CALLISTO PHARMACEUTICALS INC
Form 10-K
March 31, 2011

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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, 2010

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o 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 $21,246,086 on June 30, 2010 (based on $0.41 per share, the closing price on that day).

As of March 30, 2011 the registrant had a total of 158,466,071 shares of Common Stock outstanding.

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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 elsewhere in this annual report on Form 10-K for the year ended December 31, 2010, 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. All drug candidates to treat GI disorders and diseases, currently plecanatide and SP-333, are being developed exclusively by our subsidiary Synergy Pharmaceuticals, Inc., ("Synergy"). Use of the terms "we", "our" or "us" in connection with GI drug candidates discussed herein refer to research and development activities and plans of Synergy.

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 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 and rheumatoid arthritis (RA). Our lead drug candidates are as follows:

(1) Plecanatide, a guanylyl cyclase C ("GC-C") receptor agonist, to treat GI disorders, primarily chronic constipation ("CC") and constipation-predominant irritable bowel syndrome ("IBS-C").

(2) SP-333, a second generation GC-C receptor agonist, SP-333, now in pre-clinical development to treat gastrointestinal inflammatory diseases.

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

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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.

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, representing 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. 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.

From inception through December 31, 2010, we have sustained net losses attributable to common stockholders of $135,573,268. 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 non-cash accretion of dividends attributable to the beneficial conversion rights of convertible preferred stock and changes in fair value of derivatives. From inception through December 31, 2010 we have not generated any revenue from operations. We 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 in their early stages and we cannot make estimates of the costs or the time they will take to complete. The risk of not completing 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 December 10, 2010, we closed a Note and Warrant Exchange Agreement with the holders of our outstanding $603,163 aggregate principal amount 11% Secured Promissory Notes due April 30, 2011 (the "Notes") which were issued in December 2008 and common stock purchase warrants

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exercisable for 68,883,536 shares of common stock (the "Warrants") pursuant to which such holders exchanged the Notes plus accrued interest and the Warrants for an aggregate 72,355,770 shares of common stock.

On February 8, 2011, Synergy entered into a loan agreement (the "Agreement") with an investor (the "Lender"), pursuant to which the Lender agreed to lend an aggregate $950,000 to the Company. Simultaneously with the execution and delivery of the Agreement, the Company issued a note to the Lender in the principal amount of $500,000 (the "First Note"). The Company has the option to issue an additional note to the Lender in the principal amount of $450,000 beginning February 21, 2011 (the "Second Note" and with the First Note, the "Notes"). The Notes bear interest at 17% per annum and are payable on April 1, 2011. As of March 31, 2011 the Company had not borrowed under the Second Note.

On March 4, 2011, Synergy closed a financing with a non-U.S. investor which raised gross proceeds of $1,800,000 in a registered direct offering. Synergy issued to the investor 600,000 shares of its common stock and warrants to purchase 420,000 shares of common stock. The purchase price paid by the investor was $3.00 for each unit. The warrants expire after seven years and are exercisable at $3.10 per share. We paid fees to a non-US selling agent and legal expenses totaling $175,000 on this offering.

PROPOSED PRODUCTS

Plecanatide

We are currently developing plecanatide, a synthetic hexadecapeptide designed to mimic the actions of the GI hormone uroguanylin, for the treatment of CC and IBS-C. Plecanatide is an agonist of GC-C receptor.

Plecanatide is covered by a U.S. patent issued on May 9, 2006 with respect to composition of matter that expires on March 25, 2023, subject to possible patent term extension, and a U.S. patent issued on September 21, 2010 with respect to composition of matter that expires on June 9, 2022, subject to possible patent term extension. We have filed patent applications to broaden our patent estate covering GC-C receptor agonists.

14-Day Phase 2a Clinical Trial in CC

Summary. We recently completed a Phase 2a randomized, double-blind, placebo-controlled, 14-day repeat, oral, dose-ranging clinical trial of plecanatide in patients with CC. On October 18, 2010, we presented the results of this clinical trial at the American College of Gastroenterology Annual Scientific Meeting in San Antonio, Texas. This clinical trial enrolled 78 evaluable patients at 14 sites in the United States. The primary objective of this clinical trial was to evaluate the safety of plecanatide in patients with CC. The secondary objectives of this clinical trial were to assess the pharmacokinetic profile of plecanatide and to assess bowel function, including time to first bowel movement, frequency, completeness of evacuation, stool consistency, straining and abdominal discomfort, after treatment with plecanatide.

Clinical Trial Design. In this clinical trial we enrolled patients that met the modified Rome III criteria of CC, a standard patient assessment tool used in the diagnosis of patients with CC. Patients also had to have had a colonoscopy within five years before enrollment with no significant findings, had to be in good health as determined by a physical examination and other standard assessments and had to have reported less than six simultaneous bowel movements, or SBMs, and less than three complete SBMs, or CSBMs, in each week during the 14-days before treatment with plecanatide or placebo. SBMs are bowel movements that occur without the use of a laxative, enema or suppository within the preceding 24 hours; and CSBMs are SBMs after which the patient reports a feeling of complete evacuation.

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Patients in this clinical trial received placebo or plecanatide once-daily in the morning for 14 consecutive days at oral doses of 0.3 mg, 1.0 mg, 3.0 mg or 9.0 mg, respectively. There were 20 patients per dose level randomized 3:1, with 15 patients in each dose level receiving plecanatide and five patients in each dose level receiving placebo. A safety review was conducted after each dose level before beginning the next higher dose level.

Clinical Trial Results. Plecanatide treatment exhibited a favorable safety profile with no severe adverse events observed, and notably no patients receiving plecanatide reported diarrhea. Ten percent ($^{2}/_{20}$) of patients receiving placebo and 17.2% ($^{10}/_{58}$) of patients receiving plecanatide, respectively, reported adverse events, or AEs, related to treatment and 10% ($^{2}/_{20}$) of patients receiving placebo and 8.6% ($^{5}/_{58}$) of patients receiving plecanatide, respectively, reported GI-related AEs. The majority of AEs were mild to moderate and transient in nature. One patient on placebo discontinued from the clinical trial due to diarrhea. Additionally, no systemic absorption of plecanatide was detected in patients at any of the dose levels studied.

Patients in all plecanatide dose levels reported significant decreases in time to first bowel movement after dosing as compared to patients receiving placebo. Patients receiving plecanatide also reported increases in the number of SBMs and CSBMs per week, improved stool consistency and reduced straining during bowel movements as compared to pre-treatment levels for each of these measures of bowel function. In addition, a greater percentage of patients in each plecanatide dose level reported improvement in abdominal discomfort, constipation severity and overall relief after treatment as compared to patients receiving placebo.

Development Plan

The next clinical trial of plecanatide to treat chronic idiopathic constipation patients is planned to begin in the second half of 2011 and is being designed as a Phase II/III trial. The trial, a 90-day repeat oral dose ranging, randomized, double-blind, placebo-controlled study, will utilize approximately 800 chronic constipation patients, and will have as its primary objective the measure of CSBMs using a responder analysis. The trial will also evaluate SBMs and daily constipation symptoms including straining, stool consistency, abdominal discomfort, plus impact of plecanatide on disease specific quality of life measures.

We are also preparing to initiate a Phase 2b clinical trial of plecanatide for the treatment of IBS-C in patients during 2012.

SP-333

We are also developing a second generation GC-C receptor analog, SP-333, which is currently in pre-clinical development for the treatment of gastrointestinal inflammatory diseases. SP-333 is a synthetic analog of uroguanylin, a natriuretic hormone which is normally produced in the body's intestinal tract. Deficiency of this hormone is predicted to be one of the primary reasons for the formation of polyps that can lead to colon cancer, as well as debilitating and difficult-to-treat GI inflammatory disorders such as ulcerative colitis and Crohn's disease. Orally-administered SP-333 binds to and activates guanylate cyclase C (GC-C) expressed on epithelial cells lining the GI mucosa, resulting in activation of GC-C. In animal models, oral administration of SP-333 ameliorates GI inflammation by suppressing production of certain pro-inflammatory cytokines.

More than 500,000 Americans are afflicted with ulcerative colitis, a type of IBD that causes chronic inflammation of the colon. Along with Crohn's disease, the other major form of IBD, ulcerative colitis is painful and debilitating, and can lead to other serious and life-threatening complications such as increased incidence of colon cancer. There is currently no medical cure for ulcerative colitis. A considerable medical need exists for the control and treatment of ulcerative colitis.

On February 1, 2011 the U.S. Patent and Trademark Office issued U.S. Patent No. 7,879,802, covering Synergy's novel drug candidate SP-333 to treat inflammatory bowel disease (IBD). SP-333 is a

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second-generation guanylate cyclase C (GC-C) agonist with the potential to treat gastro-intestinal diseases such as ulcerative colitis. The patent entitled "Agonists of Guanylate Cyclase Useful for the Treatment of Gastrointestinal Disorders, Inflammation, Cancer and Other Disorders" specifically claims composition of matter of SP-333 and use in the treatment of human diseases.

We plan to submit an Investigational New Drug application, or IND, to the U.S. Food and Drug Administration, or FDA, to treat ulcerative colitis, or UC with SP-333 in 2011 and intend to initiate a Phase 1 clinical trial of SP-333 in UC volunteers during 2012.

Manufacturing of our Product Candidates

We do not have manufacturing capabilities. We currently use contract manufacturers for the manufacturing of plecanatide, SP-333 and our other product candidates. Accordingly, unless or until we develop or acquire sufficient manufacturing capabilities, we will depend on third parties to manufacture plecanatide, SP-333 and any future products that we may develop or acquire. We are in the process of seeking long-term commercial supply contracts with active pharmaceutical ingredient manufacturers, and we anticipate that we will be able to negotiate these third-party agreements on commercially reasonable terms. We are in the process of working with third-party manufacturers to develop the ability to produce plecanatide in accordance with current good manufacturing practices, or GMP, on a sufficient scale to meet our future commercial needs. It is a fundamental part of our commercial strategy to maintain two or more active pharmaceutical ingredient suppliers to ensure continuity in our supply chain.

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.

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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.

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 Status

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 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.

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

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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. As of December 31, 2010 we are not actively pursuing the in-house development of Atiprimod and are exploring out-licensing opportunities for further development of this drug.

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.

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

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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 Status

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 trials 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 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 suspended any further work on L-Annamycin in acute leukemia as of December 31, 2008. As of December 31, 2010 we are not actively pursuing the in-house development of L-Annamycin and are exploring out-licensing opportunities for further development of this drug.

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.

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.

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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 was discontinued as of December 31, 2008.

GOVERNMENT REGULATION

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. The FDA has very broad enforcement authority and failure to abide by applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution, disgorgement of profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approval, refusal to approve pending applications, and criminal prosecution.

FDA Approval Process

We believe that our product candidates will be regulated by the FDA as drugs. No manufacturer may market a new drug until it has submitted an NDA to the FDA, and the FDA has approved it. The steps required before the FDA may approve an NDA generally include:

- preclinical laboratory tests and animal tests conducted in compliance with FDA's good laboratory practice requirements;
- development, manufacture and testing of active pharmaceutical product and dosage forms suitable for human use in compliance with current good manufacturing practices, or GMP;
- the submission to the FDA of an investigational new drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its specific intended use(s);
- the submission to the FDA of an NDA; and
- FDA review and approval of the NDA.

Preclinical tests include laboratory evaluation of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the pre-clinical tests must comply with federal regulations and requirements including good laboratory practices. We must submit the results of the preclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol to the FDA as part of an IND, which must become effective before we may commence human clinical trials. The IND will automatically become effective 30 days after its receipt by the FDA, unless the FDA raises concerns or questions before that time about the conduct of the proposed trials. In such a case, we must work with the FDA to resolve any outstanding concerns before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials. The study protocol and informed consent information for patients in clinical trials must also be

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submitted to an institutional review board for approval. An institutional review board may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the institutional review board's requirements or may impose other conditions.

Clinical trials involve the administration of the product candidate to humans under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are typically conducted in three sequential phases, though the phases may overlap or be combined. In Phase 1, the initial introduction of the drug into healthy human subjects, the drug is usually tested for safety (adverse effects), dosage tolerance and pharmacologic action, as well as to understand how the drug is taken up by and distributed within the body. Phase 2 usually involves studies in a limited patient population (individuals with the disease under study) to:

evaluate preliminarily the efficacy of the drug for specific, targeted conditions;

determine dosage tolerance and appropriate dosage as well as other important information about how to design larger Phase 3 trials; and

identify possible adverse effects and safety risks.

Phase 3 trials generally further evaluate clinical efficacy and test for safety within an expanded patient population. The conduct of the clinical trials is subject to extensive regulation, including compliance with good clinical practice regulations and guidance.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. We may also suspend clinical trials at any time on various grounds.

The results of the preclinical and clinical studies, together with other detailed information, including the manufacture and composition of the product candidate, are submitted to the FDA in the form of an NDA requesting approval to market the drug. FDA approval of the NDA is required before marketing of the product may begin in the U.S. If the NDA contains all pertinent information and data, the FDA will "file" the application and begin review. The FDA may "refuse to file" the NDA if it does not contain all pertinent information and data. In that case, the applicant may resubmit the NDA when it contains the missing information and data. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drug products are reviewed within 10 months. The review process, however, may be extended by FDA requests for additional information, preclinical or clinical studies, clarification regarding information already provided in the submission, or submission of a risk evaluation and mitigation strategy. The FDA may refer an application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically inspect the facilities at which the product candidate is manufactured and will not approve the product candidate unless GMP compliance is satisfactory. FDA also typically inspects facilities responsible for performing animal testing, as well as clinical investigators who participate in clinical trials. The FDA may refuse to approve an NDA if applicable regulatory criteria are not satisfied, or may require additional testing or information. The FDA may also limit the indications for use and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

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The testing and approval process requires substantial time, effort and financial resources, and our product candidates may not be approved on a timely basis, if at all. The time and expense required to perform the clinical testing necessary to obtain FDA approval for regulated products can frequently exceed the time and expense of the research and development initially required to create the product. The results of preclinical studies and initial clinical trials of our product candidates are not necessarily predictive of the results from large-scale clinical trials, and clinical trials may be subject to additional costs, delays or modifications due to a number of factors, including difficulty in obtaining enough patients, investigators or product candidate supply. Failure by us to obtain, or any delay in obtaining, regulatory approvals or in complying with requirements could adversely affect the commercialization of product candidates and our ability to receive product or royalty revenues.

Other Regulatory Requirements

After approval, drug products are subject to extensive continuing regulation by the FDA, which include company obligations to manufacture products in accordance with GMP, maintain and provide to the FDA updated safety and efficacy information, report adverse experiences with the product, keep certain records and submit periodic reports, obtain FDA approval of certain manufacturing or labeling changes, and comply with FDA promotion and advertising requirements and restrictions. Failure to meet these obligations can result in various adverse consequences, both voluntary and FDA-imposed, including product recalls, withdrawal of approval, restrictions on marketing, and the imposition of civil fines and criminal penalties against the NDA holder. In addition, later discovery of previously unknown safety or efficacy issues may result in restrictions on the product, manufacturer or NDA holder.

We and any manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's GMP regulations. GMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet GMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and any third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

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Outside the United States, our ability to market a product is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from jurisdiction to jurisdiction. At present, foreign marketing authorizations are applied for at a national level, although within the European Union registration procedures are available to companies wishing to market a product in more than one European Union member state.

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 Hana Biosciences Inc., SGX Pharmaceuticals, Inc., Sunesis Pharmaceuticals, Inc. and Genzyme, 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 costs include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, 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. Research and development expenses were $9,588,543 for the twelve months ended December 31, 2010, as compared to $3,423,515 and $5,184,080 for the twelve months ended December 31, 2009 and 2008, respectively.

During the twelve months ended December 31, 2010, 2009 and 2008 we received $0, $0 and $30,000, respectively, which has been reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grant". We terminated in-house work on this program upon expiration of the research grant in April 2008, and we have had no funding remaining since December 31, 2008.

During the twelve months ended December 31, 2010 we were awarded a New York State Qualified Employer Tax Credit totaling $531,127 and Synergy received a $244,479 Federal credit for our Qualifying Therapeutic Discovery Project under the Patient Protection and Affordable Care Act of 2010 and earned a $250,000 New York City Biotechnology refundable tax credit. The total of these credits of $1,025,606 have been recorded as tax credits in our statement of operations.

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

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

As of March 31, 2011, we are the assignee or exclusive licensee of 6 issued United States patents and 1 pending patent application related to Atiprimod. The US patent covering the composition of matter of Atiprimod and the US patent coving the formulation of Atiprimod dimaleate salt both expire in 2016. In addition, we currently have approximately 15 issued or pending foreign patent applications related to Atiprimod. These foreign patents cover Switzerland, United Kingdom, Ireland (2), Turkey, South Africa, Japan (2), Taiwan, Hong Kong, Thailand, Chile, Mexico and Canada. One PCT (World International Patent Organization) application is pending and has the potential to be nationalized by many other countries should we elect to do so.

As of March 31, 2011, we have a license to 3 issued United States patents and 1 issued Canadian patent related to L-Annamycin. The US patent covering the composition of matter of L-Annamycin expires in 2017; the US patent covering the formulation of L-Annamycin expires in 2016.

As of March 31, 2011 Synergy had three issued United States patents which cover composition of matter of plecanatide and SP333, and expire in 2022, 2023 and 2028. In addition, Synergy had three issued foreign patents which cover composition-of-matter of plecanatide and expire in 2022. These foreign patents cover Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Sweden, Turkey, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyz Republic, Moldova, Russian Federation, Tajikistan, Turkmenistan, Hong Kong and Japan. Additionally as of March 31, 2011, Synergy had 11 pending United States patent applications (seven utility and four provisional) and 29 pending foreign patent applications covering various derivatives and analogs of plecanatide and SP-333. We may file additional patent applications and extensions. In April 2010, two parties filed an opposition to Synergy's granted European patent with the European Patent Office. We cannot predict the final outcome of the opposition, which is likely to take several years to complete.

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. On December 19, 2008, we entered into a Technology Assignment Agreement (the "Agreement") with AnorMED pursuant to which AnorMED

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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.

EMPLOYEES

As of March 31, 2011, we had 10 full-time equivalent employees. We believe our employee relations are satisfactory.

CALLISTO WEBSITE

Our website address is **www.callistopharma.com.** 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.

ITEM 1A. RISK FACTORS.

Risks Related to Our Business

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

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

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We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

To date, we have funded our operations primarily from sales of our securities. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future.

As of December 31, 2010 we had an accumulated deficit of $135,573,268. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development, continue our clinical trials of plecanatide for the treatment of GI disorders, acquire or license technologies, advance other product candidates into clinical development, including SP-333, 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.

Our net cash used in operating activities has totaled $70,234,154 since inception through December 31, 2010. We expect to continue to spend substantial amounts to:

- continue clinical development of plecanatide to treat GI disorders;
- continue development of other product candidates, including SP-333;
- finance our general and administrative expenses;
- prepare regulatory approval applications for plecanatide and other product candidates, including SP-333;
- 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 will be required to raise additional capital within the next year to continue 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;

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- the costs and timing of regulatory approval;
- the costs of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and
- general market conditions for offerings from biopharmaceutical companies.

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

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

We are largely dependent on the success of our lead product candidate, plecanatide, and we cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized.

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. We are not permitted to market any of our product candidates in the United States until we receive approval of a new drug application, or NDA, for a product candidate from the FDA or the equivalent approval from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have one lead product candidate, plecanatide for the treatment of GI disorders, and the success of our business currently depends on its successful development, approval and commercialization. This product candidate has not completed the clinical development process; therefore, we have not yet submitted an NDA or foreign equivalent or received marketing approval for this product candidate anywhere in the world.

The clinical development program for plecanatide may not lead to commercial products for a number of reasons, including if we fail to obtain necessary approvals from the FDA or foreign regulatory authorities because our clinical trials fail to demonstrate to their satisfaction that this product candidate is safe and effective. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. Any failure or delay in completing clinical trials or obtaining regulatory approval for plecanatide in a timely manner would have a material adverse impact on our business and our stock price.

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We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

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, 2010 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 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.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- if plecanatide receives regulatory approval, the level of underlying demand for that product and wholesalers' buying patterns.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially.

Our management overlaps substantially with the management and beneficial owners of our subsidiary, which may give rise to potential conflicts of interest.

Several of our executive officers and directors are also officers and/or directors of our subsidiary, Synergy, and certain of such executive officers and directors are, in turn, the principal stockholders of

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Synergy. Accordingly, there may be inherent, albeit non-specific, potential conflicts involved in the participation by members of each company's management, audit committee, compensation committee, nominating committee and other applicable board committees which will oversee questions of possible conflicts of interest and compensation, notwithstanding an effort to appoint independent directors that do not have these inherent conflicts. In addition, as a matter of practicality, efficiency and appropriate accounting, the costs of certain service (including salaries of executive officers) are allocated, which creates inter-company obligations.

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 for the intended indication of use. Clinical testing is expensive, can take many years to complete, if at all, 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 new drugs do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the filing of an NDA or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical 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 clinical trial, competing clinical trials and new drugs approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidates versus treating these patients with commercially available 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.

The FDA's expectations for clinical trials may change over time, complicating the process of obtaining evidence to support approval of our product candidates.

In March 2010, the FDA's Center for Drugs Evaluation and Research, or CDER, released a draft guidance entitled: "Irritable Bowel Syndrome Clinical Evaluation of Products for Treatment" to assist the product sponsors developing new drugs for the treatment of IBS. In pertinent part, this document provides recommendations for IBS clinical trial design and endpoints, and describes the need for the future development of patient-reported outcome, or PRO, instruments for use in IBS clinical trials. The clinical trials we have planned for plecanatide are designed to follow the recommendations included in this draft guidance. We cannot predict when the draft guidance will be finalized and, if it is finalized,

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whether the final version will include the same recommendations, or whether our currently planned clinical trials of plecanatide will meet the final recommendations.

When finalized, the guidance document will represent the FDA's thinking on the clinical evaluation of products for the treatment of IBS. FDA guidance documents, however, do not establish legally enforceable requirements, should be viewed only as recommendations, and may be changed at any time. Therefore, even insofar as we intend to follow the recommendations provided in the draft guidance document and the final guidance document when revealed, we cannot be sure that the FDA will accept the results of our clinical research even if such research follows the recommendations in the guidance document.

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, the FDA or other 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 candidate 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 fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a developer of pharmaceuticals, even though we do not intend to make referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which we conduct our business. The laws include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

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the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidates.

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

The FDA's review and approval process, including among other things, evaluation of preclinical studies and clinical trials of a product candidate as well as the manufacturing process and facility, 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 for which 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 will submit an NDA for approval for any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval or may contain significant limitations on the conditions of use.

The FDA has substantial discretion in the NDA review process and may either refuse to file our NDA for substantive review or may decide that our data are insufficient to support approval of our product candidates for the claimed intended uses. In addition, even if we obtain approval of an application to market our product candidates, the FDA may subsequently seek to withdraw approval of our NDA if it determines that new data or a reevaluation of existing data show the product is unsafe for use under the conditions of use upon the basis of which the NDA was approved, or based on new evidence of clinical experience, or upon other new information. If the FDA does not file or approve our NDA or withdraws approval of our NDA, it may require that we conduct additional clinical trials, preclinical or manufacturing studies and submit that data before it will reconsider our application. Depending on the extent of these or any other requested studies, approval of any applications that we submit may be delayed by several years, may require us to expend more resources than we have available, or may never be obtained at all.

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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 marketing the product in those countries. The approval process varies and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure 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 an approval in one country or region will result in approval elsewhere.

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 generally 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 and marketing approved products than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize GI drugs that are safer, more effective, have fewer side effects or are less expensive than our product candidates. These potential competitors 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.

If approved and commercialized, plecanatide will compete with at least one currently approved prescription therapy for the treatment of CC and IBS-C, Amitiza. In addition, over-the-counter products are also used to treat certain symptoms of CC and IBS-C. We believe other companies are developing products that could compete with plecanatide should they be approved by the FDA. For example, linaclotide is being developed by Ironwood Pharmaceuticals, Inc. This compound is being co-developed with Forest Laboratories, Inc. and has completed Phase 3 clinical trials for CC and is expecting to have data from Phase 3 clinical trials for IBS-C in the second half of 2010. Another compound, velusetrag, is being developed by Theravance, Inc. and has completed Phase 2 clinical trials for CC. To our knowledge, other potential competitors are in earlier stages of development. If our potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for plecanatide.

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

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

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to existing GI drugs. If we are unable to compete

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effectively in the GI drug market and differentiate our products from other marketed GI drugs, we may never generate meaningful revenue.

We currently have no sales and marketing organization. If we are unable to establish a direct sales force in the United States to promote our products, the commercial opportunity for our products may be diminished.

We currently have no sales and marketing organization. If any of our product candidates are approved by the FDA, we intend to market that product 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, although we would intend to use due diligence in monitoring their activities, 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.

If the manufacturers upon whom we rely fail to produce plecanatide and our product candidates, including SP-333, in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our product candidates.

We do not currently possess internal manufacturing capacity. We currently utilize the services of contract manufacturers to manufacture our clinical supplies. With respect to the manufacturing of plecanatide, we are currently pursuing long-term commercial supply agreements with multiple manufacturers. Any curtailment in the availability of plecanatide could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

We may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions with the contract manufacturers. We may not be able to enter into long-term agreements on commercially reasonable terms, or at all. If we change or add manufacturers, the FDA and comparable foreign regulators may require approval of the changes. Approval of these changes could require new testing by the manufacturer and compliance inspections to ensure the manufacturer is conforming to all applicable laws and regulations, including good manufacturing practices, or GMP. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary for the

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production of our product candidates. Peptide manufacturing is a highly specialized manufacturing business. While we believe we will have long term arrangements with a sufficient number of contract manufacturers, if we lose a manufacturer, it would take us a substantial amount of time to identify and develop a relationship, and seek regulatory approval, where necessary, for an alternative manufacturer.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

We are responsible for ensuring that each of our contract manufacturers comply with the GMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer's compliance with GMP requirements. We are responsible for regularly assessing a contract manufacturer's compliance with GMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations. Manufacturers of plecanatide and other product candidates, including SP-333, may be unable to comply with these GMP requirements and with other FDA and foreign regulatory requirements, if any. While we will oversee compliance by our contract manufacturers, ultimately we have no control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of plecanatide or other product candidates is compromised due to a manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize plecanatide or other product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of plecanatide or other product candidates, entail higher costs or result in our being unable to effectively commercialize plecanatide or other product candidates. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

To date, our product candidates have been manufactured in small quantities for preclinical studies and clinical trials. If any of our product candidates is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidate in larger quantities. We may not be able to increase successfully the manufacturing capacity for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to increase successfully the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high quality manufacturing. Our failure to achieve and maintain these high quality manufacturing standards in collaboration with our third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death,

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product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.

We rely on the third-party manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce the bulk active pharmaceutical ingredients, or APIs, and product candidates for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the APIs and finished products for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidate would be delayed, which may significantly impact our ability to develop the product candidate. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If one of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

Demonstration of efficacy;

Changes in the practice guidelines and the standard of care for the targeted indication;

Relative convenience and ease of administration;

The prevalence and severity of any adverse side effects;

Budget impact of adoption of our product on relevant drug formularies and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;

Pricing and cost effectiveness, which may be subject to regulatory control;

Effectiveness of our or any of our partners' sales and marketing strategies;

The product labeling or product insert required by the FDA or regulatory authority in other countries; and

The availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA

or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from

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that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

Guidelines and recommendations published by various organizations can impact the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our proposed products.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

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

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- initiation of investigations by regulators;
- substantial monetary awards to patients or other claimants;
- distraction of management's attention from our primary business;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

We have clinical trial liability insurance with a $5,000,000 aggregate limit. 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 liabilities that may arise.

Our failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we intend to develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend

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several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. Failure of this strategy would impair our ability to grow.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

Further, any product candidate that we 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 risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

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Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Plecanatide and other product candidates, including SP-333, would also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or GMP, regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

issue warning letters;

impose civil or criminal penalties;

suspend regulatory approval;

suspend any ongoing clinical trials;

refuse to approve pending applications or supplements to applications filed by us;

impose restrictions on operations, including costly new manufacturing requirements;

seize or detain products or request us to initiate a product recall; or

pursue and obtain an injunction.

Drugs approved to treat IBS have been subject to considerable post-market scrutiny, with consequences up to and including voluntary withdrawal of approved products from the market. This may heighten FDA scrutiny of our product candidates before or following market approval.

Products approved for the treatment of IBS have been subject to considerable post-market scrutiny. For example, in 2007, Novartis voluntarily discontinued marketing Zelnorm (tegaserod), a product approved for the treatment of women with IBS-C, after the FDA found an increased risk of serious cardiovascular events associated with the use of the drug. Earlier, in 2000, Glaxo Wellcome withdrew Lotronex (alosetron), which was approved for women with severe diarrhea-prominent IBS, after the manufacturer received numerous reports of AEs, including ischemic colitis, severely obstructed or ruptured bowel, or death. In 2002, the FDA approved the manufacturer's application to make Lotronex available again, on the condition that the drug only be made available through a restricted marketing program.

Although plecanatide is being investigated for IBS, plecanatide is from a different pharmacologic class than Zelnorm or Lotronex, and would not be expected to share the same clinical risk profile as those agents. Nevertheless, because these products are in the same or related therapeutic classes, it is possible that the FDA will have heightened scrutiny of plecanatide or any other agent under development for IBS. This could delay product approval, increase the cost of our clinical development program, or increase the cost of post-market study commitments for our IBS product candidates, including plecanatide.

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Even if our product candidates receive regulatory approval in the United States, we may never receive approval to commercialize them outside of the United States.

In the future, we may seek to commercialize plecanatide and/or other product candidates, including SP-333, in foreign countries outside of the United States. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the United States. The time required to obtain approval in other jurisdictions might differ from that required to obtain FDA approval. The regulatory approval process in other jurisdictions may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that plecanatide or other product candidates may not be approved for all indications for use included in proposed labeling or for any indications at all, which could limit the uses of plecanatide or other product candidates and have an adverse effect on our products' commercial potential or require costly post-marketing studies.

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, or CROs, under which we have delegated to the CROs the responsibility to coordinate and monitor the conduct of our clinical trials and to manage data for our clinical programs. We, our CROs and our clinical sites are required to comply with current Good Clinical Practices, or GCPs, regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our CROs and at our clinical sites to confirm compliance with these requirements. In the future, if we, our CROs or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. 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 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 their 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

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dependent upon our senior management and scientific staff, particularly Gary S. Jacob, Ph.D., our President and Chief Executive Officer. The loss of services of Dr. Jacob or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidates.

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

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with 10 full-time equivalent employees as of March 31, 2011. 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 development efforts effectively;

manage our clinical trials effectively;

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

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

hire and train additional qualified personnel.

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

Reimbursement may not be available for our product candidates, which would impede sales.

Market acceptance and sales of our product candidates may depend on reimbursement policies and health care reform measures. Decisions about formulary coverage as well as 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 as well as levels at which these payers pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of these products. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidates reimbursed by government or third party payers. 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

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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.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third party payers. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payers of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

For example, in March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the PPACA. This law will substantially change the way health care is financed by both government health plans and private insurers, and significantly impact the pharmaceutical industry. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the PPACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which we believe will increase the cost of our products. In addition, as part of the PPACA's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we will be required to provide a 50% discount on branded prescription drugs sold to beneficiaries who fall within the donut hole. Similarly PPACA increases the level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% and requires collection of rebates for drugs paid by Medicaid managed care organizations. The PPACA also included significant changes to the 340B Drug Pricing Program including expansion of the list of eligible covered entities that may purchase drugs under the program. At the same time, the expansion in eligibility for health insurance benefits created under PPACA is expected to increase the number of patients with insurance coverage who may receive our products. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

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In addition, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reformed the way Medicare covers and reimburses for pharmaceutical products. This legislation could decrease the coverage and price that we may receive for our proposed products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our proposed products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

Our ability to use our net operating loss carryforwards may be subject to limitation.

Generally, a change of more than 50% in the ownership of a company's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit a company's ability to use its net operating loss carryforwards attributable to the period prior to the change. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability for us. At December 31, 2010, we had net operating loss carryforwards aggregating approximately $70 million. We have determined that ownership changes have occurred pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, and therefore our ability to utilize our net operating loss carry forwards is limited.

In preparing our consolidated financial statements, we identified a material weakness in our internal control over financial reporting, and our failure to remedy this material weakness identified as of December 31, 2010 and our ineffective disclosure controls and procedures could result in material misstatements in our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our management identified a material weakness in our internal control over financial reporting as of December 31, 2009. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness identified by management as of December 31, 2009, which continued unremediated as of December 31, 2010, consisted of an ineffective control environment.

As a result of this continuing material weakness, our management concluded as of December 31, 2010 that our internal control over financial reporting was not effective based on criteria set forth by

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the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control An Integrated Framework (September 1992).

During the year ended December 31, 2010 we implemented and continue to implement remedial measures designed to address these material weaknesses and the ineffectiveness of our disclosure controls and procedures. If these remedial measures are insufficient to address these material weaknesses and the ineffectiveness of our disclosure controls and procedures, or if additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future and the ineffectiveness of our disclosure controls and procedures continues, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements may contain material misstatements, we could be required to restate our prior period financial results and our operating results may be harmed, we may be subject to class action litigation. Any failure to address the identified material weaknesses or any additional material weaknesses in our internal control or the ineffectiveness of our disclosure controls and procedures could also adversely affect the results of the periodic management evaluations regarding the effectiveness of our internal control over financial reporting and our disclosure controls and procedures that are required to be included in our annual report on Form 10-K. Internal control deficiencies and ineffective disclosure controls and procedures could also cause investors to lose confidence in our reported financial information. We can give no assurance that the measures we plan to take in the future will remediate the material weaknesses identified or the ineffectiveness of our disclosure controls and procedures or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or adequate disclosure controls and procedures or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent auditors addressing these assessments. We have documented and tested our internal control procedures, and during the year ended December 31, 2009, we identified material weaknesses in our internal control over financial reporting and other deficiencies. During the year ended December 31, 2010 we implemented and continue to implement remedial measures designed to address these material weaknesses. If these remedial measures are insufficient to address these material weaknesses, if additional material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls 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.

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Risks Related to Our Stock

The market price of the common stock may be volatile and adversely affected by several factors.

The market price of our common stock could fluctuate significantly in response to various factors and events, including:

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

our ability to execute our business plan;

operating results below expectations;

our issuance of additional securities, including debt or equity or a combination thereof, which will be necessary to fund our operating expenses;

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

loss of any strategic relationship;

industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;

economic and other external factors;

period-to-period fluctuations in our financial results; and

whether an active trading market in our common stock develops and is maintained.

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

We have not paid cash dividends in the past and do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the value of our common stock.

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

A sale of a substantial number of shares of the common stock may cause the price of our common stock to decline.

If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, including shares issued upon the exercise of outstanding options or warrants the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem

reasonable or appropriate. We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and biopharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. 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

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biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years.

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 and 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. We seek patent protection of inventions originating from our ongoing research and development activities that are commercially important to our business.

As of March 31, 2011, we are the assignee or exclusive licensee of 6 issued United States patents and 1 pending patent application related to Atiprimod. The US patent covering the composition of matter of Atiprimod and the US patent coving the formulation of Atiprimod dimaleate salt both expire in 2016. In addition, we currently have approximately 15 issued or pending foreign patent applications related to Atiprimod. These foreign patents cover Switzerland, United Kingdom, Ireland (2), Turkey, South Africa, Japan (2), Taiwan, Hong Kong, Thailand, Chile, Mexico and Canada. One PCT (World International Patent Organization) application is pending and has the potential to be nationalized by many countries should we elect to do so.

As of March 31, 2011, we have a license to 3 issued United States patents and 1 issued Canadian patent related to L-Annamycin. The US patent covering the composition of matter of L-Annamycin expires in 2017; the US patent covering the formulation of L-Annamycin expires in 2016.

As of March 31, 2011 Synergy had three issued United States patents which cover composition of matter of plecanatide and SP333, and expire in 2022, 2023 and 2028. In addition, Synergy had three issued foreign patents which cover composition-of-matter of plecanatide and expire in 2022. These foreign patents cover Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Sweden, Turkey, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyz Republic, Moldova, Russian Federation, Tajikistan, Turkmenistan, Hong Kong and Japan. Additionally as of March 31, 2011, Synergy had 11 pending United States patent applications (seven utility and four provisional) and 29 pending foreign patent applications covering various derivatives and analogs of plecanatide and SP-333. We may file additional patent applications and extensions. In April 2010, two parties filed an opposition to Synergy's granted European patent with the European Patent Office. We cannot predict the final outcome of the opposition, which is likely to take several years to complete.

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 issued patents or in third-party patents.

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

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

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

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In 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.

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Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO, 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We have not yet registered trademarks for plecanatide in our potential markets, and failure to secure those registrations could adversely affect our ability to market our product candidate and our business.

We have not yet registered trademarks for plecanatide in any jurisdiction. Our trademark applications in the United States, when filed, and any other jurisdictions where we may file may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the PTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our ability to market our product candidates and our business.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented

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know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None

ITEM 2. PROPERTIES.

Our corporate headquarters totals approximately 5,500 square feet, in two suites 1609 and 1701, located at 420 Lexington Avenue, New York, NY. The term of the leases at 420 Lexington Avenue expire on June 30, 2011 and September 30, 2011. We also occupy a small laboratory and several offices, totaling approximately 1,000 square feet, in the Bucks County Biotechnology Center in Doylestown, Pennsylvania under a lease expiring August 31, 2011, which we expect to renew.

ITEM 3. LEGAL PROCEEDINGS.

On December 22, 2009, , Synergy Advanced Pharmaceuticals, Inc., a wholly-owned subsidiary of Synergy, filed a complaint in the Supreme Court of the State of New York against CapeBio, LLC, CombiMab Inc. and Per Lindell alleging that defendants intentionally breached certain provisions of agreements previously entered into with us. We are requesting that the defendants be permanently restrained and enjoined from breaching such agreements and disgorging all compensation and any and all profits derived from their claimed misappropriation of plaintiff's intellectual property.

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

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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 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 Over the Counter Bulletin Board.

	2011		2010		2009	
	High	Low	High	Low	High	Low
First Quarter	$ 0.70	$ 0.57	$ 0.49	$ 0.18	$ 0.15	$ 0.07
Second Quarter	$	$	$ 0.43	$ 0.30	$ 0.28	$ 0.06
Third Quarter	$	$	$ 0.41	$ 0.22	$ 0.45	$ 0.20
Fourth Quarter	$	$	$ 0.86	$ 0.30	$ 0.42	$ 0.18

HOLDERS OF COMMON STOCK

As of March 31, 2010 we had 123 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, 2010.

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	5,647,317	$ 1.38	3,466,500
Equity Compensation Plans Not Approved by Stockholders(1)	12,696,554	0.31	
Total	18,343,871		3,466,500

(1) Consists of 2,324,555 stock options not subject to any of our stock option plans and 10,371,999 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 principle corporate headquarters totals approximately 5,500 square feet, in two suites 1609 and 1701, located at 420 Lexington Avenue, New York, NY.

We are a development stage biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal ("GI") disorders and diseases and rheumatoid arthritis ("RA"). Our lead drug candidates are as follows:

(1) Plecanatide, a guanylyl cyclase C ("GC-C") receptor agonist, to treat GI disorders, primarily chronic constipation ("CC") and constipation-predominant irritable bowel syndrome ("IBS-C").

(2) SP-333, a second generation GC-C receptor agonist, SP-333, now in pre-clinical development to treat gastrointestinal inflammatory diseases.

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.

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

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Synergy-DE, representing 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. 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 OTC QB under the symbol SGYP.

From inception through December 31, 2010, we have sustained cumulative net losses attributable to common stockholders of $135,573,268. 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 and changes in fair value of derivatives. From inception through December 31, 2010, 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.

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in Item 8. Financial Statements Note 3 *Summary of Significant Accounting Policies and New Accounting Pronouncements* . The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. We believe that the following discussion represents our critical accounting policies.

Research and Development

We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all and therefore our research and development costs are expensed as incurred. These include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of our proposed

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products, purchase of in-process research and development, regulatory and scientific consulting fees and contract research payments to outside suppliers, facilities and universities. 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.

In June 2007, the EITF of the FASB reached a consensus on ASC Topic 730, *Research and Development* ("ASC 730"). This guidance 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 are recognized as an expense. ASC 730 was adopted by the Company on January 1, 2008. As of December 31, 2010 and 2009 we had $683,182 and $1,000,000, respectively, of such deferred amounts, which are included in prepaid and other current assets on the Company's consolidated balance sheet.

Stock-Based Compensation

We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options 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, 2010 stock-based compensation expense has totaled $19,709,376 or 15% of our total deficit accumulated during development stage of $135,573,268.

ASC Topic 718 *Compensation Stock Compensation ("ASC 718)* 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.

Upon adoption of ASC 718 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. The expected term was determined based on the simplified method provided in ASC 718. 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.

Fair value of financial instruments

We have adopted FASB ASC 820 *Fair Value Measurements and Disclosures ("ASC 820")* for financial assets and liabilities that are required to be measured at fair value, and non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis. The carrying value of cash and cash equivalents, accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments.

ASC 820 provides that the measurement of fair value requires the use of techniques based on observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. The inputs create the following fair value hierarchy:

Level 1 Quoted prices for identical instruments in active markets.

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Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.

Level 3 Instruments where significant value drivers are unobservable to third parties.

Warrants

We have issued common stock warrants in connection with the execution of certain equity financings. Such warrants are classified as derivative liabilities under the provisions of FASB ASC 815 *Derivatives and Hedging ("ASC 815")*, are recorded at their fair market value as of each reporting period. Changes in fair value of derivative liabilities are recorded in the consolidated statement of operations.

The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding volatility of our common share price, remaining life of the warrant, and risk-free interest rates at each period end. We thus use model-derived valuations where inputs are observable in active markets to determine the fair value and accordingly classify such warrants in Level 3 per ASC 820. At December 31, 2010 and 2009 the fair value of such warrants was $3,487,959 and $11,870,369, respectively, which we classified as long term derivative liabilities on our balance sheet.

As of December 31, 2010 and 2009 we did not hold any Level 1 or Level 2 securities.

RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2010 AND DECEMBER 31, 2009

We had no revenues during the twelve months ended December 31, 2010 and 2009 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

For the twelve months ended December 31, 2010, research and development expenses increased $6,165,028 or 180% to $9,588,543 for the twelve months ended December 31, 2010 from $3,423,515 for the twelve months ended December 31, 2009. This increase in research and development expenses was entirely attributable to continuing the development of our plecanatide product candidate. These expenses included (i) procurement of drug substance, totaling approximately $2,625,000 as compared to $910,000 during the 12 months ended December 31, 2009 (ii) plecanatide program expenses including animal studies, analytical testing and clinical data monitoring and patient costs of approximately $5,484,000, as compared to $1,956,000 during the 12 months ended December 31, 2009; related to our phase IIa clinical trial initiated in March 2010 and concluded in October 2010, (iii) scientific and regulatory advisory fees and expenses of approximately $346,000, as compared to $224,000 during the 12 months ended December 31, 2009, (iv) in-house staff salaries and wages, stock based compensation and employee benefits of approximately $1,103,000, as compared to $643,000 during the 12 months ended December 31, 2009 as we hired additional product development personnel.

For the twelve months ended December 31, 2010, general and administrative expenses increased $2,236,719 or 44%, to $7,343,188 for the twelve months ended December 31, 2010 from $5,106,470 for the twelve months ended December 31, 2009. These expenses primarily include (i) higher facilities cost of approximately $955,000 as compared to $713,000 during the 12 months ended December 31, 2009, (ii) higher accounting, corporate legal and tax services of approximately $1,824,000, as compared to $1,172,000 during the 12 months ended December 31, 2009. This increase is primarily due to filings of registration statements and due diligence related to our registered direct offerings during the twelve months ended December 31, 2010, (iii) consultants and financial advisors of approximately $2,482,000, as compared to $1,193,000 during the 12 months ended December 31, 2009, (iv) travel of approximately $252,000, as compared to $180,000 during the 12 months ended December 31, 2009 and (v) salaries

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and wages, stock based compensation and related employee benefits of approximately $1,825,000, as compared to $1,846,000 during the 12 months ended December 31, 2009.

Net loss from operations for twelve months ended December 31, 2010, increased $8,401,746 to $16,931,731 compared to a net loss from operations of $8,529,985 incurred for the twelve months ended December 31, 2009. The increased net loss is the result of higher research and development, and general and administrative expenses discussed above, plus the following non-operating expenses for the twelve months ended December 31, 2010 and 2009.

	Twelve months ended 12/31/2010	Twelve months ended 12/31/2009	Change ($)
Loss from operations	$ (16,931,731)	$ (8,529,985)	$ (8,401,746)
Interest and investment income	25,548	25,008	540
Tax credit	1,025,606		1,025,606
Interest expense notes payable	(322,705)	(436,693)	113,988
Loss on debt extinguishment	(2,099,892)		(2,099,892)
Change in Fair Value of derivative instruments	(15,344,578)	(9,413,744)	(5,930,834)
Net loss attributable to non-controlling interest	7,854,264	3,282,393	4,571,871
Series A and B preferred stock conversion rate change accreted as a dividend		(1,815,592)	1,815,592
Net loss available to common stockholders	$ (25,793,488)	$ (16,888,613)	$ (8,904,875)

YEARS ENDED DECEMBER 31, 2009 AND DECEMBER 31, 2008

We had no revenues during the 12 months ended December 31, 2009 and 2008 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses decreased $1,760,565 or 34% to $3,423,515 for the 12 months ended December 31, 2009 from $5,184,080 for the 12 months ended December 31, 2008. This decrease in research and development expense was attributable to lower overhead, not allocated to specific programs which totaled $735,000 and $1,961,225 during the 12 months ended December 31, 2009 and 2008, respectively, a decrease of $1,225,693 or 63%. These reduced non-allocated overhead costs include clinical data management, regulatory and scientific advisory fees and other in-house personnel cost associated with monitoring our cancer trials. In addition, we reversed over accrued patient costs totaling $517,000 for Atiprimod and Annamycin due to lower than expected hospital and other dosing expenses as those programs were closed during 2009. Partially offsetting these decreases were our plecanatide program expenses incurred by Synergy which increased $383,000 to $3,004,000 for the 12 months ended December 31, 2009 up from $2,621,000 during the 12 months ended December 31, 2008.

General and administrative expenses for the 12 months ended December 31, 2009 increased 529,062 or 12% to $5,106,470 from $4,577,408 for the 12 months ended December 31, 2008. This increase was primarily due to increased legal, accounting, consulting and advisory expenses as a result of having two public reporting entities (Callisto and Synergy) for a full year during 2009.

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Net loss from operations was $8,529,985 for the 12 months ended December 31, 2009 which was $1,201,503 or 12% lower than the $9,731,488 reported in the comparable period of 2008. 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 $0 received during the 12 months ended December 31, 2009. 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.

Net loss attributable to common stockholders for the 12 months ended December 31, 2009 was $16,888,613 compared to a net loss of $9,655,471 incurred for the 12 months ended December 31, 2008. The increased net loss is the result of (i) lower operating expenses discussed above, offset by (ii) other expense comprising interest expense of $436,693 on our secured convertible notes during the 12 months ended December 31, 2009, (iii) an expense in the 12 months ended December 31, 2009 relating to a change in the fair value of the Series B warrants of $9,413,744, (iv) a credit of $3,282,393 for the net loss attributable to the non-controlling interest in our majority owned subsidiary (Synergy) and (v) the conversion rate change of the Series A and B preferred stock accreted as a dividend of $1,815,592 in the 12 months ended December 31, 2009. We had no such items (ii) through (v) during 2008.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2010, we had $1,708,982 in cash and cash equivalents, compared to $7,207,612 as of December 31, 2009. Net cash used in operating activities was $12,209,500 for the twelve months ended December 31, 2010 as compared to $9,406,972 during the twelve months ended December 31, 2009. Net cash provided by financing activities for the twelve months ended December 31, 2010 was $6,710,870, as compared to $16,313,261 provided during the twelve months ended December 31, 2009.

As of December 31, 2010 we had a negative working capital of $3,806,899, as compared to a positive working capital of $4,461,765 on December 31, 2009.

On February 8, 2011, Synergy entered into a loan agreement with an investor, pursuant to which the investor agreed to lend an aggregate $950,000 to Synergy. Simultaneously with the execution and delivery of the loan agreement, Synergy issued a note to the investor in the principal amount of $500,000. Synergy has the option to issue an additional note to the investor in the principal amount of $450,000 beginning February 21, 2011. The notes bear interest at 17% per annum and are payable on April 1, 2011.

On March 4, 2011, Synergy closed a financing with a non-U.S. investor which raised gross proceeds of $1,800,000 in a registered direct offering. Synergy issued to the investor 600,000 shares of its common stock and warrants to purchase 420,000 shares of common stock. The purchase price paid by the investor was $3.00 for each unit. The warrants expire after seven years and are exercisable at $3.10 per share.

On December 10, 2010, we closed a Note and Warrant Exchange Agreement with the holders of our outstanding $603,163 aggregate principal amount 11% Secured Promissory Notes due April 30, 2011 (the "Notes") which were issued in December 2008 and common stock purchase warrants exercisable for 68,883,536 shares of common stock (the "Warrants") pursuant to which such holders exchanged the Notes plus accrued interest and the Warrants for an aggregate 72,355,770 shares of common stock.

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

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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 us 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.

Our consolidated financial statements as of December 31, 2010 have been prepared under the assumption that we will continue as a going concern. Our independent registered public accounting firm has issued a report on our financial statements that included an explanatory paragraph referring to our recurring losses from operations 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, 2010, and is based on information appearing in the Notes to Consolidated Financial Statements included elsewhere in this annual report.

	Total	Less than 1 Year	1 - 2 Years	3 - 5 Years	More than 5 Years
Operating leases	$ 155,181	$ 155,181	$	$	$
Purchase obligations principally employment and consulting services(1)	2,677,500	892,500	1,785,000		
Purchase Obligations Major Vendors(2)	1,483,512	1,483,512			
Total obligations	$ 4,316,193	$ 2,531,193	$ 1,785,000	$	$

(1) Represents salary and bonus for remaining term of employment agreement with Gary S. Jacob, CEO and consulting fees and bonus for remaining term of consulting agreement with Gabriele M. Cerrone, Chairman.

(2) Represents amounts that will become due upon future delivery of drug substance from various suppliers, under open purchase orders as of December 31, 2010.

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OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of December 31, 2010.

RECENT ACCOUNTING PRONOUNCEMENTS

In April 2010, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2010-13, "Compensation Stock Compensation (Topic 718) Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in Which the Underlying Equity Security Trades." ASU 2010-13 provides amendments to Topic 718 to clarify that an employee share-based payment award with an exercise price denominated in the currency of a market in which a substantial portion of the entity's equity securities trades should not be considered to contain a condition that is not a market, performance, or service condition. Therefore, an entity would not classify such an award as a liability if it otherwise qualifies as equity. The amendments in ASU 2010-13 are effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2010. Callisto expects the adoption of this standard will not have a material effect on its results of operation or its financial position.

In February 2010, the FASB issued ASU 2010-09, "Subsequent Events (Topic 855) Amendments to Certain Recognition and Disclosure Requirements." ASU 2010-09 requires an entity that is an SEC filer to evaluate subsequent events through the date that the financial statements are issued and removes the requirement that an SEC filer disclose the date through which subsequent events have been evaluated. ASC 2010-09 was effective upon issuance. The Company adopted ASU 2010-09 upon issuance and such adoption had no effect on its results of operation or its financial position.

In January 2010, the FASB issued ASU 2010-06, "Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements" ("ASU 2010-06"). ASU 2010-06 includes new disclosure requirements related to fair value measurements, including transfers in and out of Levels 1 and 2 and information about purchases, sales, issuances and settlements for Level 3 fair value measurements. This update also clarifies existing disclosure requirements relating to levels of disaggregation and disclosures of inputs and valuation techniques. The Company adopted ASU 2010-06 upon issuance and such adoption did not have a material impact on the Company's financial statements.

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

At December 31, 2010 and 2009, a substantial portion of our cash and cash equivalents consists of short term, highly liquid investments in money market savings accounts held at commercial banks.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The full text of our audited consolidated financial statements as of December 31, 2010 and 2009 and for the fiscal years ended December 31, 2010, 2009 and 2008 and for the period from June 5, 1996 (inception) to December 31, 2010, begins on page F-1 of this Annual Report on Form 10-K.

ITEM 9A. CONTROLS AND PROCEDURES.

a) Disclosure Controls and Procedures

Our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2010. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

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Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2010, and due to the material weakness in our internal control over financial reporting described in our accompanying *Management's Report on Internal Control over Financial Reporting*, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were not effective.

b) Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as a process designed by, or under the supervision of, a company's 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 financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

(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 receipts and expenditures of the company are being made in accordance with authorizations of management and directors of the company; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's 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. 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.

Our chief executive officer and chief financial officer assessed the effectiveness of our internal control over financial reporting as of December 31, 2010. In connection with this assessment, we identified the following material weakness in internal control over financial reporting as of December 31, 2010. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting 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 making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control An Integrated Framework* (September 1992). Because of the material weakness described below, management concluded that, as of December 31, 2010, our internal control over financial reporting was not effective.

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Control environment

During 2010, we did not maintain an effective control environment. The control environment, which is the responsibility of senior management, sets the tone of the organization, influences the control consciousness of its people, and is the foundation for all other components of internal control over financial reporting. Our control environment was ineffective because we did not maintain an effective anti-fraud program designed to detect and prevent fraud relating to (i) an effective whistle-blower program or other comparable mechanism and (ii) an ongoing program to manage identified fraud risks.

We plan to remediate this material weakness during 2011 by:

a) Enforcing and monitoring our existing whistle-blower policy by ensuring every new employee signs a statement acknowledging and understanding our whistle-blower policy.

b) Reconfirming on an annual basis with each employee his/her understanding of our whistle-blower policy.

c) Having the Chairman of our audit committee in conjunction with our outside counsel monitor any whistle-blower reports on a quarterly basis.

d) Provide a direct channel of communication to the Chairman of our audit committee for any whistle-blowers to utilize.

e) Having our audit committee periodically review management's assessment of fraud risk and controls designed to mitigate them.

c) Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2010, no changes were identified with respect to our internal control over financial reporting that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

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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 March 31, 2011:

Name	Age	Position
Gabriele M Cerrone	38	Chairman of the Board
Gary S. Jacob	63	Chief Executive Officer, Chief Scientific Officer and Director
Bernard F. Denoyer	63	Senior Vice President, Finance and Secretary
John P. Brancaccio	63	Director
Riccardo Dalla-Favera	58	Director
Randall Johnson	64	Director

Gabriele M. Cerrone has served as our Chairman of the Board of Directors since May 2003 and 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. In May 2001, Mr. Cerrone led the restructuring of SIGA Technologies, Inc., a biotechnology company, and served on its board of directors from May 2001 to May 2003. Mr. Cerrone co-founded TrovaGene, Inc. (formerly Xenomics, Inc.), a diagnostics company, and served as Co-Chairman from July 2005 until November 2006. Mr. Cerrone also co-founded FermaVir Pharmaceuticals, Inc., a biotechnology company, and served as Chairman from August 2005 to September 2007, when the company was acquired by Inhibitex, Inc., a biotechnology company. Mr. Cerrone currently serves as a director of Inhibitex, Inc. and a director of TrovaGene, Inc. In addition, Mr. Cerrone is Chairman and a consultant to Synergy Pharmaceuticals, Inc. Mr. Cerrone is the managing partner of Panetta Partners Ltd.; a Colorado limited partnership that is a private investor in both public and private venture capital in the life sciences and technology arena as well as real estate. Mr. Cerrone's experience in finance and investment banking allows him to contribute broad financial and strategic planning expertise and led to the Board's conclusion that he should serve as a director of the company.

Gary S. Jacob, Ph.D. has served as our Chief Executive Officer as well as Chief Scientific Officer since May 2003 and a Director of the Company since October 2004. Dr. Jacob has also served as President, 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 is also a director of TrovaGene, Inc. (formerly Xenomics, Inc.), a diagnostics company. Dr. Jacob served as Chief Scientific Officer of Synergy DE from 1999 to 2003. Dr. Jacob has over twenty-five years of experience in the pharmaceutical and biotechnology industries across multiple disciplines including research & development, operations and business development. Prior to 1999, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of glycobiology, and from 1997 to 1998 was Director of Functional Genomics, Corporate Science & Technology, at Monsanto Company. Dr. Jacob also served from 1990 to 1997 as Director of Glycobiology at G.D. Searle Pharmaceuticals Inc. During the period of 1986 to 1990, he was Manager of the G.D. Searle Glycobiology Group at Oxford University, England. Dr. Jacob's broad management expertise in the pharmaceutical and biotechnology industries provides relevant experience in a number of strategic and operational areas and led to the Board's conclusion that he should serve as a director of our company.

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,

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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, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. Mr. Brancaccio is currently a director of Alfacell Corporation as well as a director of TrovaGene, Inc. (formerly Xenomics, Inc.) and Synergy Pharmaceuticals, Inc. Mr. Brancaccio's chief financial officer experience provides him with valuable financial and accounting expertise which the Board believes qualifies him to serve as a director of our company.

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. Dr. Dalla-Favera's medical experience and knowledge qualifies him to serve as a director of our company.

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. Dr. Johnson's experience in drug development qualifies him to serve as a director of our company.

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,

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replacing and discharging the independent auditors, (iii) pre-approving the professional services provided by the independent auditors, (iv) reviewing the scope of the annual audit and reports and recommendations submitted by the independent auditors, and (v) reviewing our financial reporting and accounting policies, including any significant changes, with management and the independent auditors.

The Audit Committee currently consists of John Brancaccio, chairman of the Audit Committee, and Randall Johnson. Our board of directors has determined that each of 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 John Brancaccio, Chairman of the Corporate Governance/Nominating Committee. 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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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. 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 2010, 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*.

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 2010.

Name & Principal Position	Year	Salary	Bonus	Option Awards(1)	Total
Gabriele M Cerrone(2)	2010	$ 309,750	$ 1,397,762(3)	$ 11,787,403(4)	$ 13,494,915
Chairman of the Board	2009	278,521	150,000		428,521
	2008	291,187		697,625	988,812
Gary S. Jacob	2010	315,000	189,000	11,787,403(4)	12,291,403
Chief Executive Officer and	2009	285,000	150,000		435,000
Chief Scientific Officer	2008	293,750		710,327	1,004,077
Bernard F. Denoyer	2010	195,000		329,667(4)	524,667
Senior Vice President, Finance and Principal Financial Officer	2009	176,249			176,249
	2008	170,874		76,660	247,534

(1) Amounts represent Callisto and Synergy aggregate grant date fair value in accordance with FASB ASC Topic 718.

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

(3) $1,211,912 of such amount represents an accrued realization bonus. Mr. Cerrone has agreed with Synergy to defer payment of his bonus until the earlier of (i) March 31, 2012, (ii) the completion of a financing transaction yielding gross proceeds of $30 million on a cumulative basis subsequent to October 6, 2010 or (iii) the tenth business day after termination of the consulting agreement without cause or good reason (including a termination following a "change of control" transaction as that term is defined in his consulting agreement). In consideration of Mr. Cerrone agreeing to permit Synergy to defer payment of his bonus Synergy agreed to indemnify him from any liability for taxes or penalties that he may incur pursuant to Section 409A of the Internal Revenue Code and comparable state income tax laws.

(4)

Substantially all of the options underlying these amounts vest and are exercisable at $0.70 per share upon a change of control of Synergy.

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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, 2010.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date
Gary S. Jacob		390,000	$ 0.26	130,000 January 25, 2011, 130,000 on January 25, 2012, 130,000 on January 25, 2013
	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		1.64	March 17, 2016
	75,000		0.81	February 16, 2017
Bernard F. Denoyer				
		75,000	0.26	25,000 January 25, 2011, 25,000 on January 25, 2012, 25,000 on January 25, 2013
	100,000		3.60	January 15, 2014
	50,000		1.38	July 29, 2015
	100,000		0.66	April 12, 2017
Gabriele M Cerrone				
		390,000	0.26	130,000 January 25, 2011, 130,000 on January 25, 2012, 130,000 on January 25, 2013
	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		0.96	January 25, 2017

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

DIRECTOR COMPENSATION

The following table sets forth summary information concerning the total compensation earned by our non-employee directors in 2010 for services to our company.

Name	Fees Earned or Paid In Cash
John P. Brancaccio(1)	$ 31,500
Randall Johnson(2)	$ 28,000
Riccardo Dalla-Favera(3)	$ 15,000
Christoph Bruening(4)	$ 41,125

(1)

Stock options for the purchase of an aggregate of 162,123 Callisto shares were outstanding as of December 31, 2010, of which 156,123 were exercisable

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(2) Stock options for the purchase of an aggregate of 140,500 Callisto shares were outstanding as of December 31, 2010, of which 134,500 were exercisable

(3) Stock options for the purchase of an aggregate of 107,000 Callisto shares were outstanding as of December 31, 2010, of which 101,000 were exercisable

(4) Resigned on May 26, 2010, forfeited stock options to purchase an aggregate of 154,000 Callisto shares, and there are no stock options outstanding as of December 31, 2010.

EMPLOYMENT AGREEMENTS AND CHANGE IN CONTROL AGREEMENTS

On February 1, 2010, Dr. Gary Jacob entered into an amended and restated employment agreement with Synergy in which he agreed to serve as Chief Executive Officer and President. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2012 and is automatically renewed for successive one year periods at the end of each term. Dr. Jacob's salary is $315,000 per year. 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 Synergy enters into an out-license agreement for its technology or enters into a joint venture in which Synergy contributes such rights to the joint venture where the enterprise value equals or exceeds a minimum of $150 million, $200 million and $250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, or the license fees Synergy contracts to receive equals or exceeds $50 million. The realization bonus will be equal to the enterprise value in the case of a joint venture or the sum of the license fees actually received in the case of an out license, multiplied by 0.5%. In addition, in the event Synergy engages in a merger transaction or a sale of substantially all of its assets where the enterprise value equals or exceeds $400 million, Dr. Jacob shall receive a bonus in an amount determined by multiplying the enterprise value by 2.5%.

If the employment agreement is terminated by Synergy other than for cause or as a result of Dr. Jacob's death or permanent disability or if Dr. Jacob terminates his employment for good reason which includes a change of control, Dr. Jacob shall receive (i) a severance payment equal to the higher of the aggregate amount of his base salary for the then remaining term of the agreement or twelve times the average monthly base salary paid or accrued during the three full calendar months preceding the termination, (ii) expense compensation in an amount equal to twelve times the sum of his average base salary during the three full months preceding the termination, (iii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iv) payment in respect of compensation earned but not yet paid and (v) payment of the cost of medical insurance for a period of twelve months following termination. In the event Dr. Jacob's employment was terminated upon a change of control as of December 31, 2010, he would have been entitled to receive a lump sum payment of $945,000, less applicable withholding.

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On February 1, 2010, Gabriele M. Cerrone, our Chairman of the Board, entered into an amended and restated consulting agreement with Synergy. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2012 and is automatically renewed for successive one year periods at the end of each term. Pursuant to the agreement, Mr. Cerrone's compensation is $309,750 per year. 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 Synergy enters into an out-license agreement for its technology or enters into a joint venture in which Synergy contributes such rights to the joint venture where the enterprise value equals or exceeds a minimum of $150 million, $200 million and $250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, and in the case of a financing transaction, Synergy receives not less than $20 million of gross proceeds; or the license fees Synergy contracts to receive equals or exceeds $50 million. The realization bonus will be equal to the enterprise value in the case of a joint venture or financing or the sum of the license fees actually received multiplied by 0.5%. In addition, in the event Synergy engages in a merger transaction or a sale of substantially all of its assets where the enterprise value equals or exceeds $400 million, Mr. Cerrone shall receive a bonus in an amount determined by multiplying the enterprise value by 2.5%.

On October 6, 2010 Synergy achieved the $20 million threshold required for Mr. Cerrone's realization bonus to be accrued on the cumulative gross proceeds of financing transactions since August 1, 2008. This bonus totaled $1,211,912, was deemed compensatory in nature and charged to expense during the year ended December 31, 2010. Mr. Cerrone has agreed with Synergy to defer payment of his bonus until the earlier of (i) March 31, 2012, (ii) the completion of a financing transaction yielding gross proceeds of $30 million on a cumulative basis subsequent to October 6, 2010 or (iii) the tenth business day after termination of the consulting agreement without cause or good reason (including a termination following a "change of control" transaction as that term is defined in his consulting agreement). In consideration of Mr. Cerrone agreeing to permit Synergy to defer payment of his bonus Synergy agreed to indemnify him from any liability for taxes or penalties that he may incur pursuant to Section 409A of the Internal Revenue Code and comparable state income tax laws.

If the consulting agreement is terminated by Synergy other than for cause or as a result of Mr. Cerrone's death or permanent disability or if Mr. Cerrone terminates the agreement for good reason which includes a change of control, Mr. Cerrone shall receive (i) a severance payment equal to 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. In the event Mr. Cerrone's employment was terminated upon a change of control as of December 31, 2010, he would have been entitled to receive a lump sum payment of $929,250 less applicable withholding.

On April 6, 2004, Kunwar Shailubhai, Ph.D. entered into an employment agreement with Synergy-DE in which he agreed to serve as Senior Vice President, Drug Discovery. Dr. Shailubhai's employment agreement was for a term of 12 months beginning April 6, 2004 and was automatically renewed for successive one year periods at the end of each term. On July 9, 2008, Dr. Shailubhai was appointed Chief Scientific Officer of Synergy, his salary is currently $230,000 per year and he is eligible to receive a discretionary performance bonus of up to 25% of his salary per year.

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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 3,113,817 options outstanding as of December 31, 2010 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 ten years from date of grant and there were 2,613,000 options available for future grants as of December 31, 2010.

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 853,500 option shares available for future grants as of December 31, 2010.

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

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Retirement Income Security Act of 1974, as amended (ERISA). As of December 31, 2010, we have 2,324,555 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 "Synergy 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 Synergy Plan, typically vest after three years of continuous service from the grant date and have a contractual term of ten years. As of December 31, 2010 there were 8,604,016 stock options outstanding under the Synergy Plan and 6,395,984 shares available for future issuances. On March 1, 2010, a majority of the Synergy shareholders acting by written consent approved an amendment to the Synergy Plan increasing the number of shares reserved under the Synergy Plan to 15,000,000 shares.

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 March 31, 2011 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

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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	3,509,825(2)	2.2%
Gary S. Jacob Chief Executive Officer, Chief Scientific Officer and Director	1,324,745(3)	1.0%
Bernard Denoyer Senior Vice President, Finance and Secretary	275,000(4)	*
Riccardo Dalla-Favera Director	101,000(5)	*
John Brancaccio Director	158,123(6)	*
Randall K. Johnson Director	136,500(7)	*
All Directors and Executive Officers as a group (6 persons)	5,505,193(8)	3.4%
5% or Greater Stockholders		
R. Merrill Hunter	37,876,872	24.0%

* less than 1%

(1) Applicable percentage ownership as of March 31, 2011 is based upon 157,616,071 shares of common stock outstanding.

(2) Includes 1,308,055 shares of common stock issuable upon exercise of stock options.

(3) Includes 1,187,500 shares of common stock issuable upon exercise of stock options.

(4) Consists of 275,000 shares of common stock issuable upon exercise of stock options.

(5) Consists of 101,000 shares of common stock issuable upon exercise of stock options.

(6) Consists of 158,123 shares of common stock issuable upon exercise of stock options.

(7) Consists of 136,500 shares of common stock issuable upon exercise of stock options.

(8) Includes 3,166,178 shares of common stock issuable upon exercise of stock options.

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.

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

On February 1, 2010, Gabriele M. Cerrone, our Chairman of the Board, entered into an amended and restated consulting agreement with Synergy. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2012 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. Mr. Cerrone is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Mr. Cerrone is also eligible to receive a realization bonus in the event that Synergy enters into an out-license agreement for its technology or enters into a joint venture in which Synergy contributes such rights to the joint venture where the enterprise value equals or exceeds a minimum of $150 million, $200 million and $250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, and in the case of a financing transaction, Synergy receives not less than $20 million of gross proceeds; or the license fees Synergy contracts to receive equals or exceeds $50 million. The realization bonus will be equal to the enterprise value in the case of a joint venture or financing or the sum of the license fees actually received multiplied by 0.5%. In addition, in the event Synergy engages in a merger transaction or a sale of substantially all of its assets where the enterprise value equals or exceeds $400 million, Mr. Cerrone shall receive a bonus in an amount determined by multiplying the enterprise value by 2.5%.

On October 6, 2010 Synergy achieved the $20 million threshold required for Mr. Cerrone's realization bonus to be accrued on the cumulative gross proceeds of financing transactions since August 1, 2008. This bonus totaled $1,211,912, was deemed compensatory in nature and charged to expense during the year ended December 31, 2010. Mr. Cerrone has agreed with Synergy to defer payment of his bonus until the earlier of (i) March 31, 2012, (ii) the completion of a financing transaction yielding gross proceeds of $30 million on a cumulative basis subsequent to October 6, 2010 or (iii) the tenth business day after termination of the consulting agreement without cause or good reason (including a termination following a "change of control" transaction as that term is defined in his consulting agreement). In consideration of Mr. Cerrone agreeing to permit Synergy to defer payment of his bonus Synergy agreed to indemnify him from any liability for taxes or penalties that he may incur pursuant to Section 409A of the Internal Revenue Code and comparable state income tax laws.

If the consulting agreement is terminated by Synergy other than for cause or as a result of Mr. Cerrone's death or permanent disability or if Mr. Cerrone terminates the agreement for good reason which includes a change of control, Mr. Cerrone shall receive (i) a severance payment equal to 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 Synergy's stock option plans or ten years following the termination date, (iv) payment in respect of compensation earned but not yet paid and (v) payment of the cost of medical insurance for a period of twelve months following termination.

CONFLICTS OF INTEREST

Gabriele Cerrone and his affiliates are subject to certain potential conflicts of interests. His consulting agreement expressly recognizes that he may provide consulting services to others. In addition, from time to time, he or his affiliates may be presented with business opportunities which could be suitable for our business and Mr. Cerrone is not subject to any restrictions with respect to

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other business activities, except to the extent such activities are in violation of our Code of Conduct and Ethics or violate general confidentiality provisions of his consulting agreement. In instances where there is potential conflict of interest or business opportunity, with respect to any officer or director, including Mr. Cerrone, our Audit Committee has both the authority and responsibility to review such matters and take appropriate actions.

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

AUDIT FEES

The aggregate fees billed and unbilled for the fiscal years ended December 31, 2010 and December 31, 2009, 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 $365,000 and $275,000, respectively.

AUDIT-RELATED FEES

There were no aggregate fees billed for the fiscal years ended December 31, 2010 and 2009 for assurance and related services rendered by our principal accountants related to the performance of the audit or review of our financial statements..

TAX AND OTHER FEES

The aggregate fees billed and unbilled for the fiscal years ended December 31, 2010 and 2009 for professional services rendered by our principal accountants for tax preparation services was $15,000 for each year.

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.

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ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(1)

Index to Financial Statement Schedules:

(2)

List of Documents Filed as a Part of This Report:

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.

(3)

Index to Exhibits

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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 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 3.1 filed with the Company's Current Report on Form 8-K filed on September 22, 2009)
3.6	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)
3.7	Certificate of Amendment to Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series B Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.2 filed with the Company's Current Report on Form 8-K filed on September 22, 2010)
3.8	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)

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Exhibit No.	Description
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)
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)
4.11	Form of Extension Agreement (Incorporated by reference to Exhibit 4.2 filed with the Company's Current Report on Form 8-K filed on March 23, 2010).
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)**
10.10	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 (incorporated by reference to Exhibit 10.13 filed with the Company's Annual Report on Form 10-K filed on April 15, 2009).
10.14	Form of Securities Purchase Agreement by and between Callisto Pharmaceuticals, Inc. and the several investors party thereto (incorporated by reference to Exhibit 10.14 filed with the Company's Annual Report on Form 10-K filed on April 15, 2009).
10.15	Form of Security Agreement made by Callisto Pharmaceuticals, Inc and Sommer and Schneider, LLP (incorporated by reference to Exhibit 10.15 filed with the Company's Annual Report on Form 10-K filed on April 15, 2009) .
10.16	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.16 filed with the Company's Annual Report on Form 10-K filed on April 15, 2009).
10.18	Amended and Restated Executive Employment Agreement by and between Callisto Pharmaceuticals, Inc. and Gary S. Jacob dated March 11, 2009 (incorporated by reference to Exhibit 10.18 filed with the Company's Annual Report on Form 10-K filed on April 15, 2009).*
10.19	Amended and Restated Consulting Agreement by and between Callisto Pharmaceuticals, Inc. and Gabriele M. Cerrone dated March 11, 2009 (incorporated by reference to Exhibit 10.19 filed with the Company's Annual Report on Form 10-K filed on April 15, 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 USA, 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: March 31, 2011 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)	March 31, 2011
/s/ BERNARD F. DENOYER Bernard F. Denoyer	Senior Vice President, Finance (Principal Financial and Accounting Officer)	March 31, 2011
/s/ GABRIELE M. CERRONE Gabriele M. Cerrone	Chairman of the Board	March 31, 2011
/s/ RICCARDO DALLA-FAVERA Riccardo Dalla-Favera	Director	March 31, 2011
/s/ JOHN P. BRANCACCIO John P. Brancaccio	Director	March 31, 2011
/s/ RANDALL K. JOHNSON Randall K. Johnson	Director	March 31, 2011

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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, 2010 and 2009, the related consolidated statements of operations and cash flows for each of the three years in the period ended December 31, 2010 and for the period from June 5, 1996 (inception) to December 31, 2010 and the related consolidated statement of stockholders' equity (deficit) for the period from June 5, 1996 (inception) to December 31, 2010. 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, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010 and for the period from June 5, 1996 (inception) to December 31, 2010, 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 that raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP
New York, New York
March 31, 2011

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2010	December 31, 2009
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,708,982	$ 7,207,612
Prepaid expenses and other	769,403	1,061,630
Tax credits receivable	781,127	
Total Current Assets	3,259,512	8,269,242
Property and equipment, net	9,397	14,665
Security deposits	87,740	87,740
Total Assets	$ 3,356,649	$ 8,371,647
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 4,755,361	$ 3,079,798
Accrued expenses	2,311,050	727,679
Total Current Liabilities	7,066,411	3,807,477
Notes Payable		487,130
Derivative financial instruments, at estimated fair value warrants	3,487,959	11,870,369
Total Liabilities	10,554,370	16,164,976
Commitments and contingencies		
Stockholders' Deficit:		
Series A convertible preferred stock, par value $0.0001, 700,000 shares authorized, 8,000 and 63,000 shares outstanding at December 31, 2010 and December 31, 2009, respectively	1	6
Series B convertible preferred stock, par value $0.0001, 2,500,000 shares authorized, 0 and 1,014,166 shares outstanding at December 31, 2010 and December 31, 2009, respectively		102
Common stock, par value of $.0001 per share: 225,000,000 shares authorized; 157,509,404 and 53,608,111 shares outstanding at December 31, 2010 and December 31, 2009, respectively	15,751	5,359
Additional paid-in capital	139,496,452	105,263,377
Deficit accumulated during development stage	(135,573,268)	(109,779,780)
Total Stockholders' Equity (Deficit)	3,938,936	(4,510,936)
Non-controlling interest	(11,136,657)	(3,282,393)
Total Stockholders' Deficit	(7,197,721)	(7,793,329)
Total Liabilities and Stockholders' Equity (Deficit)	$ 3,356,649	$ 8,371,647

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,
	2010	2009	2008	2010
Revenues	$	$	$	$
Costs and Expenses:				
Research and development	9,588,543	3,423,515	5,184,080	45,832,482
Government grants			(30,000)	(1,135,318)
Purchased in-process research and development				6,944,553
General and administrative	7,343,188	5,106,470	4,577,408	52,706,104
Loss from Operations	(16,931,731)	(8,529,985)	(9,731,488)	(104,347,821)
Interest and investment income	25,548	25,008	76,017	914,882
Tax credit	1,025,606			1,025,606
Interest expense on notes payable	(322,705)	(436,693)		(931,244)
Loss on debt extinguishment	(2,099,892)			(2,099,892)
Change in fair value of derivative instruments	(15,344,578)	(9,413,744)		(22,167,316)
Net Loss	(33,647,752)	(18,355,414)	(9,655,471)	(127,605,785)
Net Loss attributable to noncontrolling interest	7,854,264	3,282,393		11,136,657
Net loss attributable to controlling interest	(25,793,488)	(15,073,021)	(9,655,471)	(116,469,128)
Series A Preferred stock conversion rate change and beneficial conversion feature accreted as a dividend		(136,889)		(5,025,849)
Series B Preferred stock conversion rate change and beneficial conversion feature accreted as a dividend		(1,678,703)		(12,174,391)
Cumulative effect of adopting ASC Topic 815 January 1, 2009				(1,903,900)
Net loss attributable to common stockholders	$ (25,793,488)	$ (16,888,613)	$ (9,655,471)	$ (135,573,268)
Weighted Average Common Shares Outstanding				
Basic and Diluted	69,033,439	51,394,669	47,357,254	
Net Loss per Common Share				
Basic and Diluted	$ (0.37)	$ (0.33)	$ (0.20)	

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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CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

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

	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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CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

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

	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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CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

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

	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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CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

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

	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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CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

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

	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 CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Series B Convertible Preferred Shares	Series B Convertible Preferred Stock	Common Shares	Common Stock Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Non-Controlling Interest	Total Stockholders' Equity (Deficit)
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)
Cumulative effect of adoption of ASC Topic 815							(181,732)	(1,903,900)		(2,085,632)
Net Loss								(15,073,021)	(3,282,393)	(18,355,414)
Stock based compensation expense							1,119,856			1,119,856
Conversion of Series A preferred stock to common stock	(35,000)	(4)			894,445	89	(85)			
Conversion of Series B preferred stock to common stock			(122,884)	(12)	2,963,236	296	(284)			
Private placements of common stock of majority owned subsidiary							15,970,100			15,970,100
Fees and expenses associated with private placements of majority owned subsidiary							(260,002)			(260,002)
Preferred Stock dividend attributable to reset of conversion price in conjunction with waiver of liquidation preference							1,815,592	(1,815,592)		
Cashless Conversion of Warrants to Common Stock					193,769	19	(19)			
Balance December 31, 2009	63,000	$ 6	1,014,166	$ 102	53,608,111	$ 5,359	$ 105,263,377	$ (109,779,780)	$ (3,282,393)	$ (7,793,329)
Net Loss								(25,793,488)	(7,854,264)	(33,647,752)
Stock based compensation expense							854,651			854,651
	(55,000)	(5)			1,527,777	153	(148)			

Conversion of Series A preferred stock to common stock										
Conversion of Series B preferred stock to common stock			(1,014,166)	(102)	28,171,278	2,817	(2,715)			
Common shares in exchange for modification of convertible notes					265,770	27	100,169			100,196
Extinguishment on debt							2,809,531			2,809,531
Cashless conversion of Warrants to common stock upon extinguishment of convertible notes					72,355,769	7,236	(7,236)			
Warrants exchanged					1,505,699	151	(151)			
Direct offering of common stock of controlled subsidiary							7,179,000			7,179,000
Fair value of warrants issued in connection with controlled subsidiary registered direct offerings reclassified to derivative liability							(3,784,743)			(3,784,743)
Fees and expenses associated with direct offering of controlled subsidiary							(468,130)			(468,130)
Reclassification of derivative liability to equity upon termination of price protection							27,511,730			27,511,730
Common stock issued as settlement for director's fees					75,000	8	41,117			41,125
Balance December 31, 2010	8,000	$ 1		$	157,509,404	$ 15,751	$ 139,496,452	$ (135,573,268)	$ (11,136,657)	$ (7,197,721)

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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,
	2010	2009	2008	2010
Cash Flows From Operating Activities:				
Net loss	$ (33,647,752)	$ (18,355,414)	$ (9,655,471)	$ (127,605,785)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	5,268	5,983	6,654	107,835
Stock-based compensation expense	854,651	1,119,856	589,063	19,709,376
Purchased in-process research and development				6,841,053
Purchase discount accreted as interest income on U.S. Treasury bills			(26,950)	(26,950)
Interest expense on notes payables	322,705	436,693		759,400
Stock-based liquidated damages				579,696
Change in fair value of Series B preferred warrants from date of issuance to expiration of put options	15,344,578	9,413,744		22,167,316
Loss on debt extinguishment	2,099,892			2,099,892
Net liabilities assumed in excess of assets acquired			(42,824)	(282,752)
Changes in operating assets and liabilities:				
Prepaid expenses	292,227	(1,001,874)	29,064	(769,403)
Security deposit		(9,624)	(4,400)	(87,740)
Accounts payable and accrued expenses	3,300,058	(1,016,336)	202,489	7,055,035
Tax credit receivable	(781,127)			(781,127)
Total Adjustments	21,438,252	8,948,442	753,096)	57,371,631
Net Cash Used in Operating Activities	(12,209,500)	(9,406,972)	(8,902,375)	(70,234,154)
Cash Flows From Investing Activities:				
Short-term investments purchased				(5,921,825)
Short-term investments liquidated			2,994,640	5,948,775
Additions to property and equipment			(12,196)	(117,233)
Net Cash Provided by (Used in) Investing Activities			(2,982,444)	(90,283)
Cash Flows From Financing Activities:				
Issuance of common and preferred stock				48,719,673
Finders fees and expenses	(468,130)	(260,002		(3,782,302)
Proceeds from sale of 11% Notes		603,163		603,163
Proceeds of private placement of majority owned subsidiary's common stock, net of fees and expenses	7,179,000	15,970,100	2,951,913	26,174,100
Exercise of common stock warrants				318,785
Net Cash Provided by Financing Activities	6,710,870	16,313,261	2,951,913	72,033,419
Net (decrease) increase in cash and cash equivalents	(5,498,630)	6,906,289	(2,968,018)	1,708,982
Cash and cash equivalents at beginning of period	7,207,612	301,323	3,269,341	
Cash and cash equivalents at end of period	$ 1,708,982	$ 7,207,612	$ 301,323	$ 1,708,982
Supplementary disclosure of cash flow information:				
Cash paid for taxes	$ 56,525	$ 59,704	$ 33,370	$ 277,954
Issuance of 11% Notes payable, cash held on escrow	$	$	$ 201,908	$
Supplementary disclosure of non-cash investing and financing activities:				
Series A Preferred stock beneficial conversion feature accreted as a dividend				4,888,960
Series B Preferred stock beneficial conversion feature accreted as a dividend				10,495,688
Series A Preferred stock conversion rate change accreted as a dividend		136,889		136,889
Series B Preferred stock conversion rate change accreted as a dividend		1,678,703		1,678,703
Director's fees settled for shares of common stock	41,125			41,125
Common stock issued to extend notes payable	$ 100,196	$	$	$ 100,196

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 gastrointestinal ("GI") disorders and diseases and rheumatoid arthritis (RA). 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, 2010, Callisto has sustained cumulative net losses attributable to common stockholders of $135,573,268. 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, 2010, Callisto has not generated any revenue from operations. The Company 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 not completing 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.

2. Basis of presentation and going concern

These consolidated financial statements include (1) Callisto and subsidiaries: 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"). All intercompany balances and transactions have been eliminated.

As of December 31, 2010, Callisto had an accumulated deficit during development stage of $135,573,268. 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 plecanatide 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 $12,209,500, $9,406,972, and $8,902,375 for the twelve months ended December 31, 2010, 2009 and 2008, respectively, and $70,234,154 for the period from

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Basis of presentation and going concern (Continued)

June 5, 1996 (inception) to December 31, 2010. As of December 31, 2010 and 2009, Callisto had $1,708,982 and $7,207,612 respectively, of cash and cash equivalents.

During the twelve months ended December 31, 2010, 2009 and 2008, Callisto incurred net losses from operations of $16,931,731, $8,529,985, and $9,731,488 respectively and $104,347,821 for the period June 5, 1996 (inception) to December 31, 2010. 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, 2010, 2009 and 2008 was $6,710,870, $16,313,261and $2,951,913 respectively, and $72,033,419 for the period June 5, 1996 (inception) to December 31, 2010. As of December 31, 2010, Callisto had a negative working capital of $3,806,899, compared with a positive working capital of $4,461,765 as of December 31, 2009.

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.

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.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Summary of significant accounting policies and new accounting pronouncements (Continued)

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.

Derivative Instrument

The Company's derivative liabilities are related to warrants issued in connection with financing transactions and are therefore not designated as hedging instruments. All derivatives are recorded on the Company's balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. Changes in fair value are recorded in the Company's statement of operations

Fair Value of Financial Instruments

The Company has adopted FASB ASC 820 *Fair Value Measurements and Disclosures ("ASC 820")* for financial assets and liabilities that are required to be measured at fair value, and non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis. The carrying value of cash and cash equivalents, accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments.

ASC 820 provides that the measurement of fair value requires the use of techniques based on observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. The inputs create the following fair value hierarchy:

Level 1 Quoted prices for identical instruments in active markets.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.

Level 3 Instruments where significant value drivers are unobservable to third parties.

Warrants

Callisto has issued common stock warrants in connection with the execution of certain equity financings and as such these warrants are not designated as hedging instruments. Such warrants are classified as derivative liabilities under the provisions of FASB ASC 815 *Derivatives and Hedging ("ASC 815")* and are recorded at their fair market value as of each reporting period. Changes in fair value of derivative liabilities are recorded in the consolidated statement of operations.

The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding volatility of our common share price, remaining life of the warrant, and risk-free interest rates at each period end and Callisto classified such warrants as Level 3 instruments per ASC 820. At December 31, 2010 and 2009, the fair value of such warrants was $3,487,959 and $11,870,369, respectively, which Callisto classified as a long term derivative liability on its balance sheet. As of December 31, 2010 and 2009 the Company did not hold any Level 1 or Level 2 securities.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Summary of significant accounting policies and new accounting pronouncements (Continued)

Income Taxes

Income taxes have been determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes result from differences between the financial and tax bases of 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.

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 FASB ASC Topic 450, *Accounting for Contingencies*, ("ASC Topic 450"), 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 this guidance, does not recognize gain contingencies until realized.

Business Concentrations and Credit Risks

All of Callisto's cash and cash equivalents as of December 31, 2010 and 2009 are on deposit with commercial financial institution. Deposits at any point in time may exceed federally insured limits.

Research and Development

Callisto does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all and therefore 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, as well as contract research payments to outside suppliers, facilities and universities. While certain of its research and development costs may have future benefits, the policy of expensing all research and development expenditures is predicated on the fact that Callisto has no history of successful commercialization of biopharmaceutical products to base any estimate of the number of future periods that would be benefited.

In June 2007, the EITF of the FASB reached a consensus on ASC Topic 730, *Research and Development* ("ASC 730"). This guidance 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 are recognized as an expense. As of December 31, 2010 and 2009 Callisto had $683,182 and $1,000,000, respectively, of such deferred amounts, which are included in prepaid and other current assets on the Company's consolidated balance sheets.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Summary of significant accounting policies and new accounting pronouncements (Continued)

Stock-Based Compensation

Callisto relies heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options and restricted stock units is designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage. Since inception through December 31, 2010 stock-based compensation expense has totaled $19,709,376.

ASC Topic 718 *"Compensation Stock Compensation"* ("ASC 718) 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.

Upon adoption of ASC Topic 718, the Company selected the Black-Scholes option pricing model as the most appropriate model for determining the estimated fair value for stock-based awards. Use of this valuation model requires management to make certain assumptions with respect to selected model inputs. Expected volatility and option term were based on the historical volatility of similar public entities. The risk-free interest rate is based on observed interest rate appropriate for the expected term of our employee stock options. Forfeitures are estimated, based on our historical experience, at the time of grant.

Loss Per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, *Earnings per Share*, for all periods presented. In accordance with this guidance, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares because shares issuable pursuant to the exercise of stock options would have been antidilutive.

Recent Accounting Pronouncements

In April 2010, the FASB issued ASU 2010-13, "Compensation Stock Compensation (Topic 718) Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in Which the Underlying Equity Security Trades." ASU 2010-13 provides amendments to Topic 718 to clarify that an employee share-based payment award with an exercise price denominated in the currency of a market in which a substantial portion of the entity's equity securities trades should not be considered to contain a condition that is not a market, performance, or service condition. Therefore, an entity would not classify such an award as a liability if it otherwise qualifies as equity. The amendments in ASU 2010-13 are effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2010. Callisto expects the adoption of this standard will not have a material effect on its results of operation or its financial position.

In February 2010, the FASB issued ASU 2010-09, "Subsequent Events (Topic 855) Amendments to Certain Recognition and Disclosure Requirements." ASU 2010-09 requires an entity that is an SEC filer to evaluate subsequent events through the date that the financial statements are issued and removes the requirement that an SEC filer disclose the date through which subsequent events have

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Summary of significant accounting policies and new accounting pronouncements (Continued)

been evaluated. ASC 2010-09 was effective upon issuance. The Company adopted ASU 2010-09 upon issuance and such adoption had no effect on its results of operation or its financial position.

In January 2010, the FASB issued Accounting Standards Update ("ASU") 2010-06, "Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements" ("ASU 2010-06"). ASU 2010-06 includes new disclosure requirements related to fair value measurements, including transfers in and out of Levels 1 and 2 and information about purchases, sales, issuances and settlements for Level 3 fair value measurements. This update also clarifies existing disclosure requirements relating to levels of disaggregation and disclosures of inputs and valuation techniques. The Company adopted ASU 2010-06 upon issuance and such adoption did not have a material impact on the Company's financial statements.

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. 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.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Merger and consolidation (Continued)

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, representing 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. 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 OTCQB under the symbol SGYP.

Since July 8, 2010, Callisto has owned less than 50% of Synergy. According to ASC Topic 320, consolidation is required if investors owns over 50% of stock or otherwise controls the corporation. As of December 31, 2010, Management believes Callisto controls Synergy by reason of common executive officers and certain directors and therefore Synergy is consolidated with Callisto.

5. Derivative Financial Instruments

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, "Derivatives and Hedging: Contracts in Entity's Own Equity" ("ASC Topic 815-40"). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity's own stock, which would qualify as a scope exception under ASC Topic 815-10.

Callisto Derivative Instruments

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40 , certain warrants (the "New Warrants") issued in connection with the issuance of the 11% Notes must now be treated as derivative liabilities in the Company's statement of financial position. Prior to the adoption of ASC Topic 815-40, the Company accounted for the Warrants as components of stockholders' equity.

Consistent with ASC Topic 815's requirements, the Company recognized the cumulative effect of the change in accounting principle to reduce the opening balance of the deficit accumulated during the development stage for fiscal year 2009. The cumulative effect adjustment of $1,903,900 represents the difference between the amounts recognized in the statement financial position before initial application of ASC Topic 815 on January 1, 2009 and the initial fair value of the warrants. Additionally, the initial relative fair value of the Warrants, aggregating $181,732, which were initially recorded as additional

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Derivative Financial Instruments (Continued)

paid-in capital upon issuance, was reclassified to long-term liabilities upon adoption of Topic 815. The total amount recognized at initial issuance of $2,085,632 was determined based on the estimated fair value of the New Warrants using a Black-Scholes option pricing model.

Prospectively, the New Warrants will be re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value will be recorded as non-cash valuation adjustments in the Company's statement of operations. The Company estimates the fair value of the New Warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability described above.

On June 30, 2010, the price protection provision included in the New Warrants, which required derivative liability accounting, expired. As a result of the expiration of this provision, Callisto measured the fair value of the outstanding warrants through June 30, 2010, recognizing any changes in fair value of the derivative in earnings and then reclassified the derivative instrument liability into stockholders' equity.

The assumptions used for the year ended December 31, 2010 and December 31, 2009 valuation are noted in the following table:

	For the year ended December, 2010	For the year ended December, 2009
Expected Warrant term	7.55 to 8 years	7.25 to 8 years
Risk-free interest rate	2.7% to 3.39%	2.27% to 3.81%
Expected volatility	100% to 200%	100% to 200%
Dividend yield	0%	0%

Expected volatility is based on historical volatility of the Company's common stock. The New Warrants have a transferability provision and based on guidance provided in ASC Topic 718 for options issued with such a provision, we used the full contractual term as the expected term of the New Warrants. The risk free rate is based on the U.S. Treasury security rates consistent with the expected term of the New Warrants.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Derivative Financial Instruments (Continued)

The following table sets forth the components of changes in the Company's long term derivative financial instruments liability balance for the periods indicated:

Date	Description	New Warrants		Derivative Instrument Liability
12/31/2008	Initial relative fair value of New Warrants, upon issuance	23,216,230	$	181,732
01/01/2009	Cumulative effect adjustment upon adoption of ASC Topic 815		$	1,903,900
01/01/2009	Fair value of New Warrants upon adoption of ASC Topic 815	23,216,230	$	2,085,632
03/31/2009	Change in fair value of warrants outstanding on December 31, 2008 during the quarter ended March 31, 2009		$	(232,505)
01/31/2009	Fair value of New Warrants issued during the quarter ended March 31, 2009, on date of issuance	5,633,726	$	562,270
03/31/2009	Change in fair value of New Warrants issued during the quarter ended March 31, 2009		$	(112,662)
03/31/2009	Balance of derivative financial instruments March 31, 2009	28,849,956	$	2,302,735
06/30/2009	Change in fair value of warrants outstanding on March 31, 2009, during the quarter ended June 30, 2009		$	5,712,513
06/17/2009	Fair value of New Warrants issued during the quarter ended June 30, 2009, on date of issuance	40,236,218	$	4,365,620
06/30/2009	Change in fair value of New Warrants issued during the quarter ended June 30, 2009		$	6,812,325
06/30/2009	Balance of derivative financial instruments June 30, 2009	69,086,174	$	19,193,193
09/30/2009	Change in fair value of New Warrants outstanding on June 30, 2009 during the quarter ended September 30, 2009		$	5,735,936
09/30/2009	Balance of derivative financial instruments September 30, 2009	69,086,174	$	24,929,129
12/31/2009	Exercise of warrants	(202,638)		
12/31/2009	Change in fair value of New Warrants outstanding on September 30, 2009, during the quarter ended December 31, 2009		$	(13,058,760)
12/31/2009	Balance of derivative financial instruments December 31, 2009	68,883,536	$	11,870,369
3/31/2010	Change in fair value of New Warrants outstanding on December 31, 2009, during the quarter ended March 31, 2010			17,062,145
3/31/2010	Balance of derivative financial instruments March 31, 2010	68,883,536	$	28,932,514
6/30/2010	Change in fair value of New Warrants outstanding during the quarter ended June 30, 2010			(1,420,784)

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Derivative Financial Instruments (Continued)

Date	Description	New Warrants	Derivative Instrument Liability
6/30/2010	Reclassification of derivative liability to stockholder's equity upon expiration of supplemental condition (price protection)		(27,511,730)
12/30/2010	Warrants exchanged for common stock upon conversion of Notes	(68,883,536)	
12/31/2010	Balance of derivative financial instruments December 31, 2010		$

Callisto Fair Value Measurements

The unrealized losses on the derivative liabilities are recorded as a change in derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company performs a detailed analysis of the assets and liabilities that are subject to ASC Topic 820. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2009: No such liabilities associated with Callisto warrants existed as of December 31, 2010.

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2009	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2010
Derivative liabilities related to Warrants	$	$	$ 11,870,369	$ 11,870,369	$	$	$	$

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the twelve months ended December 31, 2009 and December 31, 2010:

Description	Balance at December 31, 2008	Cumulative Effect of the Adoption of ASC Topic 815	Accretion of Debt discounts of Notes Payable(1)	Unrealized Losses	Balance as of December 31, 2009	Unrealized Losses	Reclassified	Balance as of December 31, 2010
Derivative liabilities related to Warrants	$	2,085,632	$370,993	$ 9,413,744	$ 11,870,369	$ 15,641,361	$ (27,511,730)	

(1) Included in Other Income/Expense

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Derivative Financial Instruments (Continued)

Synergy Derivative Financial Instruments

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that the warrants issued in connection with the placement of its 2010 registered direct offerings must be recorded as derivative liabilities. In accordance with ASC Topic 815-40, the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company's statement of operations. The Company estimates the fair value of the warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability and change in fair value described above. Synergy did not have derivative instruments during the year ended December 31, 2009. The range of assumptions used to determine the fair value of the warrants at each period end during the twelve months ended December 31, 2010 were:

	Twelve month ended December 31, 2010
Estimated fair value of Synergy stock	$2.50 - $3.70
Expected warrant term	5 years
Risk-free interest rate	1.20 - 2%
Expected volatility	90%
Dividend yield	0%

Estimated fair value of the stock is based on an apportionment of the unit price paid for the shares and warrants issued in Synergy's 2010 registered direct offerings, which were deemed to be arms-length negotiated prices.

Expected volatility is based on historical volatility of the Synergy's common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates consistent with the expected term of the warrants.

The following table sets forth the components of changes in the Synergy's derivative financial instruments liability balance for the periods indicated:

Date	Description	Warrants	Derivative Instrument Liability
12/31/2009	Balance of derivative financial instruments liability		$
6/30/2010	Fair value of new warrants issued during the quarter	648,000	$ 1,045,214
9/30/2010	Fair value of new warrants issued during the quarter	103,703	$ 163,905
9/30/2010	Change in fair value of warrants during the quarter		$ (110,937)
9/30/2010	Balance of derivative financial instruments liability	751,703	$ 1,098,182
12/31/2010	Fair value of new warrants issued during the quarter	705,235	$ 2,575,624
12/31/2010	Change in fair value of warrants during the quarter		$ (185,847)
12/31/2010	Balance of derivative financial instruments liability	1,456,938	$ 3,487,959

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Derivative Financial Instruments (Continued)

Synergy Fair Value Measurements

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2010:

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2010
Derivative liabilities related to Warrants	$	$	$ 3,487,959	$ 3,487,959

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the twelve months ended December 31, 2010:

Description	Balance at December 31, 2009	Fair Value of warrants upon issuance	Unrealized (gains) or losses	Balance as of December 31, 2010
Derivative liabilities related to Warrants		$ 3,784,743	$ (296,784)	$ 3,487,959

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

6. Stockholders' deficit

On October 29, 2010, Callisto entered into a Note and Warrant Exchange Agreement with the holders of its Secured Promissory Notes due April 30, 2011 (the "Notes"), which were issued in December 2008 along with the related common stock purchase warrants exercisable for 68,883,536 shares of common stock (the "Warrants"), pursuant to which such holders exchanged the Notes plus accrued interest and the Warrants for an aggregate 72,355,770 shares of common stock.

The carrying value of the Notes extinguished, including accrued but unpaid interest, was $709,639. In accordance with ASC Topic 405-20 Callisto calculated the difference between (i) the fair value of the Warrants received plus the carrying value of Notes extinguished and (ii) the fair value of the common stock issued to the note and warrant holders. This resulted in a loss of $2,099,892 on extinguishment of the debt, which was recorded in the statement of operations.

On June 30, 2010, the price protection provision included in the New Warrants expired. As a result, we measured the fair value of the outstanding warrants as of June 30, 2010, recognized any changes in value in earnings and then reclassified the derivative instrument liability into stockholder's equity.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Stockholders' deficit (Continued)

On March 22, 2010, the Company reached an agreement with more than the requisite holders of 70% of the outstanding $603,163 principal amount of 11% Secured Promissory Notes due April 15, 2010 (the "Notes") to extend the due date of the Notes to April 30, 2011. In exchange for the amendment, the Company agreed to issue to the note holders 15% of the amount of principal and interest due on the Notes as of March 31, 2010 payable in shares of common stock, or 265,770 shares of common stock. This modification of debt was considered "substantially different" and was accounted for as a modification of debt. The carrying value of the notes payable before modification in the amount of $647,606 was extinguished and the fair value of the new debt in the amount $671,103 was recorded. The difference between the carrying value and the fair value in the amount of $23,497 was recorded as interest expense. The fair value of the shares totaled $100,196 which cost was recorded as a loss on extinguishment during the three months ended March 31, 2010 and included in interest and other expense in the statement of operations.

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. During the period from December 30, 2008 to June 17, 2009, pursuant to the Purchase Agreement, Callisto issued $603,163 principal amount of 11% Secured Notes due April 15, 2010 ("11% Notes"). Interest on the 11% Notes is due at maturity and repayment of the 11% Notes is secured by a pledge of up to 2,292,265 shares of the common stock of Synergy owned by Callisto. Pursuant to the Purchase Agreement, Callisto issued 69,086,174 common stock purchase warrants ("New Warrants") in exchange for the surrender and cancellation of 26,938,800 outstanding Series B Warrants. The New Warrants have an 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. In connection with the issuance of $349,880 of the $603,163 11% Notes in June 2009, Callisto entered into an additional security agreement granting all of the holders of the 11% Notes a security interest in the Atiprimod technology acquired by the Company in December 2008.

The proceeds from the issuance of these instruments were allocated to the 11% Notes and the New Warrants based upon the relative fair values of the 11% Notes and the New Warrants. The New Warrants had a fair value of $6,781,471 upon issuance, measured utilizing the Black Scholes fair value methodology using assumptions ranging from 7.5 to 8 years for expected term, volatility of 150% to 200%, no dividends and risk free interest rates ranging from 1.76% to 3.33%. This resulted in a debt discount of $552,728 apportioned to the New Warrants which was being accreted to the 11% Notes as interest expense over the life of the 11% Notes.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Stockholders' deficit (Continued)

On June 30, 2010, Synergy entered into securities purchase agreements to sell securities to non-U.S. investors and raised gross proceeds of approximately $2,754,000 in a registered direct offering. Synergy sold 648,000 units at $4.25 per share to investors. Each unit consists of one share of Synergy's common stock and one warrant to purchase one additional share of Synergy's common stock. The warrants expire after five years and are exercisable at $4.50 per share. The offering was made pursuant to a shelf registration statement on Form S-3 (the base prospectus effective December 10, 2009), as supplemented by a prospectus supplement filed with the Securities and Exchange Commission on June 23, 2010. As of June 30, 2010, Synergy had received proceeds of $255,000, less legal fees of $25,000 associated with this offering. The remaining $2,499,000 was held in escrow and received by Synergy on July 2 and July 8, 2010. In July 2010, the Company paid an aggregate $261,630 to selling agents in connection with this placement. In accordance with ASC 815-40, "Derivatives and Hedging Contracts in Entity's Own Equity" the warrants have been classified as a derivative liability.

On August 16, 2010, Synergy entered into a securities purchase agreement with an accredited investor to sell securities and raise gross proceeds of $400,000 in a private placement. The Company sold 98,765 units to the investor with each unit consisting of one share of the Company's common stock and one warrant to purchase one additional share of the Company's common stock. Synergy paid a fee of $33,000 to a non-US selling agent and $7,500 in legal expenses on this placement. The purchase price paid by the investor was $4.05 for each unit. The warrants expire after five years and are exercisable at $4.25 per share. In accordance with ASC 815-40, "Derivatives and Hedging Contracts in Entity's Own Equity" the warrants have been classified as a derivative liability.

On October 1, 2010, Synergy entered into a securities purchase agreement with an investor and raised gross proceeds of $2,500,000 in a registered direct offering. The Company paid a fee of $50,000 to a non-U.S. selling agent. The Company sold to the investor 1,000,000 shares of its common stock and warrants to purchase 400,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investor was $2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $2.75 per share. In accordance with ASC 815-40, "Derivatives and Hedging Contracts in Entity's Own Equity" the warrants have been classified as a derivative liability.

On October 18, 2010 Synergy entered into a securities purchase agreement with certain investors and raised gross proceeds of $1,525,000 in a registered direct offering. The Company paid a fee of $91,000 to a non-U.S. selling agent. The Company sold 610,000 shares of its common stock and warrants to purchase 244,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investors was $2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $2.75 per share. In accordance with ASC 815-40, "Derivatives and Hedging Contracts in Entity's Own Equity" the warrants have been classified as a derivative liability.

The October 1, 2010 and October 18, 2010 Synergy offerings were made pursuant to a shelf registration statement on Form S-3 (SEC File No. 333-163316, the base prospectus effective December 10, 2009), as supplemented by prospectus supplements filed with the Securities and Exchange Commission on October 1, 2010 and October 18, 2010.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Stockholders' deficit (Continued)

During the twelve months ended December 31, 2009 Synergy sold 22,814,425 shares of unregistered common stock at $0.70 per share to private investors, pursuant to a Securities Purchase Agreement, for aggregate proceeds of $15,970,100. There were no warrants issued in connection with these transactions. Synergy incurred $260,002 in fees to selling agents and legal services in connection with certain of these transactions. Pursuant to the Securities Purchase Agreement the investors agreed to be subject to a lock-up until August 15, 2010 and Synergy agreed to price protection for the investors in the event of subsequent sales of equity securities as defined, until February 15, 2011. In accordance with the guidance contained in ASC Topic 815-40, the Company has determined that the price protection provisions are embedded derivatives that require bifurcation and recognition at fair value in the company's financial statements.

On September 16, 2009, the Company amended the Series A and Series B Convertible Preferred Stock to eliminate the liquidation preference and decrease the conversion price of the Series A and B Convertible Preferred Stock to $0.36 per share from $0.50 per share. The closing price of the Company's common stock on September 16, 2009 was $0.20 per share. This modification resulted in the prospective issuance of an additional 684,444 and 8,393,513 of Callisto common stock in the event of the conversion of the remaining Series A and B Preferred Stock, respectively. The additional shares of Callisto common stock, valued at the share price on the date of the modification, have been accounted for as a dividend on the Series A and B Convertible Preferred Stock totaling $136,889 and $1,678,703, respectively, during the twelve months ended December 31, 2009.

During the twelve months ended December 31, 2010 and December 31, 2009, 55,000 and 35,000 shares of Series A Convertible Preferred Stock were converted to 1,527,777 and 894,445 shares of common stock and 1,014,166 and 122,884 shares of Series B Convertible Preferred Stock were converted to 28,171,278 and 2,963,236 shares of common stock.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Stockholders' deficit (Continued)

The following table summarizes the financial impact of the 11% Notes payable and the related interest expense for the period from December 30, 2008 through December 31, 2010:

	11% Notes Payable	Interest expense
11% Notes issued on December 30, 2008	$ 201,908	$
Apportionment of net proceeds to New Warrants recorded as additional paid in capital (11% Note discount)	(181,732)	
11% Notes balance at December 31, 2008	20,176	
11% Notes issued during the three months ended March 31, 2009	51,375	
Accretion of 11% Note discount to interest expense	34,800	34,800
11% nominal interest expense	6,685	6,685
11% Notes balance March 31, 2009	$ 113,036	$ 41,485
11% Notes issued during the three months ended June 30, 2009	349,880	
Apportionment of net proceeds to New Warrants recorded as additional paid in capital (11% Note discount)	(370,996)	
Accretion of 11% Note discount to interest expense	65,215	65,215
11% nominal interest expense	8,317	8,317
11% Notes Balance June 30, 2009	$ 165,452	$ 115,017
Accretion of 11% Note discount to interest expense	144,116	144,116
11% nominal interest expense	16,723	16,723
11% Notes Balance September 30, 2009	$ 326,291	$ 275,854
Accretion of 11% Note discount to interest expense	144,116	144,116
11% nominal interest expense	16,723	16,723
11% Notes Balance December 31, 2009	$ 487,130	$ 436,693
Accretion of 11% Note discount to interest expense	144,116	144,116
11% nominal interest expense quarter ended March 31, 2010	16,360	16,360
Loss on extinguishment	23,497	23,497
Common shares issued in exchange for modification of notes payable		100,196
11% Notes balance March 31, 2010	$ 671,103	$ 284,169
11% nominal interest expense quarter ended June 30, 2010	16,542	16,542
11% Notes balance June 30, 2010	$ 687,645	$ 300,711
11% nominal interest expense quarter ended September 30, 2010	16,723	16,723
11% Notes balance September 30, 2010	$ 704,368	$ 317,434
11% nominal interest expense through October 29th, 2010	5,271	5,271
Extinguishment on Notes payable on October 29th, 2010	(709,639)	
11% Notes balance December 31, 2010	$	$ 322,705

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

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Stockholders' deficit (Continued)

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 ASC 718 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.

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,

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

6. Stockholders' deficit (Continued)

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. The Investors also are parties to a Registration Rights Agreement, dated as of August 2, 2007 pursuant

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

6. Stockholders' deficit (Continued)

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 plecanatide 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.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Stockholders' deficit (Continued)

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 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 ASC Topic 480, "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 ASC Topic 815, "*Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, Company Stock*", 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 ASC Topic 825 "Accounting for Registration Payment Arrangements", issued in December 2006, which specifies that contingent obligations under a registration payment arrangement should be separately recognized and measured in accordance with ASC Topic 450 "*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 ASC Topic 470, "Debt" 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

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Stockholders' deficit (Continued)

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 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 $0.36 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 ASC Topic 815, Callisto has determined that the warrants should be treated as "permanent equity".

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Stockholders' deficit (Continued)

As per ASC Topic 825, which specifies that contingent obligations under a registration payment arrangement should be separately recognized and measured in accordance with FASB ASC Topic 450 "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 ASC Topic 470, 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.

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Stockholders' deficit (Continued)

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 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.

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6. Stockholders' deficit (Continued)

As provided for by ASC Topic 815, "*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.

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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Stockholders' deficit (Continued)

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

As of December 31, 2010 and 2009 Callisto had 10,371,999 and 84,842,576 warrants outstanding to investors, selling agents and advisors with a weighted average exercise price of per share, $0.75 and $0.15, respectively. All warrants were fully vested.

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

7. Share-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 3,113,817 options outstanding as of December 31, 2010 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 2,613,000 options available for future grants as of December 31, 2010.

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 853,500 option shares available for future grants as of December 31, 2010.

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, 2010, Callisto has 2,324,555 stock options outstanding not subject to our stock option plans.

Stock Option Accounting

In December 2004, the FASB issued ASC Topic 718 (Revised 2004), *Share-Based Payments* ("ASC Topic 718"). This guidance 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.

ASC Topic 718 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 non-employee option grants is being recorded in accordance with ASC Topic 505 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.

ASC Topic 718 requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Share-based payments (Continued)

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.

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, 2010
	2010	2009	2008	
Employees included in research and development	$ 5,345	$ 24,927	$ 40,608	$ 2,692,157
Employees included in general and administrative	32,257	46,754	162,262	4,828,963
Subtotal employee stock option grants	37,602	71,681	202,870	7,521,120
Non-employee included in research and development			(17,314)	102,750
Non-employee included in general and administrative	104,891	(6,387)	23,624	9,938,902
Subtotal non-employee stock option grants	104,891	(6,387)	6,310	10,041,652
Total stock-based compensation expense	$ 142,493	$ 65,294	$ 209,180	$ 17,562,772

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, 2010, 2009 and 2008.

	Year End December 31,		
	2010	2009	2008
Risk-free interest rate	2.38%	2.69%	1.55%
Expected volatility	100%	100%	200%
Expected term (in years)	5.0 yrs	5.0 yrs	5.0 yrs

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

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.

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

7. Share-based payments (Continued)

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 ASC 718, "Share-Based Payment", ("ASC 718") 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 SAB110, *Share-Based Payment*. This guidance 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 ASC 718, in developing an estimate of the expected term of "plain vanilla" share options in accordance with ASC 718. The Company will continue to use the simplified method until it has the historical data necessary to provide a reasonable estimate of expected life. 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.

Forfeitures ASC Topic 718 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, 2010, 2009 and 2008, estimated as of the grant date using the Black-Scholes option valuation model, was $0.19, $0.15 and $0.04 per share, respectively.

The unrecognized compensation cost related to Callisto's non-vested employee stock options outstanding at December 31, 2010 and 2009 was $45,193 and $12,781, respectively, to be recognized over a weighted-average vesting period of approximately 2 years and 3 months, respectively. The weighted-average remaining term of all options outstanding at December 31, 2010 was 4.2 years as compared to 4.4 years at December 31, 2009.

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

7. Share-based payments (Continued)

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, January 1, 2009	7,938,538	$ 0.08 - 6.75	$ 1.72	$
Granted	41,500	0.20	0.20	
Exercised				
Forfeited	(485,000)	0.75 - 4.90	1.95	
Balance outstanding, December 31, 2009	7,495,038	$ 0.08 - 4.90	$ 1.70	
Granted	855,000	0.26	0.26	
Exercised				
Forfeited	(378,166)	3.46	2.16	
Balance outstanding, December 31, 2010	7,971,872	0.08 - 3.60	1.46	$ 394,520
Exercisable, December 31, 2010	5,867,872	$ 0.08 - 3.60	$ 1.46	$ 34,790

ASC Topic 718 requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to the Company's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

Synergy Stock Option Plan

ASC Topic 718 "*Compensation Stock Compensation*" 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. Synergy did not issue stock options until 2008.

Synergy adopted the 2008 Equity Compensation Incentive Plan (the "Plan") on July 3, 2008. Stock options granted under the Plan typically vest after three years of continuous service from the grant date and have a contractual term of ten years. Synergy periodically issues stock options to employees and non-employees and has adopted ASC Topic 718 for employee awards on July 3, 2008 concurrently with adoption of the Plan. Prior to that date Synergy had not issued any stock options. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 Equity-Based Payment to Non-Employees whereas the value of the stock compensation is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Share-based payments (Continued)

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

	Years Ended December 31,			November 15, 2005 (inception) to
	2010	2009	2008	December 31, 2010
Employees included in research and development	$ 187,520	$ 252,541	$ 79,530	$ 519,591
Employees included in general and administrative	210,591	358,167	112,728	681,486
Subtotal employee stock based compensation	398,111	610,708	192,258	1,201,077
Non-employees included in research and development	52,184	33,913	8,548	94,646
Non-employees included in general and administrative	261,863	409,941	179,077	850,880
Subtotal non-employee stock based compensation	314,047	443,854	187,625	945,526
Total stock-based compensation expense	$ 712,158	$ 1,054,562	$ 379,883	$ 2,146,603

The estimated fair value of Synergy 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, 2010.

	Years Ended December 31,		
	2010	2009	2008
Risk-free interest rate	2.31% - 2.71%	2.20%	2.67% - 3.28%
Dividend yield			
Expected volatility	90%	90%	90%
Expected term (in years)	6.0 yrs	6.0 yrs	6.0 yrs

Risk-free interest rate Based on the daily yield curve rates for U.S. Treasury obligations with maturities which correspond to the expected term of the Company's 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 Synergy stock.

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

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Share-based payments (Continued)

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 ASC Topic 718. 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 ASC Topic 718 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, 2010 and December 31, 2009 estimated as of the grant date using the Black-Scholes option valuation model was $6.77 and $4.33 per share, respectively.

The unrecognized compensation cost related to non-vested employee stock options outstanding at December 31, 2010, December 31, 2009, and December 31, 2008 was $314,921, $1,010,250 and $1,290,122, respectively. The December 31, 2010 balance is expected to be recognized over a weighted-average remaining vesting period of approximately 6 months.

Synergy Share-Based Compensation

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

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value
Balance outstanding, January 1, 2009	4,080,016	$ 025 - 0.95	$ 0.29	$ 8,933,935
Granted(1)	149,000	$ 0.70	$ 0.70	
Exercised				
Forfeited	(15,000)	$ 0.25 - 0.95	$ 0.72	
Balance outstanding, December 31, 2009	4,214,016	$ 025 - 0.95	$ 0.30	$ 22,320,436
Granted(2)	4,465,000	$ 0.70	$ 0.70	
Exercised				
Forfeited	(75,000)	$ 0.70	$ 0.70	
Balance outstanding, December 31, 2010	8,604,016	$ 0.25 - 0.95	$ 0.51	$ 25,763,002
Exercisable at December 31, 2010	2,759,969	$ 0.25 - 0.95	$ 0.29	$ 8,847,399

(1) Contingent vesting upon change of control. The Fair Value at the date of grant was $645,539 determined using the Black-Scholes option valuation model assumptions discussed above. No stock based compensation expense associated with these options was recognized during the twelve months ended December 31, 2009 and 2010.

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

7. Share-based payments (Continued)

(2) Contingent vesting upon change of control. The Fair Value at the date of grant was $30,243,946 determined using the Black-Scholes option valuation model assumptions discussed above. No stock based compensation expense associated with these options was recognized during the twelve months ended December 31, 2010.

ASC Topic 718 requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to Synergy's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

Restricted Stock Units

Restricted stock awards, which entitle the holder to earn, 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 ASC Topic 718 in the same manner as stock options using fair value at the date of issuance. Restricted shares awarded are subject to a repurchase agreement, assumed by Synergy pursuant to the Exchange Transaction, whereby 50% of the shares vest after 1 year of continuous service and the remaining 50% vest after 2 years of continuous service from the issuance date. On July 3, 2008, 874,760 restricted stock awards were granted by Synergy-DE and assumed by Synergy as part of the Exchange Transaction and are subject to a repurchase agreement, as defined. These restricted stock units were issued to certain officers and a consultant of Synergy. The fair value of each restricted stock unit is estimated on the grant date based on the price paid by shareholders participating in the Company's July 14, 2008 private placement. Accordingly, the weighted-average grant date fair value per share of the 874,760 shares issued during the twelve months ended December 31, 2008 was determined to be $0.60. The fair value at the date of issuance was expensed ratably by month over the 2 year service period ended July 3, 2010. As of December 31, 2010 there were no restricted stock awards subject to repurchase.

8. Income taxes

At December 31, 2010, Callisto has net operating loss carryforwards ("NOLs") aggregating approximately $70 million, which, if not used, expire beginning in 2011 through 2030. The utilization of these NOLs is subject to limitations based on past and future changes in ownership of Callisto and Synergy pursuant to Internal Revenue Code Section 382. The Company has determined that ownership changes have occurred for Internal Revenue Code Section 382 purposes and therefore, the ability of the Company to utilize its NOLs is limited. 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 substantial doubt related to the Company'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, 2010. 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 ASC Topic 740 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

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

8. Income taxes (Continued)

have any unrecognized tax benefits or liabilities. Callisto also evaluated its tax positions as of December 31, 2010 and reached the same conclusion. Callisto does not currently expect any significant changes to unrecognized tax benefits during the fiscal year ended December 31, 2010. Callisto's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2010 and December 31, 2009, 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, 2010. Callisto files U.S. and state income tax returns in jurisdictions with varying statutes of limitations. The 2006 through 2009 tax years generally remain subject to examination by federal and most state tax authorities.

During the Twelve months ended December 31, 2010 Callisto was awarded a New York State Qualified Employer Tax Credit totaling $531,127 and Synergy received a $244,479 Federal credit for our Qualifying Therapeutic Discovery Project under the Patient Protection and Affordable Care Act of 2010 and earned a $250,000 New York City Biotechnology refundable tax credit. The Total of these research expenditure based incentives $1,025,606 have been recorded as tax credits in the Company's statement of operations. As of December 31, 2010 the New York State and City tax credits are recorded as receivables on the Company's balance sheet.

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.

9. Commitments and contingencies

Employment and Consulting Agreements

Gary Jacob

On February 1, 2010, Dr. Gary Jacob entered into an amended and restated employment agreement with Synergy in which he agreed to serve as Chief Executive Officer and President. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2012 and is automatically renewed for successive one year periods at the end of each term. Dr. Jacob's salary is $315,000 per year. 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 Synergy enters into an out-license agreement for its technology or enters into a joint venture in which Synergy contributes such rights to the joint venture where the enterprise value equals or exceeds a minimum of $150 million, $200 million and $250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, or the license fees Synergy contracts to receive equals or exceeds $50 million. The realization bonus will be equal to the enterprise value in the case of a joint venture or the sum of the license fees actually received in the case of an out license, multiplied by 0.5%. In addition, in the

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

9. Commitments and contingencies (Continued)

event Synergy engages in a merger transaction or a sale of substantially all of its assets where the enterprise value equals or exceeds $400 million, Dr. Jacob shall receive a bonus in an amount determined by multiplying the enterprise value by 2.5%.

If the employment agreement is terminated by Synergy other than for cause or as a result of Dr. Jacob's death or permanent disability or if Dr. Jacob terminates his employment for good reason which includes a change of control, Dr. Jacob shall receive (i) a severance payment equal to the higher of the aggregate amount of his base salary for the then remaining term of the agreement or twelve times the average monthly base salary paid or accrued during the three full calendar months preceding the termination, (ii) expense compensation in an amount equal to twelve times the sum of his average base salary during the three full months preceding the termination, (iii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iv) payment in respect of compensation earned but not yet paid and (v) payment of the cost of medical insurance for a period of twelve months following termination. In the event Dr. Jacob's employment was terminated upon a change of control as of December 31, 2010, he would have been entitled to receive a lump sum payment of $945,000, less applicable withholding.

Gabriele Cerrone

On February 1, 2010, Gabriele M. Cerrone, our Chairman of the Board, entered into an amended and restated consulting agreement with Synergy. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2012 and is automatically renewed for successive one year periods at the end of each term. Pursuant to the agreement, Mr. Cerrone's compensation is $309,750 per year. 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 Synergy enters into an out-license agreement for its technology or enters into a joint venture in which Synergy contributes such rights to the joint venture where the enterprise value equals or exceeds a minimum of $150 million, $200 million and $250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, and in the case of a financing transaction, Synergy receives not less than $20 million of gross proceeds; or the license fees Synergy contracts to receive equals or exceeds $50 million. The realization bonus will be equal to the enterprise value in the case of a joint venture or financing or the sum of the license fees actually received multiplied by 0.5%. In addition, in the event Synergy engages in a merger transaction or a sale of substantially all of its assets where the enterprise value equals or exceeds $400 million, Mr. Cerrone shall receive a bonus in an amount determined by multiplying the enterprise value by 2.5%.

On October 6, 2010 Synergy achieved the $20 million threshold required for Mr. Cerrone's realization bonus to be accrued on the cumulative gross proceeds of financing transactions since August 1, 2008. This bonus totaled $1,211,912, was deemed compensatory in nature and charged to expense during the year ended December 31, 2010. Mr. Cerrone has agreed with Synergy to defer payment of his bonus until the earlier of (i) March 31, 2012, (ii) the completion of a financing transaction yielding gross proceeds of $30 million on a cumulative basis subsequent to October 6, 2010 or (iii) the tenth business day after termination of the consulting agreement without cause or good

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

9. Commitments and contingencies (Continued)

reason (including a termination following a "change of control" transaction as that term is defined in his consulting agreement). In consideration of Mr. Cerrone agreeing to permit Synergy to defer payment of his bonus Synergy agreed to indemnify him from any liability for taxes or penalties that he may incur pursuant to Section 409A of the Internal Revenue Code and comparable state income tax laws.

If the consulting agreement is terminated by Synergy other than for cause or as a result of Mr. Cerrone's death or permanent disability or if Mr. Cerrone terminates the agreement for good reason which includes a change of control, Mr. Cerrone shall receive (i) a severance payment equal to 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. In the event Mr. Cerrone's employment was terminated upon a change of control as of December 31, 2010, he would have been entitled to receive a lump sum payment of $929,250 less applicable withholding.

Moshe Talpaz

On January 31, 2006 we entered into a consulting agreement with Dr. Moshe Talpaz, whereby Dr. Talpaz will provide consulting services for Callisto's Degrasyns program. Under the agreement Dr. Talpaz will be paid $10,000 per year and was granted 575,000 10-year options to purchase Callisto's 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.

Roman Perez-Soler

On August 12, 2004, in connection with Callisto's 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 Callisto's 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Commitments and contingencies (Continued)

Melvin K. Spigelman, M.D

On August 21, 2008, the Board of Directors 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 Synergy Board and the Committees. Additionally, the Synergy Board approved a grant of 300,000 Synergy 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. During 2009, Synergy's Clinical Oversight Board was disbanded and Dr. Spigelman is now paid a Synergy director fee comparable to the other independent Synergy Board members

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 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.

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

9. Commitments and contingencies (Continued)

Bernard F. Denoyer

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.

Effective July 14, 2008, upon Synergy becoming a publicly traded company, Mr. Denoyer's base salary was increased to $190,000 per annum. Mr. Denoyer also serves as Senior Vice President, Finance for Synergy.

Capebio, LLC

On September 25, 2007, Synergy entered into a Service Agreement with Capebio, LLC ("Capebio") to provide research and development services for the commercialization of non-oncology related gastrointestinal pharmaceutical products under the plecanatide patent. The Service Agreement is for a minimum term of eleven months starting October 1, 2007 during which period Synergy paid an initial fee of $55,000 and is obligated to pay $26,000 per month through August 31, 2008. In addition Capebio will be eligible for a bonus of $58,000 if certain performance milestones are achieved by December 31, 2008 and Synergy is required to establish an escrow of $250,000 in favor of Capebio to guarantee specific performance under the Service Agreement. This Service Agreement was terminated on July 2, 2008 and all amounts due there-under were paid.

In connection with this agreement Callisto issued a warrant to purchase 1,150,000 shares of its common stock at an exercise price of $0.47 per share to a consultant for services to be rendered to the Company's newly formed subsidiary, Synergy Advanced Pharmaceuticals, Inc. ("Synergy Advanced"), in connection with the development of plecanatide, Callisto's proprietary compound to treat GI disorders such as chronic constipation and irritable bowel syndrome. So long as the consultant continues to provide services in some capacity to the Company or any of its subsidiaries, the warrant will vest in installments of 225,000 warrant shares on each of the first four anniversaries of the initial exercise date. The remaining 250,000 warrant shares will vest immediately prior to the consummation of a sale or merger of Synergy Advanced, provided that such transaction occurs on or prior to October 1, 2009 and Synergy Advanced is valued at no less than $250,000,000. In the event there is a change of control of Callisto, all unvested warrant shares will immediately vest. All of the warrants expire on September 25, 2014. With the termination of the service agreement, the warrants were forfeited on July 2, 2008 and no stock-based compensation expense was recognized during the term of the service agreement through July 2, 2008 because none on the warrants vested prior to termination.

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

9. Commitments and contingencies (Continued)

Trilogy Capital Partners, Inc.

On July 18, 2005, Callisto entered into a letter of engagement (the "Agreement") with Trilogy Capital Partners, Inc. ("Trilogy"). The term of the Agreement is for one year beginning on July 18, 2005 and terminable thereafter by either party upon 30 days' prior written notice. Pursuant to the Agreement, Trilogy will provide marketing and financial public relations services to Callisto and will assume the responsibilities of an investor relations officer for Callisto. Callisto will pay Trilogy $12,500 per month under the Agreement.

Pursuant to the Agreement, Callisto issued warrants to Trilogy to purchase 1,793,322 shares of Common Stock of Callisto at an exercise price of $1.03 per share (the "Warrants"). The Warrants issued to Trilogy are exercisable upon issuance and would have expired on July 18, 2008. The fair value of the Warrants using the Black-Scholes methodology was $1,469,931 on the date of grant and was amortized to stock-based compensation expense over the term of the Agreement. Stock-based compensation expense associated with these warrants was $735,236 and $734,695 during the twelve months ended December 31, 2006 and 2005, respectively. During the twelve months ended December 31, 2006 Trilogy exercised 184,500 common stock warrants for cash totaling $190,035 and during the twelve months ended December 31, 2005 Trilogy exercised 125,000 common stock warrants for cash totaling $128,750.

On November 2, 2006, Trilogy Capital Partners, Inc. filed suit against Callisto in Superior Court of the State of California, County of Los Angeles, Central District, alleging that Callisto breached a Letter of Engagement dated July 18, 2005 between Callisto and Trilogy by failing to pay certain fees. Additionally, Trilogy alleged that Callisto breached a consulting agreement dated January 1, 2006 between Callisto and MBA Holdings, LLC (later assigned to Trilogy) by failing to pay certain consulting fees. Trilogy is seeking payment in the aggregate amount of $94,027.55 plus interest and attorney's fees. On December 27, 2006, Callisto filed an answer to the Trilogy complaint denying the allegations in the Trilogy complaint and on the same date, Callisto filed a cross-complaint against Trilogy in Superior Court of the State of California, County of Los Angeles, Central District, alleging, among other things, that Trilogy breached the Letter of Engagement with Callisto by failing to provide the agreed-upon services and fraudulently induced Callisto to enter into the Letter of Engagement by misrepresenting its capabilities. Callisto asked for unspecified damages plus attorneys' fees. On January 23, 2007, Trilogy answered Callisto's cross-complaint denying all of the allegations. The court ordered the parties to mediation to be completed by November 20, 2007.

On July 31, 2007 Callisto entered in a Mutual Release and Settlement Agreement with Trilogy Capital Partners, Inc. ("Trilogy") wherein the parties settled their dispute and pending litigation. Callisto paid Trilogy $47,000 which amount was accrued for during the year ended December 31, 2006.

In connection with the Settlement, Trilogy agreed to have its remaining unexercised warrants assigned. Accordingly Trilogy assigned 1,323,822 of the unexercised Trilogy warrants to two unaffiliated entities. This assignment was deemed compensatory in that this transaction was equivalent to a cancellation and re-issuance of the warrants in question. The fair value of the warrants thus re-issued on that date was $105,819 using the Black Scholes valuation methodology assumptions of 1 year expected term, no dividend, stock price of $0.69 per share, and a risk free interest rate of 4.85%. At that date there was no change in terms and conditions, the only change was in certificate holder.

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9. Commitments and contingencies (Continued)

On December 5, 2007 the Company extended the termination date of the "Trilogy Warrants" to July 18, 2011. This modification was determined to be compensatory resulting in an incremental compensation cost of $164,152 using the Black Scholes fair value methodology assumptions of .62 and 3.62 years expected term, no dividend, stock price of $0.41 and $0.49 per share and risk free interest rates of 3.22% and 2.91% immediately before and after the modification.

Donald H. Picker, Ph.D

On September 23, 2003, Callisto entered into an employment agreement with Donald H. Picker, Ph.D., to serve as Vice President, Drug Development. The employment agreement was for a term of 18 months beginning September 23, 2003 and was automatically renewable for successive one year periods at the end of the term. Dr. Picker's salary was initially $175,000 per year and he was eligible to receive a cash bonus of up to $45,000 per year upon the achievement of certain performance milestones. In connection with his employment agreement, Dr. Picker received a grant of 325,000 stock options which vest over a three year period and are exercisable at $1.50 per share. On April 6, 2004 the employment agreement of Donald H. Picker, Callisto's Executive Vice President, R&D was amended. Dr. Picker's salary was increased from $175,000 to $200,000 per year and certain milestones were added upon which cash bonuses of up to $92,500 over a 12 month period may be paid. During the year ended December 31, 2006, Dr. Picker earned a bonus of $20,000 based on achievement of certain milestones. Dr. Picker resigned his position on December 19, 2006 and earned no bonus that year.

On December 21, 2006, Callisto filed a complaint against Tapestry Pharmaceuticals, Inc., 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 Callisto and Tapestry to cause Donald Picker, Ph.D., Callisto's former Executive Vice President, Research & Development, to resign and accept a position with Tapestry. In addition, Callisto is alleging that Tapestry fraudulently entered into the confidential disclosure agreement with Callisto and intentionally interfered with Dr. Picker's employment agreement with Callisto. Callisto is seeking actual and punitive damages. The defendants had filed a motion to dismiss the complaint against Messrs. Shaykin and Larsen. During the year ended December 31, 2008 Callisto settled this lawsuit with Tapestry Pharmaceuticals, Inc for $100,000 which covered Callisto's legal fees.

On June 8, 2007 Callisto filed a complaint against Donald Picker, its former Executive Vice President, Research & Development in the Supreme Court of the State of New York alleging that (i) Dr. Picker breached his written employment agreement with Callisto by accepting employment with Tapestry Pharmaceuticals, Inc. a manner not in accordance with his agreement, (ii) Dr. Picker acted fraudulently by failing to reveal to Callisto that he was negotiating employment with Tapestry while purportedly representing Callisto in negotiations with Tapestry pursuant to a confidential disclosure agreement between Tapestry and Callisto and (iii) Dr. Picker misappropriated confidential files and materials from Callisto's offices. Callisto is seeking $80 million in damages from Dr. Picker.

During 2008 Picker moved for a summary judgment and on May 5, 2009 the court ruled in favor of Picker dismissing Callisto's complaint. On February 22, 2010 Callisto filed a brief with the Appellate Division of the New York Supreme Court (the "Appeal") seeking the summary judgment be reversed and the complaint be reinstated. The Appeal, which also requests immediate jury trial, is still pending.

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

9. Commitments and contingencies (Continued)

License Agreements

On August 28, 2002, and as amended on May 23, 2003, Synergy entered into a worldwide license agreement (the "Original License") with 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, Callisto 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 Callisto and Genzyme 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, Callisto 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 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 amounts due.

On January 10, 2006, Callisto entered into a Patent and Technology License Agreement with The University of Texas M.D. Anderson Cancer Center. Pursuant to the license agreement, Callisto was granted the exclusive right to manufacture, have manufactured, use, import, offer to sell and/or sell anti-cancer compounds called tyrphostins (renamed Degrasyns). Callisto paid a nonrefundable fee of $200,000 upon execution of this agreement, expensed as research and development and is obligated to pay annual license maintenance fees to The University of Texas M.D. Anderson Cancer Center. Callisto is also obligated under this agreement to pay for the legal fees and expenses associated with establishing and protecting the patent rights worldwide. Callisto 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 2025. In addition, at any time after two years from January 10, 2006, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if Callisto fails to provide evidence within 90 days of written notice that it has commercialized or is actively and effectively attempting to commercialize the licensed technology.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Commitments and contingencies (Continued)

On March 23, 2006, Callisto entered into a 2-year sponsored laboratory study agreement with the University of Texas M. D. Anderson Cancer Center whereby Dr. Nicholas Donato, as principal investigator, will analyze the anti-tumor activity and mechanism of action of Callisto's WP1130 Degrasyn compound and analogs. The agreement calls for payment of $145,900 to M.D. Anderson in two installments of $72,950 with the first payment due within 30 days of the effective date of the agreement, and the second payment due within six months of execution. These research expenditures were expensed as incurred during the twelve months ended December 31, 2006 consistent with Callisto's application of SFAS No.2.

On March 27, 2006, Callisto entered into a 2-year sponsored laboratory study agreement with the University of Texas M. D. Anderson Cancer Center whereby Dr. William Bornmann, as principal investigator, will perform molecular modeling and synthesize a library of compounds based on Callisto's Degrasyn platform technology. The agreement calls for payment of $127,144 to M.D. Anderson in two installments of $63,572 with the first payment due within 30 days of the effective date of the agreement, and the second payment due within six months of execution. These research expenditures were expensed as incurred during the twelve months ended December 31, 2006 consistent with Callisto's application of SFAS No.2.

On August 12, 2004, Callisto 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, an anthracycline cancer drug for leukemia therapy. 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. L-Annamycin has not reached commercialization and therefore these costs were recorded as research and development expense. Callisto 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, Callisto is 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, which the Company believes it has. In addition, at any time after 5 years from August 12, 2004, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if Callisto fails to provide evidence within 90 days of written notice that it has commercialized or it is actively and effectively attempting to commercialize L-Annamycin.

On February 24, 2004, Callisto entered into an agreement with Houston Pharmaceuticals, Inc. ("HPI") to sublicense the rights to a key patent covering a technology platform for site-directed DNA intercalation and Callisto acquired the rights to a patent covering new anthracycline analogs. Callisto issued to HPI 25,000 shares of common stock at a fair value of $56,250 and reimbursed HPI approximately $103,500 for various costs and expenses. The total consideration of $159,750 was allocated in full to the HPI patent rights, which have not yet reached technological feasibility, and having no alternative use, was accounted for as purchased in-process research and development expense during the quarter ended March 31, 2004. The fair value of the common stock issued to HPI was $2.25, based on the price per share paid in the April 2004 private placement, which closed on April 19, 2004. In addition, Callisto granted to HPI 1,170,000 performance based stock options, exercisable at $3.50 per share, which vest upon the achievement of certain milestones. Callisto also agreed to pay HPI royalties

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Commitments and contingencies (Continued)

of 2% on net sales from any products resulting from commercializing the site-directed DNA intercalation. Pursuant to the sublicense agreement, in the event Callisto's Board of Directors determined to abandon its development and commercialization of the site-directed DNA intercalation, HPI had the right to terminate the sublicense agreement. On September 19, 2005, because data from in vivo pre-clinical studies did not meet Callisto's standards for clinical development, Callisto notified HPI of its decision to terminate the sublicense agreement. On September 28, 2005 Callisto agreed with HPI that HPI would repurchase certain patent rights in exchange for forfeiting the 1,170,000 performance based stock options. Accordingly the 1,170,000 options granted to HPI were cancelled.

On August 20, 1996, Callisto 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. Callisto agreed to work toward commercialization of products related to these patents as evidenced by a minimum expenditure per year of approximately $210,000, 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 sublicensees. In addition, on July 2, 2001, Callisto entered into a license agreement for two additional patents related to the regulation of exoproteins in staphylococcus aureus. The licensed patents under these agreements are the subject of research being funded by the NIAID grant awarded to Callisto on April 1, 2005 for $885,641 over two years. On November 14, 2007, Callisto 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.

Lease Agreements

The Company's corporate headquarters totals approximately 5,500 square feet, in two suites, located at 420 Lexington Avenue, New York, New York. The New York corporate office is provided to it under a space sharing arrangement with Synergy, the Company's subsidiary. The term of the leases at 420 Lexington Avenue expire on June 30, 2011 and September 30, 2011. The Company also occupies a small laboratory and several offices, totaling approximately 1,100 square feet, in the Bucks County Biotechnology Center in Doylestown, Pennsylvania under a lease expiring August 31, 2011 which is expected to be renewed.

During the twelve months ended December 31, 2010, 2009 and 2008, total rent expense was $313,451, $282,678 and $280,612, respectively. Total annual commitments for each of the years ended December 31, are as follows:

2011	$	155,181
Total	$	155,181

10. Net loss per share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, *Earnings per Share* ("ASC Topic 260"), for all periods presented. In accordance with this guidance, 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. The Company has a net loss for

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Net loss per share (Continued)

all periods presented. Accordingly, the inclusion of common stock options, warrants and the conversion of preferred sock would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted earnings per share are the same.

The following table sets forth the potentially dilutive effect of all outstanding dilutive instruments which were not included in weighted-average common shares outstanding as of:

	December 31, 2010	December 31, 2009	December 31, 2008
Common Shares Outstanding (included in weighted-average shares)	157,509,404	53,608,111	49,556,661
Potentially Dilutive Common Shares Issuable (excluded from weighted-average shares)			
Exercise of Warrants	10,371,999	84,842,576	55,773,331
Exercise of Stock Options	7,971,872	7,495,038	7,938,538
Conversion of Series A Convertible Preferred Stock	8,000	1,750,000	1,960,000
Conversion of Series B Convertible Preferred Stock		28,171,278	22,741,000
Common Shares Outstanding Fully Diluted	175,861,275	175,867,003	137,969,530

11 Property and equipment

Equipment consists of laboratory, testing and computer equipment and furniture and fixtures consists of office furniture, both stated at cost, with useful lives ranging from 2-4 years, depreciated on a straight line basis. Depreciation expense for the years ended December 31, 2010, 2009, 2008 and from June 5, 1996 (inception) to December 31, 2010 was $5,268, $5,983, $6,654, and $107,835 respectively.

	December 31,	
	2010	2009
Equipment	$ 67,091	$ 67,091
Furniture and fixtures	38,343	38,343
Leasehold improvements	11,799	11,799
Less: accumulated depreciation	(107,836)	(102,568)
Property and equipment, net	$ 9,397	$ 14,665

12. Subsequent events

On February 8, 2011, Synergy entered into a loan agreement (the "Agreement") with an investor (the "Lender"), pursuant to which the Lender agreed to lend an aggregate $950,000 to Synergy. Simultaneously with the execution and delivery of the Agreement, Synergy issued a note to the Lender in the principal amount of $500,000 (the "First Note"). Synergy has the option to issue an additional note to the Lender in the principal amount of $450,000 beginning February 21, 2011 (the "Second Note" and with the First Note, the "Notes"). The Notes bear interest at 17% per annum and are payable on April 1, 2011. As of March 31, 2011 Synergy had not borrowed under the Second Note.

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Subsequent events (Continued)

On March 4, 2011, Synergy closed a financing with a non-U.S. investor which raised gross proceeds of $1,800,000 in a registered direct offering. Synergy issued to the investor 600,000 shares of its common stock and warrants to purchase 420,000 shares of common stock. The purchase price paid by the investor was $3.00 for each unit. The warrants expire after seven years and are exercisable at $3.10 per share. Synergy paid fees to a non-US selling agent and legal expenses totaling $175,000 on this offering.

On February 28, 2011 and March 8, 2011 Callisto entered into consulting agreements with two financial advisors who agreed to receive an aggregate of 850,000 of Callisto common stock, with a fair value of approximately $525,000, as full compensation for their services.

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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 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 3.1 filed with the Company's Current Report on Form 8-K filed on September 22, 2009)
3.6	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)
3.7	Certificate of Amendment to Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series B Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.2 filed with the Company's Current Report on Form 8-K filed on September 22, 2010)
3.8	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)

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Exhibit No.	Description
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)
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)
4.11	Form of Extension Agreement (Incorporated by reference to Exhibit 4.2 filed with the Company's Current Report on Form 8-K filed on March 23, 2010).
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)**
10.10	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 (incorporated by reference to Exhibit 10.13 filed with the Company's Annual Report on Form 10-K filed on April 15, 2009).
10.14	Form of Securities Purchase Agreement by and between Callisto Pharmaceuticals, Inc. and the several investors party thereto (incorporated by reference to Exhibit 10.14 filed with the Company's Annual Report on Form 10-K filed on April 15, 2009).
10.15	Form of Security Agreement made by Callisto Pharmaceuticals, Inc and Sommer and Schneider, LLP (incorporated by reference to Exhibit 10.15 filed with the Company's Annual Report on Form 10-K filed on April 15, 2009).
10.16	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.16 filed with the Company's Annual Report on Form 10-K filed on April 15, 2009).
10.18	Amended and Restated Executive Employment Agreement by and between Callisto Pharmaceuticals, Inc. and Gary S. Jacob dated March 11, 2009 (incorporated by reference to Exhibit 10.18 filed with the Company's Annual Report on Form 10-K filed on April 15, 2009).*
10.19	Amended and Restated Consulting Agreement by and between Callisto Pharmaceuticals, Inc. and Gabriele M. Cerrone dated March 11, 2009 (incorporated by reference to Exhibit 10.19 filed with the Company's Annual Report on Form 10-K filed on April 15, 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 USA, 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