to a Repurchase Agreement with Synergy Pharmaceuticals Inc. dated July 3, 2008 pursuant to which such shares are subject to repurchase by us in the event the holder is no longer an employee, officer, director or consultant to us. 50% of the shares are released from the repurchase option after one year from the date of the Repurchase Agreement and the remaining 50% are released from the repurchase option after two years from the date of the Repurchase Agreement. Does not include options to purchase 925,063 shares of common stock which vest over a period of 3 years and by their terms are not exercisable within 60 days of April 15, 2009.
- (2) Consists of shares of common stock which are subject to a Repurchase Agreement with Synergy Pharmaceuticals Inc. dated July 3, 2008 pursuant to which such shares are subject to repurchase by us in the event the holder is no longer an employee, officer, director or consultant to us. 50% of the shares are released from the repurchase option after one year from the date of the Repurchase Agreement and the remaining 50% are released from the repurchase option after two years from the date of the Repurchase Agreement. Does not include options to purchase 949,922 shares of common stock which vest over a period of 3 years and by their terms are not exercisable within 60 days of April 15, 2009.
- (3) Consists of shares of common stock which are subject to a Repurchase Agreement with Synergy Pharmaceuticals Inc. dated July 3, 2008 pursuant to which such shares are subject to repurchase by us in the event the holder is no longer an employee, officer, director or consultant to us. 50% of the shares are released from the repurchase option after one year from the date of the Repurchase Agreement and the remaining 50% are released from the repurchase option after two years from the date of the Repurchase Agreement. Does not include options to purchase 875,052 shares of common stock which vest over a period of 3 years and by their terms are not exercisable within 60 days of April 15, 2009.
- (4) Does not include options to purchase 150,034 shares of common stock which vest over a period of 3 years and by their terms are not exercisable within 60 days of April 15, 2009.
- (5) Does not include options to purchase 200,045 shares of common stock which vest over a period of 3 years and by their terms are not exercisable within 60 days of April 15, 2009.
- (6) Does not include options to purchase 200,045 shares of common stock which vest over a period of 3 years and by their terms are not exercisable within 60 days of April 15, 2009.
- (7) Does not include options to purchase 200,045 shares of common stock which vest over a period of 3 years and by their terms are not exercisable within 60 days of April 15, 2009.
- (8) Does not include options to purchase 300,000 shares of common stock which vest over a period of 3 years and by their terms are not exercisable within 60 days of April 15, 2009.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting and investment power with respect to securities. Beneficial ownership determined in this manner may not constitute ownership of such securities for other purposes or indicate that such person has an economic interest in such securities.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

On March 11, 2009, Gabriele M. Cerrone, our Chairman of the Board, entered into a consulting agreement with us. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2011 and is automatically renewed for successive one year periods at the end of each term. Pursuant to the agreement, Mr. Cerrone's compensation is \$295,000 per year of which 75% is to be allocated to us and 25% is to be allocated to Callisto. Mr. Cerrone is eligible to receive a cash

Table of Contents

bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Such performance objectives and bonus criteria had not been determined as of December 31, 2008 and therefore not met or earned. Mr. Cerrone is also eligible to receive a realization bonus in the event that we enter into an out-license agreement for our technology or engage in a merger or sale of substantially all our assets where the enterprise value equals or exceeds a minimum of \$150 million, \$200 million and \$250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, and in the case of a financing transaction, we receive not less than \$20 million of gross proceeds; or the license fees we contract to receive equals or exceeds \$50 million. The realization bonus will be equal to the enterprise value in the case of a merger, sale or financing or the sum of the license fees actually received multiplied by 0.5%.

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

Conflicts of Interest

Gabriele Cerrone and his affiliates are subject to certain potential conflicts of interests. His consulting agreement expressly recognizes that he may provide consulting services to others. In addition, from time to time, he or his affiliates may be presented with business opportunities which could be suitable for our business and Mr. Cerrone is not subject to any restrictions with respect to other business activities, except to the extent such activities are in violation of our Code of Conduct and Ethics or violate general confidentiality provisions of his consulting agreement. In instances where there is potential conflict of interest or business opportunity, with respect to any officer or director, including Mr. Cerrone, our Audit Committee has both the authority and responsibility to review such matters and take appropriate actions.

Any future transactions with officers, directors or 5% stockholders will be on terms no less favorable to us than could be obtained from independent parties. Any affiliated transactions must be approved by a majority of our independent and disinterested directors who have access to our counsel or independent legal counsel at our expense.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Audit Fees

The aggregate fees billed and unbilled for the fiscal year ended December 31, 2008 for professional services rendered by our principal accountants for the audits of our annual financial statements, the review of our financial statements included in our quarterly reports on Form 10-Q and consultations and consents were approximately \$174,000. The aggregate fees billed and unbilled for the fiscal year ended December 31, 2007 for professional services rendered by our principal accountants at that time, Baum & Co., for the audits of our annual financial statements, the review of our financial statements included in our quarterly reports on Form 10-Q and consultations and consents were approximately \$9,000.

Table of Contents

Audit-Related Fees

There were no aggregate fees billed for the fiscal year ended December 31, 2008 and 2007 for assurance and related services rendered by our principal accountants related to the performance of the audit or review of our financial statements, specifically accounting research.

Tax and Other Fees

The aggregate fees billed for the fiscal year ended December 31, 2008 for professional services rendered by our principal accountants for tax related research and advice was \$15,000. There were no aggregate fees billed for the fiscal years ended December 31, 2007 as there were no tax related or other services rendered by our principal accountants in connection with the preparation of our federal and state tax returns.

Consistent with SEC policies and guidelines regarding audit independence, the Audit Committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our principal accountants on a case-by-case basis. Our Audit Committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. Our Audit Committee pre-approves these services by category and service. Our Audit Committee has pre-approved all of the services provided by our principal accountants.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) List of Documents Filed as a Part of This Report:

Index to Consolidated Financial Statements	F-1
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2008 and 2007	F-3
Consolidated Statement of Operations for each of the three years ended December 31, 2008, 2007 and 2006 and for the period November 15, 2005 (inception) to December 31, 2008	F-4
Consolidated Statement of Changes in Stockholder's Equity (Deficit) for the period November 15, 2005 (inception) to December 31, 2008	F-5
Consolidated Statements of Cash Flows for each of the three years ended December 31, 2008, 2007 and 2006 and for the period November 15, 2005 (inception) to December 31, 2008	F-6
Notes to Consolidated Financial Statements	F-7

(2) Index to Financial Statement Schedules:

All schedules have been omitted because the required information is included in the consolidated financial statements or the notes thereto, or is not applicable or required.

Edgar Filing: Synergy Pharmaceuticals, Inc. - Form 10-K

Table of Contents

(3) *Index to Exhibits*

Exhibit Index

The Exhibits listed below are identified by numbers corresponding to the Exhibit Table of Item 601 of Regulation S-K. The Exhibits designated by an asterisk (*) are management contracts or compensatory plans or arrangements required to be filed pursuant to Item 15.

Exhibit No.	Description
3.1	Articles of Incorporation (incorporated by reference to Exhibit 3.1 of Form SB-2 filed February 10, 2006).
3.1(a)	Articles of Amendment of Articles of Incorporation (incorporated by reference to Exhibit 3.1 of Form 8-K filed July 23, 2008).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of Form 8-K filed August 27, 2008)
4.1	2008 Equity Compensation Incentive Plan (incorporated by reference to Exhibit 4.1 of Form 8-K filed July 18, 2008)*
10.1	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.3 of Form 8-K filed July 18, 2008)*
10.2	Form of Executive Non-statutory Stock Option Agreement (incorporated by reference to Exhibit 10.4 Form 8-K filed July 18, 2008)*
10.3	Form of Non-Executive Non-statutory Stock Option Agreement (incorporated by reference to Exhibit 10.5 Form 8-K filed July 18, 2008)*
10.4	Executive Employment Agreement dated as of March 11, 2009 between Synergy Pharmaceuticals, Inc. and Gary S. Jacob*
10.5	Consulting Agreement dated as of March 11, 2009 between Synergy Pharmaceuticals, Inc. and Gabriele M. Cerrone*
14	Code of Business Conduct and Ethics
21	List of Subsidiaries
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

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

SYNERGY PHARMACEUTICALS, INC.

(A development stage company)

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
<u>Consolidated Balance Sheets as of December 31, 2008 and 2007</u>	<u>F-3</u>
<u>Consolidated Statements of Operations for the three years ended December 31, 2008, 2007 and 2006 and November 15, 2005 (inception) to December 31, 2008</u>	<u>F-4</u>
<u>Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period November 15, 2005 (Inception) to December 31, 2008</u>	<u>F-5</u>
<u>Consolidated Statements of Cash Flows for the three years ended December 31, 2008, 2007 and 2006, and for the period November 15, 2005 (Inception) to December 31, 2008</u>	<u>F-6</u>
<u>Notes to the Consolidated Financial Statements</u>	<u>F-7</u>
Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2008 and 2007 (unaudited) and for the period November 15, 2005 (Inception) to September 30, 2008 (unaudited)	

F-1

Table of Contents

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Synergy Pharmaceuticals, Inc.
New York, New York

We have audited the accompanying consolidated balance sheets of Synergy Pharmaceuticals, Inc. and Subsidiaries (a development stage company) (the "Company") as of December 31, 2008 and 2007, the related consolidated statements of operations and cash flows for each of the three years in the period ended December 31, 2008 and for the period from November 15, 2005 (inception) to December 31, 2008 and the related consolidated statement of stockholders' equity (deficit) for the period from November 15, 2005 (inception) to December 31, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Synergy Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 and for the period from November 15, 2005 (inception) to December 31, 2008, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO SEIDMAN, LLP

BDO Seidman, LLP
New York, New York
April 15, 2009

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2008	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 216,007	\$ 1,807
Note receivable from majority shareholder	690,333	
Total Current Assets	906,340	1,807
Property and equipment, net	11,701	2,658
Security deposits	4,400	
	\$ 922,441	\$ 4,465
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	\$ 2,000,220	\$ 5,000
Accrued expenses	78,013	6,233
Loans payable related parties		4,500
Total Current Liabilities	2,078,233	15,733
Stockholders' Deficit:		
Common stock, par value of \$.0001 Authorized 150,000,000 and 50,000,000 shares at December 31, 2008 and 2007, respectively; Outstanding 65,606,434 and 165,081,215 shares (restated for stock split) at December 31, 2008 and 2007, respectively	6,560	16,508
Preferred stock, Authorized 20,000,000 shares and 0 shares outstanding at December 31, 2008 and 2007, respectively		
Additional paid-in capital	30,633,089	12,485
Deficit accumulated during development stage	(31,795,441)	(40,261)
Total Stockholders' Deficit	(1,155,792)	(11,268)
	\$ 922,441	\$ 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 consolidated financial statements.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,			For the period
	2008	2007	2006	November 15, 2005 (inception) to December 31, 2008
Revenues	\$	\$	\$	\$
Costs and Expenses:				
Research and development	1,909,226			1,909,226
Purchased in-process research and development	28,156,502			28,156,502
General and administrative	1,662,885			1,662,885
Loss from Operations	(31,728,613)			(31,728,613)
Interest and investment income	4,993			4,993
Loss from Continuing Operations	(31,723,620)			(31,723,620)
Loss from discontinued operations	(31,560)	(20,043)	(20,202)	(71,821)
Net loss	\$ (31,755,180)	\$ (20,043)	\$ (20,202)	\$ (31,795,441)
<i>Weighted Average Common Shares Outstanding</i>				
Basic and Diluted (restated for stock split)	118,600,496	165,081,215	165,081,215	
<i>Net Loss per Common Share, Basic and Diluted</i>				
Net Loss from Continuing Operations	(0.27)	.00	.00	
Discontinued Operations:				
Loss from discontinued operations	0.00	.00	.00	
Net Loss per Common Share, Basic and Diluted	\$ (0.27)	\$.00	\$.00	

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

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

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

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,			Period from
	2008	2007	2006	November 15, 2005 (Inception) to December 31, 2008
Cash Flows From Operating Activities:				
Net loss	\$(31,755,180)	\$(20,043)	\$ (20,202)	\$ (31,795,441)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	494	672	56	1,222
Stock-based compensation expense	379,883			379,883
Purchased in-process research and development	28,156,502			28,156,502
Changes in operating assets and liabilities:				
Security deposit	(4,400)			(4,400)
Accounts payable and accrued expenses	1,343,957	6,233	5,000	1,355,190
Total Adjustments	29,876,436	6,905	5,056	29,888,397
Net Cash Used in Operating Activities	(1,878,744)	(13,138)	(15,146)	(1,907,044)
Cash Flows From Investing Activities:				
Net cash paid on Exchange Transaction	(155,326)			(155,326)
Loans from (to) related parties	(694,833)	4,500		(690,333)
Additions to property and equipment	(8,809)		(3,386)	(12,195)
Net Cash used in Investing Activities	(858,968)	4,500	(3,386)	(857,854)
Cash Flows From Financing Activities:				
Capital contribution by shareholders		8,893		8,893
Issuance of common stock				18,100
Proceeds of private placement of common stock	2,951,912			2,951,912
Proceeds from sale of unregistered common stock to founders				2,000
Net Cash Provided by Financing Activities	2,951,912	8,893		2,980,905
Net increase (decrease) in cash and cash equivalents	214,200	255	(18,532)	216,007
Cash and cash equivalents at beginning of period	1,807	1,552	20,084	
Cash and cash equivalents at end of period	\$ 216,007	\$ 1,807	\$ 1,552	\$ 216,007
Supplementary disclosure of cash flow information:				
Cash paid for taxes	\$ 632	\$	\$	\$ 632
Cash paid for interest	\$	\$	\$	\$
Value of common stock issued via Exchange Transaction	\$ 27,278,861	\$	\$	\$ 27,278,861

Edgar Filing: Synergy Pharmaceuticals, Inc. - Form 10-K

Cash flow activities for the twelve months ended December 31, 2007 and 2006 represent the discontinued operations of Synergy's pet food business.

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

F-6

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 4, *Acquisition and Stockholders' Equity (Deficit)* below.

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

On July 21, 2008, Pawfect amended its articles of incorporation to effect the actions necessary to complete the transactions contemplated by the Exchange Transaction and changed its name to Synergy Pharmaceuticals, Inc. ("Synergy" or "the Company").

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

On December 9, 2008, Synergy announced the completion of the Phase I clinical trial of SP-304 in healthy volunteers that was initiated in June 2008. This first study was a double-blind, placebo-controlled, randomized single, oral, ascending dose trial performed in 71 healthy male and female volunteers. The primary objective of the Phase I clinical trial with SP-304 was to characterize the safety, tolerability, pharmacokinetic and pharmacodynamic effects of the drug in healthy volunteers. The data from the trial were included in an abstract accepted for presentation at the Digestive Disease Week conference that meets in Chicago in June 2009. Synergy plans to initiate a Phase Ib repeated-oral-dose trial of SP-304 in chronic constipation patients in late 2009 or early 2010.

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

A practical, efficient and cost effective method for producing SP-304 on a commercial scale is currently being developed by 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.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Business Overview (Continued)

SP-304 has also undergone pre-clinical animal studies as a treatment for GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of North Carolina, Chapel Hill, NC. Recent results from his laboratory also showed that SP-304 was efficacious in animal models of ulcerative colitis ("UC"). A second generation GC-C receptor analog, SP-333, is now in pre-clinical development and Synergy plans to file an IND and initiate a Phase I clinical trial in UC patients in 2009.

2. Basis of Presentation and Going Concern

As discussed above, on July 14, 2008, Synergy completed the acquisition of Synergy-DE. The acquisition of Synergy-DE was treated as an asset acquisition, since Synergy-DE is a development stage company and does not have the necessary inputs and outputs to meet the definition of a business. The results of operations of Synergy-DE are included in the accompanying consolidated financial statements from July 14, 2008 to December 31, 2008. As a result of the acquisition of Synergy-DE on July 14, 2008, the Company decided to discontinue its pet food business and accordingly, amounts in the consolidated statements of operations and related notes for all historical periods have been restated to reflect these operations as discontinued. The 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 4, *Acquisition and Stockholders' Equity (Deficit)* below.

All intercompany balances and transactions have been eliminated. These consolidated financial statements include Synergy and subsidiaries: (1) Synergy-DE, (2) Synergy Advanced Pharmaceuticals, Inc. and (3) IgX, Ltd (Ireland inactive)). These consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission ("SEC") and United States generally accepted accounting principles ("GAAP"). In the opinion of management, the accompanying consolidated financial statements include all adjustments, which include only normal recurring adjustments, necessary to present fairly Synergy's financial information. These consolidated financial statements as of December 31, 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 December 31, 2008, Synergy had an accumulated deficit of \$31,795,441 resulting primarily from acquired in-process research and development valued at \$28,156,502 which was expensed upon the acquisition of Synergy on July 14, 2008. 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 \$1,878,744 for the twelve months ended December 31, 2008. As of December 31, 2008, Synergy has \$216,007 of cash and cash equivalents. During the twelve

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Basis of Presentation and Going Concern (Continued)

months ended December 31, 2008, Synergy incurred net losses from continuing operations of \$31,723,620, resulting primarily from acquired in-process research and development valued at \$28,156,502. 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 twelve months ended December 31, 2008 was \$2,951,912.

As of December 31, 2008 Synergy had a working capital deficit of \$1,171,893. On February 13, 2009 Synergy sold 285,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$200,000. Recently worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult to obtain additional equity or credit financing, when needed. Synergy has accordingly taken steps to conserve cash which include extending payment terms to our suppliers as well as substantial management and staff salary cuts and deferrals. These actions may not be sufficient to allow the Company time to raise additional capital. During the period February 14, 2009 through April 15, 2009 Synergy raised \$1,128,000 through private placements of its common stock (see Note 10. Subsequent Events.)

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 December 31, 2008 and December 31, 2007 on deposit with U.S. commercial banks, which at any point in time, may exceed federally insured limits.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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.

Property, equipment 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 and furniture and fixtures. Expenditures for repairs and maintenance are charged to operations as incurred. Synergy periodically evaluates whether current events or circumstances indicate that the carrying value of its depreciable assets may not be recoverable.

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 7, *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.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Loss Per Share

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, *Earnings per Share*, ("SFAS No. 128") for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares because shares issuable pursuant to the exercise of stock options would have been antidilutive. For the year ended December 31, 2008 the effect of 4,080,016 outstanding stock options and other common stock equivalents were excluded from the calculation of diluted loss per share because the effect was antidilutive. As of December 31, 2007 and 2006 there were no outstanding stock options and other common stock equivalents.

Recent Accounting Pronouncements

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

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 position, results of operations or cash flows.

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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 financial position, results of operations or cash flows.

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 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, results of operations or cash flows.

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, results of operations or cash flows.

In June 2007, the EITF of the FASB reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ("EITF No. 07-3"). EITF No. 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts would be recognized as an expense. The Company adopted EITF No. 07-3 on January 1, 2008 and the adoption did not have a material effect on our consolidated financial position, results of operations or cash flows.

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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 with respect to financial assets and financial liabilities and such adoption did not have a material effect on its consolidated financial position, results of operations or cash flows.

4. 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 \$73,088, yielding net proceeds of \$2,926,912. 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 5, *Accounting for Share-Based Payments* below 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 \$27,278,855 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 \$28,156,502 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 ("IPR&D") expense as of the date of the Exchange Transaction.

In addition to purchased IPR&D, the Company retained four full time employees and acquired 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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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 liabilities assumed 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	(27,278,861)
Total consideration paid by Pawfect to acquire Synergy-DE	\$ (28,156,508)

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

On July 21, 2008, Pawfect amended its articles of incorporation in the State of Florida 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.

5. 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 2008.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Accounting for Shared-Based Payments (Continued)

During 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:

	Year Ended December 31,			November 15, 2005
	2008	2007	2006	(inception) to December 31, 2008
Employees included in research and development	\$ 79,530	\$	\$	\$ 79,530
Employees included in general and administrative	112,728			112,728
Subtotal employee stock based compensation	192,258			192,258
Non-employees included in research and development				
Non-employees included in general and administrative	187,625			187,625
Subtotal non-employee stock based compensation	187,625			187,625
Total stock-based compensation expense	\$ 379,883	\$	\$	\$ 379,883

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 year ended December 31, 2008.

	Years Ended December 31,		
	2008	2007	2006
Risk-free interest rate	2.67% - 3.28%	N/A	N/A
Dividend yield		N/A	N/A
Expected volatility	90%	N/A	N/A
Expected term (in years)	6.0 yrs	N/A	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.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. 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.

The weighted-average fair value per share of all options granted during the twelve months ended December 31, 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 December 31, 2008 was \$1,290,122, to be recognized over a weighted-average remaining vesting period of approximately 2.5 years. The weighted-average remaining term of all options outstanding at December 31, 2008 was 9.5 years. There were no options outstanding at December 31, 2007 and 2006.

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 December 31, 2008
Balance outstanding, December 31, 2007				
Granted	4,084,988	\$ 0.25 - 0.95	\$ 0.29	
Exercised				
Forfeited	(4,972)	\$ 0.25	\$ 0.25	
Balance outstanding, December 31, 2008	4,080,016	\$ 0.25 - 0.95	\$ 0.29	\$ 8,933,935
Exercisable at December 31, 2008	74,871	\$ 0.25	\$ 0.25	\$ 166,962

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Accounting for Shared-Based Payments (Continued)

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

On July 3, 2008, 874,760 restricted stock units were granted by Synergy-DE and assumed by Synergy as part of the Exchange Transaction and are subject to a repurchase agreement, as defined. These restricted stock units were issued to certain officers and a consultant of Synergy. The fair value of each 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 twelve months ended December 31, 2008 was determined to be \$0.60. As of December 31, 2008 there were 874,760 restricted stock units outstanding, included in shares outstanding. The fair value of the 874,760 restricted stock units on the date of grant was \$524,856 of which \$97,602 was recorded as stock-based compensation expense during the twelve months ended December 31, 2008.

6. Income Taxes

At December 31, 2008, Synergy-DE has net operating loss carryforwards ("NOLs") aggregating approximately \$28 million, which, if not used, beginning in 2009 and expiring through 2028. The utilization of these NOLs is subject to limitations based on past and future changes in ownership of Synergy pursuant to Internal Revenue Code Section 382. The Company has determined that an ownership change occurred as of April 30, 2003 for 382 purposes. As a result of this ownership change, the ability of the Company to utilize its NOLs is limited. The Company has no other material deferred tax items. 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 substantial 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 December 31, 2008. As a result of this valuation allowance there are no income tax benefits reflected in the accompanying consolidated statements of operations to offset pre-tax losses.

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 Synergy did not have any unrecognized tax benefits. 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.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Income Taxes (Continued)

Synergy has no uncertain tax positions subject to examination by the relevant tax authorities as of December 31, 2008. 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 Synergy-DE shares, 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-free type "B" reorganization resulting in no gain or loss recognition to the Company, for federal tax purposes.

7. Commitments and Contingencies

Employment and Consulting Agreements

Gary S. Jacob, Ph.D.

On March 11, 2009, Dr. Gary S. Jacob entered into an employment agreement with Synergy in which he agreed to serve as Acting Chief Executive Officer and President. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2011 and is automatically renewed for successive one year periods at the end of each term. Dr. Jacob's salary is \$300,000 per year of which 75% is to be allocated to Synergy and 25% is to be allocated to Callisto. Dr. Jacob is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Such performance objectives and bonus criteria had not been determined as of December 31, 2008 and therefore not met or earned. Dr. Jacob is also eligible to receive a realization bonus in the event that we enter into an out-license agreement for our technology or engage in a merger or sale of substantially all our assets where the enterprise value equals or exceeds a minimum of \$150 million, \$200 million and \$250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, or the license fees we contract to receive equals or exceeds \$50 million. The realization bonus will be equal to the enterprise value in the case of a merger or sale or the sum of the license fees actually received multiplied by 0.5%.

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

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Commitments and Contingencies (Continued)

Gabriele M. Cerrone.

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

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

Melvin K. Spigelman, M.D.

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 \$12,265 was recorded as stock-based compensation expense during the twelve months ended December 31, 2008.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. 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 discretionary performance bonus of up to 15% of his salary per year.

Lease agreements

The Company occupies a small laboratory and several offices in the Bucks County Biotechnology Center, in Doylestown, Pennsylvania at the rate of \$2,200 per month under a two year lease which ends September 30, 2010. Synergy is provided the use of corporate office space on a month-to-month basis in New York, New York by Callisto. Synergy incurred approximately \$72,000 for this space during the twelve months ended December 31, 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 4, *Acquisition and Stockholders' Equity (Deficit)* above.

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 4, *Acquisition and Stockholders' Equity (Deficit)* above.

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 GI 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 on July 2, 2008 and all amounts due were paid.

Table of Contents

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. Property and Equipment

Equipment consists of laboratory, testing and computer equipment and furniture and fixtures consists of office furniture, both stated at cost, with useful lives ranging from 2-4 years, depreciated on a straight line basis. Depreciation expense for the years ended December 31, 2008, 2007, 2006 and from November 15, 2005 (inception) to December 31, 2008 were \$494, \$672, \$56, and \$1,222, respectively.

	December 31, 2008	December 31, 2007
Furniture and fixtures	\$ 38,343	\$
Machinery and equipment	12,195	3,386
Less accumulated depreciation	(38,837)	(728)
Property and equipment, net	\$ 11,701	\$ 2,658

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 December 31, 2008.

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 4, *Acquisition and Stockholders' Equity (Deficit)* above.

On December 26, 2008 Synergy advanced Callisto \$650,000 under a 12 month unsecured promissory note which balance is included in current assets in the balance sheet caption entitled "Note receivable from majority shareholder". The note bears interest at 6% per annum.

10. Subsequent Events

On February 13, 2009, Synergy sold 285,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$200,000. There were no warrants issued or finder's fees associated with this transaction. On April 2, 2009 Synergy sold 100,000 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$70,000. On April 13, 2009 Synergy sold 180,000 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$126,000. On April 15, 2009 Synergy sold 1,045,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$732,000.

Edgar Filing: Synergy Pharmaceuticals, Inc. - Form 10-K

Table of Contents

Exhibit Index

The Exhibits listed below are identified by numbers corresponding to the Exhibit Table of Item 601 of Regulation S-K. The Exhibits designated by an asterisk (*) are management contracts or compensatory plans or arrangements required to be filed pursuant to Item 15.

Exhibit No.	Description
3.1	Articles of Incorporation (incorporated by reference to Exhibit 3.1 of Form SB-2 filed February 10, 2006).
3.1 ^(a)	Articles of Amendment of Articles of Incorporation (incorporated by reference to Exhibit 3.1 of Form 8-K filed July 23, 2008).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of Form 8-K filed August 27, 2008)
4.1	2008 Equity Compensation Incentive Plan (incorporated by reference to Exhibit 4.1 of Form 8-K filed July 18, 2008)*
10.1	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.3 of Form 8-K filed July 18, 2008)*
10.2	Form of Executive Non-statutory Stock Option Agreement (incorporated by reference to Exhibit 10.4 Form 8-K filed July 18, 2008)*
10.3	Form of Non-Executive Non-statutory Stock Option Agreement (incorporated by reference to Exhibit 10.5 Form 8-K filed July 18, 2008)*
10.4	Executive Employment Agreement dated as of March 11, 2009 between Synergy Pharmaceuticals, Inc. and Gary S. Jacob*
10.5	Consulting Agreement dated as of March 11, 2009 between Synergy Pharmaceuticals, Inc. and Gabriele M. Cerrone*
14	Code of Business Conduct and Ethics
21	List of Subsidiaries
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