

CALLISTO PHARMACEUTICALS INC
Form 10-K
March 31, 2010

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.](#)

[CALLISTO PHARMACEUTICALS, INC. \(A Development Stage Company\) Index to the Consolidated Financial Statements](#)

[Table of Contents](#)

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

FORM 10-K

(Mark one)

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

FOR THE FISCAL YEAR ENDED: DECEMBER 31, 2009

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

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

CALLISTO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware **12-3894575**
(State or Other Jurisdiction of (I.R.S. Employer
Incorporation or Organization) 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:

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

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 No

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

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

Indicate by check mark 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 No

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

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

Large accelerated filer <input type="radio"/>	Accelerated filer <input type="radio"/>	Non-accelerated filer <input type="radio"/>	Smaller reporting company <input checked="" type="radio"/>
		(Do not check if a smaller reporting company)	

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was \$14,375,218 on June 30, 2009 (based on \$0.28 per share, the closing price on that day).

As of March 30, 2010 the registrant had a total of 54,024,778 shares of Common Stock outstanding.

Table of Contents

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

FORM 10-K

TABLE OF CONTENTS

PART I

<u>Item 1.</u>	<u>Business</u>	<u>3</u>
<u>Item 2.</u>	<u>Properties</u>	<u>16</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>16</u>
<u>Item 4.</u>	<u>Reserved</u>	<u>17</u>

PART II

<u>Item 5.</u>	<u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>18</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>19</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>27</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>27</u>
<u>Item 9A(T)</u>	<u>Controls and Procedures</u>	<u>27</u>

PART III

<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>31</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>35</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>41</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>42</u>
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	<u>43</u>

PART IV

<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	<u>43</u>
	<u>Signatures</u>	<u>47</u>

Table of Contents

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, 2009, 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 SP-304 and SP-333, are being developed exclusively by Synergy Pharmaceuticals, Inc., our majority-owned subsidiary ("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, rheumatoid arthritis (RA), neuroendocrine cancer (including advanced carcinoid cancer), and acute leukemia. Our lead drug candidates are as follows:

- (1) SP-304, a guanylyl cyclase C ("GC-C") receptor agonist, to treat GI disorders, primarily chronic constipation ("CC") and constipation-predominant irritable bowel syndrome ("IBS-C").
- (2) SP-333, a second generation GC-C receptor agonist, SP-333, now in pre-clinical development to treat gastrointestinal inflammatory diseases.
- (3) Atiprimod, an orally administered drug with antiproliferative, anti-inflammatory and antiangiogenic activity.
- (4) L-Annamycin, a novel compound from the anthracycline family of proven anti-cancer drugs, which has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart.

HISTORY

In March 2002, Callisto Pharmaceuticals, Inc. ("Old Callisto"), a non-public company, purchased 99.7% of the outstanding common shares of Webtronics, Inc., ("Webtronics") a public company for

Table of Contents

\$400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations at December 31, 2002.

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

From inception through December 31, 2009, we have sustained cumulative net losses available to common stockholders of \$109,779,780. 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. From inception through December 31, 2009 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 January 27, 2009, we announced that we were focusing all further development of Atiprimod towards the treatment of RA. We recognized that although the ongoing Phase II clinical trial of Atiprimod in advanced carcinoid cancer gave encouraging results, the data were not sufficiently demonstrative to warrant further development of Atiprimod in this indication. We announced, instead, our intention that based on Atiprimod's demonstrated favorable clinical safety profile, robustly supported by earlier studies of Atiprimod in RA patients, as well as by the recent oncology trials in advanced carcinoid cancer patients, where the drug was dosed at levels and frequencies considerably higher than anticipated for use in RA, we believe that Atiprimod holds significant promise as a new class of orally-administered, disease-modifying agent in RA.

On July 14, 2008, we entered into an Exchange Agreement dated July 11, 2008 ("Exchange Agreement"), as amended and effective on July 14, 2008, with Pawfect Foods, Inc. ("Pawfect"), Synergy-DE and other holders of Synergy-DE common stock. According to the terms of the Exchange Agreement, Pawfect acquired 100% of the common stock of Synergy-DE, from us and the other holders of Synergy-DE, in exchange for 45,464,760 shares of Pawfect's common stock representing approximately 70% of Pawfect's outstanding common stock (the "Exchange Transaction"). We received 44,590,000 of the 45,464,760 shares of Pawfect's common stock exchanged for our ownership of

Table of Contents

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.

PROPOSED PRODUCTS

SP-304 TO TREAT GI DISORDERS

We are currently developing SP-304, a synthetic hexadecapeptide designed to mimic the actions of the GI hormone uroguanylin, for the treatment of CC and IBS-C. SP-304 is an agonist of GC-C. The endogenous agonists of GC-C receptor are uroguanylin and guanylin, which were discovered as natriuretic hormones based on their structural similarity to bacterial enterotoxin, the peptide secreted by pathogenic *Escherichia coli* (*E.coli*) bacteria responsible for traveler's diarrhea.

SP-304 is a new member of a novel class of non-systemic drugs for treatment of CC, IBS-C and other GI disorders and diseases. SP-304 was developed by our scientists based on structure-function studies performed in-house. SP-304 is an analog of uroguanylin, a natural peptide hormone produced in the gut that is a key regulator of intestinal function. Uroguanylin works by activating the GC-C receptor on intestinal cells which promotes fluid and ion transport in the GI tract. Under normal conditions, this receptor is activated by the natural hormone uroguanylin and/or by a similar natural hormone guanylin.

Clinical Studies

On June 4, 2008, we initiated a Phase 1 clinical trial of SP-304 in volunteers. This first study was a double-blind, placebo-controlled, randomized single, oral, ascending-dose trial performed in 71 healthy male and female volunteers. The primary objective of the clinical trial was to characterize the safety, tolerability, pharmacokinetic and pharmacodynamic effects of the drug in healthy volunteers.

On December 9, 2008, we announced the completion of the Phase 1 clinical trial of SP-304 in healthy volunteers. Cohorts of volunteers were administered a single, oral dose of SP-304 ranging in dose from 0.1, 0.3, 0.9, 2.7, 5.4, 8.1, 16.2, 24.3 and 48.6 mg, respectively or given a matching placebo dose. No detectable SP-304 was observed in the plasma of any subject administered SP-304 throughout the range from 0.1-48.6 mg. Pharmacodynamic effects of SP-304 related to the frequency and consistency of bowel movements after SP-304 administration were studied, and trends were observed related to greater increases in the number of bowel movements and looser stools for SP-304 in comparison to placebo. These findings suggested a positive pharmacodynamic effect for SP-304 administration compared to placebo. Overall, SP-304 was safe and well tolerated throughout the single-dose range from 0.1-48.6 mg.

On March 19, 2010, we initiated a Phase 2a 14-day repeated-oral-dose, placebo-controlled, dose-escalation trial of SP-304 in CC patients. In addition our plan is to begin a Phase 2b 28-day

Table of Contents

repeated-oral-dose, placebo-controlled trial in SP-304 in CC patients in early 2011 and a Phase 2b 90-day repeated-oral-dose, placebo-controlled trial of SP-304 in IBS-C patients in the second quarter of 2011.

SP-333 TO TREAT ULCERATIVE COLITIS

A second generation GC-C receptor agonist, SP-333, is now in pre-clinical development to treat gastrointestinal inflammatory diseases such as UC. We plan to file an IND for SP-333 to treat UC in the fourth quarter of 2010. We previously showed that GC-C receptor agonists are efficacious in animal models of UC. In addition, we evaluated GC-C receptor agonists in two different animal models of UC, demonstrating that oral treatment of GC-C receptor agonists were effective in ameliorating GI inflammation in mouse models of experimental colitis. GC-C receptor agonists appear to produce anti-inflammatory activity via a novel cGMP-mediated mechanism that downregulates pro-inflammatory cytokines.

Development Plan

Our plan of operations for the next twelve months is to focus primarily on the clinical trial development of SP-304 to treat CC, and SP-333 to treat UC.

We plan to initiate a Phase 1 clinical trial of SP-333 in volunteers in the fourth quarter of 2010. We expect to follow this trial in 2011 with a Phase 1b single-dose trial in UC patients to evaluate safety and pharmacokinetics of orally administered SP-333 in UC patients.

Manufacturing of our Product Candidates

We do not have manufacturing capabilities. We currently use contract manufacturers for the manufacturing of SP-304 and SP-333. Accordingly, unless or until we develop or acquire sufficient manufacturing capabilities, we will depend on third parties to manufacture SP-304, 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 SP-304 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.

At present we have 1.5 kg of SP-304 in production under GMP conditions, which will be used for non-clinical work to support further human studies. We also have sufficient supplies of GMP-grade SP-304 for our Phase 2 clinical trials in CC. Additionally, we have over 400 grams of non-GMP SP-333 available to support the non-clinical work needed for filing an IND on SP-333 in the third quarter of 2010. Manufacturing of GMP-scale SP-333 is currently underway. This material is needed for the clinical trial of SP-333 in healthy volunteers scheduled to begin in 2010.

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

Table of Contents

under the Original License were made in January 2004, 2005, 2006 and 2007 and recorded as research and development expense.

On December 31, 2007, we and Synergy entered into an Amended and Restated License Agreement with AnorMED Corporation ("AnorMED"), a wholly-owned subsidiary of Genzyme Corporation ("Genzyme"), pursuant to which the parties amended the Original License agreement for Atiprimod to eliminate all future maintenance fees and milestone payments and reduce future royalties. In return for the reduced future payments to Genzyme, we agreed to pay upfront fees which were recorded as a liability and expensed on December 31, 2007. As of December 18, 2008, \$650,000 of these upfront fees remained due and payable.

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

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

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

Table of Contents

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 demonstrative to warrant further development of Atiprimod in this indication. We announced, instead, our intention that based on Atiprimod's demonstrated favorable clinical safety profile, robustly supported by earlier studies of Atiprimod in RA patients, as well as by the recent oncology trials in advanced carcinoid cancer patients, where the drug was dosed at levels and frequencies considerably higher than anticipated for use in RA, we believe that Atiprimod holds significant promise as a new class of orally-administered, disease-modifying agent in RA.

Manufacturing of Atiprimod

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

Orphan Drug Status of Atiprimod

On January 6, 2004, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of multiple myeloma. On September 26, 2006, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of carcinoid tumors. The FDA grants orphan drug status for drug candidates that are intended to treat rare life-threatening diseases that, at the time of application, affect no more than 200,000 patients in the United States. The drug must have the ability to provide significant patient benefit over currently available treatment or fill an unmet medical need. Orphan drug designation entitles us to seven years of market exclusivity in the United States of America, and ten years of market exclusivity in Europe, upon FDA marketing approval, provided that we continue to meet certain conditions established by the FDA. Once the FDA grants

Table of Contents

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 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 regimens 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 trial with L-Annamycin.

Table of Contents

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.

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.

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;

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

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 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

Table of Contents

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.

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

Table of Contents

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.

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 Microbia Inc., Hana Biosciences Inc., SGX Pharmaceuticals, Inc., Sunesis Pharmaceuticals, Inc. and Vion Pharmaceuticals, Inc. Most of our competitors have financial, technical and marketing resources significantly greater than our resources. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint venture. We are aware of certain development projects for products to prevent or treat certain diseases targeted by us. The existence of these potential products or other products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect our ability to market the products we develop.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses consist primarily of costs associated with (i) clinical development team salaries and staff costs, (ii) application and filing for regulatory approval of our proposed products, (iii) regulatory and scientific consulting fees, (iv) clinical and patient costs for product candidates in on-going trials, (v) sponsored pre-clinical research, (vi) royalty and license fee payments, (vii) legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products, (viii) clinical drug substance and (ix) acquired in-process research and development. We expense all research and development costs as they are incurred and we expect our research and development expenses to increase significantly in the future as we develop our product candidates. Research and development expenses were \$3,936,474 for the twelve months ended

Table of Contents

December 31, 2009, compared to \$5,449,721 and \$6,507,978 for the twelve months ended December 31, 2008 and 2007, respectively.

On April 1, 2005 we were awarded an \$885,641 biodefense partnership grant from the NIAID to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over a two year period. During the twelve months ended December 31, 2009, 2008 and 2007 we received \$0, \$30,000 and \$260,853, 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.

PROPRIETARY RIGHTS

We are able to protect our technology from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents or is effectively maintained as a trade secret. Accordingly, patents or other proprietary rights are an essential element of our business. We have obtained licenses from various parties that give us rights to technologies that we deem to be necessary or desirable for our research and development. These licenses (both exclusive and non-exclusive) may require us to pay royalties to the parties in addition to upfront or milestone payments, and to expend certain minimum resources to develop these technologies. Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

As of December 31, 2009, we are the assignee or exclusive licensee of 9 pending patent applications and 11 issued patents in the United States, and currently we have approximately 150 issued or pending foreign patent applications. We seek patent protection of inventions originating from our ongoing research and development activities that are commercially important to our business. Our composition-of-matter and use patent on SP-304 issued on May 9, 2006 expires in 2023. Our composition-of-matter patents for L-Annamycin and Atiprimod expire in 2017 and 2016, respectively. Our formulation patents for L-Annamycin and Atiprimod dimaleate salt both expire in 2016.

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

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or us, we may face costly litigation and the diversion of management's attention and resources. As a result of such disputes, we may have to

Table of Contents

develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, or at all.

LICENSE AGREEMENTS

On 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

Table of Contents

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 payments due.

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

EMPLOYEES

As of March 31, 2010, we had 6 full-time and 3 part-time 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 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, 2010. 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, 2010.

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

ITEM 3. LEGAL PROCEEDINGS.

In June 2007, we filed a complaint against Dr. Donald Picker ("Picker") in the Supreme Court of the State of New York alleging breach of his employment agreement, fraud, conversion and related claims. We were seeking \$80 million in damages from Picker. During 2008 Picker moved for a summary judgment and on May 5, 2009 the court ruled in favor of Picker dismissing our complaint. On

Table of Contents

February 22, 2010 we 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. Our Appeal, which also requests immediate jury trial, is still pending.

On December 22, 2009, through our subsidiary Synergy Advanced Pharmaceuticals, Inc., we 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 non-disclosure provisions and non-compete 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. In addition, we are requesting an assignment of all patents and other intellectual property rights defendants currently hold relating to any inventions obtained in breach of the agreements as well as compensatory, consequential and punitive damages.

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

ITEM 4. RESERVED.

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

Our common stock was quoted on the American Stock Exchange ("AMEX") under the symbol "KAL" from October 25, 2004 until July 14, 2008. 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 AMEX prior to July 14, 2008 and as reported on the Over the Counter Bulletin Board subsequent to July 14, 2008.

	2009		2008	
	High	Low	High	Low
First Quarter	\$ 0.15	\$ 0.07	\$ 0.62	\$ 0.36
Second Quarter	\$ 0.28	\$ 0.06	\$ 0.40	\$ 0.24
Third Quarter	\$ 0.45	\$ 0.20	\$ 0.24	\$ 0.05
Fourth Quarter	\$ 0.42	\$ 0.18	\$ 0.14	\$ 0.03

HOLDERS OF COMMON STOCK

As of March 31, 2010 we had 408 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, 2009.

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	5,170,483	\$ 1.69	4,275,000
Equity Compensation Plans Not Approved by Stockholders(1)	87,167,131	0.10	
Total	92,337,614	\$ 0.14	4,275,000

(1)

Consists of 2,324,555 stock options not subject to any of our stock option plans and 84,842,576 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.

Table of Contents

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

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

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 neuroendocrine cancer (including advanced carcinoid cancer), rheumatoid arthritis ("RA"), acute leukemia and gastrointestinal ("GI") disorders and diseases. Our lead drug candidates are as follows:

- (1) SP-304, a guanylyl cyclase C ("GC-C") receptor agonist, to treat GI disorders, primarily chronic constipation ("CC") and constipation-predominant irritable bowel syndrome ("IBS-C").
- (2) SP-333, a second generation GC-C receptor agonist, SP-333, now in pre-clinical development to treat gastrointestinal inflammatory diseases.
- (3) Atiprimod, an orally administered drug with antiproliferative, anti-inflammatory and antiangiogenic activity.
- (4) L-Annamycin, a novel compound from the anthracycline family of proven anti-cancer drugs, which has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart.

HISTORY

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

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

Table of Contents

From inception through December 31, 2009, we have sustained cumulative net losses available to common stockholders of \$109,779,780. Our losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, stock-based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees, as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception through December 31, 2009, 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 *Summary of Significant Accounting Policies and New Accounting Pronouncements*. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. We believe that the following discussion represents our critical accounting policies.

Research and Development

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

In June 2007, the EITF of the FASB reached a consensus on ASC Topic 730, *Research and Development* ("ASC Topic 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 would be recognized as an expense. We adopted ASC Topic 730 on January 1, 2008 and the adoption did not have a material effect on our consolidated financial position, results of operations or cash flows.

Table of Contents

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, 2009 stock-based compensation expense has totaled \$18,854,725 or 17% of our total accumulated deficit of \$110,272,360.

ASC Topic 718 did not change the way we account for non-employee stock-based compensation. We continue to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. Stock-based compensation expense associated with these non-employee option grants is being recorded in accordance with ASC Topic 505-50 and accordingly (i) the measurement date will be when "performance commitment is completed" and accordingly the fair value of these options is being "marked to market" quarterly until the measurement date is determined.

Upon adoption of ASC Topic 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. Our stock price has fluctuated from \$3.95 per share as of December 31, 2003 to \$0.18 per share as of December 31, 2009. The expected term was determined based on the simplified method provided in ASC Topic 718 "*Share-Based Payment*". 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.

RESULTS OF OPERATIONS

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 \$1,513,247 or 28% to \$3,936,474 for the 12 months ended December 31, 2009 from \$5,449,721 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 \$1,960,000 during the 12 months ended December 31, 2009 and 2008, respectively, a decrease of \$1,224,693 or 62%. 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 SP-304 program expenses incurred by Synergy which increased \$384,000 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 7% to \$4,593,511 from \$4,311,767 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.

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

Table of Contents

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 \$1,815,602 in the 12 months ended December 31, 2009. We had no such items (ii) through (v) during 2008.

YEARS ENDED DECEMBER 31, 2008 AND DECEMBER 31, 2007

We had no revenues during the 12 months ended December 31, 2008 and 2007 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

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

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

Net loss from operations was \$9,731,488 for the 12 months ended December 31, 2008 which was \$832,925 or 8% lower than the \$10,564,413 reported in the comparable period of 2007. This decrease was attributable to lower research and development expenses discussed above combined with lower government grants income of \$30,000 during the 12 months ended December 31, 2008 as compared to \$260,853 received during the 12 months ended December 31, 2007. On April 1, 2005 we were awarded a biodefense partnership grant from the National Institute of Allergy and Infectious Diseases to

Table of Contents

develop a monoclonal antibody and vaccine against bacterial superantigen toxins over a two year period. Funding for this program was extended one year through April 2008. Because the bioterrorism program is not a core activity, we terminated in-house work on this program upon expiration of the research grant in April 2008

We record adjustments to the noncontrolling interests in Synergy for the allocable portion (32%) of losses to which the noncontrolling interest holders are entitled. The noncontrolling interest in Synergy as of the date of acquisition, July 14, 2008, was \$663,765 after reflecting the net proceeds from the private placement. 32% of Synergy's net loss subsequent to the date of acquisition through December 31, 2008 was \$1,151,577, excluding Synergy's charge for purchased in process research and development eliminated in consolidation. We suspended allocation of losses to the noncontrolling interest holders when the noncontrolling interest balance was reduced to zero. Any excess Synergy loss above the noncontrolling interest holder's balance was not charged to noncontrolling interests as the Synergy noncontrolling interest holders have no obligation to fund such losses. Net loss attributable to common stockholders for the 12 months ended December 31, 2008 was \$9,655,471 compared to a net loss of \$20,887,428 incurred for the 12 months ended December 31, 2007. The decreased net loss is the result of (i) lower operating expenses discussed above, (ii) the beneficial conversion feature discount related to the Series A and B preferred stock accreted as a dividend of \$13,000,163 in the 12 months ended December 31, 2007 and (iii) a benefit in the 12 months ended December 31, 2007 relating to a change in the fair value of the Series B warrants of \$2,591,005. We had no such items (ii) and (iii) during 2008.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2009 we had \$7,207,612 in cash and cash equivalents, compared to \$301,323 as of December 31, 2008. Net cash used in operating activities was \$9,406,972 and \$8,902,375 for the 12 months ended December 31, 2009 and 2008 respectively. As of December 31, 2007, we also had \$2,967,690 invested in U.S. Treasury bills classified as short-term investments on our balance sheet. These investments were liquidated into cash and cash equivalents during the 12 months ended December 31, 2008

Net cash provided by financing activities for the twelve months ended December 31, 2009 and December 31, 2008 was \$16,313,261 and \$2,951,913. Included in net cash provided by financing activities during the 12 months ended December 31, 2009 was aggregate proceeds from the private placement of 22,814,425 shares of Synergy common stock at \$0.70 per share totaling \$15,970,100 less \$260,002 of selling agent fees and other cost of capital.

In addition on December 30, 2008, we entered into a securities purchase and exchange agreement ("Purchase Agreement") with several investors, each of whom were holders of record as of November 4, 2008 of outstanding warrants to purchase shares of 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 us. Pursuant to the Purchase Agreement, Callisto issued 69,086,174 common stock purchase warrants (see Note 7) ("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

Table of Contents

Atiprimod technology acquired by the Company in December 2008 (See note 7 to our consolidated financial statements).

On March 22, 2010, we 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, we 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.

As of December 31, 2009 we had a working capital of \$4,461,765 as compared to a working capital deficit of \$4,260,826 as of December 31, 2008.

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

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of pharmaceutical research and development programs. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates, to fund the existing working capital deficit and to continue to fund operations at our current cash expenditure levels. To date, our sources of cash have been primarily limited to the sale of equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more of product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

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

Table of Contents

Our consolidated financial statements as of December 31, 2009 and December 31, 2008 have been prepared under the assumption that we will continue as a going concern for the twelve months ending December 31, 2008. Our independent registered public accounting firm has issued a report dated March 31, 2010 that includes an explanatory paragraph referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following is a summary of our significant contractual cash obligations for the periods indicated that existed as of December 31, 2009, 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
Long term debt obligations	\$ 603,163	\$ 603,163	\$	\$	\$
Operating leases	399,882	257,901	141,981		
Purchase obligations principally consulting services	1,785,000	595,000	1,190,000		
License and royalty payments	80,000	40,000	40,000		(1)
Purchase orders	1,666,578	1,666,578			
Total obligations	\$ 4,534,623	\$ 3,162,642	\$ 1,371,981	\$	\$

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

OFF-BALANCE SHEET ARRANGEMENTS

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

RECENT ACCOUNTING PRONOUNCEMENTS

In August 2009, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2009-05, "Measuring Liabilities at Fair Value" ("ASU 2009-05"). ASU 2009-05 amends ASC Topic 820 and clarifies that, where a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: 1) a valuation technique that uses a) the quoted price of the identical liability when traded as an asset or b) quoted prices for similar liabilities or similar liabilities when traded as assets and/or 2) a valuation technique that is consistent with the principles of ASC Topic 820. ASU 2009-05 also clarifies that, when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability. The adoption of ASU 2009-05 did not have a material impact on our financial statements.

In June 2009, FASB issued Accounting Standards Update No. 2009-01, "Generally Accepted Accounting Principles" (ASC Topic 105), by the Codification which establishes the FASB Accounting Standards Codification (the "Codification" or "ASC") as the single source of authoritative GAAP. All existing accounting standards in effect prior to the Codification were superseded. All other accounting guidance not included in the Codification will be considered non-authoritative. The Codification also includes all relevant SEC guidance organized using the same topical structure in separate sections

Table of Contents

within the Codification. The Codification does not change GAAP and did not impact our financial statements. All references to authoritative accounting literature (including references related to periods prior to the establishment of the Codification) are referenced in accordance with the Codification.

In May 2009, the FASB issued guidance within ASC Topic 855, "Subsequent Events," amended by ASU 2010-09, relating to subsequent events. This guidance establishes principles and requirements for subsequent events. This guidance defines the period after the balance sheet date during which events or transactions that may occur would be required to be disclosed in a company's financial statements. Public entities are required to evaluate subsequent events through the date that financial statements are issued. This guidance also provides guidelines for evaluating whether or not events or transactions occurring after the balance sheet date should be recognized in the financial statements.

In April 2009, the FASB issued guidance within ASC Topic 825, "Financial Instruments Overall," concerning interim disclosures about fair value instruments. This guidance requires that disclosures about the fair value of a company's financial instruments be made whenever summarized financial information for interim reporting periods is made. The provisions of this guidance are effective for interim periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on our financial statements.

In October 2008, the FASB issued FASB Staff Position within ASC Topic 820, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, ("ASC Topic 820"). This guidance applies to financial assets within the scope of accounting pronouncements that require or permit fair value measurements in accordance with ASC Topic 820. This guidance clarifies the application of in determining the fair values of assets or liabilities in a market that is not active. This guidance is effective upon issuance, including prior periods for which financial statements have not been issued. The adoption of this FSP did not have a material impact on our consolidated financial statements.

In June 2008, the FASB ratified the consensus reached on guidance within ASC Topic 815., *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* ("ASC Topic 815"). This guidance clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under ASC Topic 815, *Accounting for Derivative Instruments and Hedging Activities*. ASC Topic 815 is effective for financial statements issued for fiscal years beginning after December 15, 2008. The adoption of this statement did not have a material effect on our consolidated financial position, results of operations or cash flows.

In February 2008, the FASB issued ASC Topic 820, *Partial Deferral of the Effective Date of Statement 157*, ("ASC Topic 820"). This guidance delays the effective date of *Fair Value Measurements* ("ASC Topic 820") for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually) to fiscal years beginning after November 15, 2008. The adoption of this statement did not have a material effect on our consolidated financial position, results of operations or cash flows.

In December 2007, the FASB ratified ASC Topic 808, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, ("ASC Topic 808"), which provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure requirements. ASC Topic 808 is effective for fiscal years beginning after December 15, 2008. Adoption of this statement did not have a material effect on our consolidated financial position, statement of operations or cash flows.

In December 2007, the FASB issued ASC Topic 805, *Business Combinations*. The revision is intended to simplify existing guidance and converge rulemaking under U.S. GAAP with international

Table of Contents

accounting rules. This statement applies prospectively to business combinations where the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and may affect the release of our valuation allowance against prior acquisition intangibles. Adoption of this statement did not have a material effect on our consolidated financial position, statement of operations or cash flows.

In December 2007, the FASB issued ASC Topic 810, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ASC Topic 860* ("ASC Topic 810"). This guidance requires all entities to report noncontrolling (minority) interests in subsidiaries as equity in the consolidated financial statements. Its intention is to eliminate the diversity in practice regarding the accounting for transactions between an entity and noncontrolling interests. This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Adoption of this statement did not have a material effect on our consolidated financial position, statement of operations or cash flows.

In June 2007, the EITF of the FASB reached a consensus on ASC Topic 730, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ("ASC Topic 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 would be recognized as an expense. We adopted ASC Topic 730 on January 1, 2008 and the adoption did not have a material effect on our consolidated financial position, results of operations or cash flows.

In February 2007, the FASB issued Statement of Financial Accounting Standards within ASC Topic 825, *The Fair Value Option for Financial Assets and Financial Liabilities, including an Amendment to ASC Topic 320* ("ASC Topic 320"). The fair value option established by ASC Topic 825 permits all entities to measure all eligible items at fair value at specified election dates. A business entity shall report all unrealized gains and losses on items for which the fair value option has been elected, in earnings at each subsequent reporting date. We adopted ASC Topic 825 on January 1, 2008 and the adoption did not have a material effect on our consolidated financial position, results of operations or cash flows as we did not elect this fair value option on any financial assets or liabilities.

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

At December 31, 2009 and 2008, 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 (JPMorganChase, HSBC and Capstone Bank).

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The full text of our audited consolidated financial statements as of December 31, 2009 and 2008 and for the fiscal years ended December 31, 2009, 2008 and 2007 and for the period from June 5, 1996 (inception) to December 31, 2009, begins on page F-1 of this Annual Report on Form 10-K.

ITEM 9A(T). 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, 2009. 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,

Table of Contents

processed, summarized and reported, within the time periods specified in the SEC's rules and forms. 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, 2009, and due to the material weaknesses 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 the Company's 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, 2009. In connection with this assessment, we identified material weaknesses in internal control over financial reporting as of December 31, 2009. 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 weaknesses described below, management concluded that, as of December 31, 2009, our internal control over financial reporting was not effective.

(1) *Control environment* We did not maintain an effective control environment. The control environment, which is the responsibility of senior management, sets the tone of the organization,

Table of Contents

influences the control consciousness of its people, and is the foundation for all other components of internal control over financial reporting. Each of the following control environment material weaknesses also contributed to the material weaknesses discussed in items (2) through (5) below. Our control environment was ineffective because of the following material weaknesses:

(a) We did not maintain a sufficient complement of personnel with an appropriate level of accounting knowledge, experience, and training in the application of Generally Accepted Accounting Principles (GAAP) commensurate with our financial reporting requirements and business environment. This material weakness resulted in a material post closing adjustment which has been reflected in the financial statements for the year ended December 31, 2009. This adjustment caused changes in current assets, stockholders' equity, and expenses, specifically in prepaid expenses and drug substance expense which were not originally recorded in accordance with ASC Topic 730-10-55 *Research and Development*.

(b) 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.

The control environment material weaknesses described above contributed to the material weaknesses related to our monitoring of internal control over financial reporting, period end financial close and reporting, accounting for stock compensation and equity transactions described in items (2) to (5) below.

(2) *Monitoring of internal control over financial reporting* We did not maintain effective monitoring controls to determine the adequacy of our internal control over financial reporting and related policies and procedures because of the following material weaknesses:

(a) Our policies and procedures with respect to the review, supervision and monitoring of our accounting operations throughout the organization were either not designed and in place or not operating effectively.

(b) We did not maintain an effective internal control monitoring function. Specifically, there were insufficient policies and procedures to effectively determine the adequacy of our internal control over financial reporting and to monitoring the ongoing effectiveness thereof.

Each of these material weaknesses relating to the monitoring of our internal control over financial reporting contributed to the material weaknesses described in items (3) through (5) below.

(3) *Period end financial close and reporting* Due to a pervasive lack of proper segregation of duties within the finance department, we did not establish and maintain effective controls over certain of our period-end financial close and reporting processes because of the following material weaknesses:

(a) We did not maintain effective controls over the preparation and review of the interim and annual consolidated financial statements to ensure that we identified and accumulated all required supporting information to ensure the completeness and accuracy of the consolidated financial statements and that balances and disclosures reported in the consolidated financial statements reconciled to the underlying supporting schedules and accounting records.

(b) We did not maintain effective controls over the preparation, review and approval of account reconciliations. Specifically, we did not have effective controls over the completeness and accuracy of supporting schedules for substantially all financial statement account reconciliations.

(c) We did not maintain effective controls over the recording of either recurring or non-recurring journal entries. Specifically, effective controls were not designed and implemented to ensure that journal entries were properly prepared with sufficient support or documentation or were reviewed and approved to ensure the accuracy and completeness of the journal entries recorded.

Table of Contents

(4) *Equity Transactions* We did not establish and maintain effective controls to ensure the correct application of GAAP related to equity transactions. Specifically, we did not adequately review private placement agreements to identify potential derivative instruments.

(5) *Cash management* We did not establish and maintain effective controls to adequately segregate the duties over cash management. Specifically, effective controls were not designed to prevent the misappropriation of cash.

c) *Changes in Internal Control Over Financial Reporting*

During the quarter ended December 31, 2009, no changes other than those in conjunction with certain remediation plans and efforts described below, 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.

d) *Remediation Plans*

Management, in coordination with the input, oversight and support of our Audit Committee, has identified the following measures to strengthen our internal control over financial reporting and to address the material weaknesses described above. Prior to the filing of this Annual Report on Form 10-K, we hired a controller who will:

Prepare annual and quarterly consolidated financial statements

Prepare annual and quarterly account reconciliations

Prepare annual and quarterly journal entries

We believe this hire will significantly improve segregation of duties within our financial department. We are also considering the use of an independent GAAP advisor. While we expect these remedial actions to be essentially implemented in calendar year 2010, some may not be in place for a sufficient period of time to help us certify that material weaknesses have been fully remediated as of the end of calendar year 2010. We will continue to develop our remediation plans and implement additional measures during calendar year 2010 and possibly into calendar year 2011.

If the remedial measures described above are insufficient to address any of the identified material weaknesses or are not implemented effectively, or additional deficiencies arise in the future, material misstatements in our interim or annual financial statements may occur in the future and we may continue to be delinquent in our filings. We are currently working to improve and simplify our internal processes and implement enhanced controls, as discussed above, to address the material weaknesses in our internal control over financial reporting and to remedy the ineffectiveness of our disclosure controls and procedures. A key element of our remediation effort is the ability to recruit and retain qualified individuals to support our remediation efforts. While our Audit Committee and Board of Directors have been supportive of our efforts by supporting the hiring of various individuals in our finance department as well as funding efforts to improve our financial reporting system, improvement in internal control will be hampered if we can not recruit and retain more qualified professionals. Among other things, any unremediated material weaknesses could result in material post-closing adjustments in future financial statements.

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

The following table sets forth certain information regarding the directors and executive officers of Callisto Pharmaceuticals, Inc. as of March 31, 2010:

Name	Age	Position
Gabriele M Cerrone	37	Chairman of the Board
Gary S. Jacob	62	Chief Executive Officer, Chief Scientific Officer and Director
Bernard F. Denoyer	62	Senior Vice President, Finance and Secretary
John P. Brancaccio	62	Director
Christoph Bruening	42	Director
Riccardo Dalla-Favera	57	Director
Randall Johnson	63	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 consultant 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

Table of Contents

CFO and other services to emerging technology companies, including Callisto and certain portfolio companies of Marsh & McLennan Capital, LLC. From October 1994 until September 2000, Mr. Denoyer served as Chief Financial Officer and Senior Vice President at META Group, Inc., a public information technology research company, where he was instrumental in their 1995 IPO. From 1990 to 1993 he served as Vice President Finance of Environetics, Inc., a pharmaceutical water diagnostic business until acquired by IDEXX Laboratories, Inc.

John P. Brancaccio, a retired CPA, has served as a director of our company since April 2004. Since April 2004, Mr. Brancaccio has been the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. From May 2002 until March 2004, 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.

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

Table of Contents

Committee receive 5,000, 3,500 and 2,000 stock options, respectively, and members of such committees receive 3,000, 2,000 and 1,000 stock options, respectively.

Non-employee and non-consultant directors also receive an annual cash fee of \$15,000 as well as cash compensation for serving on board committees. Chairpersons of each of the Audit Committee, Compensation Committee and Corporate Governance/Nominating Committee receive \$10,000, \$7,000 and \$4,000, respectively, and members of such committees receive \$6,000, \$4,000 and \$2,500, respectively.

AUDIT COMMITTEE

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

The Audit Committee currently consists of John Brancaccio, chairman of the Audit Committee, Christoph Bruening and Randall Johnson. Our board of directors has determined that each of Mr. Bruening, Mr. Johnson and Mr. Brancaccio is "independent" as that term is defined under applicable SEC rules and under the current listing standards of NASDAQ. Mr. Brancaccio is our audit committee financial expert. The Board of Directors has adopted a written charter setting forth the authority and responsibilities of the Audit Committee. A copy of this charter is available at our web site www.callistopharma.com.

COMPENSATION COMMITTEE

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

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

Compensation Committee Interlocks and Insider Participation

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

Table of Contents

CORPORATE GOVERNANCE/NOMINATING COMMITTEE

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

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

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 2009, 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.

Table of Contents**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 2009.

Name & Principal Position	Year	Salary	Bonus	Option Awards(1)	Total
Gabriele M Cerrone(2)	2009	\$ 278,521	\$	\$	\$ 278,521
Chairman of the Board	2008	291,187		697,625	988,812
	2007	252,083	84,147	21,239	357,469
Gary S. Jacob	2009	285,000			285,000
Chief Executive Officer and	2008	293,750		710,327	1,004,077
Chief Scientific Officer	2007	300,000	78,750	109,323	488,073
Bernard F. Denoyer	2009	176,249			176,249
Senior Vice President, Finance	2008	170,874		76,660	247,534
and Principal Financial Officer	2007	123,500	12,000	29,862	165,362

- (1) Amounts represent Callisto and Synergy aggregate grant date fair value in accordance with FASB ASC Topic 718 as discussed in Item 8. *Share-Based Payments* to our Consolidated Financial Statements included elsewhere in this report.
- (2) Mr. Cerrone is being paid pursuant to a consulting agreement with us.

Table of Contents**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, 2009.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options	Option Exercise Price	Option Expiration Date
Gary S. Jacob	500,000		\$ 1.50	June 13, 2013
	112,500	162,500(1)	3.00	June 29, 2014
	200,000		1.01	July 6, 2015
	50,000		1.64	March 17, 2016
	75,000		0.81	February 16, 2017
Bernard F. Denoyer	100,000		3.60	January 15, 2014
	50,000		1.38	July 29, 2015
	75,000	25,000(2)	0.66	April 12, 2017
Gabriele M Cerrone	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.

(2) 25,000 options vest on April 12, 2010.

DIRECTOR COMPENSATION

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2009 for services to our company.

Name	Fees Paid In Cash	Option Awards(1)	Total
John P. Brancaccio(2)	\$ 29,125	\$ 123,442	\$ 152,567
Randall Johnson(3)	\$ 7,000	\$ 1,884	\$ 8,884
Riccardo Dalla-Favera(4)	\$	\$ 904	\$ 904
Christoph Bruening(5)	\$	\$ 1,357	\$ 1,357

(1) Amounts represent Callisto and Synergy aggregate grant date fair value for fiscal year 2009 of stock options granted in 2009 under ASC Topic 718 as discussed in Note 6 *Share-Based Payments* to our Consolidated Financial Statements included elsewhere in this report.

(2) Stock options for the purchase of an aggregate of 162,123 Callisto shares were outstanding as of December 31, 2009, of which 150,123 were exercisable

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

- (3) Stock options for the purchase of an aggregate of 140,500 Callisto shares were outstanding as of December 31, 2009 , of which 128,500 were exercisable
- (4) Stock options for the purchase of an aggregate of 107,000 Callisto shares were outstanding as of December 31, 2009 , of which 95,000 were exercisable
- (5) Stock options for the purchase of an aggregate of 254,000 Callisto shares were outstanding as of December 31, 2009, of which 142,000 were exercisable

Table of Contents

EMPLOYMENT AGREEMENTS AND CHANGE IN CONTROL AGREEMENTS

On March 11, 2009, Dr. Gary Jacob entered into an amended and restated employment agreement with us in which he agreed to serve as Chief Executive Officer. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2011 and is automatically renewed for successive one year periods at the end of each term. Dr. Jacob's salary is \$300,000 per year of which 25% is to be allocated to Callisto and 75% is to be allocated to our majority owned subsidiary, Synergy, where Dr. Jacob serves as President and Acting Chief Executive Officer. Dr. Jacob is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Dr. Jacob is also eligible to receive a realization bonus in the event that we enter into an out-license agreement for our technology or engage in a merger or sale of substantially all our assets where the enterprise value equals or exceeds a minimum of \$150 million, \$200 million and \$250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, or the license fees we contract to receive equals or exceeds \$50 million. The realization bonus will be equal to the enterprise value in the case of a merger or sale or the sum of the license fees actually received multiplied by 0.5%.

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

Had a "Change of Control" occurred on December 31, 2009 and the executive had been terminated on that date, Dr. Jacob would have been eligible for total compensation (salary and bonus) for the term of his employment under his employment agreement for the time remaining of such employment term of \$900,000.

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. Compensation Dr. Jacob receives under his amended and restated employment agreement with Synergy is mutually exclusive with his Callisto agreement and total base salary from both agreements is capped at \$300,000 per annum and bonus potential capped at 50% or \$150,000.

We are party to an employment agreement with Bernard Denoyer, dated January 15, 2004, as amended September 1, 2006, to serve as our Vice President, Finance. On December 10, 2007 we entered into an amended and restated employment agreement with Bernard Denoyer pursuant to which Mr. Denoyer serves as our Senior Vice President, Finance and Secretary. Mr. Denoyer's amended and restated employment agreement is for a term of 12 months beginning December 1, 2007 and is automatically renewable for successive one year periods at the end of the term. Mr. Denoyer's base salary was \$162,000 per year and he may earn a performance bonus of 15% of his base salary per year at the discretion of the Compensation Committee of the Board of Directors. Effective July 14, 2008, upon Synergy becoming a publicly traded company, Mr. Denoyer's base salary was increased to \$190,000 per annum. Mr. Denoyer also serves as Senior Vice President, Finance for Synergy. On January 25, 2010, our Compensation Committee approved a grant of stock options to Mr. Denoyer to

Table of Contents

purchase 75,000 shares of our common stock pursuant to the Plan at an exercise price equal to \$0.26 per share which vest equally over a period of three years.

CONSULTING AGREEMENTS

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

If the consulting agreement is terminated by us other than for cause or as a result of Mr. Cerrone's death or permanent disability or if Mr. Cerrone terminates the agreement for good reason which includes a change of control, Mr. Cerrone shall receive (i) a severance payment equal to the higher of the aggregate amount of his base compensation for the then remaining term of the agreement or twelve times the average monthly base compensation paid or accrued during the three full calendar months preceding the termination, (ii) expense compensation in an amount equal to twelve times the sum of his average base compensation during the three full months preceding the termination, (iii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iv) payment in respect of compensation earned but not yet paid and (v) payment of the cost of medical insurance for a period of twelve months following termination. Had Mr. Cerrone been terminated without cause or good reason on December 31, 2009, he would have been eligible for total compensation of \$885,000 for the time remaining under the amended and restated consulting agreement.

On February 1, 2010, Mr. Cerrone, entered into an amended and restated consulting agreement with Synergy extending the term of the agreement which was effective as of August 1, 2008 by one year until December 31, 2012. Compensation Mr. Cerrone receives under his amended and restated consulting agreement with Synergy is mutually exclusive with his Callisto agreement and total compensation from both agreements is capped at a combined base compensation of \$295,000 per annum and bonus potential of 50% or \$147,500.

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

On February 26, 2006 we entered into a consulting agreement with Dr. Arthur Sytkowski to be our medical monitor for clinical trials. Under the agreement Dr. Sytkowski is paid \$250 per hour and reimbursed for expenses. The term of the agreement is twelve months, is automatically renewable for

Table of Contents

successive one year periods at the end of the term and can be terminated by him or us with 90 days advance notice.

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

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

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 3,445,483 options outstanding as of December 31, 2009 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 3,468,000 options available for future grants as of December 31, 2009.

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 807,000 option shares available for future grants as of December 31, 2009.

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

Table of Contents

stockholder value. Generally, vesting for options granted under the stock option plan is determined at the time of grant, and options expire after a 10-year period. Options are generally granted at an exercise price not less than the fair market value at the date of grant. As a result of this policy, directors, executives, employees and consultants are rewarded economically only to the extent that the stockholders also benefit through appreciation in the market. Options granted to employees are based on such factors as individual initiative, achievement and performance. In administering grants to executives, the Compensation Committee of the Board of Directors evaluates each executive's total equity compensation package. The compensation committee generally reviews the option holdings of each of the executive officers, including vesting and exercise price and the then current value of such unvested options. We consider equity compensation to be an integral part of a competitive executive compensation package and an important mechanism to align the interests of management with those of our stockholders.

The options we grant under the 2005 Equity Plan may be either "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), or non-statutory stock options at the discretion of the Board of Directors and as reflected in the terms of the written option agreement. None of our stock option plans are qualified deferred compensation plans under Section 401(a) of the Code, and are not subject to the provisions of the Employee Retirement Income Security Act of 1974, as amended (ERISA). As of December 31, 2009, 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, 2009 there were 4,214,016 stock options outstanding under the Synergy Plan and 2,285,984 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.

Table of Contents**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, 2010 by (i) each person known to beneficially own more than 5% of the outstanding common stock, (ii) each of our directors, (iii) the Named Executive Officers and (iv) all directors and executive officers as a group. Except as otherwise indicated, the persons named in the table have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable. Unless otherwise indicated, the address of each beneficial owner listed below is c/o Callisto Pharmaceuticals, Inc., 420 Lexington Avenue, Suite 1609, New York, N.Y. 10170.

Name and Address of Beneficial Owner	Shares of Common Stock Beneficially Owned(1)	
	Number of Shares	Percentage and Class
Gabriele M. Cerrone Chairman of the Board	3,509,825(2)	6.3%
Gary S. Jacob Chief Executive Officer, Chief Scientific Officer and Director	1,324,745(3)	2.4%
Bernard Denoyer Senior Vice President, Finance and Secretary	250,000(4)	*
Riccardo Dalla-Favera Director	95,000(5)	*
Christoph Bruening Director	517,699(6)	1.0%
John Brancaccio Director	150,123(7)	*
Randall K. Johnson Director	128,500(8)	*
All Directors and Executive Officers as a group (7 persons)	5,975,892(9)	10.4%

*
less than 1%

(1) Applicable percentage ownership as of March 31, 2010 is based upon 54,027,778 shares of common stock outstanding.

(2) Includes 1,308,055 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone and 30,000 shares of common stock issuable upon exercise of warrants, held by Panetta Partners, Ltd. Mr. Cerrone is the sole managing partner of Panetta and in such capacity only exercises voting and dispositive control over securities owned by Panetta, despite him having only a small pecuniary interest in such securities.

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

(4) Consists of 250,000 shares of common stock issuable upon exercise of stock options.

(5) Consists of 95,000 shares of common stock issuable upon exercise of stock options.

(6) Includes 142,000 shares of common stock issuable upon exercise of stock options.

(7) Consists of 150,123 shares of common stock issuable upon exercise of stock options.

Table of Contents

- (8) Consists of 128,500 shares of common stock issuable upon exercise of stock options.
- (9) Includes 3,261,178 shares of common stock issuable upon exercise of stock options and 30,000 shares of common stock issuable upon exercise of the warrants.

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

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

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

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

CONFLICTS OF INTEREST

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

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

Table of Contents

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

AUDIT FEES

The aggregate fees billed and unbilled for the fiscal years ended December 31, 2009 and December 31, 2008, for professional services rendered by our principal accountants for the audits of our annual financial statements, the review of our financial statements included in our quarterly reports on Form 10-Q and consultations and consents were approximately \$275,000 and \$297,926, respectively.

AUDIT-RELATED FEES

There were no aggregate fees billed for the fiscal years ended December 31, 2009 and 2008 for assurance and related services rendered by our principal accountants related to the performance of the audit or review of our financial statements, specifically accounting research.

TAX AND OTHER FEES

The aggregate fees billed and unbilled for the fiscal years ended December 31, 2009 and 2008 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.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(1)

Index to Financial Statement Schedules:

<u>Index to Consolidated Financial Statements</u>	<u>F-1</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
<u>Consolidated Balance Sheets as of December 31, 2009 and 2008</u>	<u>F-3</u>
<u>Consolidated Statement of Operations for each of the three years ended December 31, 2009, 2008 and 2007 and for the period June 5, 1996 (inception) to December 31, 2009</u>	<u>F-4</u>
<u>Consolidated Statement of Changes in Stockholder's Equity (Deficit) for the period June 5, 1996 (inception) to December 31, 2009</u>	<u>F-5</u>
<u>Consolidated Statements of Cash Flows for each of the three years ended December 31, 2009, 2008 and 2007 and for the period June 5, 1996 (inception) to December 31, 2009</u>	<u>F-12</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F-13</u>

(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.

Table of Contents

(3)

*Index to Exhibits***Exhibit Index**

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

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)*

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

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).
10.17	Form of Secured Promissory Note (incorporated by reference to Exhibit 10.17 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 Seidman, LLP
31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Table of Contents

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

Index to the Consolidated Financial Statements

<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
<u>Consolidated Balance Sheets as of December 31, 2009 and 2008</u>	<u>F-3</u>
<u>Consolidated Statements of Operations for the three years ended December 31, 2009, 2008 and 2007 and June 5, 1996 (inception) to December 31, 2009</u>	<u>F-4</u>
<u>Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period June 5, 1996 (Inception) to December 31, 2009</u>	<u>F-5</u>
<u>Consolidated Statements of Cash Flows for the three years ended December 31, 2008, 2007 and 2006 and for the period June 5, 1996 (Inception) to December 31, 2009</u>	<u>F-12</u>
<u>Notes to the Consolidated Financial Statements</u>	<u>F-13</u>

F-1

Table of Contents

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, 2009 and 2008, the related consolidated statements of operations and cash flows for each of the three years in the period ended December 31, 2009 and for the period from June 5, 1996 (inception) to December 31, 2009 and the related consolidated statement of stockholders' equity (deficit) for the period from June 5, 1996 (inception) to December 31, 2009. 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, 2009 and 2008, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009 and for the period from June 5, 1996 (inception) to December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 3 to the consolidated financial statements, effective January 1, 2009, the Company has changed its method of accounting for non-controlling interest with the adoption of the guidance originally issued is FAS 160, *"Noncontrolling Interests in Consolidated Financial Statements"* (codified in FASB ASC Topic 810, Consolidation) and has changed its method of accounting for the warrants due to the adoption of EITF 07-05, *"Determining Whether an Instrument (or embedded Feature) is Indexed to an Entity's Own Stock"* (codified in FASB ASC Topic 815, Derivatives and Hedging).

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

/s/ BDO SEIDMAN, LLP

BDO Seidman, LLP

New York, New York
March 31, 2010

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2009	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 7,207,612	\$ 301,323
Cash in escrow		201,908
Prepaid expenses and other	1,061,630	59,756
 Total Current Assets	 8,269,242	 562,987
Property and equipment, net	14,665	20,649
Security deposits	87,740	78,116
 Total Assets	 \$ 8,371,647	 \$ 661,752
 LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	\$ 3,079,798	\$ 3,687,549
Accrued expenses	727,679	1,136,264
 Total Current Liabilities	 3,807,477	 4,823,813
Notes Payable	487,130	20,176
Derivative financial instruments, at estimated fair value warrants	11,870,369	
Commitments and contingencies		
Stockholders' Deficit:		
Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized, 63,000 and 98,000 shares outstanding at December 31, 2009 and December 31, 2008, respectively	6	10
Series B convertible preferred stock, par value \$0.0001, 2,500,000 shares authorized, 1,014,166 and 1,137,050 shares outstanding at December 31, 2009 and December 31, 2008, respectively	102	114
Common stock, par value of \$.0001 per share: 225,000,000 shares authorized; 53,608,111 and 49,556,661 shares outstanding at December 31, 2009 and December 31, 2008, respectively	5,359	4,955
Additional paid-in capital	105,263,377	86,799,951
Deficit accumulated during development stage	(109,779,780)	(90,987,267)
 Total Callisto Stockholders' Deficit	 (4,510,936)	 (4,182,237)
Non-controlling interest	(3,282,393)	
 Total Deficit	 (7,793,329)	 (4,182,237)
 Total Liabilities and Stockholders' Deficit	 \$ 8,371,647	 \$ 661,752

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

Table of Contents

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, 2009
	2009	2008	2007	
Revenues	\$	\$	\$	\$
Costs and Expenses:				
Research and development	3,936,474	5,449,721	6,507,978	38,034,738
Government grants		(30,000)	(260,853)	(1,135,318)
Purchased in-process research and development				6,944,553
General and administrative	4,593,511	4,311,767	4,317,288	43,572,117
Loss from Operations	(8,529,985)	(9,731,488)	(10,564,413)	(87,416,090)
Interest and investment income	25,008	76,017	84,694	889,335
Other income/(expense), net	(436,693)		1,449	(608,539)
Change in fair value of Series B Preferred investor warrants from date of issuance to expiration of put option	(9,413,744)		2,591,005	(6,822,739)
Net Loss	(18,355,414)	(9,655,471)	(7,887,265)	(93,958,033)
Net Loss attributable to noncontrolling interest	3,282,393			3,282,393
Net loss attributable to controlling interest	(15,073,021)	(9,655,471)	(7,887,265)	(90,675,640)
Series A Preferred stock beneficial conversion feature accreted as a dividend			(2,504,475)	(4,888,960)
Series B Preferred stock beneficial conversion feature accreted as a dividend			(10,495,688)	(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)
Cumulative effect of adopting ASC Topic 815 January 1, 2009				(1,903,900)
Net loss attributable to common stockholders	\$ (16,888,613)	\$ (9,655,471)	\$ (20,887,428)	\$ (109,779,780)
<i>Weighted Average Common Shares Outstanding</i>				
Basic and Diluted	51,394,669	47,357,254	41,770,669	
<i>Net Loss per Common Share</i>				
Basic and Diluted	\$ (0.33)	\$ (0.20)	\$ (0.50)	

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

Table of Contents**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.

Table of Contents

	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.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

	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.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

	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.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

	Series A Convertible Preferred Stock, Preferred Shares		Common Stock, Par Value	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.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

	Series A Convertible		Series B Convertible		Common Shares	Common Stock, Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
	Series A Convertible Preferred Shares	Preferred Stock, Par Value	Series B Convertible Preferred Shares	Preferred Stock, Par Value					
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.

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

	Series A Convertible Preferred Shares	Series A Non-convertible Preferred Stock	Series B Convertible Preferred Shares	Series B Non-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)

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,			Period from
	2009	2008	2007	June 5, 1996 (Inception) to December 31, 2009
Cash Flows From Operating Activities:				
Net loss	\$ (18,355,414)	\$ (9,655,471)	\$ (7,887,265)	\$ (93,958,033)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	5,983	6,654	3,142	102,568
Stock-based compensation expense	1,119,856	589,063	628,361	18,854,725
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	436,693			436,693
Stock-based liquidated damages				579,696
Change in fair value of Series B preferred warrants from date of issuance to expiration of put options	9,413,744		(2,591,005)	6,822,739
Net liabilities assumed in excess of assets acquired		(42,824)		(282,752)
Changes in operating assets and liabilities:				
Prepaid expenses	(1,001,874)	29,064	(22,079)	(1,061,630)
Security deposit	(9,624)	(4,400)		(87,740)
Accounts payable and accrued expenses	(1,016,336)	202,489	1,420,303	3,754,977
Total Adjustments	8,948,442	753,096	(561,278)	35,933,379
Net Cash Used in Operating Activities	(9,406,972)	(8,902,375)	(8,448,543)	(58,024,654)
Cash Flows From Investing Activities:				
Short-term investments purchased			(5,921,825)	(5,921,825)
Short-term investments liquidated		2,994,640	2,954,135	5,948,775
Additions to property and equipment		(12,196)	(11,798)	(117,233)
Net Cash Provided by (Used in) Investing Activities		2,982,444	(2,979,488)	(90,283)
Cash Flows From Financing Activities:				
Issuance of common and preferred stock			11,750,500	48,719,673
Finders fees and expenses	(260,002)		(957,360)	(3,241,085)
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	15,970,100	2,951,913		18,922,013
Exercise of common stock warrants				318,785
Net Cash Provided by Financing Activities	16,313,261	2,951,913	10,793,140	65,322,549
Net (decrease) increase in cash and cash equivalents	6,906,289	(2,968,018)	(634,891)	7,207,612
Cash and cash equivalents at beginning of period	301,323	3,269,341	3,904,232	
Cash and cash equivalents at end of period	\$ 7,207,612	\$ 301,323	\$ 3,269,341	\$ 7,207,612
Supplementary disclosure of cash flow information:				
Cash paid for taxes	\$ 59,704	\$ 33,370	\$ 4,868	\$ 221,429
Supplementary disclosure of non-cash investing and financing activities:				
Series A Preferred stock beneficial conversion feature accreted as a dividend	\$	\$	\$ 2,504,475	\$ 4,888,960
Series B Preferred stock beneficial conversion feature accreted as a dividend	\$	\$	\$ 10,495,688	\$ 10,495,688
Issuance of 11% Notes payable, cash held on escrow	\$	\$ 201,908	\$	\$ 201,908

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Business overview

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

From inception through December 31, 2009, Callisto has sustained cumulative net losses attributable to common stockholders of \$109,779,780. 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, 2009 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.

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

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

Table of Contents

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

2. Basis of presentation and going concern

All intercompany balances and transactions have been eliminated. These consolidated financial statements include Callisto and subsidiaries: (1) Callisto Research Labs, LLC (including its wholly-owned subsidiary, Callisto Pharma, GmbH (Germany inactive)), and (2) Synergy (including Synergy's wholly-owned subsidiaries, Synergy-DE, Synergy Advanced Pharmaceuticals, Inc. and IgX, Ltd (Ireland inactive)). These consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission ("SEC") and United States generally accepted accounting principles ("GAAP").

As of December 31, 2009, Callisto had an accumulated deficit during development stage of \$109,779,780. Callisto expects to incur significant and increasing operating losses for the next several years as Callisto expands its research and development, continues clinical trials of SP-304 for the treatment of GI disorders, acquires or licenses technologies, advances other product candidates into clinical development, seeks regulatory approval and, if FDA approval is received, commercializes products. Because of the numerous risks and uncertainties associated with product development efforts, Callisto is unable to predict the extent of any future losses or when Callisto will become profitable, if at all.

Net cash used in operating activities was \$9,406,972, \$8,902,375 and \$8,448,543 for the twelve months ended December 31, 2009, 2008 and 2007, respectively, and \$58,024,654 for the period from June 5, 1996 (inception) to December 31, 2009. As of December 31, 2009 and 2008, Callisto had \$7,207,612 and \$301,323 respectively, of cash and cash equivalents.

During the twelve months ended December 31, 2009, 2008 and 2007, Callisto incurred net losses from operations of \$8,529,985, \$9,731,488 and \$10,564,413, respectively and \$87,416,090 for the period June 5, 1996 (inception) to December 31, 2009. 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, 2009, 2008 and 2007 was \$16,313,261, \$2,951,913 and \$10,793,140, respectively, and \$65,322,549 for the period June 5, 1996 (inception) to December 31, 2009. As of December 31, 2009 Callisto had a working capital of \$4,461,765.

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

Table of Contents

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.

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.

Fair Value of Financial Instruments

Financial instruments consist of cash and accounts payable. These financial instruments are stated at their respective historical carrying amounts which approximate fair value due to their short term nature. The fair value of the notes payable approximates their carrying amounts. Financial instruments also include certain of the Company's warrants which were required to be accounted for as derivative liabilities under ASC Topic 815-40 and are recorded at fair value. (See Note 5)

Property and Equipment

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

Income Taxes

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

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

Table of Contents

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. For a discussion of contingencies, see Note 8. *Commitments and Contingencies* below.

Business Concentrations and Credit Risks

All of Callisto's cash and cash equivalents as of December 31, 2009 and 2008 are on deposit with commercial financial institution. Deposits at any point in time may exceed federally insured limits.

Research and Development

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

In accordance with FASB ASC Topic 730-10-55, *Research and Development*, Synergy recorded prepaid research and development expense of \$1 million for nonrefundable deposits on production of drug substance of its drug candidate SP-304 by two of its vendors. In accordance with this guidance, Synergy expenses these advance payments when drug compound is delivered.

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. Diluted weighted-average shares are the same as basic weighted-average shares because shares issuable pursuant to the exercise of stock options would have been antidilutive. (See Note 9)

Government Grants

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

On April 1, 2005 Callisto was awarded an \$885,641 biodefense partnership grant from the National Institute of Allergy and Infectious Diseases ("NIAID") to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over a two year period. Callisto receives cash funding under approved grants and records the receipt as an offset to research and development expense only when the expense is incurred. Funds received as an offset to research and development expenses incurred totaled \$0, \$30,000 and \$260,853 during the twelve months ended December 31, 2009, 2008 and 2007, respectively and has been reported on our Consolidated Statements of Operations as a separate line

Table of Contents

item entitled "Government Grants". Funding for this program was extended one year through April 2008. Because the bioterrorism program is not a core activity, Callisto terminated in-house work on this program upon expiration of the research grant in April 2008.

Recent Accounting Pronouncements

In August 2009, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2009-05, "Measuring Liabilities at Fair Value" ("ASU 2009-05"). ASU 2009-05 amends ASC Topic 820 and clarifies that, where a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: 1) a valuation technique that uses a) the quoted price of the identical liability when traded as an asset or b) quoted prices for similar liabilities or similar liabilities when traded as assets and/or 2) a valuation technique that is consistent with the principles of ASC Topic 820. ASU 2009-05 also clarifies that, when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability. The adoption of ASU 2009-05 did not have a material impact on the Company's financial statements.

In June 2009, FASB issued Accounting Standards Update No. 2009-01, "Generally Accepted Accounting Principles" (ASC Topic 105), by the Codification which establishes the FASB Accounting Standards Codification (the "Codification" or "ASC") as the single source of authoritative GAAP. All existing accounting standards in effect prior to the Codification were superseded. All other accounting guidance not included in the Codification will be considered non-authoritative. The Codification also includes all relevant SEC guidance organized using the same topical structure in separate sections within the Codification. The Codification does not change GAAP and did not impact the Company's financial statements. All references to authoritative accounting literature (including references related to period's prior to the establishment of the Codification) have been referenced in accordance with the Codification.

In May 2009, the FASB issued guidance within ASC Topic 855, *Subsequent Events*, amended by ASU 2010-09 relating to subsequent events. This guidance establishes principles and requirements for subsequent events. This guidance defines the period after the balance sheet date during which events or transactions that may occur would be required to be disclosed in a company's financial statements. Public entities are required to evaluate subsequent events through the date that financial statements are issued. This guidance also provides guidelines for evaluating whether or not events or transactions occurring after the balance sheet date should be recognized in the financial statements. Accordingly, management has evaluated subsequent events through the date the financial statements are issued.

In June 2008, the FASB ratified the consensus reached on guidance within ASC Topic 815., *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* ("ASC Topic 815"). This guidance clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under ASC Topic 815, *Accounting for Derivative Instruments and Hedging Activities*. ASC Topic 815 was effective for financial statements issued for fiscal years beginning after December 15, 2008. Adoption of this statement did have a material effect on the Company's consolidated financial position, results of operations or cashflows. 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.

In February 2008, the FASB issued ASC Topic 820, *Partial Deferral of the Effective Date of Statement 157*, ("ASC Topic 820"). This guidance delays the effective date of *Fair Value Measurements* ("ASC Topic 820") for all nonfinancial assets and nonfinancial liabilities, except those that are

Table of Contents

recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually) to fiscal years beginning after November 15, 2008. Adoption of this statement did not have a material effect on the Company's consolidated financial position, results of operations or cashflows.

In December 2007, the FASB issued ASC Topic 810, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ASC Topic 860* ("ASC Topic 810"). This guidance requires all entities to report noncontrolling (minority) interests in subsidiaries as equity in the consolidated financial statements. Its intention is to eliminate the diversity in practice regarding the accounting for transactions between an entity and noncontrolling interests. This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Adoption of this statement did not have a material effect on the Company's consolidated financial position, statement of operations or cash flows.

In December 2007, the FASB ratified ASC Topic 808, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, ("ASC Topic 808"), which provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure requirements. ASC Topic 808 was effective for fiscal years beginning after December 15, 2008. Adoption of this statement did not have a material effect on the Company's consolidated financial position, results of operations or cashflow.

4. Merger and consolidation

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

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

The merged companies are considered to be in the development stage. No revenues have been realized since inception and all activities have been concentrated in research and development of biopharmaceutical products not yet approved by the Food and Drug Administration. The fair value of the net shares issued to former Synergy shareholders in the Merger totaled \$6,335,799 through December 31, 2005. The fair value per share of \$1.50, used to determine this amount, was the value per share Callisto sold common stock in a private placement. The total consideration was allocated in

Table of Contents

full to the Synergy research and development projects which had not yet reached technological feasibility and having no alternative use was charged to purchased in-process research and development expense during the year ended December 31, 2003.

5. 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.

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 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 within other income (expense) 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.

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

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

Table of Contents

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	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	69,086,174	\$ 11,870,369

6. Fair Value Measurements

The unrealized losses on the derivative liabilities are classified in other income or (expenses) 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.

Table of Contents

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:

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
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 nine months ended December 31, 2009:

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
Derivative liabilities related to Warrants	\$	\$ 2,085,632	\$ 370,993	\$ 9,413,744	\$ 11,870,369

(1) Included in Other Income/Expense

7. Stockholders' equity (deficit)

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. The Company has determined that the fair value of the derivatives is immaterial. As of December 31, 2009 Callisto owns 50.4% of Synergy's outstanding shares.

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, 2009, 35,000 shares of Series A Convertible Preferred Stock were converted to 894,445 shares of common stock and 122,884 shares of Series B Convertible Preferred Stock were converted to 2,963,236 shares of common stock.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

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 (see Note 6) ("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 recorded as additional paid in capital and the balance of \$20,176 was reflected on the Company's balance sheet as long term notes as of December 31, 2008. The debt discount of \$552,728 will be accreted to the 11% Notes as interest expense over the life of the 11% Notes.

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, 2009:

	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

Table of Contents

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

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

On January 31, 2008, the Board of Directors approved a reassignment, as well as, a decrease in the exercise price, of the 1,323,822 warrants, previously assigned from Trilogy Capital Partners LLC to two unaffiliated entities, from \$1.03 per share to \$0.70 per share. The decrease in the exercise price was effective immediately and the reassignment will be effective at management's discretion. Callisto has determined that the price modifications was compensatory in accordance with 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, 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

Table of Contents

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 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.

Table of Contents

Material terms of the Series B Preferred Stock are:

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

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

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

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

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

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

Table of Contents

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 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

Table of Contents

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".

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.

Table of Contents

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

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

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

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

Table of Contents

\$41,000 were paid on this second closing and three year warrants to purchase a total of 66,667 common shares at a per share price of \$1.25 were issued to certain selling agents.

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

As provided for by 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.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

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

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

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

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

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

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

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

As of December 31, 2009 and 2008 Callisto had 84,842,576 and 55,773,331 warrants outstanding to investors, selling agents and advisors with a weighted average exercise price of \$0.15 and \$0.43 per share, of which 84,842,576 and 55,773,331 warrants were fully vested with an average exercise price of \$0.15 and \$0.43 per share, respectively.

Table of Contents

8. 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 3,554,483 options outstanding as of December 31, 2009 under the Plan is ten years from date of grant. The Plan terminated on January 1, 2006 under its original terms and no further options will be granted under the Plan.

On October 20, 2005, Callisto stockholders approved the 2005 Equity Compensation Incentive Plan. The maximum number of shares of common stock with respect to which awards may be granted under the 2005 Equity Plan is 5,000,000. The option term for options granted under the 2005 Equity Plan is ten years from date of grant and there were 3,468,000 options available for future grants as of December 31, 2009.

On October 20, 2005, Callisto stockholders approved our 2005 Directors' Stock Option Plan. The maximum number of shares of common stock with respect to which awards may be granted under the 2005 Directors' Plan is 1,000,000. The option term for options granted under the 2005 Directors' Plan is ten years from date of grant and there are 830,000 option shares available for future grants as of December 31, 2009.

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, 2009, 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* ("ACS 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 was effective as of January 1, 2006.

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 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

Table of Contents

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
	2009	2008	2007	June 5, 1996 (Inception) to December 31, 2009
Employees included in research and development	\$ 24,927	\$ 40,608	\$ 68,734	\$ 2,686,812
Employees included in general and administrative	46,754	162,262	321,350	4,796,707
Subtotal employee stock option grants	71,681	202,870	390,084	7,483,519
Non-employee included in research and development		(17,314)	17,314	102,750
Non-employee included in general and administrative	(6,387)	23,624	220,963	9,834,011
Subtotal non-employee stock option grants	(6,387)	6,310	238,277	9,936,761
Total stock-based compensation expense	\$ 65,294	\$ 209,180	\$ 628,361	\$ 17,420,281

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, 2009, 2008 and 2007.

	Year End December 31,		
	2009	2008	2007
Risk-free interest rate	2.69%	1.55%	3.55%
Expected volatility	100%	200%	60%
Expected term (in years)	5.0 yrs	5.0 yrs	5.0 yrs

Risk-free interest rate Based upon observed 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.

Expected volatility Based on the historical volatility of Callisto's stock.

Expected term Callisto has had no stock options exercised since inception. The expected option term represents the period that stock-based awards are expected to be outstanding based on the simplified method provided in Staff ASC Topic 980, *Share-Based Payment*, ("ASC Topic 980") 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.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

In December 2007, the SEC issued ASC Topic 225, *Share-Based Payment*, ("ASC Topic 225"). 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 Topic 980, in developing an estimate of the expected term of "plain vanilla" share options in accordance with ASC Topic 715. 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 ASC Topic 225, as amended ASC Topic 225. 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 ASC Topic 980.

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, 2009, 2008 and 2007, estimated as of the grant date using the Black-Scholes option valuation model, was \$0.15, \$0.04, and \$0.42 per share, respectively.

The unrecognized compensation cost related to Callisto's non-vested employee stock options outstanding at December 31, 2009 and 2008 was \$12,781 and \$83,455, respectively, to be recognized over a weighted-average vesting period of approximately 3 months and 1 year, respectively. The weighted-average remaining term of all options outstanding at December 31, 2009 was 4.4 years as compared to 5.1 years at December 31, 2008.

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

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Balance outstanding, December 31, 2007	8,241,207	\$ 0.47 - 6.75	\$ 1.70	\$
Granted	41,500	0.08	0.08	
Exercised				
Forfeited	(344,169)	0.47 - 1.45	0.85	
Balance outstanding, December 31, 2008	7,938,538	0.47 - 6.75	1.72	
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	\$ 0.20 - 4.90	\$ 1.70	\$
Exercisable, December 31, 2009	7,453,538	\$ 0.20 - 4.90	\$ 1.70	\$

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 Pharmaceuticals, Inc. 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

Table of Contents

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.

Synergy Stock Option Accounting

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

	Years Ended December 31,			November 15, 2005
	2009	2008	2007	(inception) to December 31, 2009
Employees included in research and development	\$ 252,541	\$ 79,530	\$	\$ 332,071
Employees included in general and administrative	358,167	112,728		470,895
Subtotal employee stock based compensation	610,708	192,258		802,966
Non-employees included in research and development	33,913	8,548		42,461
Non-employees included in general and administrative	409,941	179,077		589,018
Subtotal non-employee stock based compensation	443,854	187,625		631,479
Total stock-based compensation expense	\$ 1,054,562	\$ 379,883	\$	\$ 1,434,445

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the year ended December 31, 2009. The unrecognized compensation cost related to non-vested employee stock options and restricted stock awards outstanding at December 31, 2009, net of expected forfeitures, was \$1,010,250 to be recognized over a weighted-average remaining vesting period of approximately one year.

	Years Ended December 31,		
	2009	2008	2007
Risk-free interest rate	2.20%	2.67% - 3.28%	N/A
Dividend yield			N/A
Expected volatility	90%	90%	N/A
Expected term (in years)	6.0 yrs	6.0 yrs	N/A

F-34

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

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

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

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

Expected term Synergy has had no stock options exercised since inception. The expected option term represents the period that stock-based awards are expected to be outstanding based on the simplified method provided in ASC Topic 980, *Share-Based Payment* ("ASC Topic 980"), which averages an award's weighted-average vesting period and expected term for "plain vanilla" share options. Under This guidance, 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. 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, 2009 and December 31, 2008 estimated as of the grant date using the Black-Scholes option valuation model was \$0.70 and \$0.51 per share.

The unrecognized compensation cost related to non-vested employee stock options outstanding at December 31, 2009 and December 31, 2008 was \$1,010,250 and \$1,290,122, to be recognized over a weighted-average remaining vesting period of approximately 1.3 year and 2.5 years. There were no options outstanding at December 31, 2007.

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

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value as of December 31, 2009
Balance outstanding, December 31, 2008	4,080,016	\$ 025-0.95	\$ 0.29	\$ 8,933,935
Granted	149,000	\$ 0.70	\$ 0.70	
Exercised				
Forfeited	(15,000)	\$ 0.25-0.95	\$ 0.72	
Balance outstanding, December 31, 2009	4,214,016	\$ 0.25 - 0.95	\$ 0.30	\$ 22,320,436
Exercisable at December 31, 2009	1,417,420	\$ 0.25 - 0.95	\$ 0.29	\$ 7,521,947

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.

Table of Contents

Synergy Restricted Stock Units

Restricted Stock Units, which entitle the holder to receive, at the end of a vesting term, a specified number of shares of Synergy common stock are accounted for as stock based compensation in accordance with ASC Topic 715 in the same manner as stock options using fair value at the date of grant. Subject to a repurchase agreement assumed by Synergy pursuant to the Exchange Transaction, 50% of the units vest after 1 year of continuous service and the remaining 50% vest after 2 years of continuous service from the grant date. The total fair value is being expensed ratably by month over the 2 year service period.

On July 3, 2008, 874,760 restricted stock units were granted by Synergy-DE and assumed by Synergy as part of the Exchange Transaction and are subject to a repurchase agreement, as defined. These restricted stock units were issued to certain officers and a consultant of Synergy. The fair value of each Synergy restricted stock unit is estimated on the grant date based on the price paid by shareholders participating in Synergy's July 14, 2008 private placement. Accordingly, the weighted-average grant date fair value per share of the 874,760 shares of Synergy common stock issued during the twelve months ended December 31, 2008 was determined to be \$0.60. As of December 31, 2009 there were 874,760 restricted stock units outstanding, included in shares outstanding. The fair value of the 874,760 restricted stock units on the date of grant was \$524,856 of which \$361,104 was recorded as stock-based compensation expense during the twelve months ended December 31, 2009. The intrinsic value of the 437,380 shares which vested during the twelve months ended December 31, 2009 was \$2,449,328.

9. Income taxes

At December 31, 2009, Callisto has net operating loss carryforwards ("NOLs") aggregating approximately \$81 million, which, if not used, begin expiring 2012 through 2029. 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 an ownership change had occurred as of April 30, 2003 and Callisto believes that such change in ownership to date will restrict its ability to use pre-merger Synergy NOLs within the carryforward period. The Company has no other material deferred tax items.

Callisto records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Due to the significant doubt related to Callisto's ability to continue as a going concern and utilize its deferred tax assets, a valuation allowance for the full amount of the deferred tax assets has been established at December 31, 2009. 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 have any unrecognized tax benefits or liabilities. Callisto also evaluated its tax positions as of December 31, 2009 and reached the same conclusion. Callisto does not currently expect any significant changes to unrecognized tax benefits during the fiscal year ended December 31, 2009. Callisto's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2009 and December 31, 2008, 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, 2009. 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.

Table of Contents

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-free type "B" reorganization resulting in no gain or loss recognition to Callisto, for federal tax purposes.

10. Commitments and contingencies

Employment and Consulting Agreements

Gary S. Jacob

On March 11, 2009, Dr. Gary Jacob entered into an amended and restated employment agreement with Callisto in which he agreed to serve as Chief Executive Officer. The term of the agreement was effective as of August 1, 2008 and continues until December 31, 2011 and is automatically renewed for successive one year periods at the end of each term. Dr. Jacob's salary is \$300,000 per year of which 25% is to be allocated to Callisto and 75% is to be allocated to Callisto's majority owned subsidiary, Synergy, where Dr. Jacob serves as President and Acting Chief Executive Officer. Dr. Jacob is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Dr. Jacob is also eligible to receive a realization bonus in the event that Callisto enters into an out-license agreement for Callisto's technology or engage in a merger or sale of substantially all Callisto's assets where the enterprise value equals or exceeds a minimum of \$150 million, \$200 million and \$250 million in the first, second or third years of the term of the agreement or any years beyond the third term of the agreement, respectively, or the license fees Callisto contracts to receive equals or exceeds \$50 million. The realization bonus will be equal to the enterprise value in the case of a merger or sale or the sum of the license fees actually received multiplied by 0.5%.

If the employment agreement is terminated by the Company 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 Callisto'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.

Had a "Change of Control" occurred on December 31, 2009 and the executive had been terminated on that date, Dr. Jacob would have been eligible for total compensation (salary and bonus) for the term of his employment under his employment agreement for the time remaining of such employment term, of \$900,000.

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. Compensation Dr. Jacob receives under his amended and restated employment agreement with Synergy is mutually exclusive with his Callisto agreement and total base salary from both agreements is capped at \$300,000 per annum and bonus potential capped at 50% or \$150,000.

Table of Contents

Gabriele M. Cerrone

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

If the consulting agreement is terminated by Callisto 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 Callisto'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. Had Mr. Cerrone been terminated without cause or good reason on December 31, 2009, he would have been eligible for total compensation of \$885,000 for the time remaining under the amended and restated consulting agreement.

On February 1, 2010, Mr. Cerrone, entered into an amended and restated consulting agreement with Synergy extending the term of the agreement which was effective as of August 1, 2008 by one year until December 31, 2012. Compensation Mr. Cerrone receives under his amended and restated consulting agreement with Synergy is mutually exclusive with his Callisto agreement and total compensation from both agreements is capped at a combined base compensation of \$295,000 per annum and bonus potential of 50% or \$147,500.

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

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

Table of Contents

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.

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.

On August 21, 2008, the Board of Directors of Synergy (the "Board") appointed Melvin K. Spigelman, M.D. as a Director of Synergy. In addition, the Board of Directors appointed Dr. Spigelman Chairman of Synergy's Clinical Oversight Committee as well as a member of the Synergy Compensation and Audit Committees ("the Committees"). In connection therewith, the Board approved the payment of an annual fee of \$90,000 to Dr. Spigelman for his service on the Board and the Committees. Additionally, the Board approved a grant of 300,000 stock options to Dr. Spigelman, to purchase Synergy common stock, with an exercise price of \$0.60 per share. Such options vest in 100,000 increments over a period of 3 years. The fair value of the 300,000 options on the date of grant was \$135,655. During 2009, Synergy's Clinical Oversight Board was disbanded and Dr. Spigelman is now paid a director fee comparable to the other independent 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

Table of Contents

on the original intrinsic value, associated with the remaining 100,000 options of \$314,139, was expensed over the vesting period of the new grant (e.g. April 7, 2004 through December 31, 2004). On April 12, 2007, Dr. Shailubhai was granted 125,000 ten year incentive stock options exercisable at \$0.66 per share of which 41,667 vest on each of April 12, 2008 and 2009 and 41,666 vest on April 12, 2010.

Bernard F. Denoyer

On 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 SP-304 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 SP-304, 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 of the warrants vested prior to termination.

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

Table of Contents

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.

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

Table of Contents

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.

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.

Table of Contents

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.

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

Table of Contents

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 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, 2010. The Company also occupies 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, 2010.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

During the twelve months ended December 31, 2009, 2008 and 2007, total rent expense was \$282,678, \$280,612 and \$197,224, respectively. Total annual commitments for each of the years ended December 31, are as follows:

2010	257,901
2011	141,981
Total	\$ 399,882

11. 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 all periods presented. Accordingly, the inclusion of common stock options, warrants and the conversion of preferred stock 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, 2009	December 31, 2008	December 31, 2007
Common Shares Outstanding (included in weighted-average shares)	53,608,111	49,556,661	46,943,161
Potentially Dilutive Common Shares Issuable (excluded from weighted-average shares)			
Exercise of Warrants	84,842,576	55,773,331	45,162,920
Exercise of Stock Options	7,495,038	7,938,538	8,241,207
Conversion of Series A Convertible Preferred Stock	1,750,000	1,960,000	4,373,500
Conversion of Series B Convertible Preferred Stock	28,171,278	22,741,000	22,941,000
Common Shares Outstanding Fully Diluted	175,867,003	137,969,530	127,661,788

12. 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, 2009, 2008, 2007 and from June 5, 1996 (inception) to December 31, 2009 was \$5,984, \$6,654, \$3,142 and \$102,568, respectively.

	December 31,	
	2009	2008
Equipment	\$ 67,091	\$ 67,091
Furniture and fixtures	38,343	38,343
Leasehold improvements	11,799	11,799
Less: accumulated depreciation	(102,568)	(96,584)
Property and equipment, net	\$ 14,665	\$ 20,649

Table of Contents

13. Subsequent events

On February 1, 2010, the Compensation Committee of the Board of Directors of Synergy approved and Synergy entered into an Amended and Restated Executive Employment Agreement with Gary S. Jacob, its President and Chief Executive Officer and an Amended and Restated Consulting Agreement with Gabriele Cerrone, its Chairman. Each agreement was modified by (i) extending the term to December 31, 2012 from December 31, 2011 and (ii) deleting the bonus provision which provided for a bonus if there is a merger or sale of the Company with a minimum value of \$150 million, \$200 million and \$250 million during the first, second and third year of the agreement and replacing it with a bonus of 2.5% of the value of the Company if there is a merger or sale of the Company and the value of the Company at the time of the merger or sale equals or exceeds \$400 million.

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.

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. The fair value of these shares totaled \$100,196 which cost will be amortized over the extension period

Table of Contents**Exhibit Index**

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

Exhibit No.	Description
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)*
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)

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Table of Contents

Exhibit No.	Description
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).
10.17	Form of Secured Promissory Note (incorporated by reference to Exhibit 10.17 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 Seidman, LLP
31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
