CALLISTO PHARMACEUTICALS INC
Form 10-K
April 15, 2009

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark one)

ý **ANNUAL REPORT under SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED: DECEMBER 31, 2008

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

For the transition period from to
Commission File Number: 001-32325

CALLISTO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**12-3894575**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

420 Lexington Avenue, Suite 1609, New York, New York 10170
(Address of principal executive offices) (Zip Code)

(212) 297-0010
(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: **Common stock, $0.0001 par value**

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

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 o No ý

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 ý No o

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. ý

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $11,804,540 on June 30, 2008 (based on $0.25 per share, the closing price on the American Stock Exchange that day).

As of April 14, 2009 the registrant had a total of 50,747,661 shares of Common Stock outstanding.

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

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PART I

This Report on Form 10-K for Callisto 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 annual report on 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 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

Callisto Pharmaceuticals, Inc. (which may be referred to as "Callisto", "the Company", "we" or "us") was incorporated under the laws of the State of Delaware in May 2003. We operate through two subsidiary companies: Synergy Pharmaceuticals Inc. and Callisto Research Labs, LLC, and we own two inactive subsidiaries, IgX, Ltd (Ireland) and Callisto Pharma, GmbH (Germany). Our principal offices are located at 420 Lexington Avenue, Suite 1609, New York, NY 10170.

We are a development stage biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal ("GI") disorders and diseases, rheumatoid arthritis (RA), neuroendocrine cancer (including advanced carcinoid cancer),and acute leukemia. Our lead drug candidates 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"), currently being developed by our majority-owned subsidiary, Synergy Pharmaceuticals, Inc. ("Synergy").

(2) Atiprimod, an orally administered drug with antiproliferative, anti-inflammatory and antiangiogenic activity.

(3) L-Annamycin, a novel compound from the anthracycline family of proven anti-cancer drugs, which has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart.

HISTORY

In March 2002, Callisto Pharmaceuticals, Inc. ("Old Callisto"), a non-public company, purchased 99.7% of the outstanding common shares of Webtronics, Inc., ("Webtronics") a public company for $400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations at December 31, 2002.

On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., a wholly-owned subsidiary of Webtronics merged

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into Synergy Pharmaceuticals, Inc. ("Synergy-DE") and Callisto Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Old Callisto (collectively, the "Merger"). As a result of the Merger, Old Callisto and Synergy-DE became wholly-owned subsidiaries of Webtronics. In connection with the Merger, Webtronics issued 17,318,994 shares of its common stock in exchange for outstanding Old Callisto common stock and an additional 4,395,684 shares in exchange for outstanding Synergy-DE common stock. In May 2003, Old Callisto changed its name to Callisto Research Labs, LLC ("Callisto Research") and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware. Subsequently, 171,818 shares of common stock issued to former Synergy-DE shareholders were returned to us under the terms of certain indemnification agreements.

From inception through December 31, 2008, we have sustained cumulative net losses available to common stockholders of $90,987,267. Our losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, stock-based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees, as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception through December 31, 2008, we have not generated any revenue from operations, expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products, and 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.

Recent Developments

On January 27, 2009, we announced that we were focusing all further development of Atiprimod towards the treatment of RA. We recognized that although the ongoing Phase II clinical trial of Atiprimod in advanced carcinoid cancer gave encouraging results, the data were not sufficiently demonstrative to warrant further development of Atiprimod in this indication. We announced, instead, our intention that based on Atiprimod's demonstrated favorable clinical safety profile, robustly supported by earlier studies of Atiprimod in RA patients, as well as by the recent oncology trials in advanced carcinoid cancer patients, where the drug was dosed at levels and frequencies considerably higher than anticipated for use in RA, we believe that Atiprimod holds significant promise as a new class of orally-administered, disease-modifying agent in RA.

On July 14, 2008, we entered into an Exchange Agreement dated July 11, 2008 ("Exchange Agreement"), as amended and effective on July 14, 2008, with Pawfect Foods, Inc. ("Pawfect"), Synergy-DE and other holders of Synergy-DE common stock. According to the terms of the Exchange Agreement, Pawfect acquired 100% of the common stock of Synergy-DE, from us and the other holders of Synergy-DE, in exchange for 45,464,760 shares of Pawfect's common stock representing approximately 70% of Pawfect's outstanding common stock (the "Exchange Transaction"). We received 44,590,000 of the 45,464,760 shares of Pawfect's common stock exchanged for our ownership of Synergy-DE, and we are now the holder of 68% of Pawfect's outstanding common stock. The remaining 874,760 shares of Pawfect common stock exchanged for ownership of Synergy-DE were issued to certain executive officers of Synergy-DE who received their shares pursuant to a Repurchase Agreement with Synergy-DE dated July 3, 2008 and assumed by Pawfect. The fair value of each of the 874,760 shares was estimated on the grant date to be $0.60, which was based on the price paid by

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shareholders participating in Synergy's July 14, 2008 private placement. In connection with the Exchange Transaction Pawfect received $3,025,000 less transaction costs of $73,087, yielding net proceeds of $2,951,913 from two private placements, which we have recorded as an increase in additional paid-in capital.

Pawfect was a development stage company selling pet food products utilizing the internet, with immaterial operations at the date of the Exchange Agreement. On July 14, 2008, Pawfect discontinued its pet food business to focus all resources on continuing the development of drugs to treat GI disorders and diseases acquired in connection with the Exchange Agreement. 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 Agreement and changed its name to Synergy Pharmaceuticals, Inc. ("Synergy"). Synergy is now traded on the Over The Counter Bulletin Board under the symbol SGYP.OB.

On April 7, 2008, we received notice from the staff of the American Stock Exchange ("AMEX") of its intent to strike our common stock from the AMEX by filing a delisting application with the SEC for failure to regain compliance with Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide and falling out of compliance with Section 1003(a)(iii) of the Company Guide with shareholders' equity of less than $6,000,000 and losses from continuing operations and/or net losses in four of our five most recent fiscal years. On July 14, 2008, our common stock was delisted from the AMEX and currently trades on the Over the Counter Bulletin Board under the symbol CLSP.OB.

PRODUCTS

SP-304 TO TREAT GI 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 CFTR within the epithelial cells. Activation of CFTR leads to secretion of salts and water into the intestine, resulting

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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, Synergy 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, 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. The data are under embargo until release at the conference. Synergy plans 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 ulcerative colitis ("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

Synergy's 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, Synergy completed a Phase I clinical trial in volunteers for SP-304. Synergy is now planning to open a Phase Ib repeated-dose trial of SP-304 for CC patients during in late 2009 or early 2010. Synergy also plans 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 Synergy has 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.

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.

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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.

ATIPRIMOD

On August 28, 2002, and as amended on May 23, 2003, Synergy entered into a worldwide license agreement (the "Original License") with AnorMED Inc. ("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 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, we and Synergy entered into an Amended and Restated License Agreement with AnorMED Corporation ("AnorMED"), a wholly-owned subsidiary of Genzyme Corporation ("Genzyme"), pursuant to which the parties 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, we agreed to pay upfront fees which were recorded as a liability and expensed on December 31, 2007. As of December 18, 2008, $650,000 of these upfront fees remained due and payable.

On December 19, 2008, we entered into a Technology Assignment Agreement (the "Agreement") with AnorMED pursuant to which AnorMED transferred and assigned to us all of AnorMED's right, title and interest in and to all patents and patent applications with respect to Atiprimod in addition to all trade secrets, technical reports and data concerning Atiprimod and any analogs or derivatives in return for a cash payment of $650,000, which payment settled the upfront fees owed from December 31, 2007 Amended and Restated License Agreement. In addition the Agreement specified that the Amended and Restated License Agreement between us and AnorMED dated December 31, 2007, with respect to which AnorMED licensed to us certain patent rights and technology related to Atiprimod, was terminated with no additional amounts due.

Atiprimod is one of a class of compounds known as azaspiranes and was originally developed as a potential treatment for RA based on encouraging data from a number of animal models of arthritis and autoimmune indications. The development of this drug originated with a partnership between AnorMED and Smith Kline Beecham ("SKB") that led to the successful filing of an IND, and completion of three Phase I clinical trials involving a total of 63 patients. The drug successfully completed both single and multiple dose Phase I clinical trials in patients with RA. Both trials evaluated the safety and pharmacokinetics (how the body takes up and eliminates drugs) of Atiprimod and showed that the drug is well tolerated. In the third Phase I clinical trial, the drug was found to be well tolerated in an open label extension study performed with 43 patients from the second two studies, with patients on the drug for as long as one year.

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Preclinical Studies

Atiprimod's specific ability to lower the level of key cell growth factors, known to play an important role in the development of multiple myeloma, is the basis for its potential use as a drug to treat this disease. Atiprimod was previously shown to inhibit the production of the pro-inflammatory mediators IL-6 and TNF (alpha) in a number of animal models of inflammation and autoimmune disease. Atiprimod was also demonstrated using in vitro models of tumor cell growth to inhibit proliferation of a number of human multiple myeloma cell lines. Characterization of the mechanism of Atiprimod's antiproliferative activity in a series of experiments showed that the drug works by inducing apoptosis (programmed cell death) in myeloma cells. In a second series of experiments performed with Atiprimod on co-cultures composed of multiple myeloma cells plus bone marrow stromal cells (used to simulate the human disease), the drug was found to have a profound effect on secretion of the angiogenic (blood vessel related) growth factor VEGF. A separate set of experiments also suggest an additional explanation for the disease-modifying activity of Atiprimod originally observed in chemically-induced arthritic-rat animal studies, and provide a further rationale for the application of this drug to treat multiple myeloma. Using a bone resorption assay (bone degradation experiment) to measure the effect of drug on osteoclast-mediated bone resorption, Atiprimod demonstrated a profound effect on osteoclast, or cells that break down bone, function. The drug appears to be selectively toxic for activated osteoclasts, displaying a negligible effect on bone marrow stromal cells.

Completed Clinical Studies

Atiprimod successfully completed single and multiple dose Phase I clinical trials in patients with RA. In the initial Phase I study, 28 patients were given single escalating doses of drug (0.002 - 1.0 mg/kg), with a four month follow-up. Atiprimod was well tolerated, displaying no clinically relevant changes in any laboratory parameters. In particular, liver function tests remained in the normal range. The second Phase I study involved a 28-day multiple-dose-rising study in 35 RA patients. The study evaluated the effect of food on bioavailability, or the concentration of drug in the body, as well as the safety and pharmacokinetics of repeat dosing. Dosages included 0.1, 1.0, 5.0, and 10 mg/day plus a 14-day cohort at 30 mg/day, with four month follow-up. All doses were well tolerated and clinical tests were unremarkable. Significantly, reductions in tender and swollen joint counts were noted in a number of subjects during the course of the dosing period. Individuals from the two Phase I safety studies were also involved in a Phase I open-label extension trial at five mg/day dosage. Forty-three patients entered the study and remained on the drug as long as 12 months. Clinical laboratory results for all patients were unremarkable, in particular liver enzyme levels remained within the normal range in all patients throughout the study period.

Development Strategy

On May 26, 2004, Atiprimod commenced a Phase I/IIa clinical trial in relapsed or refractory multiple myeloma patients. These are patients that have a re-occurrence of active disease, and no longer respond to approved therapies. The Phase I/IIa clinical trial is an open label study, with the primary objective of assessing safety of drug and identifying the maximum tolerated dose. The secondary objectives are to measure the pharmacokinetics, evaluate the response in patients with refractory disease and to identify possible surrogate responses to the drug to better determine the mechanism of drug action. In December 2005, we announced interim results from this trial performed in relapsed or refractory multiple myeloma patients which consisted of 15 patients treated with Atiprimod, including 3 patients at the highest dose level of 180 mg/day. In 2006, we amended this protocol to continue the trial at higher dose levels. The amended trial included the combination of Atiprimod with a drug called ursodiol to enable patients to be dosed at levels of Atiprimod higher than 180 mg/day. In October, 2007 we met the primary objective and reached the MTD in the

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Atiprimod + ursodiol arm. However, we do not intend to pursue Atiprimod as a single agent in multiple myeloma.

On March 15, 2005, we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The trial is entitled: "An Open Label Study of the Safety and Efficacy of Atiprimod Treatment for Patients with Advanced Cancer". The primary objective is to assess the safety and determine the maximum tolerated dose of Atiprimod in advanced cancer patients. The secondary objectives are to measure the pharmacokinetics of Atiprimod and evaluate the response in a variety of relapsed solid tumors and hematological malignancies. This study was conducted at the University of Texas M.D. Anderson Cancer Center, and was closed to enrollment in November, 2006. This trial established the potential of Atiprimod to treat advanced carcinoid cancer patients based on encouraging clinical results in a cohort of 5 advanced carcinoid cancer patients within this study.

On November 7, 2006, we announced the initiation of a multi-center open-label Phase II clinical trial of Atiprimod for low-to-intermediate grade neuroendocrine cancers, primarily in advanced carcinoid cancer patients. This trial is based on earlier encouraging clinical results from a Phase I trial of Atiprimod in advanced cancer patients that showed stable disease and disease-related symptom relief in patients with advanced carcinoid cancer. On September 20, 2007, we announced that we had completed enrollment of the 40-patient Phase II clinical trial, and that patients had been on drug as along as 11 months.

In October 2007, we announced the opening of a Phase II extension trial to permit those patients who had successfully completed a full year in the Phase II advanced carcinoid cancer trial, which only permitted dosing for up to one year, to continue to receive Atiprimod therapy. We also have indicated that we are no longer dosing patients in the Phase I clinical trial of Atiprimod in relapsed or refractory multiple myeloma and have no plans at present to continue evaluating the drug in this disease indication, instead focusing on the clinical development of Atiprimod to treat advanced carcinoid cancer.

On April 14, 2008, we announced that interim data from the company's ongoing open-label Phase II clinical trial of Atiprimod in advanced carcinoid cancer was to be presented at the 44th annual meeting of the American Society of Clinical Oncology (ASCO), which was held in Chicago May 30-June 3, 2008. The study was an open-label Phase II trial designed to evaluate the anti-tumor efficacy, effect on symptoms, and safety and tolerability of Atiprimod in patients with low to intermediate grade neuroendocrine carcinoma (also called carcinoid cancer) who have metastatic or unresectable cancer and who have progression of their disease despite standard therapy (octreotide and others). Forty-six patients had been enrolled in the study at the time of the announcement, all of whom had progressing disease in the six months preceding enrollment.

On May 16, 2008, we announced interim data from the company's ongoing open-label Phase II clinical trial of Atiprimod to treat low to intermediate grade neuroendocrine carcinoma (advanced carcinoid cancer). Overall, the interim results suggested that Atiprimod is an active and well tolerated drug in the treatment of carcinoid cancer. In this interim analysis, 25 of 46 enrolled patients had sufficient data available for evaluation. The median follow up of the patients was 6 months (range 2 to over 12 months). All patients enrolled in this study had evidence of progressing disease in the 6 months preceding enrollment. Of the evaluable patients, 92% had stable disease as best response per standard RECIST criteria, with a median duration of 6 months. Actuarial progression free survival at 6 months was 76% and at 12 months it was 50%. There were no objective RECIST responses for tumor regression in the analyzed cohort. At the time of the announcement, 7 patients had completed all 12 planned cycles of Atiprimod therapy with stable disease and had entered an extension trial to continue treatment. In this slow growing cancer, Atiprimod appeared to show an ability to stabilize disease progression and to reduce the symptoms of this disease, with a side effect profile that was generally well tolerated, with reversible increases in liver transaminases as the most notable adverse event.

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On January 27, 2009, we announced that we were focusing all further development of Atiprimod towards the treatment of RA. We recognized that although the ongoing Phase II clinical trial of Atiprimod in advanced carcinoid cancer gave encouraging results, the data were not sufficiently demonstrative to warrant further development of Atiprimod in this indication. We announced, instead, our intention that based on Atiprimod's demonstrated favorable clinical safety profile, robustly supported by earlier studies of Atiprimod in RA patients, as well as by the recent oncology trials in advanced carcinoid cancer patients, where the drug was dosed at levels and frequencies considerably higher than anticipated for use in RA, we believe that Atiprimod holds significant promise as a new class of orally-administered, disease-modifying agent in RA.

Manufacturing of Atiprimod

A practical, efficient and cost effective method for producing Atiprimod on a commercial scale was originally developed by SKB. In the course of this work, a new dimaleate salt form was developed. A portion of the 7 kilos of Atiprimod drug substance, available from SKB, was used as the source for generating the Atiprimod dimaleate drug product presently being used in the Phase I/IIa clinical study. Several lots of drug substance were re-qualified to meet current FDA approved release specifications. The full package of fully validated analytical methods developed by SKB was transferred to a contract research organization used by us to perform all analytical tests. One large-scale GMP production run of Atiprimod dimaleate led to the successful release of 10 Kg of material available for future Phase II clinical studies.

Orphan Drug Status of Atiprimod

On January 6, 2004, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of multiple myeloma. On September 26, 2006, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of carcinoid tumors. The FDA grants orphan drug status for drug candidates that are intended to treat rare life-threatening diseases that, at the time of application, affect no more than 200,000 patients in the United States. The drug must have the ability to provide significant patient benefit over currently available treatment or fill an unmet medical need. Orphan drug designation entitles us to seven years of market exclusivity in the United States of America, and ten years of market exclusivity in Europe, upon FDA marketing approval, provided that we continue to meet certain conditions established by the FDA. Once the FDA grants marketing approval of a new drug, the FDA will not accept or approve other applications to market the same medicinal product for the same therapeutic indication. Other incentives provided by orphan status include certain tax benefits, eligibility for research grants and protocol assistance. Protocol assistance includes regulatory assistance and possible exemptions or reductions of certain regulatory fees.

L-ANNAMYCIN

On August 12, 2004 we entered into a worldwide exclusive license agreement with The University of Texas M.D. Anderson Cancer Center to develop and commercially exploit the L-Annamycin patent rights. L-Annamycin, an anthracycline drug for leukemia therapy, has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced toxicity.

Preclinical Studies

Nonclinical studies have shown that Annamycin delivered as a liposomal preparation (L-Annamycin) is effective against several different in vivo tumor models (animal experiments), including human tumors which are resistant to other chemotherapy drugs, grafted into animals. Additionally, results from in vitro studies (cell culture experiments) indicate that L-Annamycin and free

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Annamycin were able to partially overcome tumor resistance to chemotherapy drugs in several tumor cell lines that were resistant to other drugs such as doxorubicin. In nonclinical toxicity studies, myelosuppression (suppression of the body's immune response) was noted in mice at a single intravenous dose of 15.7 mg/kg L-Annamycin. With weekly intravenous doses of 5.2 mg/kg L-Annamycin for 6 weeks, or 3.1 and 4.2 mg/kg L-Annamycin for 10 weeks in mice, the cardiotoxicity (toxicity to heart tissue) of L-Annamycin was substantially less than an equivalent dose of doxorubicin. In dogs, a single 15-minute intravenous infusion of up to 1.42 mg/kg L-Annamycin was well tolerated, with no clinically significant adverse effects, hematological or chemical changes, or pathological changes.

Completed Clinical Studies

L-Annamycin was evaluated previously by Aronex Pharmaceuticals, Inc. in 3 clinical trials: 1) a Phase I clinical trial in 36 patients with relapsed solid tumors, 2) a Phase II clinical trial in 13 patients with doxorubicin-resistant breast cancer, and 3) a Phase I/IIa trial in 20 patients with relapsed/refractory acute myelogenous leukemia (AML) and acute lymphocytic leukemia (ALL). In the initial Phase I study, L-Annamycin was administered by a single 1- to 2-h intravenous infusion at 3-week intervals. Thirty-six patients with relapsed solid tumors were treated and 109 treatment courses were administered at doses ranging from 3 to 240 mg/m2. No cardiotoxicity was seen on biopsy of heart tissue of four patients studied. The maximum tolerated dose (MTD) for L-Annamycin in solid tumor patients was found to be 190 mg/m2. A second Phase II study of L-Annamycin was performed in 13 women with doxorubicin-resistant breast cancer. The median number of prior chemotherapy regimes was two, and six patients had two or more organ sites of involvement. L-Annamycin was administered at 190-250 mg/m2 as a single i.v. infusion over 1-2 h every 3 weeks. Of the 13 patients, 12 had clear deterioration and new tumor growth after one or two courses.

The potential of a less cardiotoxic drug that was active against multi-drug resistant tumors led to a third trial in relapsed leukemia patients (both AML and ALL). The trial involved 20 patients with relapsed/refractory AML (n=17) or ALL (n=3). The conclusions drawn from the trial were that L-Annamycin was safe, well tolerated and showed potential clinical activity in patients with acute leukemias, and that further evaluation of this novel anthracycline in patients with hematopoietic, or blood borne, malignancies was clearly warranted.

Development Strategy

We began a Phase I clinical trial at The University of Texas M.D. Anderson Cancer Center in adult relapsed or refractory ALL patients on December 1, 2005. Additional sites enrolled in this study include the Roswell Park Cancer Institute (Buffalo, NY) and the Montefiore Medical Center (New York, NY). The single-arm, open-label L-Annamycin trial was designed to enroll patients in a dose escalation Phase I portion followed by 10 patients at a final fixed dose in the Phase II portion once the maximum tolerated dose (MTD) was determined. A major goal of the trial was to confirm the MTD reported from the previous sponsor for use in adult ALL patients. The clinical data from our studies indicated that the MTD reported by the previous sponsor which indicated that patients could be dosed as high as 280 mg/m2/day for 3 consecutive days in ALL patients was too high. We utilized a uniform validated reconstitution method that we believe delivers a more uniform liposomal drug product when infused into patients. This infusion methodology was utilized across all study sites. We established an MTD of 150 mg/m2/day, given for 3 consecutive days, in the adult trial and finished dosing of 10 patients at this MTD value. The clinical data on these patients, however, did not support further clinical evaluation of L-Annamycin as a single agent to treat relapsed or refractory adult acute leukemia patients, and we do not plan any further trial with L-Annamycin.

In February, 2007, we opened a Phase I trial of L-Annamycin in pediatric relapsed or refractory ALL or AML patients. Based on the information from the ongoing adult trial, we initiated this trial at

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130 mg/m2/day given for three consecutive days. The trial was a multi-center, open-label, single-agent, dose-escalation study that utilized four clinical sites in the U.S. Due to the low number of patients with this disease, we were only able to enroll 3 patients in total, all at 130 mg/m2/day, and never achieved an MTD in children. Due to poor enrollment plus the decision to suspend further development of L-Annamycin in adults, we have suspended any further work on L-Annamycin in acute leukemia at this time.

Manufacturing of Annamycin

An improved manufacturing method for Annamycin was developed at Antibioticos S.p.A., our sole commercial supplier of GMP ("Good Manufacturing Practice") drug substance. Our agreement with Antibioticos S.p.A provided us access to up to 400 grams of GMP drug substance (Annamycin) for our L-Annamycin clinical trials.

Orphan Drug Status of L-Annamycin

On June 24, 2005, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to L-Annamycin for the treatment of acute lymphoblastic leukemia. On June 28, 2005, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to L-Annamycin for the treatment of acute myeloid leukemia.

DEGRASYNS

On January 10, 2006, we entered into a license agreement with the University of Texas M.D. Anderson Cancer Center whereby we were granted the exclusive right to manufacture, have manufactured, use, import, offer to sell and/or sell anti-cancer compounds called tyrphostins (renamed Degrasyns). Degrasyns are a second-generation class of tyrphostins developed by scientists at the University of Texas M.D. Anderson Cancer Center that have a novel anti-cancer mechanism-of-action that centers on their ability to selectively degrade key proteins that are involved in tumor cell proliferation and survival. The intention was to work with key scientists at the University of Texas M.D. Anderson Cancer Center to bring forward a pre-clinical candidate for development in the clinic. All in-house work on this program has now been discontinued.

SUPERANTIGEN-BASED BIOTERORRISM DEFENSE

On August 20, 1996, we entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University ("Rockefeller") licensed patents covering peptides and antibodies useful in treating toxic shock syndrome and septic shock. In addition, on July 2, 2001, we entered into a license agreement for two additional patents related to the regulation of exoproteins in staphylococcus aureus. On November 14, 2007, we gave 90-day notice to Rockefeller University of termination of the August, 1996 and July, 2001 license agreements, terminating these agreements effective February 14, 2008.

On April 1, 2005 we were awarded a two-year $885,641 biodefense partnership grant from the National Institute of Allergy and Infectious Diseases ("NIAID") to develop a monoclonal antibody and vaccine against bacterial superantigen toxins. Funding for this program has been extended through March 31, 2008 and as of December 31, 2007 and 2008 we had approximately $34,000 and $0 of funding remaining, respectively. Because the bioterrorism program is not a core activity of ours, we terminated in-house work on this program upon expiration of the research grant funding on March 31, 2008.

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

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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.

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 continuously a product's usage and effects. Product approvals may be withdrawn if compliance with

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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 focusing on GI include major pharmaceutical and biotechnology companies such as Ironwood (Microbia), Sucampo/Takeda and Novartis. Our competitors focusing on hematological oncology include major pharmaceutical and biotechnology companies such as Microbia Inc., Hana Biosciences Inc., SGX Pharmaceuticals, Inc., Sunesis Pharmaceuticals, Inc. and Vion Pharmaceuticals, Inc. 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) royalty and license fee payments, (vii) legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products, (viii) clinical drug substance and (ix) acquired in-process research and development. 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 $5,449,721 for the twelve months ended December 31, 2008, compared to $6,507,978 and $6,134,704 for the twelve months ended December 31, 2007 and 2006, respectively.

On April 1, 2005 we were awarded an $885,641 biodefense partnership grant from the NIAID to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over a two year period. During the twelve months ended December 31, 2008, 2007 and 2006 we received $30,000, $260,853 and $352,649, respectively, which has been reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grant". Funding for this program had been extended through April 2008 and as of December 31, 2008 we had zero funding remaining. Because the bioterrorism program is not a core activity of ours, we terminated in-house work on this program upon expiration of the research grant in April 2008.

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. We have obtained licenses from various parties that give us rights to technologies that we deem to be necessary or desirable for our research and development. These licenses (both exclusive and non-exclusive) may require us to pay royalties to the parties in addition to upfront or milestone payments, and to expend certain minimum resources to develop these technologies. 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

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country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

As of December 31, 2008, we are the assignee or exclusive licensee of 7 pending patent applications and 15 issued patents in the United States, and currently we have approximately 150 issued or 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 composition-of-matter and use patent on SP-304 issued on May 9, 2006 expires in 2023. Our composition-of-matter patents for L-Annamycin and Atiprimod expire in 2017 and 2016, respectively. Our formulation patents for L-Annamycin and Atiprimod dimaleate salt both expire in 2016.

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 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.

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LICENSE AGREEMENTS

On January 10, 2006, we entered into a Patent and Technology License Agreement with The University of Texas M.D. Anderson Cancer Center. Pursuant to the license agreement, we were granted the exclusive right to manufacture, have manufactured, use, import, offer to sell and/or sell anti-cancer compounds called tyrphostins (renamed Degrasyns). We paid a nonrefundable license fee of $200,000 upon execution of this agreement and we are obligated to pay annual license maintenance fees to The University of Texas M.D. Anderson Cancer Center. We are also obligated under this agreement to pay for legal fees and expenses associated with establishing and protecting the patent rights worldwide.

We also agreed to pay The University of Texas M.D. Anderson Cancer Center royalties based on net sales from any licensed products, plus aggregate milestone payments of up to $1,750,000 based upon achieving certain regulatory submissions and approvals. The term of the agreement is from January 10, 2006 until the end of the term for which the patent rights associated with the licensed technology have expired. If the first pending patent is issued, the agreement is projected to expire in 2024. In addition, at any time after January 10, 2008, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or are actively and effectively attempting to commercialize the licensed technology.

On August 12, 2004, we entered into a world-wide license agreement with The University of Texas M.D. Anderson Cancer Center to research, develop, sell and commercially exploit the patent rights for L-Annamycin. Consideration paid for this license amounted to $31,497 for reimbursement of out-of-pocket costs for filing, enforcing and maintaining the L-Annamycin patent rights and a $100,000 initial license fee. We also agreed to pay The University of Texas M. D. Anderson Cancer Center royalties based on net sales from any licensed products, plus aggregate milestone payments of up to $750,000 based upon achieving certain regulatory submissions and approvals. The term of the agreement is from August 12, 2004 until November 2, 2019. Under the terms of the license agreement, we are required to make certain good faith expenditures towards the clinical development of at least one licensed product within the two year period after March 2005. In addition, at any time after August 12, 2009, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or we are actively and effectively attempting to commercialize L-Annamycin.

On August 28, 2002, and as amended on May 23, 2003, Synergy entered into a worldwide license agreement (the "Original License") with AnorMED Inc. ("AnorMED") to research, develop, sell and commercially exploit the Atiprimod (SKF 106615) 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 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, we and Synergy entered into an Amended and Restated License Agreement with AnorMED Corporation ("AnorMED"), a wholly-owned subsidiary of Genzyme Corporation ("Genzyme"), pursuant to which the parties amended the Original License agreement for Atiprimod to eliminate all future maintenance fees and milestone payments and reduce future royalties to single digits. In return for the reduced future payments to Genzyme, we agreed to pay upfront fees which were recorded as a liability and expensed on December 31, 2007. As of December 18, 2008 $650,000 of these upfront fees remained due and payable.

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On December 19, 2008, we entered into a Technology Assignment Agreement (the "Agreement") with AnorMED pursuant to which AnorMED transferred and assigned to us all of AnorMED's right, title and interest in and to all patents and patent applications with respect to Atiprimod in addition to all trade secrets, technical reports and data concerning Atiprimod and any analogs or derivatives in return for a cash payment of $650,000, which payment settled the upfront fees owed from the December 31, 2007 Amended and Restated License Agreement. In addition the Agreement specified that the Amended and Restated License Agreement between us and AnorMED dated December 31, 2007, with respect to which AnorMED licensed to us certain patent rights and technology related to Atiprimod, was terminated with no additional payments due.

On August 20, 1996, we entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University licensed patents covering peptides and antibodies useful in treating toxic shock syndrome and septic shock. We agreed to work toward commercialization of products related to these patents as evidenced by a minimum expenditure of approximately $210,000 per year, plus milestone payments and royalties of between 2% and 3% of annual net sales and will pay Rockefeller 30% of any sublicense fee paid by sublicenses. The licensed patents under this agreement are the subject of research that was funded by the NIAID grant awarded to us on April 1, 2005 for $885,641over two years. In addition, on July 2, 2001, we entered into a license agreement for two additional patents related to the regulation of exoproteins in staphylococcus aureus. On February 14, 2008, we terminated both the August 1996 and July 2001 license agreements.

EMPLOYEES

As of April 14, 2009, we had 9 full-time employees. We believe our employee relations are satisfactory.

CALLISTO WEBSITE

We maintain a site on the World Wide Web at **http://www.callistopharma.com**; 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, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or 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.

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ITEM 1A. RISK FACTORS.

You should carefully consider the following risk factors and the other information included in this annual report as well as the information included in other periodic 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.

RISK RELATED TO OUR BUSINESS

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 candidates, Atiprimod for the treatment of advanced carcinoid cancer, L-Annamycin for the treatment of relapsed acute leukemia, and SP-304 for the treatment of GI disorders, are safe and effective;
- the successful development of our other product candidates;
- 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. 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 $90,987,267. We have incurred losses in each year since our inception in 1996. We incurred net losses available to common stockholders of

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$9,655,471, $20,887,428 and $15,303,714 for the twelve months ended December 31, 2008, 2007 and 2006, respectively. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development, continue the clinical trials of our active drug candidates, acquire or license new technologies, advance our other product candidates into clinical development, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock will likely decline.

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 and we expect to continue to require substantial amounts to:

- complete the clinical development of our two cancer product candidates, Atiprimod for the treatment of advanced carcinoid cancer and L-Annamycin for the treatment of acute leukemia;
- continue clinical development of SP-304 to treat GI disorders;
- continue development of our other product candidates and our SP-304 backup and second-generation program;
- 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 sales, marketing and distribution capabilities.

We expect that our cash used in operating activities will increase significantly for the next several years. For the years ended December 31, 2008, 2007 and 2006 we used approximately $8.9 million, $8.4 million and $8.3 million in operating activities, respectively.

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

- the rate of progress and cost of our clinical trials and other development activities;
- any future decisions we may make about the scope and prioritization of the programs we pursue;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the costs and timing of regulatory approval;

the costs of establishing sales, marketing and distribution capabilities;

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- the effect of competing technological and market developments;

- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and

- general market conditions for offerings from biopharmaceutical companies.

To date, our sources of cash have been primarily limited to the sale of our equity securities. Net cash provided by financing activities for the twelve months ended December 31, 2008, 2007 and 2006 was approximately $3.0 million, $10.8 million and $10.8 million, respectively. 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 our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

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

- 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.

IF OUR AGREEMENT WITH THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER TERMINATES, OUR BUSINESS WOULD BE ADVERSELY AFFECTED.

Our business is partially dependent on rights we have licensed from The University of Texas M.D. Anderson Cancer Center. Under the terms of The University of Texas M.D. Anderson Cancer Center license agreement for L-Annamycin, at any time after August 12, 2009, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or we are actively and effectively attempting to commercialize L-Annamycin. If we fail to fulfill these obligations or other material obligations, The University of Texas M.D. Anderson Cancer Center license agreement may be terminated and our business would be adversely affected.

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

In order to receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive clinical trials to demonstrate safety and efficacy of these product candidates. 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.

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

While to date there has been no delays in our clinical trials, enrollment in our Atiprimod Phase I/IIa trial in multiple myeloma was slower than anticipated due to limited availability of relapsed multiple myeloma patients. In the future, 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.

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 of America. 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 of America 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

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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 our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, marketing and distributing 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 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 adequate sales, marketing and distribution infrastructure for our product candidates.

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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 drugs. If we are unable to differentiate our products from currently marketed drugs, we may never generate meaningful revenue.

Numerous pharmaceutical and biotechnology companies have developed anthracycline drugs used to treat acute leukemias similar to our compound, L-Annamycin. These compounds include Adriamycin® and Ellence® which are marketed by Pfizer; and Cerubidine® which is marketed by Boehringer Ingelheim. These drugs have been approved by the FDA and are currently being marketed as opposed to L-Annamycin which is in clinical development. Atiprimod, our drug candidate for advanced carcinoid cancer, works through a different mechanism of action than Velcade® which is currently marketed by Millenium Pharmaceuticals and other approved drugs, such as Celgene Corporation's Revlimid®. SP-304 is our drug candidate being developed by Synergy to treat GI disorders, such as chronic constipation and irritable bowel syndrome ("IBS-C"). Only one drug, Amitiza® (lubriprostone) from Sucampo/Takeda, to the best of our knowledge, is presently approved in the U.S. to treat those indications.

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 of America 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 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.

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IF OUR RELATIONSHIP WITH OUR CONTRACT MANUFACTURER FOR L-ANNAMYCIN TERMINATES, OR THEIR FACILITIES ARE DAMAGED OR DESTROYED, WE MAY BE UNABLE TO DEVELOP OR COMMERCIALIZE L-ANNAMYCIN.

Currently, Antibioticos S.p.A. is our sole supplier of Annamycin (drug substance that is the active component of the final formulated L-Annamycin drug product). If our relationship with this contract manufacturer, or any other contract manufacturer we might use, terminates or if any of their facilities are damaged for any reason, including fire, flood, earthquake or other similar event, we may be unable to obtain supply of Annamycin. The number of contract manufacturers with the expertise, required regulatory approvals and facilities to manufacture Annamycin on a commercial scale is extremely limited, and it would take a significant amount of time to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must approve these manufacturers' facilities and processes prior to our use, which would require new testing and compliance inspections. In addition, we may not have the intellectual property rights, or may have to share intellectual property rights, to any improvements in the current manufacturing processes or any new manufacturing processes for Annamycin.

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;

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injury to our reputation;

withdrawal of clinical trial participants;

costs of related litigation;

substantial monetary awards to patients;

product recalls;

loss of revenue; and

the inability to commercialize our product candidates.

We have clinical trial liability insurance with a $5,000,000 annual aggregate limit for up to 75 patients participating at the same time in our Atiprimod, L-Annamycin and SP-304 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 the full spectrum of clinical trial services for 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 CROs, 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

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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 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 Chief Executive Officer and Kunwar Shailubhai, Ph.D., Synergy's 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 do not carry "key person" insurance covering any members of our senior management other than $1,000,000 for Dr. Jacob.

IF WE FAIL TO ACQUIRE AND DEVELOP OTHER PRODUCTS OR PRODUCT CANDIDATES, WE MAY BE UNABLE TO GROW OUR BUSINESS.

To date, we have in-licensed or acquired the rights to certain of our product candidates. As part of our growth strategy, in addition to developing our current product candidates, we intend to license or acquire additional products and product candidates for development and commercialization. Because we have limited internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license products to us. The success of this strategy depends upon our ability to identify, select and acquire new pharmaceutical product candidates and products.

Any product candidate we license or acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe or effective for approval by regulatory authorities. In addition, we cannot

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assure you that any products that we license or acquire that are approved, can be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace.

Proposing, negotiating and implementing an economically viable product acquisition or license is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition or license of product candidates and approved products. We may not be able to acquire or license the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

WE MAY UNDERTAKE ACQUISITIONS IN THE FUTURE, AND ANY DIFFICULTIES FROM INTEGRATING THESE ACQUISITIONS COULD DAMAGE OUR ABILITIES TO ATTAIN OR MAINTAIN PROFITABILITY.

We may acquire additional businesses, products or product candidates that complement or augment our existing business. Integrating any newly acquired business or product could be expensive and time-consuming. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Moreover, we may need to raise additional funds through public or private debt or equity financing to make acquisitions, which may result in dilution to stockholders and the incurrence of indebtedness that may include restrictive covenants.

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

We are a small company with 9 full-time employees as of April 14, 2009. 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 research, development, 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.

REIMBURSEMENT MAY NOT BE AVAILABLE FOR OUR PRODUCT CANDIDATES, WHICH COULD 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

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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.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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As of December 31, 2008, we are the assignee or exclusive licensee of 7 pending patent applications and 15 issued patents in the United States, and currently we have approximately 150 issued or 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 composition-of-matter and use patent on SP-304 issued on May 9, 2006 expires in 2023. Our composition-of-matter patents for L-Annamycin and Atiprimod expire in 2017 and 2016, respectively. Our formulation patents for L-Annamycin and Atiprimod dimaleate salt both expire in 2016.

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 licensed patents, or for which we are not licensed under our license agreements;
- we or our licensors might not have been the first to make the inventions covered by our pending patent application or the pending patent applications and issued patents of our licensors;
- we or our licensors 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 or one or more of the pending patent applications of our licensors will not result in issued patents;
- the issued patents of our licensors may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- 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 licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid

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

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

Because some patent applications in the United States of America may be maintained in secrecy until the patents are issued, because patent applications in the United States of America 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 licensors' issued patents or our pending applications or our licensors' pending applications or that we or our licensors 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 own or our licensors' 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.

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RISKS RELATED TO OUR COMMON STOCK

MARKET VOLATILITY MAY AFFECT OUR STOCK PRICE AND THE VALUE OF YOUR INVESTMENT.

The market prices for securities of biopharmaceutical companies in general have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

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

announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;

actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing process or sales and marketing activities;

regulatory developments in the United States of America and foreign countries;

the success of our development efforts and clinical trials;

the success of our efforts to acquire or in-license additional products or product candidates;

any intellectual property infringement action, or any other litigation, involving us;

announcements concerning our competitors, or the biotechnology or biopharmaceutical industries in general;

actual or anticipated fluctuations in our operating results;

changes in financial estimates or recommendations by securities analysts;

sales of large blocks of our common stock;

sales of our common stock by our executive officers, directors and significant stockholders; and

the loss of any of our key scientific or management personnel.

the potentially dilutive effect of all outstanding dilutive instruments as follows:

The following table sets forth the potentially dilutive effect of all outstanding dilutive instruments as of December 31, 2008:

Common Shares Outstanding	49,556,661
Potentially Dilutive Common Shares Issuable upon:	
Exercise of Warrants	55,773,331

Exercise of Stock Options	7,938,538
Conversion of Series A Preferred Stock	1,960,000
Conversion of Series B Preferred Stock	22,741,000
Common Shares Outstanding Fully Diluted	137,969,530

The occurrence of one or more of these factors may cause our stock price to decline, and investors may not be able to resell their shares at or above the price that they paid for the shares. In addition, the stock markets in general, and the markets for biotechnology and biopharmaceutical stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock.

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WE HAVE IDENTIFIED MATERIAL WEAKNESSES IN OUR DISCLOSURE CONTROLS AND PROCEDURES AND HAVE CONCLUDED THAT INTERNAL CONTROL OVER FINANCIAL REPORTING IS NOT EFFECTIVE AS OF DECEMBER 31, 2008. IN ADDITION, WE MAY EXPERIENCE ADDITIONAL MATERIAL WEAKNESSES IN THE FUTURE. ANY MATERIAL WEAKNESSES IN OUR DISCLOSURE CONTROLS AND PROCEDURES OR OUR FAILURE TO REMEDIATE SUCH MATERIAL WEAKNESSES COULD RESULT IN A MATERIAL MISSTATEMENT IN OUR FINANCIAL STATEMENTS NOT BEING PREVENTED OR DETECTED AND COULD AFFECT INVESTOR CONFIDENCE IN THE ACCURACY AND COMPLETENESS OF OUR FINANCIAL STATEMENTS, AS WELL AS OUR STOCK PRICE.

We have identified material weaknesses in our disclosure controls and procedures relating to our lack of sufficient internal accounting personnel and segregation of duties necessary to ensure that adequate review of our financial statements and notes thereto is performed and have concluded that our internal control over financial reporting is not effective as of December 31, 2008. These material weaknesses and our remediation plans are described further in ITEM 9A(T). "CONTROLS AND PROCEDURES" of this report. Material weaknesses in our disclosure controls and procedures could result in material misstatements in our financial statements not being prevented or detected. We may experience difficulties or delays in completing remediation or may not be able to successfully remediate material weaknesses at all. Any material weakness or unsuccessful remediation could affect investor confidence in the accuracy and completeness of our financial statements, which in turn could harm our business and have an adverse effect on our stock price and our ability to raise additional funds.

WE ARE AT RISK OF SECURITIES CLASS ACTION LITIGATION.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we faced such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

We have never paid cash dividends on our stock and do not anticipate paying cash dividends on our stock in the foreseeable future. The payment of cash dividends on our 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 cash dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

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 CONTROLS OVER FINANCIAL REPORTING, 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 accounting controls and procedures, or, if material weaknesses or other deficiencies are discovered in our internal controls over financial reporting, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal controls over financial reporting. We have documented and tested our internal control procedures, and have identified material weaknesses in our internal control over financial reporting and other deficiencies. These material weaknesses and deficiencies could cause

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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 of 2002. Moreover, effective internal controls are necessary for us to produce reliable financial 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 our internal control weaknesses and deficiencies.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None

ITEM 2. PROPERTIES.

We currently lease 3,886 square feet of office space located at 420 Lexington Avenue, Suite 1609, New York, New York through June 30, 2011. This facility contains our clinical management, executive and administrative offices.

We also maintain a small research laboratory and several development offices totaling approximately 700 square feet in the Bucks County Biotechnology Center, Doylestown, Pennsylvania, under a license agreement expiring on October 31, 2010.

We believe our existing facilities are well maintained, in good operating condition, and that our existing and planned facilities will be adequate to support our operations for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS.

On December 21, 2006, we filed a complaint against Tapestry Pharmaceuticals, Inc.("Tapestry"), Leonard P. Shaykin and Kai P. Larson in the Supreme Court of the State of New York alleging that Tapestry used information they obtained pursuant to a confidential disclosure agreement between us and Tapestry to cause Donald Picker, Ph.D., our former Executive Vice President, Research & Development, to resign and accept a position with Tapestry. In addition, we are alleging that Tapestry fraudulently entered into the confidential disclosure agreement with us and intentionally interfered with Dr. Picker's employment agreement with us. We are seeking actual and punitive damages. During the year ended December 31, 2008 Callisto settled with Tapestry Pharmaceuticals, Inc. for $100,000 which was used to pay for our legal fees.

In June 2007, we filed a complaint against Donald Picker in the Supreme Court of the State of New York alleging breach of his employment agreement, fraud, conversion and related claims. We were seeking $80 million in damages from Dr. Picker. During 2008 Picker moved for a summary judgment and that motion is still pending.

We are not a party to any other pending legal proceedings.

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.

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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 had been quoted on the American Stock Exchange ("AMEX") under the symbol "KAL" since October 25, 2004. On April 7, 2008, we received notice from the staff of the AMEX of its intent to strike our common stock from the AMEX by filing a delisting application with the Securities Exchange Commission for failure to regain compliance with Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide and falling out of compliance with Section 1003(a)(iii) of the Company Guide with shareholders' equity of less than $6,000,000 and losses from continuing operations and/or net losses in four of our five most recent fiscal years. On July 14, 2008, our common stock was delisted from the AMEX and currently trades on the Over the Counter Bulletin Board under the symbol "CLSP.OB".

The following table shows the reported high and low closing prices per share for our common stock as reported on the AMEX prior to July 14, 2008 and as reported on the Over the Counter Bulletin Board subsequent to July 14, 2008.

	2008		2007	
	High	Low	High	Low
First Quarter	$0.62	$0.36	$0.97	$0.71
Second Quarter	0.40	0.24	0.77	0.64
Third Quarter	0.24	0.05	0.72	0.47
Fourth Quarter	0.14	0.03	0.54	0.33

HOLDERS OF COMMON STOCK

As of April 15, 2009, we had 397 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 and Warrants (a)	Weighted-Average Exercise Price of Outstanding Options and Warrants	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity Compensation Plans Approved by Stockholders	5,586,205	$ 1.73	4,298,000
Equity Compensation Plans Not Approved by Stockholders(1)	58,125,664	0.48	0
Total	63,711,869	$ 0.59	4,298,000

(1)

Consists of 2,352,333 stock options not subject to any of our stock option plans and 55,773,331 warrants. These non-plan stock options and warrants have been primarily issued in conjunction with our private placements of common stock and consulting services agreements.

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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.

BUSINESS OVERVIEW

Callisto Pharmaceuticals, Inc. (which may be referred to as "Callisto", "the Company", "we" or "us") was incorporated under the laws of the State of Delaware in May 2003. We operate through two subsidiary companies: Synergy Pharmaceuticals Inc. and Callisto Research Labs, LLC, and we own two inactive subsidiaries, IgX, Ltd (Ireland) and Callisto Pharma, GmbH (Germany). Our principal offices are located at 420 Lexington Avenue, Suite 1609, New York, NY 10170.

We are a development stage biopharmaceutical company focused primarily on the development of drugs to treat neuroendocrine cancer (including advanced carcinoid cancer), rheumatoid arthritis ("RA"), acute leukemia and gastrointestinal ("GI") disorders and diseases. Our lead drug candidates 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"), currently being developed by our majority-owned subsidiary, Synergy Pharmaceuticals, Inc. ("Synergy").

2. Atiprimod, an orally administered drug with antiproliferative and antiangiogenic activity.

3. L-Annamycin, a novel compound from the anthracycline family of proven anti-cancer drugs, which has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart.

HISTORY

In March 2002, Callisto Pharmaceuticals, Inc. ("Old Callisto"), a non-public company, purchased 99.7% of the outstanding common shares of Webtronics, Inc., ("Webtronics") a public company for $400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations at December 31, 2002.

On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Synergy Pharmaceuticals, Inc. ("Synergy-DE") and Callisto Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Old Callisto (collectively, the "Merger"). As a result of the Merger, Old Callisto and Synergy-DE became wholly-owned subsidiaries of Webtronics. In connection with the Merger, Webtronics issued 17,318,994 shares of its common stock in exchange for outstanding Old Callisto common stock and an additional 4,395,684 shares in exchange for outstanding Synergy-DE common stock. In May 2003, Old Callisto changed its name to Callisto Research Labs, LLC ("Callisto Research") and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware. Subsequently, 171,818 shares of common stock issued to former Synergy-DE shareholders were returned to us under the terms of certain indemnification agreements.

From inception through December 31, 2008, we have sustained cumulative net losses available to common stockholders of $90,987,267. Our losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of

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proposed products, stock-based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees, as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception through December 31, 2008, we have not generated any revenue from operations, expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products, and 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.

Recent Developments

On January 27, 2009, we announced that we were focusing all further development of Atiprimod towards the treatment of RA. We recognized that although the ongoing Phase II clinical trial of Atiprimod in advanced carcinoid cancer gave encouraging results, the data were not sufficiently demonstrative to warrant further development of Atiprimod in this indication. We announced, instead, our intention that based on Atiprimod's demonstrated favorable clinical safety profile, robustly supported by earlier studies of Atiprimod in RA patients, as well as by the recent oncology trials in advanced carcinoid cancer patients, where the drug was dosed at levels and frequencies considerably higher than anticipated for use in RA, we believe that Atiprimod holds significant promise as a new class of orally-administered, disease-modifying agent in RA.

On December 19, 2008, we entered into a Technology Assignment Agreement (the "Agreement") with AnorMED pursuant to which AnorMED transferred and assigned to us all of AnorMED's right, title and interest in and to all patents and patent applications with respect to Atiprimod in addition to all trade secrets, technical reports and data concerning Atiprimod and any analogs or derivatives in return for a cash payment of $650,000, which payment settled the upfront fees owed from December 31, 2007 Amended and Restated License Agreement. In addition the Agreement specified that the Amended and Restated License Agreement between us and AnorMED dated December 31, 2007, with respect to which AnorMED licensed to us certain patent rights and technology related to Atiprimod, was terminated with no additional amounts due.

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. We plan to initiate a repeated-oral-dose trial of SP-304 in chronic constipation patients in late 2009 or early 2010.

On July 14, 2008, we entered into an Exchange Agreement dated July 11, 2008 ("Exchange Agreement"), as amended and effective on July 14, 2008, with Pawfect Foods, Inc. ("Pawfect"), Synergy Pharmaceuticals, Inc. ("Synergy-DE"), a majority-owned subsidiary of ours, and other holders of Synergy-DE common stock. According to the terms of the Exchange Agreement, Pawfect acquired 100% of the common stock of Synergy-DE, from us and the other holders of Synergy-DE, in exchange for 45,464,760 shares of Pawfect's common stock representing approximately 70% of Pawfect's

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outstanding common stock (the "Exchange Transaction"). We received 44,590,000 of the 45,464,760 shares of Pawfect's common stock exchanged for our ownership of Synergy-DE, and we are now the holder of 68% of Pawfect's outstanding common stock. The remaining 874,760 shares of Pawfect common stock exchanged for ownership of Synergy-DE were issued to certain executive officers of Synergy-DE who received their shares pursuant to a Repurchase Agreement with Synergy-DE dated July 3, 2008 and assumed by Pawfect. The fair value of each of the 874,760 shares was estimated on the grant date to be $0.60, which was based on the price paid by shareholders participating in Synergy's July 14, 2008 private placement. Stock based compensation expense of $524,856 related to these shares is being amortized over the vesting period of 2 years. In connection with the Exchange Transaction Pawfect received $3,025,000 less transaction costs of $73,087, yielding net proceeds of $2,951,913 from two private placements, which we have recorded as an increase in additional paid-in capital.

Pawfect was a development stage company selling pet food products utilizing the internet, with immaterial operations to date. On July 14, 2008, Pawfect discontinued its pet food business to focus all resources on continuing the development of drugs to treat GI disorders and diseases acquired in connection with the Exchange Agreement.

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 Agreement and changed its name to Synergy Pharmaceuticals, Inc. ("Synergy"). Synergy is now traded on the Over The Counter Bulletin Board under the symbol SGYP.OB.

On April 2, 2008, we filed an investigational new drug ("IND") application with the United States Food and Drug Administration ("FDA") relating to SP-304. 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.

On April 7, 2008, we received notice from the staff of the American Stock Exchange ("AMEX") of its intent to strike our common stock from the AMEX by filing a delisting application with the SEC for failure to regain compliance with Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide and falling out of compliance with Section 1003(a)(iii) of the Company Guide with shareholders' equity of less than $6,000,000 and losses from continuing operations and/or net losses in four of our five most recent fiscal years. On July 14, 2008, our common stock was delisted from the AMEX and currently trades on the Over The Counter Bulletin Board under the symbol CLSP.OB.

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 chronic constipation and IBS-C.

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

SP-304 has also undergone pre-clinical animal studies as a treatment for GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of North Carolina, Chapel Hill, NC. Recent results from his laboratory also showed that SP-304 was efficacious

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in animal models of ulcerative colitis ("UC"). A second generation GC-C receptor SP-333 is now in pre-clinical development and Synergy plans to file an IND and initiate a Phase I clinical trial in volunteers in 2010.

On November 7, 2006, we announced the initiation of a multi-center open-label Phase II clinical trial of Atiprimod for low-to-intermediate grade neuroendocrine cancers, primarily in advanced carcinoid cancer patients. On September 20, 2007, we announced that we had completed enrollment of the 40-patient Phase II clinical trial, and that patients had been on drug as along as 11 months. In October 2007, we announced the opening of a Phase II extension trial to permit those patients who had successfully completed a full year in the Phase II advanced carcinoid cancer trial to continue to receive Atiprimod therapy. We also indicated that we are no longer dosing patients in relapsed or refractory multiple myeloma and have no plans at present to continue evaluating the drug in this disease indication, instead focusing on the clinical development of Atiprimod to treat advanced carcinoid cancer. On May 16, 2008, we announced interim data from the company's ongoing open-label Phase II clinical trial of Atiprimod to treat low to intermediate grade neuroendocrine carcinoma (advanced carcinoid cancer). On January 27, 2009, we announced that we were focusing all further development of Atiprimod towards the treatment of rheumatoid RA. We recognized that although the ongoing Phase II clinical trial of Atiprimod in advanced carcinoid cancer gave encouraging results, the data were not sufficiently demonstrative to warrant further development of Atiprimod in this indication. We announced our belief that Atiprimod holds significant promise as a new class of orally-administered, disease-modifying agent in RA.

L-Annamycin was evaluated in two clinical trials: 1) a Phase I/IIa clinical trial in adult relapsed acute myelogenous leukemia ("AML") or refractory acute lymphocytic leukemia ("ALL") patients at three clinical sites in the U.S.; and 2) a Phase I clinical trial in children and young adults with relapsed or refractory ALL or AML. We established an MTD of 150 mg/m2/day given for 3 consecutive days in the adult trial and finished dosing of 10 patients at this MTD value. The clinical data, however, did not warrant further clinical evaluation of L-Annamycin as a single agent to treat relapsed or refractory adult acute leukemia patients. The Phase I trial of L-Annamycin in pediatric relapsed or refractory ALL or AML patients was initiated at a dose of 130 mg/m2/day. Due to the low number of patients with this disease, we were only able to enroll 3 patients in total, all at 130 mg/m2/day, and never achieved an MTD in children. Due to this poor enrollment plus the decision to suspend further development of L-Annamycin in adults, we have suspended any further work on L-Annamycin in acute leukemia at this time.

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.

CRITICAL ACCOUNTING POLICIES

We prepare our financial statements in conformity with accounting principles generally accepted in the U.S. The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and contingent liabilities, at the date of

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the financial statements and the reported amounts of revenue and expenses during the reporting period. Because of the uncertainty of factors surrounding the estimates or assumptions used in the preparation of the consolidated financial statements, actual results may vary from these estimates.

Share-Based Payments

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 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 $17,734,869 or 19% of our total accumulated deficit of $90,987,267.

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 and accordingly we adopted SFAS No. 123R on January 1, 2006.

SFAS No. 123R did not change the way we account for non-employee stock-based compensation. We continue to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. Stock-based compensation expense associated with these most of our non-employee option grants is being recorded in accordance with EITF 96-18 and accordingly (i) the measurement date will be when "performance commitment is completed" and accordingly the fair value of these options is being "marked to market" quarterly until the measurement date is determined.

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 our historical volatility. Our stock price has fluctuated from $3.95 per share as of December 31, 2003 to $0.09 per share as of December 31, 2008. The expected term was 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 stock options. Forfeitures are estimated, based on our historical experience, at the time of grant.

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 and royalty 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.

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RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2008 AND DECEMBER 31, 2007

We had no revenues during the 12 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.

Research and development expenses decreased $1,058,257 or 16%, to $5,449,721 for the 12 months ended December 31, 2008 from $6,507,978 for the 12 months ended December 31, 2007. This decrease in research and development expense was attributable to a decrease in Atiprimod and Annamycin clinical program expenses partially offset by an increase in SP-304 clinical program expenses. Expenses incurred on our Atiprimod program decreased $1,586,000 or 74% to $561,000 for the 12 months ended December 31, 2008 from $2,147,000 during the 12 months ended December 31, 2007. Clinical expenses incurred on our Annamycin program decreased $366,000 or 56% to $292,000 for the 12 months ended December 31, 2008 from $658,000 during the 12 months ended December 31, 2007. Our SP-304 program expenses incurred by our majority-owned subsidiary Synergy increased $1,730,000 or 76% to $4,018,000 for the 12 months ended December 31, 2008 from $2,288,000 during the 12 months ended December 31, 2007. Research and development expenses for non-clinical overhead, not allocated to specific programs, totaled $562,000 and $1,400,000 during the 12 months ended December 31, 2008 and 2007, respectively, a decrease of $838,000 or 60%, as we focused more of our research and development resources on established clinical programs and curtailed our non-clinical laboratory supplies and sponsored outside research. As a percent of our total research and development costs, these non-program specific non-clinical overhead expenses decreased to 10% from 22% of total research and development expenses during the 12 months ended December 31, 2008 and 2007, respectively.

General and administrative expenses for the 12 months ended December 31, 2008 were essentially unchanged at $4,311,767 from $4,317,288 for the 12 months ended December 31, 2007. Increased accounting, consulting and advisory expenses as a result of having two public reporting entities (Callisto and Synergy) during 2008, were offset by a decrease in legal and public relations expenses.

Net loss from operations was $9,731,488 for the 12 months ended December 31, 2008 which was $832,925 or 8% lower than the $10,564,413 reported in the comparable period of 2007. This decrease was attributable to lower research and development expenses discussed above combined with lower government grants income of $30,000 during the 12 months ended December 31, 2008 as compared to $260,853 received during the 12 months ended December 31, 2007. On April 1, 2005 we were awarded a biodefense partnership grant from the National Institute of Allergy and Infectious Diseases to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over a two year period. Funding for this program was extended one year through April 2008. Because the bioterrorism program is not a core activity, we terminated in-house work on this program upon expiration of the research grant in April 2008

We record adjustments to the minority interests in Synergy for the allocable portion (32%) of losses to which the minority interest holders are entitled. The minority interest in Synergy as of the date of acquisition, July 14, 2008, was $663,765 after reflecting the net proceeds from the private placement. 32% of Synergy's net loss subsequent to the date of acquisition through December 31, 2008 was $1,151,577, excluding Synergy's charge for purchased in process research and development eliminated in consolidation. We suspended allocation of losses to the minority interest holders when the minority interest balance was reduced to zero. Any excess Synergy loss ($487,812) above the minority interest holder's balance was not charged to minority interests as the Synergy minority interest holders have no obligation to fund such losses.

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Net loss available to common stockholders for the 12 months ended December 31, 2008 was $9,655,471 compared to a net loss of $20,887,428 incurred for the 12 months ended December 31, 2007. The decreased net loss is the result of (i) lower operating expenses discussed above, (ii) the beneficial conversion feature discount related to the Series A and B preferred stock accreted as a dividend of $13,000,163 in the 12 months ended December 31, 2007 and (iii) a benefit in the 12 months ended December 31, 2007 relating to a change in the fair value of the Series B warrants of $2,591,005. We had no such items (ii) and (iii) during 2008.

YEARS ENDED DECEMBER 31, 2007 AND DECEMBER 31, 2006

We had no revenues during the 12 months ended December 31, 2007 and 2006 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses increased $373,274, or 6%, to $6,507,978 for the 12 months ended December 31, 2007 from $6,134,704 for the 12 months ended December 31, 2006. This increase in research and development expense was attributable to significantly higher SP-304 and Atiprimod program expenses. Program expenses incurred with outside contract research organizations ("CROs"), include pre-clinical animal testing, drug formulation, tableting, hospital patient costs, blood testing, data collection, clinical monitoring and FDA consultants. Our SP-304 program expenses increased approximately $1,700,000, or 300%, to approximately $2,300,000 for the 12 months ended December 31, 2007 from approximately $600,000 during the 12 months ended December 31, 2006. Atiprimod program costs increased approximately $400,000, or 27%, to approximately $2,100,000 during the 12 months ended December 31, 2007 from $1,700,000 during the 12 months ended December 31, 2006. Partially offsetting these increased research expenditure were lower Annamycin program expenses of approximately $650,000 during the 12 months ended December 31, 2007, which was a 50% decrease from approximately $1,300,000 expensed during the 12 months ended December 31, 2006. During the 12 months ended December 31, 2006 we purchased and expensed a supply of Annamycin drug substance which was used in both our 2006 and 2007 clinical trials. Our Degrasyns program was also curtailed during the 12 months ended December 31, 2007, during which time we incurred only $12,593 on this pre-clinical program, as compared to $690,226 during the 12 months ended December 31, 2006.

Research and development in-house overhead, not allocated to specific programs, totaled approximately $1,400,000 and $1,700,000, during the 12 months ended December 31, 2007 and 2006, respectively, a decrease of approximately $300,000, or 19%. As a percent of our total costs these non program specific overhead research and development expenses represented 22% and 29% of total R&D during the 12 months ended December 31, 2007 and 2006, respectively. This decrease was attributable to lower stock-based compensation expense which totaled $86,048 and $523,434 during the 12 months ended December 31, 2007 and 2006, respectively. This decrease of approximately $440,000 or 84% was primarily attributable to warrants we issued to certain scientific advisors (including Dr. Moshe Talpaz) and fully expensed during the 12 months ended December 31, 2006. Partially offsetting this decrease were approximately $200,000 in higher scientific advisory fees and consulting services incurred primarily to replace our Executive Vice President of R&D, Donald Picker, who resigned December 15, 2006.

On April 1, 2006 we received an $885,641 biodefense partnership grant from the NIAID to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over the next two years. Government grant funding for the 12 months ended December 31, 2007 and 2006 was $260,853 and $352,649, respectively. This grant terminated April 1, 2008 and we had approximately $34,000 remaining unused as of December 31, 2007.

General and administrative expenses for the 12 months ended December 31, 2007 decreased $2,066,828, or 32%, to $4,317,288 during the 12 months ended December 31, 2007 from $6,384,116 for

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the 12 months ended December 31, 2006. This was primarily due to lower stock-based compensation expense recorded during the 12 months ended December 31, 2007 which totaled $542,312 as compared to $2,223,044 recorded during the 12 months ended December 31, 2006. This decrease of approximately $1,700,000 or 76% was primarily attributable to warrants we issued to certain investor relations consultants and fully expensed during the 12 months ended December 31, 2006. Also contributing to reduced general and administrative expenses was a decrease of approximately $400,000 in investor relations costs during the 12 months ended December 31, 2007.

Net loss for the 12 months ended December 31, 2007 was $7,887,265 compared to a net loss of $12,919,229 incurred for the 12 months ended December 31, 2006. The decreased net loss is the result of lower general and administrative expenses, partially offset by higher research and development expenses, both of which are discussed above. In addition, (i) other expense for the 12 months ended December 31, 2006 was $801,690 due to liquidated damages incurred for failure to register shares of our common stock sold in a private placement in February and April 2006. There were no such expense during the 12 months ended December 31, 2007, and (ii) we recorded a $2,591,005 gain on the change in the fair value of the warrants issued to our Lead Investors in the Series B Preferred Stock private placement, from the date of issue through September 30, 2007, the expiration date of the Put Option. The Put Option permitted warrant holders to redeem the warrants if certain triggering events occurred prior to the Put Option expiration date. Accordingly, the warrants were classified as liabilities and marked to market each period, with changes in fair value recorded in earnings through the Put Option expiration date. Upon expiration of the Put options, the warrants were reclassified to equity.

During the 12 months ended December 31, 2007 we accreted a beneficial conversion dividend to the Series B Preferred stockholders of $10,495,688 and we also accreted a beneficial conversion dividend to the Series A preferred stockholders of $2,504,475, resulting in a net loss available to common stockholders of $20,887,428. During the 12 months ended December 31, 2006 we accreted a beneficial conversion dividend to the Series A preferred stockholders of $2,384,485 resulting in a net loss available to common stockholders of $15,303,714.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2008 we had $301,323 in cash and cash equivalents, compared to $3,269,341 as of December 31, 2007. Net cash used in operating activities was $8,902,376 and $8,448,543 for the 12 months ended December 31, 2008 and 2007 respectively. As of December 31, 2007, we also had $2,967,690 invested in U.S. Treasury bills classified as short-term investments on our balance sheet. These investments were liquidated into cash during the 12 months ended December 31, 2008. As of December 31, 2008 we had a working capital deficit of $4,260,826.

On December 30, 2008, we entered into a securities purchase and exchange agreement ("Purchase Agreement") with several investors, each of whom were holders of record as of November 4, 2008 of outstanding warrants to purchase shares of our common stock, exercisable at $0.50 or $0.70 per share until August 2, 2010 ("Series B Warrants"). The Series B Warrants were issued in connection with the private placement of the Company's Series B Preferred Shares on August 2, 2007. Pursuant to the Purchase Agreements we issued $201,905 of an authorized $500,000 11% Secured Notes due April 15, 2010 ("11% Notes") with no discount. Interest on the 11% Notes is due on maturity, whether on April 15, 2010 or by acceleration and payment of the 11% Notes is secured by a pledge of up to 1,900,000 shares (if all $500,000 principal amount of the 11% Notes is sold) of the common stock of Synergy Pharmaceuticals, Inc. owned by us. (See note 5 to our consolidated financial statements)

Pursuant to the Purchase Agreement, Callisto issued, to the December 30, 2008 purchasers of the 11% Notes, 23,219,104 common stock purchase warrants ("New Warrants") in exchange for the surrender and cancellation of 11,298,134 outstanding Series B Warrants. The New Warrants have an

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exercise price, subject to certain anti-dilution adjustments, of $0.02 per share and are exercisable at any time on or prior to December 31, 2016.

On February 3, 2009 we issued an additional $53,161 of the authorized $500,000 11% Secured Notes bringing the aggregate proceeds from issuance of 11% Notes since inception to $255,066. 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, allow it to continue its efforts to raise additional financing for approximately six 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 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.

On July 14, 2008, we entered into an Exchange Agreement dated July 11, 2008 ("Exchange Agreement"), as amended and effective on July 14, 2008, with Pawfect Foods, Inc. ("Pawfect"), Synergy Pharmaceuticals, Inc. ("Synergy-DE"), our majority-owned subsidiary, and other holders of Synergy-DE common stock. According to the terms of the Exchange Agreement, Pawfect acquired 100% of the common stock of Synergy-DE, from us and the other holders of Synergy-DE, in exchange for 45,464,760 shares of Pawfect's common stock representing approximately 70% of Pawfect's outstanding common stock (the "Exchange Transaction"). We received 44,590,000 of the 45,464,760 shares of Pawfect's common stock exchanged for its ownership of Synergy-DE, and we are now the holder of 68% of Pawfect's outstanding common stock. The remaining 874,760 shares of Pawfect common stock exchanged for ownership of Synergy-DE were issued to certain executive officers of Synergy-DE who received their shares pursuant to a Repurchase Agreement with Synergy-DE dated July 3, 2008 and assumed by Pawfect. The fair value of each of the 874,760 shares was estimated on the grant date to be $0.60, which was based on the price paid by shareholders participating in Synergy's July 14, 2008 private placement. Stock based compensation expense of $524,856 related to these shares is being amortized over the vesting period of 2 years. In connection with the Exchange Transaction Pawfect

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received $3,025,000 less transaction costs of $73,087, yielding net proceeds of $2,951,913 from two private placements, which we have recorded as an increase in additional paid-in capital.

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 for the twelve months ending December 31, 2008. Our independent registered public accounting firm has issued a report dated April 15, 2009 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 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 is a summary of our significant 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	
Long term debt obligations	$ 201,908	$	$ 201,908	$	$	
Operating leases	448,309	184,046	264,263			
Purchase obligations principally consulting services	2,877,500	932,500	1,865,000	80,000		
Lease royalty payments	120,000	40,000	40,000	40,000		(1)
Total obligations	$3,647,617	$1,156,546	$2,371,171	$120,000	$	

(1) For purposes of this schedule we have assumed that all patents not commercialized within 5 years will be abandoned, license agreements will be terminated and associated minimum license fee payments will cease.

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

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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 March 2008, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 161, *Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133* ("SFAS No. 161"). SFAS No. 161 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. The guidance in SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. This Statement encourages, but does not require, comparative disclosures for earlier periods at initial adoption. We are currently assessing the impact of SFAS No. 161 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 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 the 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 are continuing to evaluate the impact of adopting the provisions SFAS No.141(R); however, 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 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 are continuing to evaluate the impact of adopting the provisions SFAS No.160 on our consolidated financial position, results of operations or cash flows.

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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. The provisions of SFAS No. 159 are effective for fiscal years beginning after November 15, 2007. 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 respect to its financial assets and financial liabilities on January 1, 2008 and such adoption did not did not have a material effect on its 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 money market funds managed by money center banks (JPMorganChase, HSBC and TD Bank). Original maturities of temporary investments are all less than three months as of December 31, 2007.

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 June 5, 1996 (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.

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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.

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 plan to add financial staff resources to our accounting and finance department.

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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.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

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

Name	Age	Position
Gabriele M Cerrone	37	Chairman of the Board
Gary S. Jacob	62	Chief Executive Officer, Chief Scientific Officer and Director
Bernard F. Denoyer	61	Senior Vice President, Finance and Secretary
John P. Brancaccio	61	Director
Christoph Bruening	41	Director
Riccardo Dalla-Favera	56	Director
Randall Johnson	62	Director

Gabriele M. Cerrone has served as our Chairman of the Board of Directors since May 2003 and as a consultant since January 2005. 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 currently serves as Chairman of the Board and a consultant to Synergy and a director of Inhibitex, Inc., a biotechnology company. 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.

Gary S. Jacob, Ph.D. has served as our Chief Executive Officer as well as Chief Scientific Officer since May 2003 and a Director since October 2004. Dr. Jacob has also served as President, Acting Chief Executive Officer and a Director of Synergy Pharmaceuticals, Inc. since July 2008, Chairman of Synergy-DE from October 2003 until July 2008 and 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.

Bernard F. Denoyer, CPA has served as our Senior Vice President, Finance since December 2007 and from January 2004 to November 2007 served as our Vice President, Finance and Secretary. Since July 2008 Mr. Denoyer has also served as Senior Vice President,, Finance and Secretary of Synergy. 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 business until acquired by IDEXX Laboratories, Inc..

John P. Brancaccio, a retired CPA, has served as a Director of our company since April 2004. 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,

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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, Synergy as well as a director of Xenomics, Inc.

Christoph Bruening has served as a Director of our company since May 2003. Mr. Bruening organized Value Relations GmbH, a full service investor relations firm operating in Frankfurt, Germany in 1999 and currently serves as its Managing Partner. From 1998 to 1999, Mr. Bruening served as a funds manager and Director of Asset Management for Value Management and Research AG, a private investment fund and funds manager in Germany. From 1997 to 1998, Mr. Bruening was a financial analyst and Head of Research for Value Research GmbH. Mr. Bruening is currently a member of the advisory board of Clarity AG.

Riccardo Dalla-Favera, M.D has served as a Director of our company since June 2005. Dr. Dalla-Favera has been Director of the Herbert Irving Comprehensive Cancer Center at Columbia University since early 2005, Director for the Institute for Cancer Genetics at Columbia University since 1999 and Professor in the Department of Genetics & Development at Columbia University since 1992. Dr. Dalla-Favera was formerly Deputy Director of Columbia-Presbyterian Cancer Center from 1992 to 1998.

Randall Johnson, Ph.D. has served as a Director of our company since February 2005. Since February 2002, Dr. Johnson has been serving as a consultant to various venture capital, biotechnology and pharmaceutical companies focusing on oncology. From October 1982 to February 2002, Dr. Johnson served in a number of capacities at GlaxoSmithKline PLC/SmithKline Beecham Pharmaceuticals, most recently as a Group Director in the Department of Oncology Research.

COMPENSATION OF DIRECTORS

Under the 2005 Directors' Stock Option Plan, upon election to the Board, each non-employee and non-consultant director receives a grant of 45,000 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. Upon re-election to the Board, each of our non-employee and non-consultant directors receive an annual grant of 6,000 options vesting over three years having an exercise price equal to the fair market value of the common stock on the date of grant. In addition, non-employee and non-consultant directors will receive an annual grant of options with an exercise price equal to the fair market value of the common stock on the date of grant for serving on Board committees which will vest in one year. Chairpersons of each of the Audit Committee, Compensation Committee and Corporate Governance/Nominating Committee receive 5,000, 3,500 and 2,000 stock options, respectively, and members of such committees receive 3,000, 2,000 and 1,000 stock options, respectively.

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 each of the Audit Committee, Compensation Committee and Corporate Governance/Nominating Committee receive $10,000, $7,000 and $4,000, respectively, and members of such committees receive $6,000, $4,000 and $2,500, 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.

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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 Brancaccio, chairman of the Audit Committee, Christoph Bruening and Randall Johnson. Our board of directors has determined that each of Mr. Bruening, Mr. Johnson and Mr. Brancaccio is "independent" as that term is defined under applicable SEC rules and under the current listing standards of NASDAQ. 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. A copy of this charter is available at our web site www.callistopharma.com.

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 Randall Johnson, chairman of the Compensation Committee and John Brancaccio. The Board of Directors has determined that all of the members are "independent" under the current listing standards of NASDAQ. The Board of Directors has adopted a written charter setting forth the authority and responsibilities of the Compensation Committee. A copy of this charter is available at our web site www.callistopharma.com.

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, except for Gabriele M. Cerrone and Gary S. Jacob.

CORPORATE GOVERNANCE/NOMINATING COMMITTEE

The Corporate Governance/Nominating Committee has responsibility for assisting the Board in, among other things, effecting Board organization, membership and function including identifying qualified Board nominees; effecting the organization, membership and function of Board committees including composition and recommendation of qualified candidates; establishment of and subsequent periodic evaluation of successor planning for the chief executive officer and other executive officers; development and evaluation of criteria for Board membership such as overall qualifications, term limits, age limits and independence; and oversight of compliance with the Corporate Governance Guidelines. The Corporate Governance/Nominating Committee shall identify and evaluate the qualifications of all candidates for nomination for election as directors.

The Corporate Governance/Nominating Committee currently consists of Christoph Bruening, chairman of the Corporate Governance/Nominating Committee, and John Brancaccio. The Board of Directors has determined that all of the members are "independent" under the current listing standards of NASDAQ. The Board of Directors has adopted a written charter setting forth the authority and responsibilities of the Corporate Governance/Nominating Committee. A copy of this charter is available at our web site www.callistopharma.com.

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CLINICAL AND SCIENTIFIC ADVISORY BOARD

Our clinical and scientific advisory board assists us in planning the clinical development of our drugs, identifying research and development opportunities, in reviewing with management the progress of our projects and in recruiting and evaluating scientific staff. Although we expect to receive guidance from the members of our scientific advisory board, all of its members are employed on a full-time basis by others and, accordingly, are able to devote only a small portion of their time to us. Management expects to meet with its scientific advisory board members individually from time to time on an informal basis. We have entered into a consulting agreement with each member of the scientific advisory board. The scientific advisory board consists of the following scientists:

Moshe Talpaz, M.D. Dr. Talpaz is the chairman of our Scientific Advisory Board and currently is associated with the University of Michigan Comprehensive Cancer Center where he holds the titles of Professor, Internal Medicine, Associate Director, Translational Research and Associate Chief of Hematologic Malignancies. Dr. Talpaz was formerly the Professor of Medicine, David Burton, Jr. Endowed Chair at the M.D. Anderson Cancer Center, Houston, Texas. Dr. Talpaz was formerly Chairman of the Department of Bioimmunotherapy of the M.D. Anderson Cancer Center. Dr. Talpaz has been and continues to be involved in the clinical development of numerous cancer drugs and has been a pioneer in developing currently accepted treatment protocols especially in the leukemia area. Dr. Talpaz is a member of many committees such as the National Comprehensive Cancer Network Guidelines Panel and sits on several editorial and advisory boards, such as Hematology Digest, Bone Marrow Transplantation and Clinical Cancer Research. In 2003, Dr. Talpaz received the prestigious "Leukemia and Lymphoma Society Service to Mankind Award" for his pioneering work in this cancer field. Dr. Talpaz discovered the use of interferon-a for treating chronic myeloid leukemia (CML) and he was the principal investigator until FDA approval. In addition, Dr. Talpaz has acted as a consultant to Hoffman LaRoche with regards to the FDA approval process for interferon.

Douglas A. Drossman, M.D. is Professor of Medicine and Psychiatry, University of North Carolina School of Medicine, Division of Gastroenterology & Heptalogy, and Co-Director of the Center for Functional GI & Motility Disorders. He has had a long-standing interest in the research and evaluation of difficult to diagnose and treat GI disorders. Dr. Drossman has published more that 400 books, articles and abstracts relating to epidemiology, psychosocial and quality of life assessment, design of treatment trials, and outcomes of research in GI disorders. He serves on six editorial boards in medicine, gastroenterology and psychosomatic medicine, and is currently editor of Digestive Health Matters. Dr. Drossman is a Fellow of the American College of Physicians and a Master of the American College of Gastroenterology. He is President of the Rome Foundation and Scientific Director and member of the Board of the International Foundation for Functional GI Disorders.

Roman Perez-Soler, M.D. Dr. Perez-Soler is currently Gutman Professor of Oncology and Chairman of the Department of Oncology at Montefiore Medical Center as well as Associate Director of Clinical Research at the Albert Einstein Cancer Center and Chief of the Division of Medical Oncology at the Albert Einstein College of Medicine. Dr. Perez-Soler was formerly Professor of Medicine and Deputy Chairman of the Department of Thoracic/Head and Neck Medical Oncology at The University of Texas M.D. Anderson Cancer Center and Associate Director for Clinical and Translational Research at the Kaplan Cancer Center at New York University. Dr. Perez-Soler is a nationally and internationally renowned clinical translational researcher in the areas of new anticancer drug development, with a strong emphasis in liposome delivery and thoracic malignancies.

COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT

Section 16(a) of the Securities Exchange Act of 1934 requires our officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission and American

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Stock Exchange. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

Based on a review of the copies of such forms received, we believe that during 2008, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with.

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 this Code of Business Conduct and Ethics is posted on our website at *www.callistopharma.com*.

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ITEM 11. EXECUTIVE COMPENSATION.

SUMMARY COMPENSATION TABLE

The following table provides certain summary information concerning compensation awarded to, earned by or paid to our Chief Executive Officer, Principal Financial Officer and two other 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	Year	Salary	Bonus	Option Awards(1)	Total
Gabriele M Cerrone(2)	2008	$ 296,917	$ 61,875	$ 83,358	$ 442,150
Chairman of the Board	2007	252,083	84,147	130,793	467,023
	2006	213,542	125,855		339,397
Gary S. Jacob					
	2008	300,000	11,250	211,961	523,211
Chief Executive Officer and	2007	300,000	78,750	109,323	488,073
Chief Scientific Officer	2006	287,500	48,125	82,147	417,772
Bernard F. Denoyer					
	2008	174,832	26,500	28,398	229,730
Senior Vice President, Finance	2007	123,500	12,000	29,862	165,362
and Principal Financial Officer	2006	111,576	10,461		122,037

(1) Amounts represent Callisto and Synergy combined stock-based compensation expense for fiscal year 2008, 2007 and 2006 for stock options vesting in 2008, 2007 and 2006 in accordance with fair value measurement guidelines of SFAS 123R and discussed in Note 6 *Accounting for Share-Based Payments* of the Notes to our Consolidated Financial Statements included elsewhere in this report.

(2) Mr. Cerrone is being paid pursuant to a consulting agreement with us.

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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 Callisto stock options, as well as the exercise prices and expiration dates thereof, as of December 31, 2008.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date
Gary S. Jacob	500,000		$ 1.50	June 13, 2013
	112,500	162,500(1)	3.00	June 29, 2014
	200,000		1.01	July 6, 2015
	50,000	50,000(2)	1.64	March 17, 2016
	75,000	75,000(3)	0.81	February 16, 2017
Bernard F. Denoyer				
	100,000		3.60	January 15, 2014
	50,000		1.38	July 29, 2015
	75,000	50,000(4)	0.66	April 12, 2017
Gabriele M Cerrone				
	27,778		0.75	October 1, 2009
	200,000		1.25	January 18, 2011
	333,055		1.30	April 22, 2013
	75,000		1.50	June 13, 2013
	100,000		3.20	April 26, 2014
	375,000		1.70	January 10, 2015
	225,000	75,000(7)	0.96	January 25, 2017

(1) The remaining 162,500 options vest upon certain drug development or licensing benchmarks.

(2) The remaining 50,000 options vest on March 17, 2009.

(3) The remaining 75,000 options vest on December 31, 2009.

(4) 25,000 options vest on each of April 12, 2009 and 2010.

(7) The remaining 75,000 options vest on December 31, 2009.

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	Option Awards(1)	Total
John P. Brancaccio(2)	$ 31,500	$ 3,875	$35,375
Randall Johnson(3)	$ 28,000	$ 5,155	$31,155
Riccardo Dalla-Favera(4)	$ 15,000	$ 9,097	$24,097
Christoph Bruening(5)	$ 11,750	$ 3,467	$15,217
Stephen K. Carter(6)	$ 11,500	$ 2,721	$14,221

(1) Amounts represent Callisto and Synergy combined stock-based compensation expense for fiscal year 2008for stock options vesting in 2008 in accordance with fair value measurement guidelines of SFAS 123R and discussed in Note 6 *Accounting for Share-Based Payments* of the Notes to our Consolidated Financial Statements included elsewhere in this report.

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(2) Stock options for the purchase of an aggregate of 148,123 shares were outstanding as of December 31, 2008, with a grant date fair value of $229,095.

(3) Stock options for the purchase of an aggregate of 128,000 shares were outstanding as of December 31, 2008, with a grant date fair value of $113,535.

(4) Stock options for the purchase of an aggregate of 101,000 shares were outstanding as of December 31, 2008, with a grant date fair value of $65,989.

(5) Stock options for the purchase of an aggregate of 148,000 shares were outstanding as of December 31, 2008, with a grant date fair value of $437,792.

(6) Stock options for the purchase of an aggregate of 84,861 shares were outstanding as of December 31, 2008, with a grant date fair value of $108,674. Dr. Carter resigned effective 7/1/08.

EMPLOYMENT AGREEMENTS AND CHANGE IN CONTROL AGREEMENTS

On March 11, 2009, Dr. Gary Jacob entered into an amended and restated employment agreement with us in which he agreed to serve as Chief Executive Officer. 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 25% is to be allocated to Callisto and 75% is to be allocated to our majority owned subsidiary, Synergy, where Dr. Jacob serves as President and Acting Chief Executive Officer. 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. 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.

Had a "Change of Control" occurred on December 31, 2008 and the executive had been terminated on that date, Dr. Jacob would have been eligible for total compensation (salary and bonus) for the term of his employment under his employment agreement for the time remaining of such employment term, of $1,350,000.

As of December 31, 2008, the unrecognized fair value of all Dr. Jacob's unvested options was $468,255.

We are party to an employment agreement with Bernard Denoyer, dated January 15, 2004, as amended September 1, 2006, to serve as our Vice President, Finance. On December 10, 2007 we entered into an amended and restated employment agreement with Bernard Denoyer pursuant to

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which Mr. Denoyer serves as our Senior Vice President, Finance and Secretary. Mr. Denoyer's amended and restated employment agreement is for a term of 12 months beginning December 1, 2007 and is automatically renewable for successive one year periods at the end of the term. Mr. Denoyer's base salary was $162,000 per year and he may earn a performance bonus of 15% of his base salary per year at the discretion of the Compensation Committee of the Board of Directors. Effective July 14, 2008, upon Synergy becoming a publicly traded company, Mr. Denoyer's base salary was increased to $190,000 per annum and we have since that time apportioned his compensation 50% to Synergy where Mr. Denoyer also serves as Senior Vice President, Finance.

CONSULTING AGREEMENTS

On March 11, 2009, Gabriele M. Cerrone, our Chairman of the Board, entered into an amended and restated 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 25% is to be allocated to Callisto and 75% is to be allocated to our majority owned subsidiary, Synergy, where Mr. Cerrone also serves as a consultant. Mr. Cerrone is eligible to receive a cash bonus of up to 50% of his base compensation per year based on meeting certain performance objectives and bonus criteria. 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. Had Mr. Cerrone been terminated without cause or good reason on December 31, 2008, he would have been eligible for total compensation of $1,327,500 for the time remaining under the amended and restated consulting agreement.

As of December 31, 2008, the unrecognized fair value of all Mr. Cerrone's unvested options was $422,788.

On December 18, 2007 we entered into a consulting agreement with Dr. Douglas A. Drossman to become a member of our Clinical and Scientific Advisory Board and to provide consulting services related to our SP-304 clinical development program. Under the agreement Dr. Drossman is paid $4,000 per day or $400 per hour, whichever is less for the consulting period, and reimbursed for expenses. The term of the agreement is twelve months, is automatically renewable for successive one year periods at the end of the term and can be terminated by us at our discretion, at any time.

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On February 26, 2006 we entered into a consulting agreement with Dr. Arthur Sytkowski to be our medical monitor for clinical trials. Under the agreement Dr. Sytkowski is paid $250 per hour and reimbursed for expenses. The term of the agreement is twelve months, is automatically renewable for successive one year periods at the end of the term and can be terminated by him or us with 90 days advance notice.

On January 31, 2006 we entered into a consulting agreement with Dr. Moshe Talpaz, whereby Dr. Talpaz will provide consulting services for our Degrasyns program. Under the agreement Dr. Talpaz will be paid $10,000 per year and was granted 575,000 10-year options to purchase our common stock at $1.60 per share. Such options vest based on milestones related to the Degrasyns compounds being developed towards FDA approval. In addition, pursuant to the agreement we agreed to issue 75,000 restricted shares of common stock to Dr. Talpaz subject to stockholder approval. The term of the agreement is for the length of time we are developing the Degrasyns platform of compounds in all indications.

On August 12, 2004, in connection with our L-Annamycin license, we entered into a consulting agreement with Roman Perez-Soler, M.D., for a term concurrent with the L-Annamycin license agreement. In connection therewith Dr. Perez-Soler agreed to be appointed to our Scientific Advisory Board. As consideration for consulting and advisory services Dr. Perez-Soler shall receive a $30,000 per year consulting fee and 44,000 shares of restricted common stock. In addition, we granted to Dr. Perez-Soler an option to purchase 468,500 shares of common stock at an exercise price of $3.00 per share.

On August 21, 2008, the Board of Directors of Synergy (the "Board") appointed Melvin K. Spigelman, M.D. as a Director of Synergy. In addition, the Board of Directors appointed Dr. Spigelman Chairman of Synergy's Clinical Oversight Committee as well as a member of the Synergy Compensation and Audit Committees ("the Committees"). In connection therewith, the Board 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, to purchase Synergy common stock, 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.

STOCK OPTION PLANS

We rely on incentive compensation in the form of stock options to retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options 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.

Callisto Pharmaceuticals, Inc. Stock Option plans

In 1996, Callisto adopted the 1996 Incentive and Non-Qualified Stock Option Plan (the "Plan") for employees, consultants and outside directors to purchase up to 2,000,000 shares of common stock. This Plan was amended in December 2002 to increase the number of shares authorized under the Plan to 10,000,000. The option term for the 3,884,205 options outstanding as of December 31, 2008 under the Plan is ten years from date of grant. The Plan terminated on January 1, 2006 under its original terms and no further options will be granted under the Plan.

On October 20, 2005, our stockholders approved the 2005 Equity Compensation Incentive Plan. The maximum number of shares of common stock with respect to which awards may be granted under the 2005 Equity Plan is 5,000,000. The option term for options granted under the 2005 Equity Plan is

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ten years from date of grant and there were 3,468,000 options available for future grants as of December 31, 2008.

On October 20, 2005, our stockholders approved our 2005 Directors' Stock Option Plan. The maximum number of shares of common stock with respect to which awards may be granted under the 2005 Directors' Plan is 1,000,000. The option term for options granted under the 2005 Directors' Plan is ten years from date of grant and there are 830,000 option shares available for future grants as of December 31, 2008.

Our 2005 Equity Compensation Incentive Plan authorizes the grant of stock options to directors (excluding outside directors), eligible employees, including executive officers and consultants. The value realizable from exercisable options is dependent upon the extent to which our performance is reflected in the value of our common stock at any particular point in time. Equity compensation in the form of stock options is designed to provide long-term incentives to directors, executive officers and other employees. We approve the granting of options in order to motivate these employees to maximize stockholder value. Generally, vesting for options granted under the stock option plan is determined at the time of grant, and options expire after a 10-year period. Options are generally granted at an exercise price not less than the fair market value at the date of grant. As a result of this policy, directors, executives, employees and consultants are rewarded economically only to the extent that the stockholders also benefit through appreciation in the market. Options granted to employees are based on such factors as individual initiative, achievement and performance. In administering grants to executives, the Compensation Committee of the Board of Directors evaluates each executive's total equity compensation package. The compensation committee generally reviews the option holdings of each of the executive officers, including vesting and exercise price and the then current value of such unvested options. We consider equity compensation to be an integral part of a competitive executive compensation package and an important mechanism to align the interests of management with those of our stockholders.

The options we grant under the 2005 Equity Plan may be either "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), or non-statutory stock options at the discretion of the Board of Directors and as reflected in the terms of the written option agreement. None of our stock option plans are qualified deferred compensation plans under Section 401(a) of the Code, and are not subject to the provisions of the Employee Retirement Income Security Act of 1974, as amended (ERISA). As of December 31, 2008, we have 2,352,333 stock options outstanding not subject to our stock option plans.

Synergy Pharmaceuticals, Inc. Stock Option Plan

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 Synergy 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 Synergy's businesses by affording such persons equity participation in Synergy and (iii) associating the interests of such persons with those of Synergy 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. The maximum aggregate number of shares of Synergy common stock that may be (i) issued under the Plan pursuant to the exercise of options and (ii) issued pursuant to Restricted Stock Awards is 6,500,000 shares of Synergy 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.

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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 14, 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 Callisto Pharmaceuticals, Inc., 420 Lexington Avenue, Suite 1609, New York, N.Y. 10170.

	Shares of Common Stock Beneficially Owned(1)	
Name and Address of Beneficial Owner	**Number of Shares**	**Percentage and Class**
Gabriele M. Cerrone Chairman of the Board	3,462,570(2)	6.7%
Gary S. Jacob Chief Executive Officer, Chief Scientific Officer and Director	1,249,745(3)	2.4%
Bernard Denoyer Senior Vice President, Finance and Secretary	225,000(4)	*
Riccardo Dalla-Favera Director	89,000(5)	*
Christoph Bruening Director	605,699(6)	1.2%
John Brancaccio Director	128,123(7)	*
Randall K. Johnson Director	109,500(8)	*
All Directors and Executive Officers as a group (7 persons)	5,869,637(9)	10.9%

* less than 1%

(1) Applicable percentage ownership as of April 14, 2009 is based upon 50,747,661 shares of common stock outstanding.

(2) Includes 1,260,833 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone and 30,000 shares of common stock issuable upon exercise of warrants, held by Panetta Partners, Ltd. Mr. Cerrone is the sole managing partner of Panetta and in such capacity only exercises voting and dispositive control over securities owned by Panetta, despite him having only a small pecuniary interest in such securities.

(3) Includes 1,112,500 shares of common stock issuable upon exercise of stock options.

(4) Consists of 225,000 shares of common stock issuable upon exercise of stock options.

(5)

Consists 89,000 shares of common stock issuable upon exercise of stock options.

(6) Includes 130,000 shares of common stock issuable upon exercise of stock options.

(7) Consists of 128,123 shares of common stock issuable upon exercise of stock options.

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(8) Consists of 109,500 shares of common stock issuable upon exercise of stock options.

(9) Includes 3,054,956 shares of common stock issuable upon exercise of stock options and 30,000 shares of common stock issuable upon exercise of the warrants.

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 an amended and restated 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 25% is to be allocated to Callisto and 75% is to be allocated to Synergy. Mr. Cerrone is eligible to receive a cash bonus of up to 50% of his base compensation per year based on meeting certain performance objectives and bonus criteria. Such performance objectives and bonus criteria have not been determined as of December 31, 2008 and therefore have not been 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%.

The agreement, the amendment and their respective terms were approved by our Compensation Committee, which consists solely of independent members of the Board. Additional information concerning the terms of the consulting agreement are set forth in Items 8 and 11 of this annual report.

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.

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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 $297,926. The aggregate fees billed and unbilled for the fiscal year ended December 31, 2007 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 $131,000.

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 and unbilled for the fiscal year ended December 31, 2008 for professional services rendered by our principal accountants for Tax Advisory services was $15,000 in connection with a review of the tax consequences of the Exchange Transaction dated July 14, 2008 . There were no aggregate fees billed for the fiscal years ended December 31, 2007 as there was 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 June 5, 1996 (inception) to December 31, 2008	F-4
Consolidated Statement of Changes in Stockholder's Equity (Deficit) for the period June 5, 1996 (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 June 5, 1996 (inception) to December 31, 2008	F-9
Notes to Consolidated Financial Statements	F-10

(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.

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(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. Two asterisks (**) indicate confidential treatment requested with respect to deleted portions of this agreement.

Exhibit No.	Description
3.1	Certificate of Incorporation, as amended (Incorporated by reference to Exhibit 2.1 filed with the Company's Annual Report on Form 10-K filed on March 28, 2008)
3.2	Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed on October 27, 2006)
3.3	Certificate of Amendment to Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.2 filed with the Company's Current Report on Form 8-K filed on December 27, 2006)
3.4	Certificate of Amendment to Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.2 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
3.5	Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series B Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
3.6	Bylaws, as amended (Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed on June 4, 2007)
4.1	1996 Incentive and Non-Qualified Stock Option Plan (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on May 15, 2003)
4.2	Form of Warrant to purchase shares of common stock issued in connection with the sale of common stock (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on January 28, 2004)
4.4	2005 Equity Compensation Incentive Plan (Incorporated by reference to Appendix B filed with the Company's Definitive Proxy Statement on Schedule 14A filed on August 31, 2005)
4.5	2005 Directors' Stock Option Plan (Incorporated by reference to Appendix C filed with the Company's Definitive Proxy Statement on Schedule 14A filed on August 31, 2005)
4.6	Form of Warrant to purchase Common Stock issued in connection with the sale of Common Stock (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on February 9, 2006)

4.7 Form of Warrant to purchase Common Stock issued to certain selling agents in connection with the sale of Common Stock (Incorporated by reference to Exhibit 4.2 filed with the Company's Current Report on Form 8-K filed on February 9, 2006)

4.8 Form of Warrant issued pursuant to the Letter Agreement dated September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on September 14, 2006)

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Exhibit No.	Description
4.9	Form of Warrant to purchase shares of Common Stock issued in connection with the sale of the Series A Convertible Preferred Stock (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on October 27, 2006)
4.10	Form of Warrant to purchase shares of Common Stock issued in connection with the sale of the Series B Convertible Preferred Stock (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
10.1	Employment Agreement dated April 6, 2004 by and between Synergy Pharmaceuticals Inc. and Kunwar Shailubhai (Incorporated by reference to Exhibit 10.2 filed with the Company's Annual Report on Form 10-KSB on April 14, 2004)*
10.2	Amended and Restated License Agreement dated as of December 31, 2007 by and between Callisto Pharmaceuticals, Inc. and AnorMED Corporation, as successor in interest to AnorMED, Inc. (Incorporated by reference to Exhibit 10.3 filed with the Company's Annual Report on Form 10-K on March 28, 2008)**
10.3	Patent and Technology License Agreement dated August 12, 2004 by and between The Board of Regents of the University of Texas System, on behalf of The University of Texas M.D. Anderson Cancer Center and Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on September 7, 2004)**
10.4	Amendment dated October 19, 2005 to the Employment Agreement dated as of April 6, 2004 by and between Synergy Pharmaceuticals Inc. and Kunwar Shailubhai (Incorporated by reference to Exhibit 10.5 filed with the Company's Current Report on Form 8-K filed on October 21, 2005)*
10.5	Patent and Technology License Agreement dated January 10, 2006 between The University of Texas M.D. Anderson Cancer Center and Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.22 filed with the Company's Annual Report on Form 10-K filed on March 31, 2006)**
10.6	Form of Letter Agreement dated September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on September 14, 2006)
10.17	Form of Amendment Agreement dated as of September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on September 14, 2006)
10.8	Form of Securities Purchase Agreement dated August 2, 2007 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
10.9	Form of Registration Rights Agreement dated August 2, 2007 by and among Callisto Pharmaceuticals, Inc. and the purchaser's signatory thereto (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
10.10	Amended and Restated Employment Agreement dated December 10, 2007 by and between Callisto Pharmaceuticals, Inc and Bernard Denoyer (Incorporated by reference to Exhibit 10.26 filed with the Company's Annual Report on Form 10-K on March 28, 2008)*

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Exhibit No.	Description
10.11	Exchange Agreement dated July 14, 2008 among Callisto Pharmaceuticals, Inc. Synergy Pharmaceuticals, Inc. the individuals named on the signature pages thereto and Pawfect Foods, Inc. (incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on July 18, 2008)
10.12	Amendment to Exchange Agreement dated July 14, 2008 among Callisto Pharmaceuticals, Inc. Synergy Pharmaceuticals, Inc. the individuals named on the signature pages thereto and Pawfect Foods, Inc. (incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on July 18, 2008)
10.13	Technology Assignment Agreement between Callisto Pharmaceuticals, Inc. and AnorMED Corporation, a wholly owned subsidiary of Genzyme Corporation, dated December 19, 2008.
10.14	Form of Securities Purchase Agreement by and between Callisto Pharmaceuticals, Inc. and the several investors party thereto.
10.15	Form of Security Agreement made by Callisto Pharmaceuticals, Inc and Sommer and Schneider, LLP.
10.16	Form of Common Stock Purchase Warrant.
10.17	Form of Secured Promissory Note.
10.18	Amended and Restated Executive Employment Agreement by and between Callisto Pharmaceuticals, Inc. and Gary S. Jacob dated March 11, 2009.*
10.19	Amended and Restated Consulting Agreement by and between Callisto Pharmaceuticals, Inc. and Gabriele M. Cerrone dated March 11, 2009.*
14	Code of Business Conduct and Ethics (Incorporated by reference to Exhibit 14 filed with the Company's Annual Report on Form 10-KSB filed on April 14, 2004)
21	List of Subsidiaries
23	Consent of BDO Seidman, LLP
31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CALLISTO PHARMACEUTICALS, INC.
(Registrant)

Date: April 15, 2009 By: /s/ GARY S. JACOB

Gary S. Jacob,
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ GARY S. JACOB Gary S. Jacob	Chief Executive Officer and Director (Principal Executive Officer)	April 15, 2009
/s/ BERNARD F. DENOYER Bernard F. Denoyer	Senior Vice President, Finance (Principal Financial and Accounting Officer)	April 15, 2009
/s/ GABRIELE M. CERRONE Gabriele M. Cerrone	Chairman of the Board	April 15, 2009
/s/ RICCARDO DALLA-FAVERA Riccardo Dalla-Favera	Director	April 15, 2009
/s/ JOHN P. BRANCACCIO John P. Brancaccio	Director	April 15, 2009
/s/ CHRISTOPH BRUENING Christoph Bruening	Director	April 15, 2009
/s/ RANDALL K. JOHNSON Randall K. Johnson	Director	April 15, 2009

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

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Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of Callisto 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 June 5, 1996 (inception) to December 31, 2008 and the related consolidated statement of stockholders' equity (deficit) for the period from June 5, 1996 (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 Callisto 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 June 5, 1996 (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

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CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2008	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 301,323	$ 3,269,341
Short term investments		2,967,690
Cash in escrow	201,908	
Prepaid expenses and other	59,756	88,820
Total Current Assets	562,987	6,325,851
Property and equipment, net	20,649	15,108
Security deposits	78,116	73,716
Total Assets	$ 661,752	$ 6,414,675
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 3,687,549	$ 3,254,992
Accrued expenses	1,136,264	1,366,333
Total Current Liabilities	4,823,813	4,621,325
Notes payable	20,176	
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Series A convertible preferred stock, par value $0.0001, 700,000 shares authorized, 98,000 shares outstanding at December 31, 2008 with a liquidation preference of $980,000 and 218,675 shares outstanding at December 31, 2007 with a liquidation preference of $2,186,750	10	22
Series B convertible preferred stock, par value $0.0001, 2,500,000 shares authorized, 1,137,050 shares outstanding at December 31, 2008 with a liquidation preference of $11,370,500 and 1,147,050 shares outstanding at December 31, 2007 with a liquidation preference of $11,470,500	114	115
Common stock, par value of $.0001 per share: Authorized 225,000,000 shares at December 31, 2008 and December 31, 2007; 49,556,661 and 46,943,161 shares outstanding at December 31, 2008 and December 31, 2007, respectively	4,955	4,694
Additional paid-in capital	86,799,951	83,120,315
Deficit accumulated during development stage	(90,987,267)	(81,331,796)
Total Stockholders' Equity (Deficit)	(4,182,237)	1,793,350
Total Liabilities and Stockholders' Equity (Deficit)	$ 661,752	$ 6,414,675

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

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CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,			For the period June 5, 1996 (inception) to December 31,
	2008	**2007**	**2006**	**2008**
Revenues	$	$	$	$
Costs and Expenses:				
Research and development	5,449,721	6,507,978	6,134,704	34,098,264
Government grants	(30,000)	(260,853)	(352,649)	(1,135,318)
Purchased in-process research and development				6,944,553
General and administrative	4,311,767	4,317,288	6,384,116	38,978,606
Loss from Operations	(9,731,488)	(10,564,413)	(12,166,171)	(78,886,105)
Interest and investment income	76,017	84,694	48,632	864,327
Other income/(expense), net		1,449	(801,690)	(171,846)
Change in fair value of Series B Preferred investor warrants from date of issuance to expiration of put option		2,591,005		2,591,005
Net Loss	(9,655,471)	(7,887,265)	(12,919,229)	(75,602,619)
Series A Preferred stock beneficial conversion feature accreted as a dividend		(2,504,475)	(2,384,485)	(4,888,960)
Series B Preferred stock beneficial conversion feature accreted as a dividend		(10,495,688)		(10,495,688)
Net loss available to common stockholders	$ (9,655,471)	$(20,887,428)	$(15,303,714)	$(90,987,267)
Weighted Average Common Shares Outstanding				
Basic and Diluted	47,357,254	41,770,669	37,941,267	
Net Loss per Common Share				
Basic and Diluted	$ (0.20)	$ (0.50)	$ (0.40)	

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

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CALLISTO PHARMACEUTICALS, INC.

(A development stage company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Preferred Shares	Preferred Stock, Par Value	Common Shares	Common Stock, Par Value	Additional Paid in Capital
Balance at inception, June 5, 1996		$		$	$
Issuance of founder shares			2,642,500	264	528
Common stock issued			1,356,194	136	272
Common stock issued via private placement			1,366,667	137	1,024,863
Balance, December 31, 1996			5,365,361	537	1,025,663
Net loss for the year					
Common stock issued via private placement			1,442,666	144	1,081,855
Balance, December 31, 1997			6,808,027	681	2,107,518
Net loss for the year					
Amortization of stock-based compensation					52,778
Common stock issued via private placement			1,416,667	142	1,062,358
Common stock issued for services			788,889	79	591,588
Common stock repurchased and cancelled			(836,792)	(84)	(96,916)
Balance, December 31, 1998			8,176,791	818	3,717,326
Net loss for the year					
Deferred compensation stock options					9,946
Amortization of stock-based compensation					
Common stock issued for services					3,168,832
Common stock issued via private placement			346,667	34	259,966
Balance, December 31, 1999			8,523,458	852	7,156,070
Net loss for the year					
Amortization of stock-based compensation					
Common stock issued			4,560,237	455	250,889
Other					432
Preferred shares issued	3,485,299	348			5,986,302
Preferred stock issued for services	750,000	75			1,124,925
Balance, December 31, 2000	4,235,299	$ 423	13,083,695	$ 1,307	$ 14,518,618

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

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	Unamortized Deferred Stock-Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance at inception, June 5, 1996	$	$	$
Issuance of founder shares		(404,005)	(403,213)
Common stock issued			408
Common stock issued via private placement			1,025,000
Balance, December 31, 1996		(404,005)	622,195
Net loss for the year		(894,505)	(894,505)
Common stock issued via private placement			1,081,999
Balance, December 31, 1997		(1,298,510)	809,689
Net loss for the year		(1,484,438)	(1,484,438)
Amortization of stock-based compensation			52,778
Common stock issued via private placement			1,062,500
Common stock issued for services			591,667
Common stock repurchased and cancelled			(97,000)
Balance, December 31, 1998		(2,782,948)	935,196
Net loss for the year		(4,195,263)	(4,195,263)
Deferred compensation stock options	(9,946)		
Amortization of stock-based compensation	3,262		3,262
Common stock issued for services			3,168,832
Common stock issued via private placement			260,000
Balance, December 31, 1999	(6,684)	(6,978,211)	172,027
Net loss for the year		(2,616,261)	(2,616,261)
Amortization of stock-based compensation	4,197		4,197
Common stock issued			251,344
Other			432
Preferred shares issued			5,986,650
Preferred stock issued for services			1,125,000
Balance, December 31, 2000	$ (2,487)	$ (9,594,472)	$ 4,923,389

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

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	Preferred Shares	Preferred Stock, Par Value	Common Shares	Common Stock, Par Value	Additional Paid in Capital
Balance, December 31, 2000	4,235,299	$ 423	13,083,695	$ 1,307	$ 14,518,618
Net loss for the year					
Deferred compensation stock options					20,000
Amortization of stock-based compensation					
Balance, December 31, 2001	4,235,299	423	13,083,695	1,307	14,538,618
Net loss for the year					
Amortization of stock-based compensation					
Balance, December 31, 2002	4,235,299	423	13,083,695	1,307	14,538,618
Net loss for the year					
Conversion of preferred stock in connection with the merger	(4,235,299)	(423)	4,235,299	423	
Common stock issued to former Synergy stockholders			4,329,927	432	6,494,458
Common stock issued in exchange for Webtronics common stock			1,503,173	150	(150)
Deferred compensation stock options					9,313,953
Amortization of stock-based compensation					
Private placement of common stock, net			2,776,666	278	3,803,096
Balance, December 31, 2003			25,928,760	2,590	34,149,975
Net loss for the year					
Common stock issued via private placements, net			3,311,342	331	6,098,681
Warrant and stock-based compensation for services in connection with the merger					269,826
Common stock returned from former Synergy stockholders			(90,000)	(9)	(159,083)
Stock issued for patent rights			25,000	3	56,247
Common stock issued for services			44,000	7	70,833
Variable account for stock options					(816,865)
Amortization of stock-based compensation					
Stock-based compensation					240,572
Balance, December 31, 2004		$	29,219,102	$ 2,922	$ 39,910,186

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

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	Unamortized Deferred Stock-Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance, December 31, 2000	$ (2,487)	$ (9,594,472)	$ 4,923,389
Net loss for the year		(1,432,046)	(1,432,046)
Deferred compensation stock options	(20,000)		
Amortization of stock-based compensation	22,155		22,155
Balance, December 31, 2001	(332)	(11,026,518)	3,513,498
Net loss for the year		(1,684,965)	(1,684,965)
Amortization of stock-based compensation	332		332
Balance, December 31, 2002		(12,711,483)	1,828,865
Net loss for the year		(13,106,247)	(13,106,247)
Conversion of preferred stock in connection with the merger			
Common stock issued to former Synergy stockholders			6,494,890
Common stock issued in exchange for Webtronics common stock			
Deferred compensation stock options	(9,313,953)		
Amortization of stock-based compensation	3,833,946		3,833,946
Private placement of common stock, net			3,803,374
Balance, December 31, 2003	(5,480,007)	(25,817,730)	2,854,828
Net loss for the year		(7,543,467)	(7,543,467)
Common stock issued via private placements, net			6,099,012
Warrant and stock-based compensation for services in connection with the merger			269,826
Common stock returned from former Synergy stockholders			(159,092)
Stock issued for patent rights			56,250
Common stock issued for services			70,840
Variable account for stock options			(816,865)
Amortization of stock-based compensation	3,084,473		3,084,473
Stock-based compensation	93,000		333,572
Balance, December 31, 2004	$ (2,302,534)	$ (33,361,197)	$ 4,249,377

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

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	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock, Par Value	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Unamortized Deferred Stock-Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance, December 31, 2004		$	29,219,102	$ 2,922	$39,910,186	$ (2,302,534)	$ (33,361,197)	$ 4,249,377
Net loss for the year							(11,779,457)	(11,779,457)
Deferred stock-based compensation new grants					1,571,772	(1,571,772)		
Amortization of stock-based compensation						2,290,843		2,290,843
Variable accounting for stock options					75,109			75,109
Common stock issued via private placement March 2005			1,985,791	198	3,018,203			3,018,401
Common stock issued via private placement August 2005			1,869,203	187	1,812,940			1,813,127
Finders fees and expenses					(176,249)			(176,249)
Exercise of common stock warrant			125,000	13	128,737			128,750
Common stock issued for services			34,000	3	47,177			47,180
Balance, December 31, 2005			33,233,096	3,323	46,387,875	(1,583,463)	(45,140,654)	(332,919)
Net loss for the year							(12,919,229)	(12,919,229)
Amortization of stock-based compensation					2,579,431			2,579,431
Reclassification of deferred unamortized stock-based compensation upon adoption of SFAS No. 123R					(1,583,463)	1,583,463		
Common stock issued via private placement February 2006			4,283,668	428	5,139,782			5,140,210
Common stock issued via private placement April 2006			666,667	67	799,933			800,000
Finders fees and expenses	11,775	1			(1,051,717)			(1,051,716)
Waiver and lock-up agreement			740,065	74	579,622			579,696
Common stock issued for services			87,000	9	121,101			121,110
Exercise of common stock warrants			184,500	18	190,017			190,035
Series A convertible preferred stock issued via private placement	574,350	57			5,743,443			5,743,500
Detachable warrants					2,384,485			2,384,485
Beneficial conversion feature accreted as a dividend							(2,384,485)	(2,384,485)
Balance, December 31, 2006	586,125	$ 58	39,194,996	$ 3,919	$61,290,509	$	$ (60,444,368)	$ 850,118

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

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	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock, Par Value	Series B Convertible Preferred Shares	Series B Convertible Preferred Stock, Par Value	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance, December 31, 2006	586,125	$ 58		$	39,194,996	$ 3,919	$61,290,509	$ (60,444,368)	$ 850,118
Net loss for the year								(7,887,265)	(7,887,265)
Stock-based compensation expense							591,561		591,561
Common stock issued for services					80,000	8	36,792		36,800
Series A convertible preferred stock, issued via private placement	28,000	4					279,997		280,001
Finders fees and expenses, Series A private placement							(36,400)		(36,400)
Conversion of Series A preferred stock to common stock	(395,450)	(40)			7,668,165	767	(727)		
Beneficial conversion feature accreted as a dividend to Series A convertible preferred stock							2,504,475	(2,504,475)	
Series B convertible preferred stock, issued via private placement			1,147,050	115			11,470,385		11,470,500
Finders fees and expenses, Series B private placement							(920,960)		(920,960)
Beneficial conversion feature accreted as a dividend to Series B convertible preferred stock							10,495,688	(10,495,688)	
Change in fair value of Series B warrants from date of issuance to expiration of put option							(2,591,005)		(2,591,005)
Balance, December 31, 2007	218,675	22	1,147,050	115	46,943,161	4,694	83,120,315	(81,331,796)	1,793,350
Net loss for the year								(9,655,471)	(9,655,471)
Recapitalization of majority owned subsidiary via private placements of common stock							2,951,913		2,951,913
Minority interest in equity of subsidiary acquired							(42,824)		(42,824)
Stock-based compensation expense							589,063		589,063
Proceeds from issuance of 11% Notes attributable to detachable warrants							181,732		181,732
Conversion of Series A preferred stock to common stock	(120,675)	(12)			2,413,500	241	(229)		
Conversion of Series B preferred stock to common stock			(10,000)	(1)	200,000	20	(19)		

Balance, December 31, 2008	98,000	$	10	1,137,050	$	114	49,556,661	$ 4,955	$ 86,799,951	$ (90,987,267)	$ (4,182,237)

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

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CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,			Period from June 5, 1996 (Inception) to December 31,
	2008	2007	2006	2008
Cash Flows From Operating Activities:				
Net loss	$ (9,655,471)	$ (7,887,265)	$ (12,919,229)	$ (75,602,619)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	6,654	3,142	2,151	96,584
Stock-based compensation expense	589,063	628,361	2,746,478	17,734,869
Purchased in-process research and development				6,841,053
Purchase discount accreted as interest income on U.S. Treasury bills	(26,950)			(26,950)
Stock-based liquidated damages			579,696	579,696
Change in fair value of Series B preferred warrants from date of issuance to expiration of put options		(2,591,005)		(2,591,005)
Minority interest in net losses of majority owned subsidiary	(42,824)			(335,252)
Changes in operating assets and liabilities:				
Prepaid expenses	29,064	(22,079)	114,543	(59,756)
Security deposit	(4,400)		8,480	(78,116)
Accounts payable and accrued expenses	202,489	1,420,303	1,138,176	4,823,814
Total Adjustments	753,096	(561,278)	4,589,524	26,984,937
Net Cash Used in Operating Activities	(8,902,375)	(8,448,543)	(8,329,705)	(48,617,682)
Cash Flows From Investing Activities:				
Short-term investments purchased		(5,921,825)		(5,921,825)
Short-term investments liquidated	2,994,640	2,954,135		5,948,775
Additions to property and equipment	(12,196)	(11,798)	(8,602)	(117,233)
Net Cash Provided by (Used in) Investing Activities	2,982,444	(2,979,488)	(8,602)	(90,283)
Cash Flows From Financing Activities:				
Issuance of common and preferred stock		11,750,500	11,683,710	48,719,673
Finders fees and expenses		(957,360)	(1,051,716)	(2,981,083)
Proceeds of private placement of majority owned subsidiary's common stock, net of fees and expenses	2,951,913			2,951,913
Exercise of common stock warrants			190,035	318,785
Net Cash Provided by Financing Activities	2,951,913	10,793,140	10,822,029	49,009,288
Net (decrease) increase in cash and cash equivalents	(2,968,018)	(634,891)	2,483,722	301,323
Cash and cash equivalents at beginning of period	3,269,341	3,904,232	1,420,510	
Cash and cash equivalents at end of period	$ 301,323	$ 3,269,341	$ 3,904,232	$ 301,323
Supplementary disclosure of cash flow information:				
Cash paid for taxes	$ 33,370	$ 4,868	$ 13,880	$ 161,725
Cash paid for interest	$	$	$	$
Supplementary disclosure of non-cash investing and financing activities:				
Series A Preferred stock beneficial conversion feature accreted as a dividend	$	$ 2,504,475	$ 2,384,485	$ 4,888,960

Series B Preferred stock beneficial conversion feature accreted as a dividend	$	$ 10,495,688	$	$ 10,495,688
Issuance of 11% Notes payable, cash held on escrow	$ 201,908	$	$	$

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

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CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Business overview

Callisto Pharmaceuticals, Inc. ("Callisto" or the "Company") is a development stage biopharmaceutical company, whose primary focus has been on the development of drugs to treat neuroendocrine cancer (including advanced carcinoid cancer), acute leukemia and gastrointestinal ("GI") disorders and diseases. Callisto was incorporated in the state of Delaware on June 5, 1996 (inception). Since inception, Callisto's efforts have been principally devoted to research and development, securing and protecting patents and raising capital.

From inception through December 31, 2008, Callisto has sustained cumulative net losses available to common stockholders of $90,987,267. Callisto's losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, stock-based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees, as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception through December 31, 2008, Callisto has not generated any revenue from operations, expects to incur additional losses to perform further research and development activities and does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all.

Callisto's product development efforts are thus in their early stages and Callisto 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.

On July 14, 2008, Callisto entered into an Exchange Agreement dated July 11, 2008 ("Exchange Agreement"), as amended and effective on July 14, 2008, with Pawfect Foods, Inc. ("Pawfect"), Synergy Pharmaceuticals, Inc. ("Synergy-DE"), a majority-owned subsidiary of Callisto, and other holders of Synergy-DE common stock. According to the terms of the Exchange Agreement, Pawfect acquired 100% of the common stock of Synergy-DE, from Callisto and the other holders of Synergy-DE, in exchange for 45,464,760 shares of Pawfect's common stock representing approximately 70% of Pawfect's outstanding common stock (the "Exchange Transaction"). Callisto received 44,590,000 of the 45,464,760 shares of Pawfect's common stock exchanged for its ownership of Synergy-DE, and Callisto is now the holder of 68% of Pawfect's outstanding common stock. The remaining 874,760 shares of Pawfect common stock exchanged for ownership of Synergy-DE were issued to certain executive officers of Synergy-DE who received their shares pursuant to a Repurchase Agreement with Synergy-DE dated July 3, 2008 and assumed by Pawfect. The fair value of each of the 874,760 shares was estimated on the grant date to be $0.60, which was based on the price paid by shareholders participating in Synergy's July 14, 2008 private placement. Stock based compensation expense of $524,856 related to these shares is being amortized over the vesting period of 2 years. In connection with the Exchange Transaction Pawfect received $3,025,000 less transaction costs of $73,087, yielding net proceeds of $2,951,913 from two private placements, which the Company has recorded as an increase in additional paid-in capital.

Pawfect was a development stage company selling pet food products utilizing the World Wide Web, with immaterial operations to date. On July 14, 2008, Pawfect discontinued its pet food business to focus all resources on continuing the development of drugs to treat GI disorders and diseases acquired in connection with the Exchange Agreement. On July 21, 2008 Pawfect, amended its articles of

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incorporation, in the state of Florida, to effect the actions necessary to complete the transactions contemplated by the Exchange Agreement and changed its name to Synergy Pharmaceuticals, Inc. ("Synergy"). Synergy is now traded on the Over The Counter Bulletin Board under the symbol SGYP.OB.

2. Basis of presentation and going concern

All intercompany balances and transactions have been eliminated. These consolidated financial statements include Callisto and subsidiaries: (1) Callisto Research Labs, LLC (including its wholly-owned subsidiary, Callisto Pharma, GmbH (Germany inactive)), and (2) Synergy (including Synergy's wholly-owned subsidiaries, Synergy-DE, Synergy Advanced Pharmaceuticals, Inc. and 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").

The Company records adjustments to the minority interests in Synergy for the allocable portion of losses to which the minority interest holders are entitled. The Company suspended allocation of losses to minority interest holders when the minority interest balance was reduced to zero during the Quarter ended December 31, 2008. Any excess loss above the minority interest holder's balance is not charged to minority interests as the minority interest holders have no obligation to fund such losses.

Since Synergy has incurred losses during the period July 14, 2008 to December 31, 2008, Callisto reduced its minority interest for 32% of Synergy's losses, or $1,151,577, which excludes Synergy's charge for purchased in process research and development eliminated in consolidation. Consequently, Callisto has effectively recorded 100% of the net losses of Synergy in the accompanying consolidated statements of operations and the minority interest in equity of majority owned subsidiary is zero on the accompanying balance sheet as of December 31, 2008.

As of December 31, 2008, Callisto had an accumulated deficit during development stage of $90,987,267. Callisto expects to incur significant and increasing operating losses for the next several years as Callisto 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, Callisto is unable to predict the extent of any future losses or when Callisto will become profitable, if at all.

Net cash used in operating activities was $8,902,375, $8,448,543 and $8,329,705 for the twelve months ended December 31, 2008, 2007 and 2006, respectively, and $48,617,682 for the period from June 5, 1996 (inception) to December 31, 2008. As of December 31, 2008 and 2007, Callisto had $301,323 and $3,269,341 respectively, of cash and cash equivalents. As of December 31, 2007 Callisto also had $2,967,690 of temporary investments which were liquidated in full during the twelve months ended December 31, 2008 and used in operations.

During the twelve months ended December 31, 2008, 2007 and 2006, Callisto incurred net losses from operations of $9,731,488, $10,564,413 and $12,166,171, respectively and $78,886,105 for the period June 5, 1996 (inception) to December 31, 2008. To date, Callisto's sources of cash have been primarily limited to sale of equity securities. Net cash provided by financing activities for the twelve months ended December 31, 2008, 2007 and 2006 was $2,951,913, $10,793,140, and $10,822,029, respectively, and $49,009,288 for the period June 5, 1996 (inception) to December 31, 2008. As of December 31, 2008 Callisto had a working capital deficit of $4,260,826.

On December 30, 2008, Callisto entered into a securities purchase and exchange agreement ("Purchase Agreement") with several investors, each of whom were holders of record as of

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November 4, 2008 of outstanding warrants to purchase shares of the Company's common stock, exercisable at $0.50 or $0.70 per share until August 2, 2010 ("Series B Warrants"). The Series B Warrants were issued in connection with the private placement of the Company's Series B Preferred Shares on August 2, 2007. Pursuant to the Purchase Agreements Callisto issued $201,905 of an authorized $500,000 of 11% Secured Notes due April 15, 2010 ("11% Notes") with no discount. Interest on the 11% Notes is due on maturity, whether on April 15, 2010 or by acceleration. Payment of the 11% Notes is secured by a pledge of up to 1,900,000 shares (if all $500,000 principal amount of the 11% Notes were to be sold) of the common stock of Synergy Pharmaceuticals, Inc. owned by the Company. As of December 31, 2008, the $201,905 was held in escrow in the Company's name and received subsequent to year end. (See Note 5.)

On February 3, 2009 we issued an additional $53,161 of the authorized $500,000 11% Secured Notes bringing the aggregate proceeds from issuance of 11% Notes since inception to $255,066. 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, allow it to continue its efforts to raise additional financing for approximately six 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. Callisto has 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.

These consolidated financial statements have been prepared under the assumption that Callisto will continue as a going concern for the next twelve months. Callisto'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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Callisto 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. Callisto cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Callisto raises additional funds by issuing equity securities, Callisto's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Callisto's ability to conduct business. If Callisto is unable to raise additional capital when required or on acceptable terms, Callisto 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 Callisto would otherwise seek to develop or commercialize ourselves on unfavorable terms.

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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 short term, highly liquid investments, with original maturities of less than three months when purchased and are stated at cost.

Short-term Investments

Short-term investments are considered held-to-maturity securities at December 31, 2007 and consist of $2,967,690 million in United States Treasury Bills maturing in January and April 2008. The Company had no such investments at December 31, 2008. Held-to-maturity securities are those securities which Callisto has the ability and intent to hold until maturity and are recorded at amortized cost adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method.

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 and Equipment

Expenditures for additions, renewals and improvements are capitalized at cost. Depreciation is generally computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of the major classes of depreciable assets are 2 to 5 years for equipment, furniture and fixtures. Callisto 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 Callisto'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. (See Note 7.)

Contingencies

In the normal course of business, Callisto 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*

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Contingencies, ("SFAS No. 5"), Callisto 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. Callisto, in accordance with SFAS No. 5, does not recognize gain contingencies until realized. For a discussion of contingencies, see Note 8. *Commitments and Contingencies* below.

Business Concentrations and Credit Risks

All of Callisto's cash and cash equivalents as of December 31, 2008 and 2007 are on deposit with commercial financial institution. Deposits at any point in time may exceed federally insured limits.

Research and Development

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

Loss Per Share

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, *Earnings per Share*, ("SFAS No. 128") for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares because shares issuable pursuant to the exercise of stock options would have been antidilutive. (See Note 9)

Government Grants

On October 7, 2003 Callisto was awarded a $265,697 Small Business Technology Transfer Research grant from the National Institutes of Health ("NIH") for studies on Atiprimod. The Principal and Co-Principal Investigators of the grant entitled "Atiprimod to Treat Multiple Myeloma and Bone Resorption" are Dr. Gary S. Jacob, Chief Executive Officer of Callisto, and Dr. Kenneth C. Anderson, Director of the Jerome Lipper Multiple Myeloma Center of the Dana-Farber Cancer Institute, respectively. Funding for the total amount of this grant was received during the twelve months ended December 31, 2004 and $265,697 was reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grant".

On April 1, 2005 Callisto was awarded an $885,641 biodefense partnership grant from the National Institute of Allergy and Infectious Diseases ("NIAID") to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over a two year period. Callisto receives cash funding under approved grants and records the receipt as an offset to research and development expense only when the expense is incurred. Funds received as an offset to research and development expenses incurred totaled $30,000, $260,853 and $352,649 during the twelve months ended December 31, 2008, 2007 and 2006, respectively and has been reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grants". Funding for this program was extended one year through April 2008. Because the bioterrorism program is not a core activity, Callisto terminated in-house work on this program upon expiration of the research grant in April 2008.

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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 statements.

In June 2008, the FASB ratified the consensus reached on Emerging Issues Task Force ("EITF") Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* ("EITF No. 07-05"). EITF No. 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. EITF No. 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. The Company is currently evaluating the impact of the pending adoption of EITF No. 07-05 on its consolidated financial statements.

In March 2008, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 161, *Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133* ("SFAS No. 161"). SFAS No. 161 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. The guidance in SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. This Statement encourages, but does not require, comparative disclosures for earlier periods at initial adoption. The Company is currently assessing the impact of SFAS No. 161 on its consolidated financial statements.

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

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

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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 currently assessing the impact of adopting the provisions of SFAS No. 160 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 the 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. Callisto adopted EITF No. 07-3 on January 1, 2008 and the adoption did not have a material effect on its 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 No. 159 on January 1, 2008 and such adoption did not have a material effect on Callisto's financial statements, as Callisto 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 its 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.

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4. Merger and consolidation

In March 2002, Callisto Pharmaceuticals, Inc. ("Old Callisto"), a non-public company, purchased 99.7% of the outstanding common shares of Webtronics, Inc., ("Webtronics") a public company for $400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations during the twelve months ended December 31, 2002. The purchase price of Webtronics was treated as a cost of becoming a public company, however because there was no capital raised at the time, the amount was charged to general and administrative expense during the twelve months ended December 31, 2002.

On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Synergy Pharmaceuticals Inc. ("Synergy") and Callisto Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Old Callisto (collectively, the "Merger"). As a result of the Merger, Old Callisto and Synergy became wholly-owned subsidiaries of Webtronics. In connection with the Merger Webtronics issued 17,318,994 shares of its common stock in exchange for outstanding Old Callisto common stock and an additional 4,395,684 shares in exchange for outstanding Synergy common stock. Subsequently, 171,818 shares of common stock issued to former Synergy shareholders were returned to Callisto under the terms of certain indemnification agreements. The Merger was accounted for as a recapitalization of Old Callisto by an exchange of Webtronics common stock for the net assets of Old Callisto consisting primarily of cash and fixed assets. Old Callisto then changed its name to Callisto Research Labs, LLC and Webtronics changed its name to Callisto Pharmaceuticals, Inc.("Callisto") and changed its state of incorporation from Florida to Delaware. Callisto remains the continuing legal entity and registrant for Securities and Exchange Commission reporting purposes.

The merged companies are considered to be in the development stage. No revenues have been realized since inception and all activities have been concentrated in research and development of biopharmaceutical products not yet approved by the Food and Drug Administration. The fair value of the net shares issued to former Synergy shareholders in the Merger totaled $6,335,799 through December 31, 2005. The fair value per share of $1.50, used to determine this amount, was the value per share Callisto sold common stock in a private placement. The total consideration was allocated in full to the Synergy research and development projects which had not yet reached technological feasibility and having no alternative use was charged to purchased in-process research and development expense during the year ended December 31, 2003.

5. Stockholders' equity (deficit)

On December 30, 2008, Callisto entered into a securities purchase and exchange agreement ("Purchase Agreement") with several investors, each of whom were holders of record as of November 4, 2008 of outstanding warrants to purchase shares of the Company's common stock, exercisable at $0.50 or $0.70 per share until August 2, 2010 ("Series B Warrants"). The Series B Warrants were issued in connection with the private placement of the Company's Series B Preferred Shares on August 2, 2007. Pursuant to the Purchase Agreements Callisto issued $201,905 of an authorized $500,000 of 11% Secured Notes due April 15, 2010 ("11% Notes") with no discount. Interest on the 11% Notes is due on maturity, whether on April 15, 2010 or by acceleration. Payment of the 11% Notes is secured by a pledge of up to 1,900,000 shares (if all $500,000 principal amount of the 11% Notes were to be sold) of the common stock of Synergy Pharmaceuticals, Inc. owned by the Company. As of December 31, 2008, the $201,905 was held in escrow in the Company's name and received subsequent to year end.

Pursuant to the Purchase Agreement, Callisto issued, to the December 30, 2008 purchasers of the 11% Notes, 23,219,104 common stock purchase warrants ("New Warrants") in exchange for the surrender and cancellation of 11,298,134 outstanding Series B Warrants. The New Warrants have an

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exercise price, subject to certain anti-dilution adjustments, of $0.02 per share and are exercisable at any time on or prior to December 31, 2016.

The proceeds from the issuance of these instruments were allocated to the notes and warrants based upon the relative fair value amounts of the fair value of the notes and the estimated fair value of the warrants. The New Warrants had a fair value of approximately $1,900,000, measured utilizing the Black Scholes fair value methodology using assumptions of 8 years for expected term, volatility of 200%, no dividends and a risk free interest rate of 0.76%, as of December 30, 2008. This resulted in a debt discount of approximately $182,000. The debt discount will be amortized to interest expense over the life of the 11% Notes. Interest expense relating to these warrants was immaterial for the year ended December 31, 2008. The 11% Notes are shown, net of the unamortized debt discount in the accompanying balance sheet.

On July 14, 2008, Callisto entered into an Exchange Agreement dated July 11, 2008 ("Exchange Agreement"), as amended and effective on July 14, 2008, with Pawfect Foods, Inc. ("Pawfect"), Synergy Pharmaceuticals, Inc. ("Synergy-DE"), a majority-owned subsidiary of Callisto, and other holders of Synergy-DE common stock. According to the terms of the Exchange Agreement, Pawfect acquired 100% of the common stock of Synergy-DE, from Callisto and the other holders of Synergy-DE, in exchange for 45,464,760 shares of Pawfect's common stock representing approximately 70% of Pawfect's outstanding common stock (the "Exchange Transaction"). Callisto received 44,590,000 of the 45,464,760 shares of Pawfect's common stock exchanged for its ownership of Synergy-DE, and Callisto is now the holder of 68% of Pawfect's outstanding common stock. The remaining 874,760 shares of Pawfect common stock exchanged for ownership of Synergy-DE were issued to certain executive officers of Synergy-DE who received their shares pursuant to a Repurchase Agreement with Synergy-DE dated July 3, 2008 and assumed by Pawfect. The fair value of each of the 874,760 shares was estimated on the grant date to be $0.60, which was based on the price paid by shareholders participating in Synergy's July 14, 2008 private placement. Stock based compensation expense of $524,856 related to these shares is being amortized over the vesting period of 2 years. In connection with the Exchange Transaction Pawfect received $3,025,000 less transaction costs of $73,087, yielding net proceeds of $2,951,913 from two private placements, which the Company has recorded as an increase in additional paid-in capital.

On April 7, 2008, Callisto received notice from the staff of the American Stock Exchange ("AMEX") of its intent to strike Callisto's common stock from the AMEX by filing a delisting application with the SEC for failure to regain compliance with Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide and falling out of compliance with Section 1003(a)(iii) of the Company Guide with shareholders' equity of less than $6,000,000 and losses from continuing operations and/or net losses in four of our five most recent fiscal years. On July 14, 2008, Callisto's common stock was delisted from the AMEX and currently trades on the Over The Counter Bulletin Board under the Symbol CLSP.OB.

On January 31, 2008, the Board of Directors approved a reassignment, as well as, a decrease in the exercise price, of the 1,323,822 warrants, previously assigned from Trilogy Capital Partners LLC to two unaffiliated entities, from $1.03 per share to $0.70 per share. The decrease in the exercise price was effective immediately and the reassignment will be effective at management's discretion. Callisto has determined that the price modifications was compensatory in accordance with SFAS 123R and the associated stock-based compensation expense of $45,086 was recorded during the quarter ended March 31, 2008. As of December 31, 2008, Callisto had not reassigned the warrants any further.

On September 27, 2007, Callisto filed a Certificate of Amendment to its Certificate of Incorporation increasing its authorized number of shares of common stock from 150,000,000 to 225,000,000. The Certificate of Amendment was approved by Callisto's stockholders at its annual meeting on September 26, 2007. On March 2, 2007, at a Special Meeting of Stockholders of the Corporation, the stockholders voted to amend the Callisto's Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock, par value $.0001 per share, from 100,000,000 shares to 150,000,000 shares.

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During August 2007, Callisto closed a private placement of 1,147,050 shares of Series B Preferred Stock and 22,941,000 Warrants to certain Investors for aggregate gross proceeds of $11,470,500 pursuant to a Securities Purchase Agreement dated as of August 2, 2007. Each share of Series B Preferred Stock was immediately convertible into that number of shares of common stock determined by dividing the stated value of $10.00 of such share of Series B Preferred Stock by $0.50, at the option of the holder, at any time and from time to time. The Warrants are immediately exercisable at $0.70 per share at any time within three years from the date of issuance. In connection with this transaction, Callisto paid aggregate fees and expenses of $920,960 and issued warrants to purchase 2,518,900 shares of common stock exercisable at $0.50 per share at any time within three years from the date of issuance and 2,518,900 shares of common stock exercisable at $0.70 per share at any time within four years from the date of issuance to certain selling agents. The fair value of the selling agent warrants on the date of grant was $1,839,962 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.57% to 4.31%, no dividend, an expected life of 4 years and a stock price on the dates of grant ranging from $0.66 to $0.68 per share. This fair value was accounted for as a cost of capital.

During the twelve months ended December 31, 2008, 10,000 shares of Series B Convertible Preferred Stock were converted to 200,000 shares of common stock at a conversion price of $0.50 per share. There were no conversions of the Series B Convertible Preferred Stock during the twelve months ended December 31, 2007.

Other than pursuant to certain issuances, for the twelve month period beginning on the effective date of the Registration Statement registering the resale of the shares of Common Stock underlying the Warrants by the Holder, if the Company at any time while the Warrants are outstanding, shall sell or grant any option to acquire shares of Common Stock, at an effective price lower than the then exercise price then, the exercise price shall be reduced to such lower price.

Subsequent to closing, $8,480,000 of the net proceeds were placed into escrow at the request of RAB Special Situations (Master) Fund Limited and Absolute Octane Master Fund Limited (collectively, the "Lead Investors"), each of which invested $5,000,000 in the private placement. Pursuant to a Put Option Agreement, the Lead Investors had the right until October 30, 2007 to require redemption by the Company of all of the Series B Convertible Preferred Stock and 85% of the Warrants purchased by them only upon the occurrence of any of the following events:

(i)

The Company shall have not received the approval of its common stockholders of the issuance of shares of Common Stock issuable upon the conversion of the Series B Convertible Preferred Stock or the exercise of the Warrants (the "Underlying Shares") by 5:00 pm New York time on September 30, 2007. Such approval was obtained at a meeting of stockholders held on September 26, 2007.

or

(ii)

The American Stock Exchange shall not have approved the Listing of Additional Securities application filed by the Company relating to the Underlying Shares by 5:00 pm New York time on September 30, 2007 (for a reason other than the Lead Investors failing to timely provide American Stock Exchange with information reasonably requested by Amex Listing Qualification as part of their review of the application); The American Stock Exchange approved the Company's Listing of Additional Securities on September 26, 2007.

or

(iii)

The American Stock Exchange or the Company delists the Common Stock on or before 5:00 pm New York time on September 30, 2007. As of September 30, 2007 Callisto stock continued to be listed on the American Stock Exchange.

Having satisfied these conditions of the Put Option the escrow was released on October 1, 2007.

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The Investors also are parties to a Registration Rights Agreement, dated as of August 2, 2007 pursuant to which the Company agreed to file, within 45 days of closing, a registration statement covering the resale of the shares of common stock underlying the Series B Preferred Stock and Warrants issued to the Investors. Failure to file a registration statement and maintain its effectiveness as agreed will result in the Company being required to pay liquidated damages equal to 1% per month of the aggregate purchase price paid by the Investors, not to exceed an aggregate of 18%. The Company filed a Form S-3 Registration Statement covering the sale of the common shares underlying the conversion of the Series B Preferred Stock and the Warrants on September 11, 2007 and this Form S-3 was declared effective by the SEC on September 27, 2007.

Material terms of the Series B Preferred Stock are:

Use of Proceeds. At least 50% of the net proceeds from the sale of the Series B Preferred Stock to the Lead Investors shall be dedicated to the development and clinical trials of SP-304 and the remaining net proceeds shall be used for working capital purposes.

Voting Rights. The Series B Preferred Stock shall have no voting rights. However, so long as any shares of Series B Preferred Stock are outstanding, the Company shall not, without the affirmative vote of the holders of the shares of the Series B Preferred Stock then outstanding, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the Certificate of Designation (whether by merger, consolidation or otherwise), (b) authorize or create any class of stock ranking as to dividends, redemption or distribution of assets upon a Liquidation senior to or otherwise *pari passu* with the Series B Preferred Stock, (c) amend its certificate of incorporation or other charter documents so as to affect adversely any rights of the holders, (d) increase the authorized number of shares of Series B Preferred Stock, or (e) enter into any agreement with respect to the foregoing.

Liquidation. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders shall be entitled to receive out of the assets of the Company, whether such assets are capital or surplus, for each share of Series B Preferred Stock an amount equal to the stated value of $10.00 per share, plus any accrued and unpaid dividends thereon and any other fees or liquidated damages owing thereon before any distribution or payment shall be made to the holders of any junior securities, and if the assets of the Company shall be insufficient to pay in full such amounts, then the entire assets to be distributed to the Holders shall be distributed among the holders ratably in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Conversions at Option of Holder. Each share of Series B Preferred Stock shall be convertible into that number of shares of common stock determined by dividing the stated value of $10.00 of such share of Series B Preferred Stock by $0.50 (the "Conversion Price"), at the option of the holder, at any time and from time to time.

Conversion at the Option of the Company. Beginning August 2, 2008, provided certain conditions are satisfied, if the volume weighted average price of the Company's common stock equals $1.00 per share for the 20 consecutive trading days and the average daily volume of the common stock is at least 0.5% of the shares that are being converted, the Company shall have the right to convert any portion of the Series B Preferred Stock into shares of common stock at the then-effective Conversion Price.

Subsequent Equity Sales. For the twelve (12) month period beginning on the effective date of the registration statement registering the resale of the shares of common stock underlying the Series B Preferred Stock by the holder, if the Company at any time while Series B Preferred Stock is outstanding, shall sell or grant any option to purchase or otherwise dispose of or issue any common stock or common stock equivalents entitling any Person to acquire shares of Common Stock, at an

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effective price per share less than the then Conversion Price (the "*Base Conversion Price*"), then, the Conversion Price shall be reduced to an amount equal to the Base Conversion Price.

As per FASB Statement of Financial Accounting Standards No. 150: *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*, the Company determined the balance sheet classification of the Series B Preferred Stock to be equity given that the mandatory redemption option had expired as of September 30, 2007. The escrow was released on October 1, 2007 with no further claims or restrictions on the cash.

As per Emerging Issues Task Force ("EITF") Issue 00-19, "*Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, Company Stock*", ("EITF 00-19") Callisto has determined that the fair value of the Series B Warrants issued to the Lead Investors should be treated as a liability upon issuance and reclassified to permanent equity based on the fair value upon expiration of the Put Option. The change in fair value of the Series B Lead Investor warrant from the date of issuance through the expiration of the Put Option was recorded as other income totaling $2,591,005 during the three and nine months ended September 30, 2007. Callisto has determined that the warrants issued to other than Lead Investors should be treated as "permanent equity".

As per FSP No. 00-19-2 "*Accounting for Registration Payment Arrangements*" ("FSP 00-19-2"), issued in December 2006, which specifies that contingent obligations under a registration payment arrangement should be separately recognized and measured in accordance with FASB Statement No.5 "*Accounting for Contingencies*". Callisto has determined that no liability needed to be recorded because the Company filed a timely registration statement covering the sale of the common shares underlying the conversion of the Series B Preferred Stock and the Warrants on September 11, 2007.

As per EITF 00-27, "Application *of Issue 98-5 to Certain Convertible Instruments*" ("EITF 00-27") Callisto evaluated the Series B Preferred Stock transaction and accordingly found that there was an embedded beneficial conversion feature. The fair value of the detachable warrants on the date of grant was $6,677,513 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.57% to 4.31%, no dividend, an expected life of 3 years and a stock price on that dates of grant ranging from $0.66 to $0.68 per share. The conversion rights of the Series B Preferred Stock contained an embedded beneficial conversion feature totaling $10,495,688 that was immediately accreted to the Series B Convertible Preferred Stock as a dividend because the preferred stock could be converted immediately upon issuance.

From October 23, 2006 until January 10, 2007, Callisto placed 602,350 shares of Series A Convertible Preferred Stock and 8,031,333 warrants to certain investors for aggregate gross proceeds of $6,023,500. As of December 31, 2006 Callisto had closed on 574,350 shares of such Series A Convertible Preferred Stock for aggregate gross proceeds of $5,743,500. The final tranche of this financing closed January 10, 2007 when Callisto placed 28,000 shares of such Series A Convertible Preferred Stock for aggregate gross proceeds of $280,000. The shares of Series A Convertible Preferred Stock are convertible into shares of common stock at a conversion price of $0.75 per share. The investors also are parties to a Registration Rights Agreement, dated as of October 23, 2006 pursuant to which Callisto agreed to file, within 60 days of closing, a registration statement with the SEC covering the resale of the shares of common stock underlying the Series A Convertible Preferred Stock and the warrants issued to the investors. The warrants are immediately exercisable at $0.75 per share, will expire five years from the date of issuance, and have certain anti-dilution rights for the twelve month period beginning on the effective date of the registration statement registering the shares of common stock underlying the warrants. Callisto (i) paid aggregate fees and expenses of $485,308 ($448,908 prior to December 31, 2006) in cash and (ii) issued an aggregate 11,775 shares of Series A Convertible Preferred Stock and 1,228,761 warrants to purchase common stock, to certain selling agents. The warrants are immediately exercisable at $0.75 per share, will expire five years after issuance and have the same anti-dilutive rights as the investor warrants. The fair value of the selling agent warrants on the date of grant was $640,481 using Black Scholes assumptions of 60% volatility, a risk free interest rate

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of 4.60%, no dividend, an expected life of 5 years and a stock price on the dates of grant of $0.88 per share. This fair value was accounted for as a cost of capital.

The material terms of the Series A Preferred Stock consist of:

Dividends. Holders of the Series A Convertible Preferred Stock shall not be entitled to receive dividends except as and if declared at Callisto's sole election.

Voting Rights. Shares of the Series A Convertible Preferred Stock shall have no voting rights. However, so long as any shares of Series A Convertible Preferred Stock are outstanding, Callisto shall not, without the affirmative vote of a majority in interest of the shares of Series A Convertible Preferred Stock then outstanding, (a) alter or change adversely the powers, preferences or rights given to the Series A Convertible Preferred Stock, (b) authorize or create any class of stock senior or equal to the Series A Convertible Preferred Stock, (c) amend its articles of incorporation or other charter documents, so as to affect adversely any rights of the holders of Series A Convertible Preferred Stock or (d) increase the authorized number of shares of Series A Convertible Preferred Stock.

Liquidation. Subject to the rights of the holders of the Series B Convertible Preferred Stock, upon any liquidation, dissolution or winding-up of Callisto, the holders of the Series A Convertible Preferred Stock shall be entitled to receive an amount equal to the Stated Value per share, which is $10 per share plus any accrued and unpaid dividends.

Conversion Rights. Each share of Series A Convertible Preferred Stock shall be convertible into that number of shares of common stock determined by dividing the Stated Value, currently $10 per share, by the conversion price, currently $0.75 per share. The conversion price is subject to adjustment for dilutive issuances.

Automatic Conversion. Beginning October 24, 2007, if the price of the common stock equals $1.50 per share for 20 consecutive trading days, and an average of 50,000 shares of common stock per day shall have been traded during the 20 trading days, Callisto shall have the right to deliver a notice to the holders of the Series A Convertible Preferred Stock, to convert any portion of the shares of Series A Convertible Preferred Stock into shares of Common Stock at the conversion price.

As per EITF 00-19, Callisto has determined that the warrants should be treated as "permanent equity".

As per FSP No. 00-19-2 which specifies that contingent obligations under a registration payment arrangement should be separately recognized and measured in accordance with FASB Statement No.5 "*Accounting for Contingencies*", Callisto has determined that no liability needed to be recorded. On January 12, 2007 Callisto filed a registration statement on Form S-3 registering the common stock issuable upon (i) the conversion of the all Series A Convertible Preferred Stock, (ii) the exercise of all related investor warrants and (iii) the exercise of all selling agent warrants. On February 15, 2007 Amendment No.1 to this registration statement was declared effective by the SEC.

As per EITF 00-27, Callisto evaluated the Series A Convertible Preferred Stock transaction and accordingly found that there was an embedded beneficial conversion feature. The fair value of the detachable warrants on the date of grant was $3,557,872 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.57% to 4.84%, no dividend, an expected life of 5 years and a stock price on that dates of grant ranging from $0.88 to $0.75 per share. The conversion rights of the Series A Convertible Preferred Stock issued during the twelve months ended December 31, 2006 contained a beneficial conversion feature totaling $2,384,485. This beneficial conversion feature was immediately accreted to the Series A Convertible Preferred Stock as a dividend because the preferred stock could be converted immediately upon issuance. The beneficial conversion feature associated with final tranche of 28,000 shares of Series A Convertible Preferred Stock placed on January 10, 2007 amounted to $119,685 and was recorded as a beneficial conversion feature accreted as a dividend in the quarter ended March 31, 2007.

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The Series A Preferred Stock and Warrants issued from October 23, 2006 through January 10, 2007 have certain anti-dilution rights. As a result of the August 2, 2007 Series B Preferred Stock financing the conversion price of the then remaining Series A Preferred Stock and the exercise price of the then remaining Series A Warrants was reset from $0.75 per share to $0.50 per share. This modification resulted in $2,384,790 of additional beneficial conversion accreted as a dividend during the quarter ended September 30, 2007. The total beneficial conversion feature accreted as a dividend for the twelve months ended December 31, 2007 and 2006 was $2,504,475 and $2,384,485, respectively.

During the twelve months ended December 31, 2007, 36,125 shares of Series A Convertible Preferred Stock were converted to 481,666 shares of common stock prior to August 2, 2007 at a conversion price of $0.75 per share and 359,325 shares of Series A Convertible Preferred Stock were converted to 7,186,500 shares of common stock subsequent to August 2, 2007, at a conversion price of $0.50 per share. During the twelve months ended December 31, 2008, 120,675 shares of Series A Convertible Preferred Stock were converted to 2,413,500 shares of common stock at a conversion price of $0.50 per share.

On September 8, 2006 Callisto entered into a Letter Agreement with certain investors (the "Investors") who participated in a private placement of our common stock and warrants in February and April 2006 (the "Prior Placement" see below). Pursuant to this Letter Agreement, the Investors agreed to amend (the "Amendment") the securities purchase agreement (the "Securities Purchase Agreement"), entered into in connection with the Prior Placement, to (i) delete the mandatory registration rights set forth in the Securities Purchase Agreement and add piggyback registration rights and (ii) waive any unpaid penalties pursuant to the liquidated damages provisions contained in the Securities Purchase Agreement. In addition, the Investors agreed to enter into a lock-up agreement (the "Lock-up Agreement") pursuant to which they agreed not to sell or transfer the shares of common stock and warrants acquired in the Prior Placement for a period of nine months beginning September 1, 2006. In exchange for the Investors entering into the Amendment and the Lock-Up Agreement, Callisto agreed to issue to each Investor one share of common stock and 2.35 five year warrants exercisable at $1.00 per share (the "New Warrants") for every five shares of common stock they purchased in the Prior Placement. In addition, Callisto agreed in the Letter Agreement to amend the warrants (the "Old Warrants") issued in the Prior Placement to the Investors to (i) extend the expiration date of the Old Warrants by 42 months thereby making them 5 year warrants and (ii) eliminate the provision in the Old Warrants by which Callisto can force exercise of the unexercised warrants. During October and November 2006 Callisto entered into the Amendment and Lock-up Agreements with each Investor pursuant to which Callisto issued 740,065 shares of common stock and 2,086,988 New Warrants. $153,797 in cash liquidated damages, payable to these Investors as of September 30, 2006, was concurrently waived.

The fair value of the shares issued to the Investors was $643,858 using the stock price on September 8, 2006 of $0.87 per share. The fair value of the New Warrants was $934,928 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.25%, no dividend, an expected life of 5 years and a stock price on that date of $0.87 per share, resulting in a total consideration associated with this transaction of $1,578,786. $425,899 of this fair value was allocated to additional stock-based liquidated damages expense during the quarter ended December 31, 2006 which, when combined with $153,797 of accrued liquidated damages waived as of September 30, 2006, resulted in total non-cash share based liquidated damages of $579,696 for the twelve months ended December 31, 2006. The balance of the total consideration, $999,090, was charged to additional paid in capital as a cost of placing the Series A Convertible Preferred Stock discussed above.

On February 3, 2006, Callisto closed a private placement of 4,283,668 shares of common stock and 1,070,917 common stock purchase warrants to certain accredited investors. The warrants are exercisable for 18 months from closing at an exercise price of $1.60 per share. The securities were sold at a price of $1.20 per share for aggregate proceeds of $5,140,210 and Callisto paid an aggregate transaction

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related fees and expenses of $561,808, yielding net proceeds of $4,578,402. In addition Callisto issued an aggregate 390,284 warrants to certain selling agents, which are exercisable at $1.25 per share and will expire three years after closing.

On April 7, 2006 Callisto had a second closing of the financing described above, in which Callisto sold an additional 666,667 shares of common stock and issued 166,667 common stock purchase warrants at the same terms, for gross proceeds of $800,000, bringing the total gross proceeds of the financing to $5.94 million and net proceeds to $5.34 million. Transaction related fees and expenses of $41,000 were paid on this second closing and three year warrants to purchase a total of 66,667 common shares at a per share price of $1.25 were issued to certain selling agents.

Callisto agreed to file, within 60 days after the closing, a registration statement covering the resale of the shares of common stock and the shares underlying the warrants or pay financial liquidated damages to the investors up to a maximum of 8% of the gross proceeds. As of December 31, 2006 Callisto had incurred $801,690 in liquidated damages related to the registration rights agreement which have been classified as other expense on our consolidated statement of operations. On January 12, 2007 Callisto filed a registration statement on Form S-3 registering the common stock issued (i) on February 3, 2006, (ii) on April 7, 2006 and (iii) the common stock underlying the selling agent warrants. On February 15, 2007 Amendment No.1 to this registration statement was declared effective by the SEC.

As provided for by EITF Issue 00-19, "*Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*" the warrants were classified as permanent equity. The fair value of the investor warrants on the dates of grant was $1,269,978 using Black Scholes assumptions of 79% volatility, a risk free interest rate of 4.25%, no dividend, an expected life of 5 years and a stock price on that date of $1.59 per share. This fair value allocated to the investor warrants was recorded as additional paid in capital during the year ended December 31, 2006.

On October 20, 2005, at the Annual Meeting of Stockholders, Callisto stockholders voted to amend Callisto's certificate of incorporation to increase the authorized number of shares of common stock from 75,000,000 shares to 100,000,000 shares. In addition the stockholders voted to adopt the Callisto 2005 Equity Compensation Incentive Plan and the Callisto 2005 Directors' Stock Option Plan. (Note 6) The details of these stockholder resolutions are included in Callisto's Proxy Statement (Schedule 14A Information) filed September 1, 2005 with the Securities and Exchange Commission.

On August 22, 2005, Callisto sold and issued in a private placement an aggregate 1,869,203 shares of common stock at a price of $0.97 per share for aggregate proceeds of $1,813,127 and paid an aggregate $151,250 to certain selling agents.

On March 9, 2005, Callisto sold and issued in a private placement 1,985,791 shares of common stock at a per share price of $1.52, for aggregate gross proceeds of $3,018,401 and net proceeds of $2,993,401. Because this transaction was completed with certain existing institutional shareholders and certain members of management, Callisto paid no selling agent fees and legal fees were $25,000.

On April 19, 2004, Callisto sold and issued in a private placement to accredited investors an aggregate 2,151,109 shares of common stock at an issue price of $2.25 per share for aggregate gross proceeds of $4,839,995. Callisto incurred fees and expenses aggregating $294,241 to various selling agents. In addition, Callisto issued an aggregate 124,711 warrants to purchase common stock to such selling agents. The warrants are immediately exercisable at $2.48 per share and will expire five years after issuance.

In January 2004 Callisto recorded $209,076 of purchased in process research and development as a result of the issuance of 263,741 warrants to two Callisto shareholders, which warrants are immediately exercisable at $1.50 per share and will expire ten years after issuance; and $60,750 of stock-based compensation expense associated with shares of common stock issued to a shareholder for services performed.

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From November 2003 through January 2004, Callisto sold and issued 3,905,432 shares of common stock at an issue price of $1.50 for aggregate gross proceeds of $5,858,148. Callisto incurred an aggregate of $501,516 in fees to various selling agents. In addition Callisto issued 31,467 shares of common stock and 370,543 warrants to purchase common stock to such selling agents. The warrants are immediately exercisable at $1.90 per share and will expire five years after issuance.

As of December 31, 2003 Callisto had closed on a portion of this transaction, specifically 2,776,666 shares of common stock at a price of $1.50 per share for aggregate gross proceeds of $4,164,999, less $361,625 incurred in fees to various selling agents. During January 2004, Callisto completed this private placement begun in late 2003 and issued 1,128,766 shares of common stock at an issue price of $1.50 for aggregate proceeds of $1,693,149, less $139,891 in fees to various selling agents.

During 2000, the Board of Directors approved an increase in the authorized common shares from 35,000,000 shares to 60,000,000 shares and a one-for-three reverse split of the common stock. All share and per share information has been adjusted to reflect the stock split as if it had occurred at the beginning of the earliest period presented. In May 2003, as part of the Merger, the authorized common shares were increased to 75,000,000 shares.

During 2000, Callisto sold 2,252,441 shares of Series A convertible preferred stock at $1.70 per share and 1,232,858 shares of Series B convertible preferred stock at $1.75 per share. In addition, the Board of Directors authorized the issuance of 750,000 shares of Series C convertible preferred stock at $0.10 per share to an executive officer of Callisto. The net proceeds from the sale of these 4,235,299 shares of convertible preferred stock totaled $6,061,650. The holders of the convertible preferred stock had equal voting rights with the common stockholders, had certain liquidation preferences and were convertible at any time into shares of common stock at a ratio of one share of common stock for each share of convertible preferred stock at the election of the holder. Callisto recorded compensation expenses of approximately $1,050,000 related to the shares sold to the executive officer. During the second quarter of 2003, all of the convertible preferred stockholders converted their shares of preferred stock to common stock in connection with the Merger.

During 2000, Callisto also sold 4,526,903 shares of common stock at a purchase price of $0.05 per share to certain officers and directors for services performed in the year 1999. Based on the most recent private placement of common stock during the fourth quarter of 1999, the value of these shares was determined to be $0.70 per share and Callisto recorded $3,168,832 as stock-based compensation expense.

During 1998, as part of a settlement agreement between the founding partners of CSO Ventures, Inc. and Callisto, one of the founders of CSO sold 836,792 shares of common stock back to Callisto at a price of approximately $0.12 per share, for $97,000. Concurrently, Callisto entered into a stock purchase agreement with a private investor to sell him 766,667 shares of common stock at a price of $92,000 or $0.12 per share. The fair value of the common stock issued was determined to be $0.75 per share and Callisto recorded $483,000 of stock-based compensation expense.

During the period from December 1996 to December 1999, Callisto completed the following private placements of its common stock:

	Shares	Price Per Share	Gross Proceeds
December 1996	1,366,667	$ 0.75	$ 1,025,000
December 1997	1,442,667	$ 0.75	1,081,999
October 1998	1,416,667	$ 0.75	1,062,500
January 1999	146,667	$ 0.75	110,000
December 1999	200,000	$ 0.75	150,000
Total	4,572,668		$ 3,429,499

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As of December 31, 2008 and 2007 Callisto had 55,773,331 and 45,162,920 warrants outstanding to investors, selling agents and advisors with a weighted average exercise price of $0.43 and $0.71 per share, of which 55,773,331 and 44,012,920 warrants were fully vested with an average exercise price of $0.43 and $0.72 per share, respectively.

6. Shared-based payments

Callisto Pharmaceuticals, Inc. Stock Option Plans

In 1996, Callisto adopted the 1996 Incentive and Non-Qualified Stock Option Plan (the "Plan") for employees, consultants and outside directors to purchase up to 2,000,000 shares of common stock. This Plan was amended in December 2002 to increase the number of shares authorized under the Plan to 10,000,000. The option term for the 3,884,205 options outstanding as of December 31, 2008 under the Plan is ten years from date of grant. The Plan terminated on January 1, 2006 under its original terms and no further options will be granted under the Plan.

On October 20, 2005, Callisto stockholders approved the 2005 Equity Compensation Incentive Plan. The maximum number of shares of common stock with respect to which awards may be granted under the 2005 Equity Plan is 5,000,000. The option term for options granted under the 2005 Equity Plan is ten years from date of grant and there were 3,468,000 options available for future grants as of December 31, 2008.

On October 20, 2005, Callisto stockholders approved our 2005 Directors' Stock Option Plan. The maximum number of shares of common stock with respect to which awards may be granted under the 2005 Directors' Plan is 1,000,000. The option term for options granted under the 2005 Directors' Plan is ten years from date of grant and there are 830,000 option shares available for future grants as of December 31, 2008.

The options Callisto grant under the 2005 Equity Plan may be either "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), or non-statutory stock options at the discretion of the Board of Directors and as reflected in the terms of the written option agreement. None of our stock option plans are qualified deferred compensation plans under Section 401(a) of the Code, and are not subject to the provisions of the Employee Retirement Income Security Act of 1974, as amended (ERISA). As of December 31, 2008, Callisto has 2,352,333 stock options outstanding not subject to our stock option plans.

Stock Option Accounting

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 was effective as of January 1, 2006.

SFAS No. 123R did not change the way Callisto account for non-employee stock-based compensation. Callisto continues to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. Stock-based compensation expense associated with these most of our non-employee option grants is being recorded in accordance with EITF 96-18 and accordingly (i) the measurement date will be when "performance commitment is completed" and accordingly the fair value of these options is being "marked to market" quarterly until the measurement date is determined.

FASB 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

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from financing activities and cash outflows from operating activities. Due to Callisto's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

Prior to January 1, 2006, Callisto had adopted SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). As provided for by SFAS 123, Callisto had elected to continue to account for stock-based compensation according to the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"). Accordingly, compensation expense had been recognized to the extent of employee or director services rendered based on the intrinsic value of stock options granted under the plan.

Callisto accounts for common stock, stock options, and warrants granted to non-employees based on the fair market value of the instrument, using the Black-Scholes option pricing model based on assumptions for expected stock price volatility, term of the option, risk-free interest rate and expected dividend yield at the grant date.

Callisto Share-Based Compensation

Stock options issued by Callisto typically vest after three years of continuous service from the grant date and have a contractual term of ten years. The fair values are amortized to share-based compensation pro-rata over the vesting term.

Share-based payments have been recognized in operating results as follow:

	Year Ended December 31,			Period from June 5, 1996 (Inception) to December 31,
	2008	2007	2006	2008
Employees included in research and development	$ 40,608	$ 68,734	$ 420,683	$ 2,661,885
Employees included in general and administrative	162,262	321,350	951,804	4,749,953
Subtotal employee stock option grants	202,870	390,084	1,372,487	7,411,838
Non-employee included in research and development	(17,314)	17,314	102,750	102,750
Non-employee included in general and administrative	23,624	220,963	1,271,241	9,840,398
Subtotal non-employee stock option grants	6,310	238,277	1,373,991	9,943,398
Total stock-based compensation expense	$ 209,180	$ 628,361	$ 2,746,478	$ 17,354,986

The estimated fair value of each employee and non-employee stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the twelve months ended December 31, 2008, 2007 and 2006.

	Year End December 31,		
	2008	2007	2006
Risk-free interest rate	1.55%	3.55%	4.25 - 4.57%
Dividend yield			
Expected volatility	200%	60%	60% - 79%
Expected term (in years)	5.0 yrs	5.0 yrs	3.0 - 7.0 yrs

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

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Dividend yield Callisto 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 Callisto's stock.

Expected term Callisto 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 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 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. Callisto estimated future unvested option forfeitures based on historical Company experience and has incorporated this rate in determining the fair value of employee option grants.

The weighted-average fair value of all options granted under Callisto's Plans during the twelve months ended December 31, 2008, 2007 and 2006, estimated as of the grant date using the Black-Scholes option valuation model, was $0.04. $0.42 and $0.91 per share, respectively.

The unrecognized compensation cost related to Callisto's non-vested employee stock options outstanding at December 31, 2008 and 2007 was $83,455 and $285,885, respectively, to be recognized over a weighted-average vesting period of approximately 6 months and 1 year, respectively. The weighted-average remaining term of all options outstanding at December 31, 2008 was 5.1 years as compared to 5.9 years at December 31, 2007.

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

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Balance outstanding, December 31, 2006	8,053,375	$0.75 - 6.75	$ 1.75	$
Granted	784,500	$0.47 - 0.96	$ 0.78	
Exercised				
Forfeited	(596,668)	$0.75 - 1.60	$ 1.24	
Balance outstanding, December 31, 2007	8,241,207	$0.47 - 6.75	$ 1.70	$
Granted	41,500	$ 0.08	$ 0.08	
Exercised				
Forfeited	(344,169)	$0.47 - 1.45	$ 0.85	
Balance outstanding, December 31, 2008	7,938,538	$0.47 - 6.75	$ 1.72	$
Exercisable, December 31, 2008	5,980,205	$0.47 - 6.75	$ 1.75	$

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 the Company's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

Synergy Pharmaceuticals, Inc. Stock Option Plan

During 2008, Synergy adopted The 2008 Equity Compensation Incentive Plan (the "Plan") which is intended to promote the best interests of Synergy stockholders by (i) assisting Synergy 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 Synergy by affording such persons equity participation in the Company and (iii) associating the interests of such persons with those of Synergy 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. Synergy did not issue stock options until 2008.

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Synergy Stock Option Accounting

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 (inception) to December 31, 2008
	2008	2007	2006	
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-employee stock based compensation included in general and administrative	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.

	Year 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.

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 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

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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 $0.50 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 Synergy 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	Aggregate Intrinsic Value
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

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.

Synergy Restricted Stock Units

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

On July 3, 2008, 874,760 restricted stock units were granted by Synergy-DE and assumed by Synergy as part of the Exchange Transaction and are subject to a repurchase agreement, as defined. These restricted stock units were issued to certain officers and a consultant of Synergy. The fair value of each Synergy restricted stock unit is estimated on the grant date based on the price paid by shareholders participating in Synergy's July 14, 2008 private placement. Accordingly, the weighted-average grant date fair value per share of the 874,760 shares of Synergy common stock issued during the twelve months ended December 31, 2008 was determined to be $0.60. As of December 31, 2008 there were 874,760 Synergy restricted stock units outstanding. The fair value of the 874,760 Synergy restricted stock units on the date of grant was $524,856 of which $97,602 was recorded as stock-based compensation expense during the twelve months ended December 31, 2008.

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7. Income taxes

At December 31, 2008, Callisto has net operating loss carryforwards ("NOLs") aggregating approximately $38,000,000, which, if not used, begin expiring 2011 through 2028. The utilization of these NOLs is subject to limitations based on past and future changes in ownership of Callisto pursuant to Internal Revenue Code Section 382. The Company has determined that an ownership change had occurred as of April 30, 2003 and Callisto believes that such change in ownership to date will restrict its ability to use pre-merger Synergy NOLs within the carryforward period. The Company has no other material deferred tax items.

Callisto records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Due to the significant doubt related Callisto'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 FIN No. 48 were adopted by Callisto on January 1, 2007 and had no effect on Callisto's financial position, cash flows or results of operations upon adoption, as Callisto did not have any unrecognized tax benefits or liabilities. Callisto also evaluated its tax positions as of December 31, 2008 and reached the same conclusion. Callisto does not currently expect any significant changes to unrecognized tax benefits during the fiscal year ended December 31, 2009. Callisto's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2008 and December 31, 2007, Callisto had no accrued interest or penalties.

Callisto has no uncertain tax positions subject to examination by the relevant tax authorities as of December 31, 2008. Callisto files U.S. and state income tax returns in jurisdictions with varying statutes of limitations. The 2005 through 2008 tax years generally remain subject to examination by federal and most state tax authorities.

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

8. Commitments and contingencies

Employment and Consulting Agreements

Gabriele M. Cerrone

On December 27, 2004, Callisto entered into a consulting agreement (the "Agreement") with Gabriele M. Cerrone, Callisto's Chairman of the Board (the "Consultant"). The duties of the Consultant and the obligations of Callisto to pay compensation commenced on January 10, 2005 (the "Start Date"). The duties of the Consultant pursuant to the Agreement will consist of strategic planning and capital markets consulting advice. The term of the Agreement will commence upon the Start Date and continue until December 31, 2006 with automatic renewal for successive one year periods unless either party gives notice to the other not to renew the Agreement. Callisto will pay Consultant the annual sum of $205,000 (the "Base Compensation") at the rate of $17,083.33 per month commencing on the Start Date. During the twelve months ended December 31, 2006 and 2005, Mr. Cerrone earned bonuses totaling $125,855 and $30,750, respectively under this Agreement.

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In conjunction with the Agreement, Consultant was granted 375,000 ten year non-qualified stock options at an exercise price of $1.70 per share. One half of such options vested on each of the first two anniversaries of the Agreement, December 27, 2005 and 2006. Stock-based compensation expense associated with these option grants was recorded in accordance with EITF 96-18 and accordingly (i) the measurement date will be the earliest of December 27, 2006 when "performance commitment" was completed and (ii) the fair value of these options was "marked to market" quarterly until the measurement date was determined. Accordingly stock-based compensation expense recorded during the twelve months ended December 31, 2005 was $212,619, of which $53,217 was reversed during the twelve months ended December 31, 2006 as a result of a decline in the price of Callisto's stock from $1.38 to $0.86 per share from December 31, 2005 to December 31, 2006. There was no stock-based compensation recorded for these options during the twelve months ended December 31, 2007 because the performance commitment under the Agreement was completed on December 31, 2006.

On January 25, 2007, Callisto entered into an Extension and Amendment Agreement with Mr. Cerrone. The agreement extends the term of the consulting agreement between us and Mr. Cerrone, dated as of December 27, 2004, to December 31, 2009. Among other things, the agreement increases Mr. Cerrone's compensation from $205,000 to $275,000 per year. Additionally, pursuant to the agreement, in recognition of the services beyond that required by Mr. Cerrone during 2006, Mr. Cerrone earned a bonus of $125,855, Under the Extension and Amendment Agreement, Mr. Cerrone may earn a performance bonus of 22.5% of his base compensation, for each twelve month period during the term of the Extension and Amendment Agreement, based on meeting performance objectives and bonus criteria to be mutually identified by Mr. Cerrone and the Compensation Committee of our Board of Directors. During 2008 and 2007, Mr. Cerrone exceeded his performance objectives and earned a performance bonus of $61,875 and $84,147, respectively, under the Extension and Amendment Agreement.

In conjunction with the Extension and Amendment Agreement, Mr. Cerrone was granted 225,000 ten year non-qualified stock options at an exercise price of $0.96 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. Stock-based compensation expense associated with these option grants is being recorded in accordance with EITF 96-18 and accordingly (i) the measurement date will be the earliest of December 31, 2009 (when "performance commitment is completed") or the accelerated vesting date if Mr. Cerrone is terminated without cause or good reason prior to December 31, 2009 and (ii) the fair value of these options is being "marked to market" quarterly until the measurement date is determined. Stock-based compensation expense associated with these options reversed during the twelve months ended December 31, 2008 was $17,073 As of December 31, 2008, there was no unrecognized fair value associated with Mr. Cerrone's unvested options.

On March 11, 2009, Gabriele M. Cerrone, our Chairman of the Board, entered into an amended and restated 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 25% is to be allocated to Callisto and 75% is to be allocated to Synergy. Mr. Cerrone is eligible to receive a cash bonus of up to 50% of his base compensation per year based on meeting certain performance objectives and bonus criteria. Such performance objectives and bonus criteria had not been established 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

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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. Had Mr. Cerrone been terminated without cause or good reason on December 31, 2008, he would have been eligible for total compensation of $1,327,500 for the time remaining under the amended and restated consulting agreement.

Gary S. Jacob, Ph.D

On June 13, 2003, Callisto entered into an employment agreement with Gary S. Jacob, Ph.D., to serve as Chief Executive Officer and Chief Scientific Officer. Dr. Jacob's employment agreement is for a term of 18 months beginning June 13, 2003 and was automatically renewable for successive one year periods at the end of the term. In connection with his employment agreement, Dr. Jacob received a grant of 500,000 stock options which vested over a three year period through June 13, 2006 and are exercisable at $1.50 per share. On March 17, 2006, pursuant to Compensation Committee approval, Dr. Jacob's salary was increased to $300,000 per year; he became eligible to receive a cash bonus of up to 15% of his salary per year and received a grant of 150,000 stock options which vest over a three year period which are exercisable at $1.64 per share. During the years ended December 31, 2008, 2007 and 2006, Dr. Jacob earned a bonus of $11,250, $78,750 and $48,125, respectively.

On February 16, 2007, Dr. Jacob entered into an Extension and Amendment Agreement with Callisto as approved by the Compensation Committee which extended the term under his employment agreement to June 30, 2009. In addition, pursuant to the Extension and Amendment Agreement, Dr. Jacob was granted 225,000 ten year stock options exercisable at $0.81 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. His salary and other compensation were unchanged. As of December 31, 2008, the unrecognized fair value of all Dr. Jacob's unvested options was $37,516.

On March 11, 2009, Dr. Gary Jacob entered into an amended and restated employment agreement with us in which he agreed to serve as Chief Executive Officer. 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 25% is to be allocated to Callisto and 75% is to be allocated to Synergy. 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 established 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

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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. Had a "Change of Control" occurred on December 31, 2008 and the executive had been terminated on that date, Dr. Jacob would have been eligible for total compensation (salary and bonus) for the term of his employment under his employment agreement for the time remaining of such employment term, of $1,350,000.

Melvin K. Spigelman

On August 21, 2008, the Board of Directors ("the Board") of Synergy appointed Melvin K. Spigelman, M.D. as a Director of Synergy. In addition, the Board of Directors appointed Dr. Spigelman Chairman of Synergy's Clinical Oversight Committee as well as a member of the Synergy Compensation and Audit Committees ("the Committees"). In connection therewith, the Board 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, to purchase Synergy common stock, 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.

Kunwar Shailubhai, Ph.D

On April 6, 2004, Kunwar Shailubhai, Ph.D. entered into an employment agreement with Synergy 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 to the position of Chief Scientific Officer of Synergy, his base salary was increased to $190,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. Dr. Shailubhai received a grant of 100,000 Callisto stock options which are exercisable at $1.50 per share. 50,000 of such stock options vested in June 2004 and 50,000 options vested in December 2004.

Callisto previously had an employment agreement dated June 13, 2003 with Kunwar Shailubhai, Ph.D. to serve as Executive Vice President and Head of Research and Development for a term of 18 months beginning June 13, 2003. Dr. Shailubhai's salary was $170,000 per year and he was eligible to receive a cash bonus of up to 15% of his salary per year. In connection with his employment agreement, Dr. Shailubhai received a grant of 25,000 stock options which were fully vested and have an exercise price of $1.50 per share. Dr. Shailubhai also received a grant of 325,000 stock options which were to have vested over a three year period and were exercisable at $1.50 per share. This employment agreement was terminated on April 6, 2004 and all unvested options were forfeited.

The new grant of 100,000 options was not subject to variable accounting under FIN 44 because it was deemed that Dr. Shailubhai continued as an employee within a consolidated group and there were

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no change in the exercise price. The unamortized deferred compensation cost associated with the 225,000 cancelled options of $706,813 as of the date of cancellation, was charged to stock-based compensation expense during the quarter ended June 30, 2004. The remaining deferred balance, based on the original intrinsic value, associated with the remaining 100,000 options of $314,139, was expensed over the vesting period of the new grant (e.g. April 7, 2004 through December 31, 2004). On April 12, 2007, Dr. Shailubhai was granted 125,000 ten year incentive stock options exercisable at $0.66 per share of which 41,667 vest on each of April 12, 2008 and 2009 and 41,666 vest on April 12, 2010.

Bernard F. Denoyer

On January 15, 2004, Callisto entered into an employment agreement with Bernard Denoyer, to serve as Vice President, Finance. Mr. Denoyer's employment agreement was for a term of 12 months beginning January 15, 2004 and was automatically renewable for successive one year periods at the end of the term. Mr. Denoyer's salary was $90,000 per year and he was eligible to receive a cash bonus of up to 10% of his salary per year. Mr. Denoyer received a grant of 100,000 stock options which vest over a three year period and are exercisable at $3.60 per share. On July 29, 2005 Mr. Denoyer was granted an additional 75,000 stock options which vest over three years and are exercisable at $1.38 per share. On September 1, 2006 Mr. Denoyer's salary was increased to $120,000 per year.

On December 10, 2007, Callisto entered into an Amended and Restated Employment Agreement (the "Amendment Agreement") with Mr. Denoyer which extends the term of the employment agreement between the Company and the Executive dated as of January 15, 2004, as amended October 19, 2005, to December 1, 2008. Among other things, the Amendment Agreement increases the Executive's salary from $120,000 to $162,000 per year (the "Base Salary"), he was promoted to Senior Vice President and he shall be eligible to earn a cash bonus of up to 15% of the Base Salary for each twelve month period during the term of the Amendment Agreement at the discretion of the Compensation Committee of the Company's Board of Directors.

During the years ended December 31, 2008, 2007 and 2006, Mr. Denoyer earned a bonus of $26,500, $12,000 and $10,461, respectively. On April 12, 2007, Mr. Denoyer was granted 75,000 ten year incentive stock options exercisable at $0.66 per share of which 25,000 vest on each of April 12, 2008, 2009 and 2010.

Effective July 14, 2008, upon Synergy becoming a publ