

CALLISTO PHARMACEUTICALS INC  
Form 10-K  
March 28, 2008

[QuickLinks](#) -- Click here to rapidly navigate through this document

**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, 2007**

**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** **13-3894575**  
(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**

(Issuer's telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
Common Stock, \$.0001 par value Securities registered pursuant to section 12(g) of the Act:	American Stock Exchange

Title of class: **None**

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  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 definition of "*large accelerated filer*", "*accelerated filer*" and "*smaller reporting company*" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer       Accelerated filer       Non-accelerated filer       Smaller reporting company   
(do not check if 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 \$25,520,017 on June 29, 2007 (based on \$0.69 per share, the closing price on the American Stock Exchange that day).

As of March 25, 2008 the registrant had a total of 47,218,161 shares of Common Stock outstanding.

---

---

---

## CALLISTO PHARMACEUTICALS, INC.

## FORM 10-K

## INDEX

	<u>PAGE</u>
<b>PART I</b>	
Item 1. Business	3
Item 1A. Risk Factors	15
Item 1B. Unresolved Staff Comments	30
Item 2. Properties	30
Item 3. Legal Proceedings	30
Item 4. Submission of Matters to a Vote of Security Holders	30
<b>PART II</b>	
Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	31
Item 6. Selected Consolidated Financial Data	32
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	33
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	41
Item 8. Financial Statements and Supplementary Data	42
Item 9. Changes in and Disagreements with Accountants On Accounting and Financial Disclosure	42
Item 9A. Controls and Procedures	42
Item 9A(T) Controls and Procedures	43
Item 9B. Other Information	44
<b>PART III</b>	
Item 10. Directors, Executive Officers and Corporate Governance	45
Item 11. Executive Compensation	50
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	60
Item 13. Certain Relationships and Related Transactions	61
Item 14. Principal Accountant Fees and Services	62
<b>PART IV</b>	
Item 15. Exhibits and Financial Statement Schedules	62
Signatures	66

**PART I**

This Form 10-K contains forward-looking statements that involve risks and uncertainties. Such forward-looking statements are characterized by future or conditional verbs and include, but are not limited to, statements regarding the results of product development efforts, clinical trials and applications for marketing approval of pharmaceutical products, and the scope and success of future operations. Such statements are only predictions and our actual results may differ materially from those anticipated in these forward-looking statements. Factors that may cause such differences include, but are not limited to, those discussed under "Risk Factors" and elsewhere in this Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission, including the uncertainties associated with product development, the risk that products that appeared promising in early clinical trials do not demonstrate efficacy in larger-scale clinical trials, the risk that we will not obtain approval to market our products, the risks associated with dependence upon key personnel and the need for additional financing. We do not assume any obligation to update forward-looking statements as circumstances change.

**ITEM 1. BUSINESS.**

Callisto Pharmaceuticals, Inc. is referred to throughout this report as "Callisto," "we" or "us."

We are a biopharmaceutical company focused primarily on the development of drugs to treat neuroendocrine cancer (including advanced carcinoid cancer), acute leukemia and gastrointestinal disorders and diseases. Our lead drug candidate in the clinic, Atiprimod, is an orally administered drug with antiproliferative and antiangiogenic activity. On November 7, 2006, we announced the initiation of a multi-center open-label Phase II clinical trial of Atiprimod for low-to-intermediate grade neuroendocrine cancers, primarily in advanced carcinoid cancer patients. This trial is based on earlier encouraging clinical results from a Phase I trial of Atiprimod in advanced cancer patients that showed stable disease and disease-related symptom relief in patients with advanced carcinoid cancer. On September 20, 2007, we announced that we had completed enrollment of the 40-patient Phase II clinical trial, and that patients had been on drug as long as 11 months. In October 2007, we announced the opening of a Phase II extension trial to permit those patients who had successfully completed a full year in the Phase II advanced carcinoid cancer trial, which only permitted dosing for up to one year, to continue to receive Atiprimod therapy. We are no longer dosing patients in the Phase I clinical trial of Atiprimod in relapsed or refractory multiple myeloma and have no plans at present to continue evaluating the drug in this disease indication, instead focusing on the clinical development of Atiprimod to treat advanced carcinoid cancer.

Our second drug candidate, L-Annamycin, earlier completed an initial Phase I/IIa clinical trial in relapsed or refractory leukemia patients with a prior sponsor. L-Annamycin is 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. L-Annamycin was in-licensed by us in October 2004 and is presently in two clinical trials: 1) a Phase I/IIa clinical trial in adult relapsed or refractory acute lymphocytic leukemia (ALL) patients at three clinical sites in the U.S.; and 2) a Phase I clinical trial in children and young adults with relapsed or refractory ALL or AML. We recently reached the maximum tolerated dose (MTD) in the adult trial and are currently evaluating its potential at the fixed-dose portion of the trial. We have not yet established the MTD in children. We plan to review future development of this drug once data from the adult trial are available.

In October 2007 we announced a major strategic initiative to develop SP-304 (Guanilib), our guanylyl cyclase C (GC-C) receptor agonist, to treat gastrointestinal disorders, primarily chronic constipation and constipation-predominant irritable bowel syndrome (IBS-C). We plan to file an investigational new drug (IND) application with FDA in the second quarter of 2008, and to initiate a

Phase I clinical trial in volunteers upon FDA approval of our IND application. We also plan to open a Phase Ib trial of SP-304 (Guanilib) in late 2008.

Our plan of operations for the next twelve months is to focus primarily on the Phase II clinical trial development of Atiprimod to treat advanced carcinoid cancer, and on the Phase I clinical trial development of SP-304 (Guanilib) to treat gastrointestinal disorders.

## **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") 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 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. 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 shareholders were returned to us under the terms of certain indemnification agreements.

## **ATIPRIMOD TO TREAT ADVANCED CARCINOID CANCER PATIENTS**

On August 28, 2002, our wholly-owned subsidiary, Synergy, entered into a worldwide license agreement with AnorMED Inc. ("AnorMED"), a Canadian corporation, to research, develop, sell and commercially exploit the Atiprimod (SKF 106615) patent rights.

On December 31, 2007, Callisto entered into an Amended and Restated License Agreement with AnorMED Corporation (successor in interest to AnorMED Inc.), a wholly-owned subsidiary of Genzyme Corporation ("Genzyme"), pursuant to which Callisto and Genzyme amended the license agreement for Atiprimod to eliminate all maintenance fees and milestone payments and reduce royalties owed to Genzyme to single digits. In return for the reduced future payments to Genzyme, Callisto is paying an upfront fee in 2008.

Atiprimod is one of a class of compounds known as azaspiranes and was originally developed as a potential treatment for rheumatoid arthritis 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 SmithKline Beecham ("SKB") that led to the successful filing of an investigational new drug application, or 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 rheumatoid arthritis. 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.

## PRECLINICAL STUDIES

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

## COMPLETED CLINICAL STUDIES

Atiprimod successfully completed single and multiple dose Phase I clinical trials in patients with rheumatoid arthritis (RA). In the initial Phase I study, 28 patients were given single escalating doses of drug (0.002 - 1.0 mg/kg), with a 4-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 4-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 5 mg/day dosage. Forty-three patients entered the study and remained on the drug as long as 12 months. Clinical laboratory results for all patients were unremarkable, in particular liver enzyme levels remained within the normal range in all patients throughout the study period.

## DEVELOPMENT STRATEGY

Atiprimod commenced a Phase I/IIa clinical trial in relapsed or refractory multiple myeloma patients on May 26, 2004. These are patients that have a re-occurrence of active disease, and no longer respond to approved therapies. The Phase I/IIa clinical trial is an open label study, with the primary objective of assessing safety of drug and identifying the maximum tolerated dose. The secondary objectives are to measure the pharmacokinetics, evaluate the response in patients with refractory disease and to identify possible surrogate responses to the drug to better determine the mechanism of drug action. In December 2005, we announced interim results from this trial performed in relapsed or refractory multiple myeloma patients which consisted of 15 patients treated with Atiprimod, including 3 patients at the highest dose level of 180 mg/day. In 2006, we amended this protocol to continue the trial at higher dose levels. The amended trial included the combination of Atiprimod with a drug called ursodiol to enable patients to be dosed at levels of Atiprimod higher than 180 mg/day. In October, 2007 we met the primary objective and reached the MTD in the Atiprimod + ursodiol arm. However, we do not intend to pursue Atiprimod as a single agent in multiple myeloma.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

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

On November 7, 2006, we announced the initiation of a multi-center, open-label Phase II clinical trial of Atiprimod in neuroendocrine carcinoma, comprised primarily of advanced carcinoid cancer patients. The primary objective of this trial was to evaluate efficacy of Atiprimod in patients with low to intermediate grade neuroendocrine carcinoma who have metastatic or unresectable cancer and who have either symptoms, despite standard therapy (octreotide), or progression of neuroendocrine tumors. Patients, after signing an informed consent, were required to complete two weeks of a symptoms diary to establish their symptoms baseline before commencing Atiprimod dosing. A maximum of 40 evaluable patients were planned for this trial. On September 20, 2007 we announced that we had completed full enrollment of this study, and that patients had been on drug as long as 11 months. There are presently eight clinical sites participating in the study in the U.S., with patients currently enrolled in seven of these sites.

In October 2007, we announced the opening of a Phase II extension trial to permit those patients who had successfully completed a full year on the Phase II advanced carcinoid cancer trial, which only permitted dosing for up to one year, to continue to receive Atiprimod therapy. We plan to release interim data from the advanced carcinoid cancer trials in the first quarter of 2008. We also plan to arrange to meet with the FDA on the design of a registration trial after sufficient clinical data have been collected from the ongoing Phase II trial.

### **MANUFACTURING OF ATIPRIMOD**

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

### **ORPHAN DRUG STATUS OF ATIPRIMOD**

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

marketing approval of a new drug, the FDA will not accept or approve other applications to market the same medicinal product for the same therapeutic indication. Other incentives provided by orphan status include certain tax benefits, eligibility for research grants and protocol assistance. Protocol assistance includes regulatory assistance and possible exemptions or reductions of certain regulatory fees.

#### **L-ANNAMYCIN TO TREAT RELAPSED ACUTE LEUKEMIA**

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

#### **PRECLINICAL STUDIES**

Nonclinical studies have shown that Annamycin delivered as a liposomal preparation (L-Annamycin) is effective against several different in vivo tumor models (animal experiments), including human tumors which are resistant to other chemotherapy drugs, grafted into animals. Additionally, results from in vitro studies (cell culture experiments) indicate that L-Annamycin and free Annamycin were able to partially overcome tumor resistance to chemotherapy drugs in several tumor cell lines that were resistant to other drugs such as doxorubicin. In nonclinical toxicity studies, myelosuppression (suppression of the body's immune response) was noted in mice at a single intravenous dose of 15.7 mg/kg L-Annamycin. With weekly intravenous doses of 5.2 mg/kg L-Annamycin for 6 weeks, or 3.1 and 4.2 mg/kg L-Annamycin for 10 weeks in mice, the cardiotoxicity (toxicity to heart tissue) of L-Annamycin was substantially less than an equivalent dose of doxorubicin. In dogs, a single 15-minute intravenous infusion of up to 1.42 mg/kg L-Annamycin was well tolerated, with no clinically significant adverse effects, hematological or chemical changes, or pathological changes.

#### **COMPLETED CLINICAL STUDIES**

L-Annamycin was evaluated previously by Aronex Pharmaceuticals, Inc. in 3 clinical trials: 1) a Phase I clinical trial in 36 patients with relapsed solid tumors, 2) a Phase II clinical trial in 13 patients with doxorubicin-resistant breast cancer, and 3) a Phase I/IIa trial in 20 patients with relapsed/refractory AML and 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/m<sup>2</sup>. 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/m<sup>2</sup>. 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/m<sup>2</sup> as a single i.v. infusion over 1-2 h every 3 weeks. Of the 13 patients, 12 had clear deterioration and new tumor growth after one or two courses.

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



## **DEVELOPMENT STRATEGY**

We began a Phase I clinical trial at The University of Texas M.D. Anderson Cancer Center in adult relapsed or refractory acute lymphocytic leukemia (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 indicate that the MTD reported by the previous sponsor which indicated that patients could be dosed as high as 280 mg/m<sup>2</sup>/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 is being utilized across all study sites. We recently established an MTD of 150 mg/m<sup>2</sup>/day given for 3 consecutive days in the adult trial and are currently evaluating patients in the fixed-dose portion of the trial. We plan to finish dosing of 10 patients at the MTD value and then determine whether the clinical data warrant further clinical evaluation of L-Annamycin in adult acute leukemia patients.

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/m<sup>2</sup>/day given for three consecutive days. The trial is a multi-center, open-label, single-agent, dose-escalation study that is utilizing POETIC a consortium of ten pediatric cancer centers located in the U.S. and Canada. The trial is presently open at four clinical sites in the U.S. We have not yet established the MTD in children. We plan to review future development of this drug once data from the adult trial are available. Our key employee responsible for coordinating this L-Annamycin program with our pediatric clinical sites, Dr. Donald Picker, former Executive Vice President of Research & Development, resigned from our company in December, 2006. Consequently, work on this clinical program was scaled back.

## **MANUFACTURING OF ANNAMYCIN**

An improved manufacturing method for Annamycin has been developed at Antibioticos S.p.A., our commercial supplier of GMP ("Good Manufacturing Practice") drug substance. GMP material is currently being produced in sufficient quantity for all three anticipated trials outlined in the development strategy section. The analytical methods developed previously have been successfully transferred, and are in the process of being validated by Quantitative Technologies, Inc., our analytical contract research organization, or CRO, for Annamycin development work. The final lyophilized GMP formulated drug product is being manufactured by Pharmaceutical Services, Inc., who previously produced final product for the earlier clinical trials. Currently, Antibioticos S.p.A. is our sole supplier of Annamycin for our clinical trials. Our agreement with Antibioticos provides that Antibioticos will provide 400 grams of GMP drug substance (Annamycin) for our L-Annamycin clinical trials.

## **ORPHAN DRUG STATUS OF L-ANNAMYCIN**

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

## **SP-304 (GUANILIB) TO TREAT GASTROINTESTINAL DISORDERS**

We announced on October 3, 2007 a major strategic initiative to develop SP-304 (Guanilib), Callisto's guanylyl cyclase C receptor agonist, to treat gastrointestinal disorders, primarily chronic

constipation and constipation-predominant irritable bowel syndrome (IBS-C). SP-304 (Guanilib) was developed by our scientists based on structure-function studies performed in-house. A patent covering composition of matter and therapeutic applications of SP-304 (Guanilib) was granted by the U.S. Patent and Trademark Office on May 9, 2006.

SP-304 (Guanilib) is an analog of uroguanylin, a natural gastro-intestinal hormone produced in the gut that is a key regulator of intestinal function. Uroguanylin works by activating a unique receptor on intestinal cells. The receptor, called the guanylate cyclase C (GC-C) receptor, promotes fluid and ion transport in the gastro-intestinal (GI) tract. Under normal conditions, the receptor is activated by the natural hormones uroguanylin and guanylin. Activation of the receptor leads to the transport of chloride and bicarbonate into the intestine, and water is carried with these ions into the lumen of the intestine, thereby producing a liquid and watery stool, and other pharmacologic effects that could potentially benefit patients with gastrointestinal disorders such as chronic constipation and IBS-C.

#### **PRECLINICAL STUDIES**

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

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

#### **DEVELOPMENT PLAN**

We currently have a major preclinical program underway to support the filing of an investigational new drug (IND) application with FDA in the second quarter of 2008. The plan is to evaluate SP-304 (Guanilib)'s clinical potential first in chronic constipation and IBS-C. The initial Phase I trial is planned to be performed in volunteers in early 2008. The purpose of this trial is to establish the safety of the drug when given as a single oral dose. We also expect to demonstrate that SP-304 (Guanilib) is not systemically absorbed (i.e. taken up in the blood and distributed throughout the body) which means that the compound is likely to be non-toxic in clinical use. We also plan to open a Phase Ib trial of SP-304 (Guanilib) in late 2008.

#### **MANUFACTURING OF SP-304 (GUANILIB)**

A practical, efficient and cost effective method for producing SP-304 (Guanilib) on a commercial scale is currently being developed by a CRO, who has produced a 100 gram-scale GMP run of SP-304 (Guanilib), which was released in January 2008.

#### **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 in 2007 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. Our key employee responsible for this program, Dr. Donald Picker, former Executive Vice President of Research & Development, resigned from our company in December 2006. Consequently, work on this program has been significantly scaled back.

#### **SUPERANTIGEN-BASED BIOTERRORISM DEFENSE**

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

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

#### **GOVERNMENT REGULATION**

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

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

The FDA closely monitors the progress of each of the three phases of clinical testing and may, in its discretion, reevaluate, alter, suspend or terminate the testing based on the data that have been

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

If the product is approved for sale, FDA regulations govern the production process and marketing activities, and a post-marketing testing and surveillance program may be required to monitor continuously a product's usage and effects. Product approvals may be withdrawn if compliance with regulatory standards is not maintained, and other countries, in which any products developed by us are marketed, may impose a similar regulatory process.

## **COMPETITION**

The biopharmaceutical industry is characterized by rapidly evolving technology and intense competition. Our competitors include major pharmaceutical and biotechnology companies focusing on hematological oncology 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 salaries and other personnel-related expenses, facilities costs, laboratory supplies, license fees and patent legal costs. Research and development expenses were \$6,507,978 for the twelve months ended December 31, 2007, compared to \$6,134,704 and \$6,430,505 for the twelve months ended December 31, 2006 and 2005, 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, 2007 and 2006 we received \$260,853 and \$352,649, respectively, which has been reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grant". Funding for this program has been extended through April, 2008 and as of December 31, 2007 we had approximately \$34,000 of funding remaining. Because the bioterrorism program is not a core activity of ours, we plan to terminate in-house work on this program upon expiration of the research grant in April, 2008.

## **PROPRIETARY RIGHTS**

We are able to protect our technology from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents or is effectively maintained as a trade secret. Accordingly, patents or other proprietary rights are an essential element of our business. As of December 31, 2007, we are the assignee or exclusive licensee of 7 pending patent applications and 15 issued patents in the United States, and currently we have approximately 150 issued or pending foreign

patent applications. We seek patent protection of inventions originating from our ongoing research and development activities that are commercially important to our business. Our composition-of-matter and use patent on SP-304 (Guanilib) issued on May 9, 2006. 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.

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.

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

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

## 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 2025. In addition, at any time after 2 years from January 10, 2006, 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 5 years from August 12, 2004, 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, our wholly-owned subsidiary, Synergy, entered into a worldwide license agreement with AnorMED Inc. ("AnorMED"), a Canadian corporation, to research, develop, sell and commercially exploit the Atiprimod (SKF 106615) patent rights.

On December 31, 2007, we entered into an amended and restated license agreement with AnorMED to research, develop, sell and commercially exploit the Atiprimod patent rights. The license agreement provides for us to pay AnorMED royalties on net sales as well as an upfront payment. The license agreement will terminate in 2018.

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 November 14, 2007, we gave 90-day notice to Rockefeller University of termination of the August, 1996 and July, 2001 License agreements, effective February 14, 2008.

**EMPLOYEES**

As of March 25, 2008, we had 11 full-time and 2 part-time employees. We believe our employee relations are satisfactory.

**AVAILABLE INFORMATION**

We operate three wholly owned subsidiary companies Callisto Research Labs, LLC, Synergy Pharmaceuticals Inc. ("Synergy") and Synergy Advanced Pharmaceuticals, Inc. a wholly owned subsidiary of Synergy and we own two inactive subsidiaries, IgX, Ltd (Ireland) and Callisto Pharma, GmbH (Germany). We were incorporated in Delaware in May 2003 and our principal offices are at 420 Lexington Avenue, Suite 1609, New York, NY 10170.

We maintain a site on the world wide web at <http://www.callistopharma.com>; however, information found on our website is not incorporated by reference into this report. We make available free of charge through our website our Securities and Exchange Commission, or SEC, filings, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

**ITEM 1A. RISK FACTORS**

You should carefully consider the following risk factors and the other information included herein (specifically, but not limited to, Item 9A(T) of this annual report) as well as the information included in other reports and filings made with the SEC before investing in our common stock. If any of the following risks actually occurs, our business, financial condition or results of operations could be harmed. The trading price of our common stock could decline due to any of these risks, and you may lose part or all of your investment.

**RISKS RELATED TO OUR BUSINESS**

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

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

demonstration in Phase I and Phase II clinical trials that our product candidates, Atiprimod for the treatment of advanced carcinoid cancer, L-Annamycin for the treatment of relapsed acute leukemia, and SP-304 (Guanilib) for the treatment of gastrointestinal disorders are safe and effective;

the successful development of our other product candidates;

our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;

the successful commercialization of our product candidates; and

market acceptance of our products.

All of our existing product candidates will require extensive additional clinical evaluation, regulatory review, significant marketing efforts and substantial investment before they could provide us with any revenue. For example, Atiprimod for the treatment of multiple myeloma entered Phase I/IIa clinical trials in May 2004 and L-Annamycin for the treatment of acute leukemia entered clinical trials in December 2005. Our other product candidates are in preclinical development. As a result, if we do not successfully develop and commercialize Atiprimod or L-Annamycin, we will be unable to generate any revenue for many years, if at all. We do not anticipate that we will generate revenue for several years, at the earliest, or that we will achieve profitability for at least several years after generating material revenue, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

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

As of December 31, 2007 we had an accumulated deficit of \$81,331,796. We have incurred losses in each year since our inception in 1996. We incurred net losses available to common stockholders of \$20,887,428, \$15,303,714 and \$11,779,457 for the twelve months ended December 31, 2007, 2006 and 2005, respectively. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development, continue our clinical trials of Atiprimod for the treatment of multiple myeloma and advanced carcinoid cancer, continue and initiate our clinical trials of L-Annamycin for the treatment of acute leukemias, acquire or license technologies, advance our other product candidates into clinical development, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties



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

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

Our consolidated financial statements as of December 31, 2007 have been prepared under the assumption that we will continue as a going concern for the year ending December 31, 2007. Our independent registered public accounting firm has issued a report dated March 25, 2008 that included an explanatory paragraph referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

complete the clinical development of our two cancer product candidates, Atiprimod for the treatment of advanced carcinoid cancer and L-Annamycin for the treatment of acute leukemia;

initiate and continue clinical development of SP-304 (Guanilib) to treat gastrointestinal disorders.

continue development of our other product candidates and the SP-304 (Guanilib) backup and second-generation program;

finance our general and administrative expenses;

prepare regulatory approval applications and seek approvals for Atiprimod, SP-304 (Guanilib) and L-Annamycin and our other product candidates;

license or acquire additional technologies;

launch and commercialize our product candidates, if any such product candidates receive regulatory approval; and

develop and implement sales, marketing and distribution capabilities.

We expect that our cash used in operating activities will increase significantly for the next several years. For the years ended December 31, 2007, 2006 and 2005 we used approximately \$8.4 million, \$8.3 million and \$8.7 million in operating activities, respectively.

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

the rate of progress and cost of our clinical trials and other development activities;

any future decisions we may make about the scope and prioritization of the programs we pursue;

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

the costs and timing of regulatory approval;

the costs of establishing sales, marketing and distribution capabilities;

the effect of competing technological and market developments;

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

general market conditions for offerings from biopharmaceutical companies.

To date, our sources of cash have been primarily limited to the sale of our equity securities. Net cash provided by financing activities for the twelve months ended December 31, 2007, 2006 and 2005 was approximately \$10.8 million, \$10.8 million and \$4.8 million, respectively. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

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

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

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

Our business is partially dependent on rights we have licensed from The University of Texas M.D. Anderson Cancer Center. Under the terms of The University of Texas M.D. Anderson Cancer Center license agreement for L-Annamycin, at any time after 5 years from August 12, 2004, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or we are actively and effectively attempting to commercialize L-Annamycin. If we fail to fulfill these obligations or other material obligations, The University of Texas M.D. Anderson Cancer Center license agreement may be terminated and our business would be adversely affected.

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

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

The results of preclinical studies and early clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to

support the submission of a new drug application or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

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

While to date there has been no delays in our clinical trials, enrollment in our Atiprimod Phase I/IIa trial in multiple myeloma was slower than anticipated due to limited availability of relapsed multiple myeloma patients. In the future, we may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval to conduct a trial at a prospective site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new drugs approved for the conditions we are investigating. Prescribing physicians will also have to decide to use our product candidates over existing drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and delay our ability to generate revenue.

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

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

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

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

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

This regulatory review and approval process, which includes evaluation of preclinical studies and clinical trials of a product candidate as well as the evaluation of our manufacturing process and our contract manufacturers' facilities, is lengthy, expensive and uncertain. To receive approval, we must,

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

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

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

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

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

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

successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;

maintain a proprietary position for our products and manufacturing processes and other related product technology;

attract and retain key personnel;

develop relationships with physicians prescribing these products; and

build an adequate sales and marketing infrastructure for our product candidates.

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

Numerous pharmaceutical and biotechnology companies have developed anthracycline drugs used to treat acute leukemias similar to our compound, L-Annamycin. These compounds include Adriamycin® and Ellence® which are marketed by Pfizer and Cerubidine® which is marketed by Boehringer Ingelheim. These drugs have been approved by the FDA and are currently being marketed as opposed to L-Annamycin which is in clinical development. Atiprimod, our drug candidate for relapsed multiple myeloma, works through a different mechanism of action than Velcade which is currently marketed by Millenium Pharmaceuticals and other drugs in development, such as Celgene Corporation's Revlimid.

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

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

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

In the future, if appropriate regulatory approvals are obtained, we intend to commercialize our product candidates in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. Currently, we do not have any plans to enter international markets. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

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

Currently, Antibioticos S.p.A. is our sole supplier of Annamycin (drug substance that is the active component of the final formulated L-Annamycin drug product). If our relationship with this contract manufacturer, or any other contract manufacturer we might use, terminates or if any of their facilities are damaged for any reason, including fire, flood, earthquake or other similar event, we may be unable to obtain supply of Annamycin. If any of these events were to occur, we may need to find alternative manufacturers or manufacturing facilities. The number of contract manufacturers with the expertise, required regulatory approvals and facilities to manufacture Annamycin on a commercial scale is extremely limited, and it would take a significant amount of time to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must approve these manufacturers' facilities and processes prior to our use, which would require new testing and compliance inspections. In addition, we may not have the intellectual property rights, or may have to share intellectual property rights, to any improvements in the current manufacturing processes or any new manufacturing processes for Annamycin. Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of L-Annamycin, entail higher costs, and could result in our being unable to commercialize L-Annamycin successfully. Furthermore, if our contract manufacturers fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we were unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for L-Annamycin and we would lose potential revenue.

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

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

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

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

decreased demand for our product candidates;

injury to our reputation;

withdrawal of clinical trial participants;

costs of related litigation;

substantial monetary awards to patients;

product recalls;

loss of revenue; and

the inability to commercialize our product candidates.

We have clinical trial liability insurance with a \$5,000,000 annual aggregate limit for up to 40 patients participating at the same time in our Atiprimod and L-Annamycin clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

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

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

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

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

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

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

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

The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies. We do not carry "key person" insurance covering any members of our senior management other than \$1,000,000 for Dr. Jacob.

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

To date, we have in-licensed or acquired the rights to each of our product candidates. As part of our growth strategy, in addition to developing our current product candidates, we intend to license or



acquire additional products and product candidates for development and commercialization. Because we have limited internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license products to us. The success of this strategy depends upon our ability to identify, select and acquire the right pharmaceutical product candidates and products.

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

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

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

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

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

We are a small company with 11 full-time and 2 part-time employees as of March 3, 2008. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Over the next 12 months depending on the progress of our planned clinical trials, we plan to add additional employees to assist us with our clinical programs. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

manage our development efforts effectively;

manage our clinical trials effectively;

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

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

hire and train additional qualified personnel.

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

**REIMBURSEMENT MAY NOT BE AVAILABLE FOR OUR PRODUCT CANDIDATES, WHICH COULD DIMINISH OUR SALES.**

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

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

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

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

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

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

**RISKS RELATED TO OUR INTELLECTUAL PROPERTY**

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

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

As of December 31, 2007, we own and/or have licensed rights to 15 issued United States patents and 7 United States patent applications. We have approximately 150 issued and/or pending foreign patent applications. We may file additional patent applications and extensions. Our issued United States patents we own and license primarily are composition of matter and formulation patents related to Atiprimod and L-Annamycin. 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 (preferred salt form) both expire in 2016.

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

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

others may be able to make compounds that are competitive with our product candidates but that are not covered by the claims of our licensed patents, or for which we are not licensed under our license agreements;

we or our licensors might not have been the first to make the inventions covered by our pending patent application or the pending patent applications and issued patents of our licensors;

we or our licensors might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

it is possible that our pending patent application or one or more of the pending patent applications of our licensors will not result in issued patents;

the issued patents of our licensors may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;

we may not develop additional proprietary technologies that are patentable; or

the patents of others may have an adverse effect on our business.

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



United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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

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

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

**RISKS RELATED TO OUR COMMON STOCK**

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

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

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing process or sales and marketing activities;
- regulatory developments in the United States of America and foreign countries;
- the success of our development efforts and clinical trials;
- the success of our efforts to acquire or in-license additional products or product candidates;
- any intellectual property infringement action, or any other litigation, involving us;
- announcements concerning our competitors, or the biotechnology or biopharmaceutical industries in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- our ability to maintain listing requirements on the American Stock Exchange;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders; and
- the loss of any of our key scientific or management personnel.
- the potentially dilutive effect of all outstanding dilutive instruments as follows:

	<b>December 31, 2007</b>	<b>December 31, 2006</b>	<b>December 31, 2005</b>
Common Shares outstanding	46,943,161	39,194,996	33,233,096

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

	December 31, 2007	December 31, 2006	December 31, 2005
Potentially dilutive common shares issuable upon:			
Exercise of warrants	45,162,920	15,841,154	2,567,317
Exercise of stock options	8,241,207	8,053,375	8,008,210
Conversion of Series A Convertible Preferred Stock	4,373,500	7,658,000	
Conversion of Series B Convertible Preferred Stock	22,941,000		
<b>Total fully diluted</b>	<b>127,661,788</b>	<b>70,747,525</b>	<b>43,808,623</b>

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

**THE LIQUIDITY OF YOUR STOCK DEPENDS IN PART ON CONTINUED LISTING OF OUR SHARES OF COMMON STOCK ON THE AMERICAN STOCK EXCHANGE.**

On October 3, 2006, we received notice from the staff of the American Stock Exchange indicating that we are not in compliance with Section 1003(a)(i) of the Company Guide with shareholders' equity of less than \$2,000,000 and losses from continuing operations and/or net losses in two of our three most recent fiscal years and Section 1003(a)(iv) of the Company Guide in that we have sustained losses which are so substantial in relation to our overall operations or our existing financial resources, or our financial condition has become so impaired that it appears questionable, in the opinion of the Exchange, as to whether we will be able to continue operations and/or meet our obligations as they mature.

On November 2, 2006 we submitted a plan advising the American Stock Exchange of the actions we have taken, or will take, that would bring us into compliance with Section 1003(a)(iv) of the Company Guide by April 3, 2007 and with Section 1003(a)(i) of the Company Guide by April 3, 2008. The plan was approved on January 24, 2007. We will continue to maintain our listing during the plan period of up to 18 months, during which time we will be subject to periodic review to determine if we are making progress consistent with the plan. If we are not in compliance with the continued listing standards at the end of the plan period, or we do not make progress consistent with the plan during the plan period, the American Stock Exchange staff may initiate delisting proceedings.

On June 18, 2007, we received notice from the staff of the American Stock Exchange indicating that we are not in compliance with Section 1003(a)(ii) of the Company Guide with shareholders' equity of less than \$4,000,000 and losses from continuing operations and/or net losses in three of our four most recent fiscal years.

We submitted a plan on July 18, 2007, advising the American Stock Exchange of the actions we have taken, or plan to take, that would bring it into compliance with Section 1003(a)(ii) of the Company Guide by April 3, 2008. On August 27, 2007, the American Stock Exchange notified us that they have accepted our plan. There is no guarantee that we will be able to make progress consistent with the plan. As of December 31, 2007 we had stockholders' equity of \$1,793,350 and there have been no financing events since that date, through the date of this annual report, which would increase stockholder's equity.

While the plan is under periodic review by the American Stock Exchange, we expect that our common stock will continue to trade without interruption on the American Stock Exchange. If we are delisted by the American Stock Exchange you may experience difficulty in trading your shares of our common stock.

**WE HAVE IDENTIFIED MATERIAL WEAKNESSES IN OUR DISCLOSURE CONTROLS AND PROCEDURES AND HAVE CONCLUDED THAT INTERNAL CONTROL OVER FINANCIAL REPORTING IS NOT EFFECTIVE AS OF DECEMBER 31, 2007. IN ADDITION, WE MAY EXPERIENCE ADDITIONAL MATERIAL WEAKNESSES IN THE FUTURE. ANY MATERIAL WEAKNESSES IN OUR DISCLOSURE CONTROLS AND PROCEDURES OR OUR FAILURE TO REMEDIATE SUCH MATERIAL WEAKNESSES COULD RESULT IN A MATERIAL MISSTATEMENT IN OUR FINANCIAL STATEMENTS NOT BEING PREVENTED OR DETECTED AND COULD AFFECT INVESTOR CONFIDENCE IN THE ACCURACY AND COMPLETENESS OF OUR FINANCIAL STATEMENTS, AS WELL AS OUR STOCK PRICE.**

We have identified material weaknesses in our disclosure controls and procedures relating to our lack of sufficient internal accounting personnel and segregation of duties necessary to ensure that adequate review of our financial statements and notes thereto is performed and have concluded that our internal control over financial reporting is not effective as of December 31, 2007. These material weaknesses and our remediation plans are described further in ITEM 9A(T) "CONTROLS AND PROCEDURES" of this report. Material weaknesses in our disclosure controls and procedures could



result in material misstatements in our financial statements not being prevented or detected. We may experience difficulties or delays in completing remediation or may not be able to successfully remediate material weaknesses at all. Any material weakness or unsuccessful remediation could affect investor confidence in the accuracy and completeness of our financial statements, which in turn could harm our business and have an adverse effect on our stock price and our ability to raise additional funds.

**WE ARE AT RISK OF SECURITIES CLASS ACTION LITIGATION.**

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

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

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

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None

**ITEM 2. PROPERTIES.**

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

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

**ITEM 3. LEGAL PROCEEDINGS.**

On November 2, 2006, Trilogy Capital Partners, Inc. ("Trilogy") filed suit against us in Superior Court of the State of California, County of Los Angeles, Central District, alleging that we breached a Letter of Engagement dated July 18, 2005 between us and Trilogy by failing to pay certain fees. On July 27, 2007, we entered into a mutual release and settlement agreement with Trilogy.

On December 21, 2006, we filed a complaint against Tapestry Pharmaceuticals, Inc. ("Tapestry"), Leonard P. Shaykin and Kai P. Larson in the Supreme Court of the State of New York alleging that Tapestry used information they obtained pursuant to a confidential disclosure agreement between us and Tapestry to cause Donald Picker, Ph.D., our former Executive Vice President, Research & Development, to resign and accept a position with Tapestry. In addition, we are alleging that Tapestry fraudulently entered into the confidential disclosure agreement with us and intentionally interfered with Dr. Picker's employment agreement with us. We are seeking actual and punitive damages. In June 2007, we filed a complaint against Donald Picker in the Supreme Court of the State of New York alleging breach of his employment agreement, fraud, conversion and related claims. We are seeking \$80 million in damages from Dr. Picker.

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

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

None

## PART II

**ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.****MARKET INFORMATION**

Our common stock has been quoted on the American Stock Exchange under the symbol "KAL" since October 25, 2004. The following table shows the reported high and low closing prices per share for our common stock as reported on the American Stock Exchange.

2007	HIGH	LOW
Fourth Quarter	\$ 0.54	\$ 0.33
Third Quarter	0.72	0.47
Second Quarter	0.77	0.64
First Quarter	0.97	0.71
<b>2006</b>	<b>HIGH</b>	<b>LOW</b>
Fourth Quarter	\$ 0.97	\$ 0.71
Third Quarter	1.25	0.81
Second Quarter	1.54	1.16
First Quarter	1.70	1.34

**NUMBER OF STOCKHOLDERS**

As of March 25, 2008, we had 379 holders of record of our common stock.

**DIVIDEND POLICY**

Historically, we have not declared 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 PLAN INFORMATION**

The following table summarizes information about our equity compensation plans as of December 31, 2007.

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 (b)	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Stockholders	5,888,874	\$ 1.69	4,259,500
Equity Compensation Plans Not Approved by Stockholders(1)	47,515,253	\$ 0.76	
<b>Total</b>	<b>53,404,127</b>	<b>\$ 0.87</b>	<b>4,259,500</b>

(1)

Consists of 2,352,333 stock options not subject to any of our stock option plans and 45,162,920 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 as discussed in Notes 5, 6 and 8 to our consolidated financial statements.



**ITEM 6. SELECTED FINANCIAL DATA**

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K. The statements of operations data for the twelve months ended December 31, 2007, 2006 and 2005 and the balance sheet data at December 31, 2007 and 2006 are derived from our audited financial statements which are included elsewhere in this Form 10-K. The statement of operations data for the years ended December 31, 2004 and 2003 and the balance sheet data at December 31, 2005, 2004 and 2003 are derived from our audited financial statements which are not included in this Form 10-K. Our historical results are not necessarily indicative of results to be expected for future periods. The following information is presented in thousands, except per share data.

**For the Twelve Months Ended December 31,**

	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>Consolidated Statements of Operations Data:</b>					
Revenues	\$ -0-	\$ -0-	\$ -0-	\$ -0-	\$ -0-
Operating expenses:					
Research and development	6,508	6,135	6,431	4,326	1,804
Government grant	(261)	(353)	(226)	(266)	
Purchased in process research and development				210	6,735
General and administrative	4,317	6,384	5,857	3,587	4,798
Loss from operations	(10,564)	(12,166)	(12,062)	(7,857)	(13,337)
Other income (expense)	1	(802)	177	229	222
Change in fair value of Series B Warrants from issuance to expiration of put option	2,591				
Interest and investment income	85	49	105	84	9
Net loss	(7,887)	(12,919)	(11,780)	(7,544)	(13,106)
Preferred stock beneficial conversion feature accreted as a dividend	(13,000)	(2,385)			
Net loss available to common stockholders	\$ (20,887)	\$ (15,304)	\$ (11,780)	\$ (7,544)	\$ (13,106)
Net loss per common share basic and diluted	\$ (0.50)	\$ (0.40)	\$ (0.37)	\$ (0.26)	\$ (0.61)
Weighted average number of common shares outstanding basic and diluted	41,771	37,941	31,527	28,485	21,358

**As of December 31,**

	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents(1)	\$ 3,269	\$ 3,904	\$ 1,421	\$ 5,323	\$ 3,956
Short term investments	2,968				
Total assets	6,415	4,051	1,684	5,470	4,119
Total current liabilities	4,621	3,201	2,017	1,220	1,264
Accumulated deficit during development stage	(81,332)	(60,444)	(45,141)	(33,361)	(25,818)
Total stockholders' equity (deficit)	\$ 1,793	\$ 850	\$ (333)	\$ 4,249	\$ 2,855

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

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

**OVERVIEW**

We are a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. Since inception in June 1996 our efforts have been principally devoted to research and development, securing patent protection, obtaining corporate relationships and raising capital. Since inception through December 31, 2007, we have sustained net losses available to common stockholders of \$81,331,796. Our losses have resulted primarily from cash expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, patent filing and maintenance expenses, outside accounting and legal services and regulatory, scientific and financial consulting fees. Non-cash items included in the above cumulative net losses available to common stockholders totaled approximately \$37 million, comprising stock-based compensation expense, purchase of in-process research and development, beneficial conversion features of preferred stock accreted as dividends, change in fair value of warrants as well as stock-based liquidated damages.

From inception through December 31, 2007 we have not generated any revenue from operations. We expect to incur substantial and increasing losses for the next several years as we develop our product candidates, expand our clinical development team and prepare for the commercial launch of our product candidates. We 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 completion of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, the nature and timing of costs and competing technologies being developed by organizations with significantly greater resources.

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

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

**HISTORY**

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

during the year 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. Old Callisto changed its name to Callisto Research Labs, LLC and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware.

### 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 Note 3 of the notes to our consolidated financial statements included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2007. The financial statements are prepared in accordance with accounting principles generally accepted in the United States of America, which 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.

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, 2007 stock based compensation expense has totaled \$17,145,806 or 21% of our total accumulated deficit of \$81,331,796.

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard ("SFAS") No. 123 (Revised 2004), *Share-Based Payments* ("SFAS 123R"). SFAS 123R requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005 and accordingly we adopted SFAS 123R on January 1, 2006.

SFAS 123R provides for two transition methods. The "modified *prospective*" method requires that share-based compensation expense be recorded for any employee options granted after the adoption date and for the unvested portion of any employee options outstanding as of the adoption date. The "modified *retrospective*" method requires that, beginning in the first quarter of 2006, all prior periods presented be restated to reflect the impact of share-based compensation expense consistent with the proforma disclosures previously required under SFAS 123. We have elected to use the "modified *prospective*" method in adopting this standard.

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

SFAS 123R did not change the way we account for non-employee stock-based compensation. We continue to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

For all fair value computations required for employee and non-employee stock-based compensation we use the Black-Scholes option-pricing model which requires assumptions for expected stock price volatility, expected term of the option, risk-free interest rate and expected dividend yield at the grant date. Our stock price fluctuated from \$3.95 per share as of December 31, 2003 to \$0.47 per share as of December 31, 2007.

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

### RESULTS OF OPERATIONS

#### YEARS ENDED DECEMBER 31, 2007 AND DECEMBER 31, 2006

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

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

Research and development in-house overhead, not allocated to specific programs, totaled approximately \$1,400,000 and \$1,700,000, during the twelve months ended December 31, 2007 and 2006, respectively, a decrease of approximately \$300,000, or 19%. As a percent of our total costs these non program specific overhead research and development expenses represented 22% and 29% of total R&D during the twelve months ended December 31, 2007 and 2006, respectively. This decrease was attributable to lower stock-based compensation expense which totaled \$86,048 and \$523,434 during the twelve months ended December 31, 2007 and 2006, respectively. This decrease of approximately \$440,000 or 84% was primarily attributable to warrants we issued to certain scientific advisors

(including Dr. Moshe Talpaz) and fully expensed during the twelve months ended December 31, 2006. Partially offsetting this decrease were approximately \$200,000 in higher scientific advisory fees and consulting services incurred primarily to replace our Executive Vice President of R&D, Donald Picker, who resigned December 15, 2006.

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

General and administrative expenses for the twelve months ended December 31, 2007 decreased \$2,066,828, or 32%, to \$4,317,288 during the twelve months ended December 31, 2007 from \$6,384,116 for the twelve months ended December 31, 2006. This was primarily due to lower stock-based compensation expense recorded during the twelve months ended December 31, 2007 which totaled \$542,312 as compared to \$2,223,044 recorded during the twelve months ended December 31, 2006. This decrease of approximately \$1,700,000 or 76% was primarily attributable to warrants we issued to certain investor relations consultants and fully expensed during the twelve months ended December 31, 2006. Also contributing to reduced general and administrative expenses was a decrease of approximately \$400,000 in investor relations costs during the twelve months ended December 31, 2007.

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

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

#### **YEARS ENDED DECEMBER 31, 2006 AND DECEMBER 31, 2005**

We had no revenues during the twelve months ended December 31, 2006 and 2005 because we did 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 \$295,801, or 5%, to \$6,134,704 for the twelve months ended December 31, 2006 from \$6,430,506 for the twelve months ended December 31, 2005. The single most significant factor contributing to this decrease in research and development expense was our L-Annamycin project where our program expenses decreased to approximately \$1,300,000 during the twelve months ended December 31, 2006. Program expenses, incurred with CROs, include



hospital patient costs, blood testing, drug formulation, synthesis, tableting, data collection, clinical monitoring and FDA consultants. This decreased level of expenditure during the twelve months ended December 31, 2006 compared to approximately \$2,500,000 during the twelve months ended December 31, 2005 during which period we purchased and expensed a supply of drug substance which was used in our 2006 Annamycin clinical trials. Atiprimod clinical program expenses decreased to approximately \$1,700,000 during the twelve months ended December 31, 2006 as compared to approximately \$1,900,000 for the twelve months ended December 31, 2005. Partially offsetting this decrease in L-Annamycin and Atiprimod program expenses were higher expenditures for two of our pre-clinical drug candidates, Degrasyns and SP-304 (Guanilib), increasing to approximately \$1,200,000 during the twelve months ended December 31, 2006, as compared to approximately \$100,000 during the twelve months ended December 31, 2005. Research and development in-house overhead, not allocated to specific clinical programs, totaled approximately \$1,700,000, during the twelve months ended December 31, 2006, a decrease of approximately \$100,000, or 5%, in line with our overall decrease in program expenses. Partially offsetting these decreases in the above cash-based expenditures was higher stock-based compensation expense associated with grants to research and development employees. During the twelve months ended December 31, 2006 and 2005 stock-based compensation expense totaled \$523,434 and \$276,250, respectively. This increase was primarily attributable to our adoption of SFAS 123R on January 1, 2006.

On April 1, 2005 we received an \$885,641 biodefense partnership grant from the NIAID to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over the next two years. Government grant funding under our NIAID grant for the twelve months ended December 31, 2006 and 2005 was \$352,649 and \$226,119, respectively.

General and administrative expenses for the twelve months ended December 31, 2006 were \$6,384,115, an increase of \$526,590 or 9%, from \$5,857,525 for the twelve months ended December 31, 2005. This increase was entirely due to higher cash-based general and administrative expenses partially offset by lower stock-based compensation expense. Cash-based general and administrative expenses increased approximately \$400,000, or 12%, primarily due to approximately \$300,000 of increased investor relations costs and \$150,000 in higher compensation costs, partially offset by lower Sarbanes-Oxley compliance testing services, as a result of regulatory extensions during 2006. Stock-based compensation expense, attributable to general and administrative employees, decreased \$79,601, or 4%, to \$2,223,045 during the twelve months ended December 31, 2006.

Other expense for the twelve months ended December 31, 2006 of \$801,690 was entirely attributable to liquidated damages incurred for not having filed a registration statement covering our February and April 2006 private placements of common stock in accordance with the terms of the registration rights agreement we had with the investors. During the twelve months ended December 31, 2005 Synergy sold certain New Jersey State tax loss carry forwards under a state economic development program for cash of approximately \$177,000. This state tax benefit was recorded as other income and as of December 31, 2005 we had no remaining New Jersey State tax loss carry forwards available for sale.

Net loss for the twelve months ended December 31, 2006 was \$12,919,229 compared to a net loss of \$11,779,457 reported for the twelve months ended December 31, 2005, increased for the reasons discussed above.

The beneficial conversion dividend accreted to the Series A preferred stockholders, upon issuance in the quarter ended December 31, 2006, was \$2,384,485, resulting in a net loss available to common stockholders of \$15,303,714 for the twelve months ended December 31, 2006. This compared to a net loss available to common stockholders of \$11,779,457 reported for the twelve months ended December 31, 2005, during which period we had no preferred share transactions and thus no beneficial conversion feature that needed to be accreted as a dividend.

## LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2007 we had \$3,269,341 in cash and cash equivalents, compared to \$3,904,232 as of December 31, 2006. Net proceeds from our private placements of Series A and B Convertible Preferred Stock yielded \$10,800,000. We used approximately \$8,400,000 in operating activities and invested approximately \$3,000,000 in marketable securities (US Treasury Bills with a maturity of 120 days as of December 31, 2007).

In August 2007, we closed a private placement of 1,147,050 shares of Series B Convertible Preferred Stock (the "Series B Preferred Stock") and 22,941,000 warrants (the "Warrants") to certain investors (the "Investors") for aggregate gross proceeds of \$11,470,500 pursuant to a Securities Purchase Agreement dated as of August 2, 2007 (the "SPA"). 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 (the "Conversion Price"), at the option of the holder, at any time and from time to time. The Warrants are immediately exercisable at \$0.70 per share and are exercisable at any time within three years from the date of issuance. In connection with this transaction we 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 and 2,518,900 shares of common stock exercisable at \$0.70 per share to certain selling agents. The warrants will expire three years after issuance. Pursuant to the SPA, 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 (Guanilil) and the remaining net proceeds shall be used for working capital purposes.

From October 2006 until January 2007, we 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 we 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 we 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 we agreed to file, within 60 days of closing, a registration statement with the Securities and Exchange Commission (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 antidilution rights for the twelve month period beginning on the effective date of the registration statement registering the shares of common stock underlying the warrants. We paid aggregate fees and expenses of \$485,308 (\$448,908 prior to December 31, 2006) in cash, 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. On January 12, 2007 we 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 a result of the August 2, 2007 Series B Preferred Stock financing the conversion price of Series A Preferred Stock and the exercise price of the Series A Warrants was reset from \$0.75 per share to \$0.50 per share as per the antidilution rights discussed above. The proceeds from any prospective exercise of the 8,031,333 Series A Warrants outstanding on the date of reset was decreased by approximately \$2.0 million.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

On September 25, 2007 Synergy, a wholly owned subsidiary, 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 (Guanilib) 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. As of December 31, 2007 such milestones had not been achieved and the escrow had not been established.

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; pre-clinical and clinical testing; obtaining regulatory approvals; technological advances and our ability to establish collaborative arrangements with research organizations and individuals needed to commercialize our products. Our capital resources will be focused primarily on the clinical development and regulatory approval of our current product candidates, and the acquisition of licenses and rights to certain other cancer related drug technologies. We will be required to raise additional capital to complete the development and commercialization of our current product candidates.

Our consolidated financial statements as of December 31, 2007 have been prepared under the assumption that we will continue as a going concern for the twelve months ending December 31, 2008. Our independent registered public accounting firm has issued a report dated March 25, 2008 that included an explanatory paragraph referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

To date, our sources of cash have been primarily limited to the sale of our equity securities. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at its current cash expenditure levels. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

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

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

**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, 2007, and is based on information appearing in the Notes to Consolidated Financial Statements.

	<u>Total</u>	<u>Less than 1 Year</u>	<u>1-2 Years</u>	<u>3-5 Years</u>	<u>More than 5 Years</u>
Operating leases facilities	\$ 554,463	\$ 154,555	\$ 318,444	\$ 81,464	
Purchase obligation principally consulting services	1,210,548	713,673	416,875	80,000	
Minimum spending obligations(1)	2,807,512	2,807,512			
License royalty payments(2)	1,230,000	1,070,000	80,000	80,000	(3)
<b>Total obligations</b>	<b>\$ 5,802,523</b>	<b>\$ 4,745,740</b>	<b>\$ 815,319</b>	<b>\$ 241,464</b>	

(1) This line item represents our minimum obligations to spend monies for product development and commercialization of SP-304 (Guanilib) as set forth in our Series B Preferred Stock purchase agreement.

(2) This line item represents our minimum license fee payments to (i) AnorMED, Inc. for our Atiprimod license and (ii) the University of Texas M.D. Anderson Cancer Center for our Degrasyns license. Our patent license agreements also include milestone royalty payments to be paid in cash upon the achievement of certain regulatory approval and product commercialization goals. These milestone payments have not been estimated because of the uncertainty surrounding the duration of on-going early stage clinical trials and the extent of regulatory approval and review cycles. Since inception we have never achieved regulatory approval of any of our proposed products and we do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years. (See Footnote 8 to our consolidated financial statements for a more detailed description of the terms of our license agreements).

(3) 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, 2007.

**RECENT ACCOUNTING PRONOUNCEMENTS:**

In December 2007, the FASB ratified Emerging Issues Task Force ("EITF") Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, ("EITF 07-1"), which provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure requirements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. We are continuing to evaluate the impact of adopting the provisions EITF 07-1; however, we do not anticipate that adoption will have a material effect on our consolidated results of operations or financial position.

In December 2007, the FASB issued SFAS No. 141(R), a revised version of SFAS No. 141, *Business Combinations*. The revision is intended to simplify existing guidance and converge rulemaking under U.S. generally accepted accounting principles (GAAP) with international accounting rules. This statement applies prospectively to business combinations where the acquisition date is on or after the

beginning of the first annual reporting period beginning on or after December 15, 2008, and may affect the release of our valuation allowance against prior acquisition intangibles. An entity may not apply it before that date. We do not expect that the adoption of this Statement will have a material effect on our financial condition or results of operations.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an amendment of ARB No. 51*. SFAS No. 160 requires all entities to report noncontrolling (minority) interests in subsidiaries as equity in the consolidated financial statements. Its intention is to eliminate the diversity in practice regarding the accounting for transactions between an entity and noncontrolling interests. This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. We do not expect that the adoption of this Statement will have a material effect on our financial condition or results of operations.

In June 2007, the EITF of the FASB reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ("EITF 07-3"). EITF 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts would be recognized as an expense. This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2007 and earlier application is not permitted. This consensus is to be applied prospectively for new contracts entered into on or after the effective date and is not expected to have a material effect on our financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No.159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an Amendment to SFAS 115* ("SFAS 159"). The fair value option established by SFAS 159 permits all entities to measure all eligible items at fair value at specified election dates. A business entity shall report all unrealized gains and losses on items for which the fair value option has been elected, in earnings at each subsequent reporting date. The provisions of SFAS 159 are effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact, if any, of the provisions of SFAS 159.

In September 2006, the FASB issued Statement of Financial Accounting Standards No.157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 does not require any new fair value measurements. SFAS 157 emphasizes a "market-based" as opposed to an "entity-specific" measurement perspective, establishes a hierarchy of fair value measurement methods and expands disclosure requirements about fair value measurements including methods and assumptions and the impact on earnings. Originally, SFAS 157 was to be effective January 1, 2008 and applied prospectively. In February 2008, the FASB issued a Staff Position that partially defers the effective date of SFAS 157 for one year for certain nonfinancial assets and nonfinancial liabilities. We are currently evaluating the impact, if any, of the provisions of SFAS 157.

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

At December 31, 2007 and 2006, a substantial portion of our cash and cash equivalents consists of short term, highly liquid investments in a money market fund managed by a large money center bank (JPMorganChase). Original maturities of fund investments are all less than three months.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

The full text of our audited consolidated financial statements as of December 31, 2007 and 2006 and for the fiscal years ended December 31, 2007, 2006 and 2005 and for the period from June 5, 1996 (inception) to December 31, 2007, begins on page F-1 of this Annual Report on Form 10-K.

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

None

**ITEM 9A. CONTROLS AND PROCEDURES.**

Not applicable

**ITEM 9A(T) CONTROLS AND PROCEDURES.**

*Evaluation of disclosure controls and procedures.* Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of December 31, 2007, our Chief Executive Officer and Principal Financial Officer have concluded that, due to the material weaknesses in our internal control over financial reporting noted below, our disclosure controls and procedures were not effective.

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

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

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

In connection with the preparation of our annual financial statements, we have assessed the effectiveness of internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls. Based on this evaluation, management has determined that as of December 31, 2007, there were material weaknesses in our internal control over financial reporting. In addition, our independent registered public accountants noted certain errors in the calculations required to properly account for complex equity instruments during the third quarter of 2007 which led to the recording of material adjustments to our financial statements, as well as various omissions to our financial statement disclosures. The material weaknesses identified during management's assessment were (i) a lack of sufficient internal accounting expertise to provide reasonable assurance that our financial statements and notes thereto, are prepared in accordance with generally accepted accounting principles (GAAP) and (ii) a lack of segregation of duties to ensure adequate review of financial statement preparation. In light of these material weaknesses, management has concluded that, as of December 31, 2007, we did not maintain effective internal control over financial reporting. As defined by the Public Company Accounting Oversight Board Auditing Standard No. 5, a material weakness is a deficiency or a combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not

be prevented or detected. In order to ensure the effectiveness of our disclosure controls in the future we have added financial staff resources to our accounting and finance department.

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

*Changes in internal control over financial reporting.* There were no changes in our internal controls over financial reporting during the fourth quarter of the year ended December 31, 2007 that have materially affected or are reasonably likely to materially affect our internal controls over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.



## 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 25, 2008:

Name	Age	Positions
Gabriele M. Cerrone	36	Chairman of the Board
Gary S. Jacob	61	Chief Executive Officer, Chief Scientific Officer and Director; Chairman of Synergy Pharmaceuticals Inc.
Bernard F. Denoyer	60	Senior Vice President, Finance and Secretary
John P. Brancaccio	60	Director
Christoph Bruening	40	Director
Riccardo Dalla-Favera	55	Director
Stephen K. Carter	69	Director
Randall Johnson	61	Director

Gabriele M. Cerrone has served as our Chairman of the Board of Directors since May 2003 and as a consultant since January 2005. From March 1999 to January 2005 Mr. Cerrone served as a Senior Vice President of Investments of Oppenheimer & Co. Inc., a financial services firm. Prior to such affiliation, Mr. Cerrone held the position of Managing Director of Investments at Barrington Capital, L.P., a merchant bank, between March 1998 and March 1999. Between May 2001 and May 2003, Mr. Cerrone served on the board of directors of SIGA Technologies, Inc. Mr. Cerrone currently serves as a director of Inhibitex, Inc., a biotechnology company. Mr. Cerrone is the managing partner of Panetta Partners Ltd., a Colorado limited partnership, that is a private investor in real estate and public and private companies engaged in biotechnology and other areas.

Gary S. Jacob, Ph.D. has served as our Chief Executive Officer as well as Chief Scientific Officer since May 2003 and a Director since October, 2004. Dr. Jacob has also served as Chairman of Synergy Pharmaceuticals Inc. since October 2003. Dr. Jacob served as Chief Scientific Officer of Synergy Pharmaceuticals Inc. from 1999 to 2003. From 1990 to 1998, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of Glycobiology. From 1997 to 1998, Dr. Jacob was Director of Functional Genomics, Corporate Science & Technology, Monsanto, where he played a pivotal role in the rapid development of Monsanto's plant genomics strategy and the buildup of the in-house advanced genomics program. From 1990 to 1997, Dr. Jacob was Director of Glycobiology, G.D. Searle Pharmaceuticals Inc. From 1986 to 1990, Dr. Jacob was Manager of the G.D. Searle Glycobiology Group located at Oxford University, England.

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

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 Xenomics, Inc.

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

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

Stephen K. Carter, M.D. has served as a Director of our company since August 2004. Since 2000, Dr. Carter has been employed as an independent consultant. From 1998 to 2000, Dr. Carter was senior vice president, clinical and regulatory affairs of SUGEN, Inc. (subsequently acquired by Pharmacia & Upjohn, Inc.). From 1995 to 1996, Dr. Carter was senior vice president, research and development with Boehringer Ingelheim Pharmaceuticals, Inc. and from 1982 to 1995 held various positions with Bristol-Myers Squibb Company, including senior vice president, worldwide clinical research and development. Dr. Carter is a director of Vion Pharmaceuticals, Inc., Cytogen Corp., Emisphere Technologies Inc., Alfacell Corp. and Tapestry Pharmaceuticals Inc. (each a biotechnology 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.

## COMPENSATION OF DIRECTORS

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

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

## **AUDIT COMMITTEE**

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

The Audit Committee currently consists of John Brancaccio, chairman of the Audit Committee, Christoph Bruening and Randall Johnson. Our board of directors has determined that each of Mr. Bruening, Mr. Johnson and Mr. Brancaccio is "independent" as that term is defined under applicable SEC rules and under the current listing standards of the American Stock Exchange. 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](http://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, John Brancaccio and Stephen Carter. The Board of Directors has determined that all of the members are "independent" under the current listing standards of the American Stock Exchange. 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](http://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.

## **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.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

The Corporate Governance/Nominating Committee currently consists of Stephen Carter, chairman of the Corporate Governance/Nominating Committee, John Brancaccio and Christoph Bruening. The Board of Directors has determined that all of the members are "independent" under the current listing standards of the American Stock Exchange. 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](http://www.callistopharma.com).

### CLINICAL AND SCIENTIFIC ADVISORY BOARD

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

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

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

Kenneth C. Anderson, M.D. Dr. Anderson is the Kraft Family Professor of Medicine at Harvard Medical School; and serves as Chief of the Division of Hematologic Neoplasia, Director of the Jerome Lipper Multiple Myeloma Center and Vice Chair of the Joint Program in Transfusion Medicine at Dana-Farber Cancer Institute. His translational research focuses on development of novel therapeutics targeting the myeloma cell in its microenvironment. He hosted the VI International Myeloma Workshop on Multiple Myeloma, serves on the Board of Directors and as Chairman of the Scientific Advisors of the Multiple Myeloma Research Foundation, and is a Doris Duke Distinguished Clinical Research Scientist.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

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

### **COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT.**

Section 16(a) of the Securities Exchange Act of 1934 requires our officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission and American Stock Exchange. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

Based on a review of the copies of such forms received, we believe that during 2007, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with, except that a Form 4 with respect to Christoph Bruening and Randall Johnson was filed late.

### **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](http://www.callistopharma.com).

**ITEM 11. EXECUTIVE COMPENSATION.**

**Compensation Committee Report**

*Under the rules of the SEC, this Compensation Committee Report is not deemed to be incorporated by reference by any general statement incorporating this Annual Report by reference into any filings with the SEC.*

The Compensation Committee has reviewed and discussed the following Compensation Discussion and Analysis with management. Based on this review and these discussions, the Compensation Committee recommended to the Board of Directors that the following Compensation Discussion and Analysis be included in this Annual Report on Form 10-K.

*Submitted by the Compensation Committee*

Randall Johnson, Chairman

John Brancaccio

Stephen Carter

**Compensation Discussion and Analysis**

*Overview*

We compete with many other biotechnology companies in seeking to attract and retain a skilled work force. To meet this challenge, we have developed our compensation structure to enable our management to make decisions regarding our compensation programs, to manage these programs, and to effectively communicate the goals of these programs to our employees and stockholders.

Our compensation philosophy is to offer our employees compensation and benefits that are competitive and that meet our goals of attracting, retaining and motivating highly skilled employees so that we can achieve our financial and strategic objectives.

Utilizing this philosophy, our compensation programs are designed to:

be "market-based" and reflect the competitive environment for personnel;

stress our "pay for performance" approach to managing pay levels;

share risks and rewards with employees at all levels;

be affordable, within the context of our operating expense model;

align the interests of our employees with those of our stockholders;

reflect our values; and

be fairly and equitably administered.

In addition, as we administer our compensation programs, we plan to:

evolve and modify our programs to reflect the competitive environment and our changing business needs;

focus on simplicity, flexibility and choice wherever possible;

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

openly communicate the details of our programs with our employees and managers to ensure that our programs and their goals are understood; and

provide our managers and employees with the tools they need to administer our compensation programs.

### *Elements of Our Compensation Program*

As a total rewards package, we design our compensation program to enable us to attract and retain talented personnel. The individual elements of our compensation program serve to satisfy this larger goal in specific ways as described below.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

We design base pay to provide the essential reward for an employee's work, and is required to be competitive in attracting talent. Once base pay levels are initially determined, increases in base pay are provided to recognize an employee's specific performance achievements. Consistent with our compensation philosophy, we implement a "pay for performance" approach that provides higher levels of compensation to individual employees whose results merit greater rewards. Our managers typically make performance assessments throughout the year, and provide ongoing feedback to employees, provide resources and maximize individual and team performance levels.

We design equity-based compensation, including stock options, to ensure that we have the ability to retain talent over a longer period of time, and to provide optionees with a form of reward that aligns their interests with those of our stockholders. Employees whose skills and results we deem to be critical to our long-term success are eligible to receive higher levels of equity-based compensation.

We also utilize various forms of variable compensation, including cash bonuses that allow us to remain competitive with other companies while providing upside potential to those employees who achieve outstanding results.

Core benefits, such as our basic health benefits, are designed to provide a stable array of support to employees and their families throughout various stages of their careers, and are provided to all employees regardless of their individual performance levels.

The four key elements of our compensation structure are:

base pay;

variable pay;

equity-based pay; and

benefits.

Consistent with our compensation philosophy, we have structured each element of our rewards package as follows:

### ***Base Pay***

We create a set of base pay structures that are both affordable and competitive in relation to the market. We continuously monitor base pay levels within the market and make adjustments to our structures as needed. In general, an employee's base pay level should reflect the employee's overall sustained performance level and contribution to our company over time. We seek to structure the base pay for our top performers to be aggressive in relation to the market.

### ***Variable Pay***

We design our variable pay programs to be both affordable and competitive in relation to the market. We monitor the market and adjust our variable pay programs as needed. Our variable pay programs, such as our bonus program, are designed to motivate employees to achieve overall goals. Our programs are designed to avoid entitlements, to align actual payouts with the actual results achieved and to be easy to understand and administer.

### ***Equity-Based Rewards***

We design our equity programs to be both affordable and competitive in relation to the market. We monitor the market and applicable accounting, corporate, securities and tax laws and regulations and adjust our equity programs as needed. Stock options and other forms of equity compensation are designed to reflect and reward a high level of sustained individual performance over time. We design our equity programs to align employees' interests with those of our stockholders.



***Benefits Programs***

We design our benefits programs to be both affordable and competitive in relation to the market while conforming with local laws and practices. We monitor the market, local laws and practices and adjust our benefits programs as needed. We design our benefits programs to provide an element of core benefits, and to the extent possible, offer options for additional benefits, be tax-effective for employees in each country and balance costs and cost sharing between us and our employees.

*Determining the Amount of Each Element of Compensation*

***Base Pay.*** We provide our executive officers and other employees with base salary to compensate them for services rendered during the fiscal year. The Compensation Committee intends to compensate our executive officers competitively within the industry. The Compensation Committee considered the scope of and accountability associated with each executive officer's position and such factors as the performance and experience of each executive officer when setting base salary levels for fiscal year 2007. With respect to executive officers other than Dr. Jacob, who is discussed below, the Compensation Committee targeted base salaries to be competitive with our peers within the biotechnology industry. In some circumstances it is necessary to provide compensation above these levels; these circumstances include the need to retain key individuals, to recognize roles that were larger in scope or accountability than standard market positions and/or to reward individual performance.

Salary levels are typically reviewed annually as part of our performance review process as well as upon a promotion or other change in job responsibility.

***Variable Pay.*** The Compensation Committee and the executive officer work together to establish targets and goals for the executive officer. Upon completion of the fiscal year, the Compensation Committee assesses the executive officer's performance and with input from management determines the amount of variable pay to be awarded within the parameters of the executive officer's agreement with us..

***Equity-Based Pay.*** The Compensation Committee may provide our executive officers with long-term incentive awards through grants of stock options. The Compensation Committee is responsible for determining who will receive awards, when awards will be granted, the exercise price of each stock option grant, and the number of shares of our common stock subject to each option. The Compensation Committee considers grants of long-term incentive awards to executive officers each fiscal year. Stock options enhance the link between the creation of stockholder value and long-term executive incentive compensation. Stock options provide our executive officers with the opportunity to purchase and maintain an equity interest in our company and to share in the appreciation of the value of our common stock. Additionally, stock options maintain a competitive level of total compensation. The Compensation Committee believes that stock options are inherently performance-based and are a form of at-risk compensation, as the optionee does not receive any benefit unless our stock price rises after the date that the option is granted, thus providing direct incentive for future performance. Stock option award levels are determined based on prevailing market practice and market data and vary among participants based on their positions within our company.

Our stock options typically have annual vesting over a three-year period and a term of ten years, in order to encourage a long-term perspective and to encourage key employees to remain with us. We also use performance based vesting in our option grants. Generally, vesting and exercise rights cease upon termination of employment. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including voting rights and the right to receive dividends or dividend equivalents.

*Timing of Equity Awards*

Only the Compensation Committee may approve stock option grants to our executive officers. Stock options are generally granted at predetermined meetings of the Compensation Committee. On limited occasions, grants may occur upon unanimous written consent of the Compensation Committee, which occurs primarily for the purpose of approving a compensation package for newly hired or promoted executive. The exercise price of a newly granted option is the closing price of our common stock on the American Stock Exchange on the date of grant.

*Executive Equity Ownership*

We encourage our executives to hold a significant equity interest in our company. However, we do not have specific share retention and ownership guidelines for our executives.

*Performance-Based Compensation and Financial Restatement*

We have not considered or implemented a policy regarding retroactive adjustments to any cash or equity-based incentive compensation paid to our executives and other employees where such payments were predicated upon the achievement of certain financial results that were subsequently the subject of a financial restatement.

*Severance and Change in Control Arrangements*

Several of our executives have employment and other agreements which provide for severance payment arrangements and/or acceleration of stock option vesting that would be triggered by an acquisition or other change in control of our company. See " Employment Agreements and Change of Control Arrangements" below for a description of the severance and change in control arrangements for our named executive officers.

*Effect of Accounting and Tax Treatment on Compensation Decisions*

In the review and establishment of our compensation programs, we consider the anticipated accounting and tax implications to us and our executives.

Section 162(m) of the Internal Revenue Code imposes a limit on the amount of compensation that we may deduct in any one year with respect to our chief executive officer and each of our next four most highly compensated executive officers, unless certain specific and detailed criteria are satisfied. Performance-based compensation, as defined in the Internal Revenue Code, is fully deductible if the programs are approved by stockholders and meet other requirements. We believe that grants of equity awards under our existing stock plans qualify as performance-based for purposes of satisfying the conditions of Section 162(m), thereby permitting us to receive a federal income tax deduction in connection with such awards. In general, we have determined that we will not seek to limit executive compensation so that it is deductible under Section 162(m). However, from time to time, we monitor whether it might be in our interests to structure our compensation programs to satisfy the requirements of Section 162(m). We seek to maintain flexibility in compensating our executives in a manner designed to promote our corporate goals and therefore our compensation committee has not adopted a policy requiring all compensation to be deductible. Our compensation committee will continue to assess the impact of Section 162(m) on our compensation practices and determine what further action, if any, is appropriate.

*Role of Executives in Executive Compensation Decisions*

Our board of directors and our Compensation Committee generally seek input from our Chief Executive Officer, Gary S. Jacob, when discussing the performance of, and compensation levels for executives other than himself. The Compensation Committee also works with Dr. Jacob and our Vice President, Finance evaluating the financial, accounting, tax and retention implications of our various

compensation programs. Neither Dr. Jacob nor any of our other executives participates in deliberations relating to his or her own compensation.

### Chief Executive Officer Compensation for Fiscal Year 2007

On February 16, 2007, Dr. Jacob entered into an Extension and Amendment Agreement with us as approved by the Compensation Committee which extended the term under his employment agreement to June 30, 2009. In addition, pursuant to the agreement, Dr. Jacob was granted 225,000 ten year incentive stock options exercisable at \$0.81 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. The Compensation Committee believes the grant of options to Dr. Jacob is a key component of his compensation and an important means of ensuring that as Chief Executive Officer he continues to share significantly in the success of our business with the other stockholders. The Compensation Committee determined that it was appropriate to grant these options for these reasons and due to Dr. Jacob's performance. Dr. Jacob received a salary of \$300,000 for 2007. Dr. Jacob also earned a bonus \$78,750 for 2007. Dr. Jacob's bonus was earned pursuant to this employment agreement and is based on achieving key performance objectives for our company as approved and measured by the Compensation Committee.

### 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 2007.

Name & Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards \$(1)	Total (\$)
<b>Gabriele M. Cerrone(2)</b> Chairman of the Board	2007	252,083	84,147	130,793	467,023
	2006	213,542	125,855		339,397
	2005	191,498	30,750		222,248
<b>Gary S. Jacob</b> Chief Executive Officer and Chief Scientific Officer	2007	300,000	78,750	109,323	488,073
	2006	287,500	48,125	82,147	417,772
	2005	225,000	33,750		258,750
<b>Bernard F. Denoyer</b> Senior Vice President, Finance and Secretary	2007	123,500	12,000	29,862	165,362
	2006	111,576	10,461		122,037
	2005	79,167	6,563		85,730
<b>Daniel S. D'Agostino(3)</b> Former Chief Business Officer	2007	102,083			102,083
	2006	175,000	32,814		207,814

- (1) Amounts represent stock-based compensation expense for fiscal year 2007 and 2006 for stock options granted in 2007 and 2006 under SFAS 123R as discussed in Note 3 Summary of Significant Accounting Policies subheading "Share-based payments," of the Notes to our Consolidated Financial Statements included elsewhere in this report.
- (2) Mr. Cerrone is being paid pursuant to a consulting agreement with us.
- (3) Mr. D'Agostino was appointed Chief Business Officer in October 2005. From October 2004 to October 2005, Mr. D'Agostino served as a consultant to us. Mr. D'Agostino left our company on August 1, 2007.

## GRANTS OF PLAN-BASED AWARDS

The following table sets forth information regarding stock option awards to our named executive officers under our stock option plans during the fiscal year ended December 31, 2007:

Name	Grant Date	Number of Securities Underlying Options(#)	Exercise or Base Price of Option Awards (\$/Share)	Fair Value at Grant Date of Option Awards(1)
Gary S. Jacob	February 16, 2007	225,000(2)	0.81	\$ 29,188
Bernard F. Denoyer	April 12, 2007	75,000(3)	0.66	\$ 5,297
Gabriele M. Cerrone	January 25, 2007	225,000(2)	0.96	\$ 13,851

- (1) Amount represents stock-based compensation expense for stock options granted in 2007 under SFAS 123R as discussed in Note 3 Summary of Accounting Policies subheading "Share-based payments," of the Notes to our Consolidated Financial Statements included elsewhere in this annual report.
- (2) 75,000 options vest on each of December 31, 2007, 2008 and 2009.
- (3) 25,000 options vest on each of April 12, 2008, 2009 and 2010.

## OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table sets forth information for the named executive officers regarding the number of shares subject to both exercisable and unexercisable stock options, as well as the exercise prices and expiration dates thereof, as of December 31, 2007.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Gary S. Jacob	500,000		1.50	June 13, 2013
	112,500	162,500(1)	3.00	June 29, 2014
	200,000	150,000(2)	1.01	July 6, 2015
	50,000	100,000(3)	1.64	March 17, 2016
	75,000	150,000(4)	0.81	February 16, 2017
Bernard F. Denoyer	100,000		3.60	January 15, 2014
	50,000	25,000(5)	1.38	July 29, 2015
		75,000(6)	0.66	April 12, 2017
Gabriele M. Cerrone	189,167		0.75	May 3, 2008
	27,778		0.75	October 1, 2009
	200,000		1.25	January 18, 2011
	333,055		1.30	April 22, 2013
	75,000		1.50	June 13, 2013
	100,000		3.20	April 26, 2014
	375,000		1.70	January 10, 2015
	75,000	150,000(7)	0.96	January 25, 2017
Daniel S. D'Agostino	100,000		1.53	October 10, 2015

- (1) The remaining 162,500 options vest upon certain drug development or licensing benchmarks.
- (2) 150,000 options vest on July 6, 2008.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

- (3) 50,000 options vest on each of March 17, 2008 and 2009.
- (4) 75,000 options vest on each of December 31, 2008 and 2009.
- (5) 25,000 options vest on July 29, 2008.
- (6) 25,000 options vest on each of April 12, 2008, 2009 and 2010.
- (7) 75,000 options vest on each of December 31, 2008 and 2009.

### DIRECTOR COMPENSATION

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2007 for services to our company.

Name	Fees Earned or Paid in Cash (\$)	Option Awards \$(1)	Total (\$)
Christoph Bruening(2)	28,750	269	29,019
Riccardo Dalla-Favera(3)	15,000	167	15,167
John P. Brancaccio(4)	31,500	537	32,037
Stephen K. Carter(5)	23,125	323	23,448
Randall Johnson(6)	22,750	457	23,207

- (1) Amounts represent the expensed fair value for fiscal year 2007 of stock options granted in 2007 under SFAS 123R as discussed in Note 3 Summary of Significant Accounting Policies subheading "Share-based payments," of the Notes to Consolidated Financial Statements included in this annual report.
- (2) Stock options for the purchase of an aggregate of 236,000 shares were outstanding as of December 31, 2007, with a grant date fair value of \$437,260.
- (3) Stock options for the purchase of an aggregate of 95,000 shares were outstanding as of December 31, 2007, with a grant date fair value of \$65,723.
- (4) Stock options for the purchase of an aggregate of 134,123 shares were outstanding as of December 31, 2007, with a grant date fair value of \$228,474.
- (5) Stock options for the purchase of an aggregate of 114,861 shares were outstanding as of December 31, 2007, with a grant date fair value of \$121,873.
- (6) Stock options for the purchase of an aggregate of 115,500 shares were outstanding as of December 31, 2007, with a grant date fair value of 112,891.

### EMPLOYMENT AGREEMENTS AND CHANGE IN CONTROL ARRANGEMENTS

We are party to an employment agreement with Gary S. Jacob, Ph.D. dated June 13, 2003, pursuant to which Dr. Jacob serves as our Chief Executive Officer and Chief Scientific Officer. Dr. Jacob's employment agreement, as amended, is in effect until December 31, 2009. Dr. Jacob's

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

base salary is \$300,000 per year and he may earn a performance bonus of 20% of his base salary, per year, based on meeting performance objectives and bonus criteria to be mutually identified by Dr. Jacob and the Compensation Committee of the Board of Directors. During 2007, Dr. Jacob exceeded his performance objectives and earned a bonus of \$78,750. On February 16, 2007, Dr. Jacob was granted 225,000 ten year incentive stock options exercisable at \$0.81 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009.

Dr. Jacob is a party to an Extension and Severance Agreement with us dated June 9, 2005 as amended February 16, 2007 which provides that in the event there is a change of control of our company and the executive's employment shall have been terminated within two years after a change in control by him for good reason or by our company and such termination did not occur as a result of (i) the executive's death, (ii) the executive's disability, (iii) the executive's retirement or (iv) the

executive's termination for cause, the executive shall be entitled to an amount equal to the compensation due to the executive for the term of his employment under his employment agreement for the time remaining of such employment term. In addition, all of the executive's unvested stock options shall immediately and irrevocably vest and the exercise period of such options will be extended to the later of the longest period permitted by our stock option plans or ten years following termination. A "Change in Control" shall be deemed to have occurred if (i) there shall be consummated (A) any consolidation or merger of our company in which we are not the continuing or surviving corporation or pursuant to which shares of our common stock would be converted into cash, securities or other property, other than a merger of our company in which the holders of our common stock immediately prior to the merger have substantially the same proportionate ownership of common stock of the surviving corporation immediately after the merger, or (B) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all or substantially all the assets of our company; or (ii) the stockholders of our company shall approve any plan or proposal for the liquidation or dissolution of our company, (ii) any person (as such term is used in Sections 13(d) and 14(d)(2) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than us or any employee benefit plan sponsored by us, shall become the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act) of our securities representing 20% or more of the combined voting power of our then outstanding securities ordinarily (and apart from rights accruing in special circumstances) having the right to vote in the election of directors, as a result of a tender or exchange offer, open market purchases, privately negotiated purchases or otherwise, or (iv) at any time during a period of two consecutive years, individuals who at the beginning of such period constituted the Board of Directors of our company shall cease for any reason to constitute at least a majority thereof, unless the election or the nomination for election by our stockholders of each new director during such two-year period was approved by a vote of at least two-thirds of the directors then still in office who were directors at the beginning of the two-year period (or in the case that Dr. Jacob is our CEO, in addition if the Board appoints a new CEO during the term of the agreement or substantially reduces the title and authority of Dr. Jacob without his prior consent). Had a "Change of Control" occurred on December 31, 2007 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 \$720,000. As of December 31, 2007 the unrecognized fair value of all Dr. Jacob's unvested options was \$147,471.

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 is \$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. During 2007, Mr. Denoyer earned a bonus of \$12,000. On April 12, 2007, Mr. Denoyer was granted 75,000 ten year incentive stock options exercisable at \$0.66 per share of which 25,000 vest on each of April 12, 2008, 2009 and 2010.

#### **CONSULTING AGREEMENTS**

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 (Guanilib) 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 and can be terminated by us at our discretion, at any time.



## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

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 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 December 27, 2004, we entered into a consulting agreement (the "Original Agreement") with Gabriele M. Cerrone, our Chairman of the Board and a principal stockholder. On January 25, 2007, we entered into an Extension and Amendment Agreement with Mr. Cerrone. The Extension and Amendment Agreement extends the term of the Original Agreement between us and Mr. Cerrone to December 31, 2009. Among other things, the Extension and Amendment Agreement increases Mr. Cerrone's compensation from \$205,000 to \$275,000 per year. In addition, Mr. Cerrone was granted 225,000 ten year non-qualified stock options at an exercise price of \$0.96 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. Under the Original Agreement, Mr. Cerrone received a grant of 375,000 ten year non-qualified stock options at an exercise price of \$1.70 per share, all of which have vested. Additionally, pursuant to the Original Agreement, in recognition of the services beyond that required of Mr. Cerrone during 2006, Mr. Cerrone earned a bonus of \$125,855. Under the Extension and Amendment Agreement Mr. Cerrone may earn a performance bonus of 22.5% of his base compensation, for each twelve month period during the term of the Extension and Amendment Agreement, based on meeting performance objectives and bonus criteria to be mutually identified by Mr. Cerrone and the Compensation Committee of our Board of Directors. During 2007 Mr. Cerrone exceeded his performance objectives and earned a performance bonus of \$84,147 under the Extension and Amendment Agreement. As of December 31, 2007 the unrecognized fair value of all Mr. Cerrone's unvested options was \$30,758.

In the event the agreement is terminated without cause or for good reason, Mr. Cerrone will receive a cash payment equal to the aggregate amount of his annual fee for the then remaining term of the Agreement and all unvested stock options will immediately vest and the exercise period of such options will be extended to the later of the longest period permitted by our stock option plans or ten years following termination. In the event a change of control of the Company occurs, Mr. Cerrone shall be entitled to such compensation upon the subsequent termination of the agreement within two years of the change in control unless such termination is the result of Mr. Cerrone's death, disability or retirement or his termination for cause. Had Mr. Cerrone been terminated without cause or good reason on December 31, 2007 he would have been eligible for total compensation of \$673,750 for the time remaining under the Extension and Amendment Agreement.

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.

In 1996, we 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 4,148,374 options outstanding to date 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 3,418,000 options available for future grants as of December 31, 2007.

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 841,500 option shares available for future grants as of December 31, 2007.

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

The options we grant under the 2005 Equity Plan may be either "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), or non-statutory stock options at the discretion of the Board of Directors and as reflected in the terms of the written option agreement. None of our stock option plans are qualified deferred compensation plans under Section 401(a) of the Code, and are not subject to the provisions of the Employee Retirement Income Security Act of 1974, as amended (ERISA). As of December 31, 2006, we have 2,352,333 stock options outstanding not subject to our stock option plans.

**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 25, 2008 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 of Class
Gabriele M. Cerrone Chairman of the Board	3,576,737(2)	7.3%
Gary S. Jacob Chief Executive Officer, Chief Scientific Officer and Director	1,124,745(3)	2.3%
Bernard Denoyer Senior Vice President, Finance and Secretary	150,000(4)	*
Daniel S. D'Agostino Former Chief Business Officer	116,448(5)	*
Riccardo Dalla-Favera Director	57,000(6)	*
Stephen Carter Director	98,861(7)	*
Christoph Bruening Director	596,699(8)	1.3%
John Brancaccio Director	114,123(9)	*
Randall K. Johnson Director	97,000(10)	*
All Directors and Executive Officers as a group (9 persons)	5,956,613(12)	11.8%

\*  
less than 1%

(1)  
Applicable percentage ownership as of March 25, 2008 is based upon 47,218,161 shares of common stock outstanding.

(2)  
Consists of 1,375,000 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone and 2,126,737 shares of common stock, 45,000 shares of common stock issuable upon conversion of 2,250 shares of Series A Convertible Preferred Stock and 30,000 shares of common stock issuable upon exercise of warrants, each 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 987,500 shares of common stock issuable upon exercise of stock options.
- (4) Consists of 175,000 shares of common stock issuable upon exercise of stock options.
- (5) Includes 100,000 shares of common stock issuable upon exercise of stock options.
- (6) Consists of 57,000 shares of common stock issuable upon exercise of stock options.
- (7) Consists of 98,861 shares of common stock issuable upon exercise of stock options.
- (8) Includes 121,000 shares of common stock issuable upon exercise of stock options.
- (9) Consists of 114,123 shares of common stock issuable upon exercise of stock options.
- (10) Consists of 97,000 shares of common stock issuable upon exercise of stock options.
- (12) Includes 3,125,484 shares of common stock issuable upon exercise of stock options, 45,000 shares of common stock issuable upon conversion of 2,250 shares of Series A Convertible Preferred Stock 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.**

On December 27, 2004 we entered into a consulting agreement with Gabriele M. Cerrone, our Chairman of the Board and a principal shareholder. On January 25, 2007, we entered into an Extension and Amendment Agreement with Mr. Cerrone. The agreement extends the term of the consulting agreement between us and Mr. Cerrone dated as of December 27, 2004 to December 31, 2009. Among other things, the agreement increases Mr. Cerrone's compensation from \$205,000 to \$275,000 per year. In addition, Mr. Cerrone was granted 225,000 ten year non-qualified stock options at an exercise price of \$0.96 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. Additionally pursuant to the agreement, in recognition of the services beyond that required of Mr. Cerrone during the period from July 1, 2006 to January 25, 2007, we will accrue a bonus to Mr. Cerrone of \$75,000, payable on March 31, 2007. Mr. Cerrone shall be eligible to earn a cash bonus of up to 22.5% of his base compensation for each twelve month period during the term of the agreement based on meeting performance objectives and bonus criteria to be mutually identified by Mr. Cerrone and our Board.

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 Item 9 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.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

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

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

#### AUDIT FEES.

The aggregate fees billed and unbilled for the fiscal year ended December 31, 2007 for professional services rendered by our principal accountants for the audits of our annual financial statements, the review of our financial statements included in our quarterly reports on Form 10-Q and consultations and consents were approximately \$131,000. The aggregate fees billed and unbilled for the fiscal year ended December 31, 2006 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 \$138,750.

#### AUDIT-RELATED FEES.

There were no aggregate fees billed for the fiscal year ended December 31, 2007 and 2006 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.

There were no aggregate fees billed for the fiscal years ended December 31, 2007 and 2006 as there were no tax related or other services rendered by our principal accountants in connection with the preparation of our federal and state tax returns.

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

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a)

*List of Documents Filed as a Part of This Report:*

(1)	<i>Index to Consolidated Financial Statements:</i>	F-1
	Report of Independent Registered Public Accounting Firm	F-2
	Consolidated Balance Sheets as of December 31, 2007 and 2006	F-3
	Consolidated Statements of Operations for each of the three years in the period ended December 31, 2007 and for the period from June 5, 1996 (inception) to December 31, 2007	F-4
	Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period from June 5, 1996 (inception) to December 31, 2007	F-5
	Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2007 and for the period from June 5, 1996 (inception) to December 31, 2007	F-12
	Notes to Consolidated Financial Statements	F-13

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

(2)

### *Index to Financial Statement Schedules:*

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

(3)

### *Index to Exhibits*

#### **Index to Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
3.1	Certificate of Incorporation, as amended
3.2	Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed on October 27, 2006)
3.3	Certificate of Amendment to Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.2 filed with the Company's Current Report on Form 8-K filed on December 27, 2006)
3.4	Certificate of Amendment to Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.2 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
3.5	Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series B Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
3.6	Bylaws, as amended (Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed on June 4, 2007)
4.1	1996 Incentive and Non-Qualified Stock Option Plan (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on May 15, 2003)
4.2	Form of Warrant to purchase shares of common stock issued in connection with the sale of common stock (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on January 28, 2004)
4.3	Form of Warrant issued to Trilogy Partners, Inc. (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on July 22, 2005)
4.4	2005 Equity Compensation Incentive Plan (Incorporated by reference to Appendix B filed with the Company's Definitive Proxy Statement on Schedule 14A filed on August 31, 2005)
4.5	2005 Directors' Stock Option Plan (Incorporated by reference to Appendix C filed with the Company's Definitive Proxy Statement on Schedule 14A filed on August 31, 2005)
4.6	Form of Warrant to purchase Common Stock issued in connection with the sale of Common Stock (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on February 9, 2006)
4.7	Form of Warrant to purchase Common Stock issued to certain selling agents in connection with the sale of Common Stock (Incorporated by reference to Exhibit 4.2 filed with the Company's Current Report on Form 8-K filed on February 9, 2006)
4.8	Form of Warrant issued pursuant to the Letter Agreement dated September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on September 14, 2006)





## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

- 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 Common Stock Purchase Warrant to purchase 1,150,000 shares of common stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on October 1, 2007)
- 10.1 Employment Agreement dated June 13, 2003 by and between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (Incorporated by reference to Exhibit 10.1 filed with the Company's Quarterly Report on Form 10-QSB filed on August 20, 2003)\*
- 10.2 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)\*
- 10.3 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.\*\*
- 10.5 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)\*\*
- 10.6 License Agreement between Callisto Pharmaceuticals, Inc. and The Rockefeller University effective as of July 25, 2001 (Incorporated by reference to Exhibit 10.12 filed with the Company's Annual Report on Form 10-K filed on June 6, 2005)
- 10.7 Extension and Severance Compensation Agreement dated June 9, 2005 between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on June 15, 2005)\*
- 10.10 Amendment dated October 19, 2005 to the Employment Agreement dated as of June 13, 2003 by and between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on October 21, 2005)\*
- 10.12 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)\*
- 10.13 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)\*\*
- 10.15 Form of Letter Agreement dated September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on September 14, 2006)
- 10.16 Form of Amendment Agreement dated as of September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on September 14, 2006)

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

- 10.18 Form of Securities Purchase Agreement dated October 23, 2006 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on October 27, 2006)
- 10.19 Form of Registration Rights Agreement dated October 23, 2006 by and among Callisto Pharmaceuticals, Inc. and the purchaser's signatory thereto (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on October 27, 2006)
- 10.20 Form of Securities Purchase Agreement dated December 20, 2006 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on December 27, 2006)
- 10.21 Form of Securities Purchase Agreement dated January 10, 2007 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on January 17, 2007)
- 10.22 Extension and Amendment Agreement dated January 25, 2007 between Callisto Pharmaceuticals, Inc. and Gabriele M. Cerrone (Incorporated by reference to Exhibit 10.23 filed with the Company's Annual Report on Form 10-K filed on April 17, 2007)\*
- 10.23 Extension and Amendment Agreement dated February 16, 2007 between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (Incorporated by reference to Exhibit 10.22 filed with the Company's Annual Report on Form 10-K filed on April 17, 2007)\*
- 10.24 Form of Securities Purchase Agreement dated August 2, 2007 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
- 10.25 Form of Registration Rights Agreement dated August 2, 2007 by and among Callisto Pharmaceuticals, Inc. and the purchaser's signatory thereto (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
- 10.26 Amended and Restated Employment Agreement dated December 10, 2007 by and between Callisto Pharmaceuticals, Inc and Bernard Denoyer\*
- 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

\*

Management contract or compensatory plan or arrangement required to be filed as an Exhibit to this form pursuant to Item 601 of Regulation S-K.

\*\*

Confidential treatment has been requested with respect to deleted portions of this agreement.



**SIGNATURES**

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

CALLISTO PHARMACEUTICALS, INC.

Date: March 27, 2008

By: /s/ GARY S. JACOB

Gary S. Jacob,  
*Chief Executive Officer*

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

<b>SIGNATURE</b>	<b>TITLE</b>	<b>DATE</b>
/s/ GARY S. JACOB	Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2008
Gary S. Jacob		
/s/ BERNARD F. DENOYER	Senior Vice President, Finance (Principal Financial and Accounting Officer)	March 27, 2008
Bernard F. Denoyer		
/s/ GABRIELE M. CERRONE	Chairman of the Board	March 27, 2008
Gabriele M. Cerrone		
/s/ RICCARDO DALLA-FAVERA	Director	March 27, 2008
Riccardo Dalla-Favera		
/s/ JOHN P. BRANCACCIO	Director	March 27, 2008
John P. Brancaccio		
/s/ STEPHEN K. CARTER	Director	March 27, 2008
Stephen K. Carter		
/s/ CHRISTOPH BRUENING	Director	March 27, 2008
Christoph Bruening		
/s/ RANDALL K. JOHNSON	Director	March 27, 2008
Randall K. Johnson		

**CALLISTO PHARMACEUTICALS, INC.**

(A Development Stage Company)

**Index to Consolidated Financial Statements**

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

F-1

---

**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, 2007 and 2006, the related consolidated statements of operations and cash flows for each of the three years in the period ended December 31, 2007 and for the period from June 5, 1996 (inception) to December 31, 2007 and the related consolidated statement of stockholders' equity (deficit) for the period from June 5, 1996 (inception) to December 31, 2007. 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, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 and for the period from June 5, 1996 (inception) to December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

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

As described in Note 3, in 2006 the Company adopted the provisions of Statement of Financial Accounting Standard No. 123(R) "Share Based Payments" utilizing the modified prospective transition method.

/s/ BDO SEIDMAN, LLP

---

New York, New York  
March 25, 2008

## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

## CONSOLIDATED BALANCE SHEETS

	<u>December 31, 2007</u>	<u>December 31, 2006</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,269,341	\$ 3,904,232
Short term investments	2,967,690	
Prepaid expenses and other	88,820	66,741
	<u>6,325,851</u>	<u>3,970,973</u>
Property and equipment net	15,108	6,451
Security deposits	73,716	73,716
	<u>\$ 6,414,675</u>	<u>\$ 4,051,140</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,254,992	\$ 1,843,422
Accrued expenses	1,366,333	1,357,600
	<u>4,621,325</u>	<u>3,201,022</u>
Stockholders' equity:		
Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized, 218,675 shares outstanding at December 31, 2007 with a liquidation preference of \$2,186,750 and 586,125 shares outstanding at December 31, 2006 with a liquidation preference of \$5,861,250	22	58
Series B convertible preferred stock, par value \$0.0001, 2,500,000 shares authorized, 1,147,050 shares outstanding at December 31, 2007 with a liquidation preference of \$11,470,500	115	
Common stock, par value \$.0001, 225,000,000 and 100,000,000 shares authorized and 46,943,161 and 39,194,996 shares outstanding at December 31, 2007 and 2006, respectively	4,694	3,919
Additional paid-in capital	83,120,315	61,290,509
Deficit accumulated during development stage	(81,331,796)	(60,444,368)
	<u>1,793,350</u>	<u>850,118</u>
	<u>\$ 6,414,675</u>	<u>\$ 4,051,140</u>

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

## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

## CONSOLIDATED STATEMENTS OF OPERATIONS

	For the years ended December 31,			For the period From June 5, 1996 (Inception) to December 31, 2007
	2007	2006	2005	
Revenues	\$	\$	\$	\$
Costs and expenses:				
Research and development	6,507,978	6,134,704	6,430,505	28,648,543
Government grant	(260,853)	(352,649)	(226,119)	(1,105,318)
Purchased in process research and development				6,944,553
General and administrative	4,317,288	6,384,116	5,857,525	34,666,839
Loss from operations	(10,564,413)	(12,166,171)	(12,061,911)	(69,154,617)
Interest and investment income	84,694	48,632	105,303	788,310
Other income (expense)	1,449	(801,690)	177,151	(171,846)
Change in fair value of Series B Preferred stock investor warrants from date of issuance to expiration of put option	2,591,005			2,591,005
Net loss	(7,887,265)	(12,919,229)	(11,779,457)	(65,947,148)
Series A Preferred stock beneficial conversion feature accreted as a dividend	(2,504,475)	(2,384,485)		(4,888,960)
Series B Preferred stock beneficial conversion feature accreted as a dividend	(10,495,688)			(10,495,688)
Net loss available to common stockholders	\$ (20,887,428)	\$ (15,303,714)	\$ (11,779,457)	\$ (81,331,796)
Weighted average shares outstanding:				
basic and diluted	41,770,669	37,941,267	31,527,060	
Net loss per common share:				
basic and diluted	\$ (0.50)	\$ (0.40)	\$ (0.37)	

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



## 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					
Net loss for the year					
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
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

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance at inception, June 5, 1996			
Net loss for the year		(404,005)	(404,005)
Issuance of founder shares			792
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			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 issue			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
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

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

	Preferred Stock	Preferred Stock Par Value	Common Stock	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, 2002	4,235,299	423	13,083,695	1,307	14,538,618		\$ (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	(4,235,299)	(423)	4,235,299	423				
Common stock issued to former Synergy stockholders			4,329,927	432	6,494,458			6,494,890
Common stock issued in exchange for Webtronics common stock			1,503,173	150	(150)			
Deferred Compensation stock options					9,313,953	(9,313,953)		
Amortization of deferred Stock based Compensation						3,833,946		3,833,946
Private placement of common stock, net			2,776,666	278	3,803,096			3,803,374
Balance, December 31, 2003			25,928,760	2,590	34,149,975	(5,480,007)	(25,817,730)	2,854,828

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

	Preferred Stock	Preferred Stock Par Value	Common Stock	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, 2003			25,928,760	2,590	34,149,975	(5,480,007)	(25,817,730)	2,854,828
Net loss for the year							(7,543,467)	(7,543,467)
Amortization of deferred Stock-based compensation expense						3,084,473		3,084,473
Variable accounting for stock options					(816,865)			(816,865)
Stock-based compensation net of forfeitures					240,572	93,000		333,572
Common stock issued via private placements, net			3,311,342	331	6,098,681			6,099,012
Warrant and stock-based compensation for services in connection with the Merger					269,826			269,826
Common stock returned from former Synergy stockholders			(90,000)	(9)	(159,083)			(159,092)
Stock issued for patent rights			25,000	3	56,247			56,250
Common stock issued for services			44,000	7	70,833			70,840
Balance, December 31, 2004			29,219,102	2,922	39,910,186	(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

	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity(Deficit)
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 deferred 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
August 2005	1,869,203	187	1,812,940			1,813,127
Finders fees and expenses			(176,250)			(176,250)
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)

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Common Stock	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, 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)
Reclassification of deferred unamortized stock-based compensation upon adoption of FAS 123R					(1,583,463)	1,583,463		
Stock based compensation expense					2,579,431			2,579,431
Common stock issued via private placement:								
February 2006			4,283,668	428	5,139,782			5,140,210
Finders fees and expenses					(561,808)			(561,808)
April 2006			666,667	67	799,933			800,000
Finders fees and expenses					(41,000)			(41,000)
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
Finders fees and expenses	11,775	1			(448,909)			(448,908)
Detachable warrants					2,384,485			
Beneficial conversion feature accreted as a dividend							(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

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Series B Convertible Preferred Shares	Series B Convertible Preferred Stock	Common Shares	Common Stock Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance, December 31, 2006	586,125	\$ 58		\$	39,194,996	\$ 3,919	\$ 61,290,509	\$ (60,444,368)	\$ 850,118
Net loss for the year								(7,887,265)	(7,887,265)
Stock based compensation expense							591,561		591,561
Common stock issued for services					80,000	8	36,792		36,800
Series A convertible preferred stock, issued via private placement	28,000	3					279,997		280,000
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

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

## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the years ended December 31,			Period from June 5, 1996 (inception) to December 31, 2007
	2007	2006	2005	
<b>Cash flows from operating activities:</b>				
Net loss	\$ (7,887,265)	\$ (12,919,229)	\$ (11,779,457)	\$ (65,947,148)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>				
Depreciation	3,142	2,151	18,856	89,930
Stock-based compensation expense	628,361	2,746,478	2,419,694	17,145,806
Purchased in-process research and development (non-cash portion)				6,841,053
Stock-based liquidated damages		579,696		579,696
Change in fair value if Series B preferred warrants from date of issuance to expiration of put option	(2,591,005)			(2,591,005)
<b>Changes in operating assets and liabilities:</b>				
Prepaid expenses	(22,079)	114,543	(136,053)	(88,820)
Security deposit		8,480		(73,716)
Accounts payable and accrued expenses	1,420,303	1,138,176	790,058	4,328,897
<b>Total adjustments</b>	<b>(561,278)</b>	<b>4,589,524</b>	<b>3,092,555</b>	<b>26,231,841</b>
<b>Net cash used in operating activities</b>	<b>(8,448,543)</b>	<b>(8,329,705)</b>	<b>(8,686,902)</b>	<b>(39,715,307)</b>
<b>Cash flows from investing activities:</b>				
Short term investments purchased	(5,921,825)			(5,921,825)
Short term investments liquidated	2,954,135			2,954,135
Acquisition of equipment	(11,798)	(8,602)		(105,037)
<b>Net cash used in investing activities</b>	<b>(2,979,488)</b>	<b>(8,602)</b>		<b>(3,072,727)</b>
<b>Cash flows from financing activities:</b>				
Issuance of common and preferred stock	11,750,500	11,683,710	4,831,528	48,719,673
Finders fees and expenses	(957,360)	(1,051,716)	(176,250)	(2,981,083)
Exercise of common stock warrants		190,035	128,750	318,785
<b>Net cash provided by financing activities</b>	<b>10,793,140</b>	<b>10,822,029</b>	<b>4,784,028</b>	<b>46,057,375</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(634,891)</b>	<b>2,483,722</b>	<b>(3,902,874)</b>	<b>3,269,341</b>
Cash and cash equivalents at beginning of period	3,904,232	1,420,510	5,323,384	
<b>Cash and cash equivalents at end of period</b>	<b>\$ 3,269,341</b>	<b>\$ 3,904,232</b>	<b>\$ 1,420,510</b>	<b>\$ 3,269,341</b>
<b>Supplementary disclosure of cash flow information:</b>				
Cash paid for taxes	\$ 4,868	\$ 13,880	\$ 46,643	\$ 128,355
Cash paid for interest	\$	\$	\$	\$
<b>Supplemental disclosure of non-cash investing and financing activities:</b>				



Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

For the years ended December 31,

Series A Preferred stock beneficial conversion feature accreted as a dividend	2,504,475	\$	2,384,485	\$	\$	4,888,960		
Series B Preferred stock beneficial conversion feature accreted as a dividend	\$	\$	10,495,688	\$	\$	10,495,688		
Stock options, warrants and common stock issued for services	\$	628,361	\$	2,746,478	\$	2,419,694	\$	17,145,806
Stock-based liquidated damages	\$		\$	579,676	\$		\$	579,676
Change in fair value if Series B preferred warrants gain recognized from date of issuance to expiration of put option	\$	(2,591,005)	\$		\$		\$	(2,591,005)
Purchased in-process research and development (non-cash portion)	\$		\$		\$		\$	6,841,053

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

F-12

**CALLISTO PHARMACEUTICALS, INC.**

(A Development Stage Company)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Business overview:**

Callisto Pharmaceuticals, Inc. ("Callisto") is a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. See footnote 4 for a complete description of Merger and consolidation. Since inception in June of 1996, Callisto's efforts have been principally devoted to research and development, securing and protecting patents and raising capital. From inception through December 31, 2007, Callisto has sustained cumulative net losses available to common stockholders of \$81,331,796. 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, 2007, Callisto has not generated any revenue from operations, expects to incur additional losses to perform further research and development activities and does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all.

Callisto's product development efforts are thus in their early stages and Callisto cannot make estimates of the costs or the time they will take to complete. The risk of completion of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, the nature and timing of costs and competing technologies being developed by organizations with significantly greater resources.

**2. Basis of presentation and going concern:**

The accompanying consolidated financial statements of Callisto which include its wholly owned subsidiaries: (1) Callisto Research Labs, LLC (including its wholly owned subsidiary, Callisto Pharma, GmbH (Germany inactive)) and (2) Synergy Pharmaceuticals Inc. ("Synergy"), (including its wholly owned subsidiaries, Synergy Advanced Pharmaceuticals, Inc. and IgX, Ltd (Ireland inactive)), have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The results of operations of Synergy are included in the consolidated financial statements from May 1, 2003 to December 31, 2007. All intercompany balances and transactions have been eliminated.

The consolidated financial statements as of December 31, 2007 have been prepared under the assumption that Callisto will continue as a going concern for the twelve months ending December 31, 2008. 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 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 twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at its current cash expenditure levels.

Cash used in operating activities was \$8.4 million, \$8.3 million and \$8.7 million for the twelve months ended December 31, 2007, 2006 and 2005 respectively. During the years ended December 31, 2007, 2006 and 2005 Callisto incurred net losses available to common stockholders of approximately \$20.9 million, \$15.3 million and \$11.8 million, respectively.

To date, Callisto's sources of cash have been primarily limited to the sale of equity securities. Net cash provided by financing activities for the twelve months ended December 31, 2007, 2006 and 2005 was approximately \$10.8 million, \$10.8 million and \$4.8 million, respectively.

Callisto cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Callisto can raise additional funds by issuing equity securities, Callisto's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Callisto's ability to conduct its business. If Callisto is unable to raise additional capital when required or on acceptable terms, it may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of Callisto's product candidates. Callisto also may be required to 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; and relinquish licenses or otherwise dispose of rights to technologies, product candidates or products.

### 3. Summary of significant accounting policies

*Use of Estimates* The preparation of financial statements in conformity with 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* consists of short term, highly liquid investments, with original maturities of less than three months when purchased and are stated at cost.

*Short term investments* are considered held-to-maturity securities at December 31, 2007 and consist of approximately \$3.0 million in United States Treasury Bills with a maturity date of May 1, 2008. Held-to-maturity securities are those securities which Callisto has the ability and intent to hold until maturity and are recorded at amortized cost adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method. Callisto monitors its investment portfolio for impairment on a periodic basis. In the event that the carrying value of an investment exceeds its fair value and the decline in value is determined to be other-than-temporary, Callisto records an impairment charge and established a new cost basis for the investment at its then current fair value. In order to determine whether a decline in value is other-than-temporary, we evaluate, among other factors: the duration and extent to which the fair value has been less than the carrying value and our intent and ability to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value. Declines in market values below amortized cost that are considered other-than-temporary are reported in the statement of operations as losses.

*Fair value of financial instruments* Callisto's financial instruments consist of cash and accounts payable. These financial instruments are stated at their respective carrying values which are equivalent to fair value due to their short term nature.

*Business concentrations and credit risks* All of Callisto's cash and cash equivalents as of December 31, 2007 and 2006 are on deposit with a major money center financial institution. Deposits at any point in time may exceed federally insured limits.

*Share-based payments* In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard ("SFAS") No. 123 (Revised 2004), *Share-Based Payments* ("SFAS 123R"). SFAS 123R requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005 and accordingly Callisto adopted SFAS 123R on January 1, 2006.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

SFAS 123R provides for two transition methods. The "modified *prospective*" method requires that share-based compensation expense be recorded for any employee options granted after the adoption date and for the unvested portion of any employee options outstanding as of the adoption date. The "modified *retrospective*" method requires that, beginning in the first quarter of 2006, all prior periods presented be restated to reflect the impact of share-based compensation expense consistent with the proforma disclosures previously required under SFAS 123. Callisto has elected to use the "modified *prospective*" method in adopting this standard.

Prior to January 1, 2006, Callisto had adopted SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). As provided for by SFAS 123, Callisto had elected to continue to account for stock-based compensation according to the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"). Accordingly, compensation expense had been recognized to the extent of employee or director services rendered based on the intrinsic value of stock options granted under the plan. Callisto accounts for common stock, stock options, and warrants granted to non-employees based on the fair market value of the instrument, using the Black-Scholes option pricing model based on assumptions for expected stock price volatility, term of the option, risk-free interest rate and expected dividend yield at the grant date.

The unrecognized compensation cost related to non-vested share-based compensation arrangements for all employee stock options outstanding at December 31, 2007 and 2006 was \$285,885 and \$621,853, respectively, to be recognized over a weighted average remaining vesting period of 1.0 and 1.37 years, respectively.

Effective with the adoption of SFAS 123R stock-based compensation expense related to Callisto's share-based compensation arrangements is being recorded as a component of general and administrative expense and research and development expense in accordance with the guidance of Staff Accounting Bulletin 107, Topic 14, paragraph F . *Classification of Compensation Expense Associated with Share-Based Payment Arrangements* ("SAB 107"). Stock based compensation expense related to employee and non-employee stock options recognized in operating results for the twelve months ended December 31, 2007, 2006 and 2005 and for the period from June 6, 1996 (inception), through December 31, 2007 was as follow:

	Twelve Months Ended December 31,			June 5, 1996 (Inception) to December 31 2007
	2007	2006	2005	
<b>Stock based compensation expense</b>				
Employees included in research and development	\$ 68,734	\$ 420,683	\$ 276,250	\$ 2,621,277
Employees included in general and administrative	321,350	951,804	1,254,167	4,587,691
<b>Subtotal employee stock option grants</b>	<b>390,084</b>	<b>1,372,487</b>	<b>1,530,417</b>	<b>7,208,968</b>
Non-employee research and development	17,314	102,750		120,064
Non-employee general and administrative	220,963	1,271,241	889,277	9,816,774
<b>Subtotal non-employee stock option grants</b>	<b>238,277</b>	<b>1,373,991</b>	<b>889,277</b>	<b>9,936,838</b>
<b>Total stock based compensation expense</b>	<b>\$ 628,361</b>	<b>\$ 2,746,478</b>	<b>\$ 2,419,694</b>	<b>\$ 17,145,806</b>

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Since January 1, 2006 the estimated fair value of each employee option award granted was determined in accordance with SFAS 123R on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for employee options granted during the twelve months ended December 31:

	2007	2006
Risk free interest rate	4.7%	4.25% - 4.57%
Dividend yield	0.0%	0.0%
Expected volatility	60%	60% - 79%
Expected term	5 - 6 years	3 - 7 years

*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:* Based on SAB 107 guidance which permits companies to use the "simplified" method to estimate expected term, based on the mid-point of the period between vesting date and contractual term, averaged on a tranche-by-tranche basis. Callisto has used the simplified method for its expected term assumption for both 2006 and 2007 because Callisto has had no employee options exercised since inception, June 5, 1996. Prior to January 1, 2006, Callisto had estimated expected term based on a sampling of industry comparables for publicly traded companies. The expected term for consultant awards is the remaining period to contractual expiration on the date of grant.

*Forfeitures:* SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Callisto estimated future unvested option forfeitures based on historical Company experience and has incorporated this rate in determining the fair value of employee option grants.

Callisto's determination of fair value is affected by Callisto's stock price as well as the assumptions discussed above that require judgment. The weighted-average fair value of all options granted during the twelve months ended December 31, 2007, 2006 and 2005 estimated as of the grant date using the Black-Scholes option valuation model, was \$0.42, \$0.91 and \$0.91 per share, respectively. See footnotes 6. *Stock option plans and 8. Commitments and contingencies*, for additional information about Callisto's stock option plans and option grants.

A summary of stock option activity as of December 31, 2007 and of changes in options outstanding under Callisto's plans during the twelve months ended December 31, 2007 is presented below:

	Number of options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value Per Share
Balance, January 1, 2007	8,053,375	\$ 0.75 - 6.75	\$ 1.75	
Granted	784,500	\$ 0.47 - 0.96	\$ 0.78	
Forfeitures	(596,668)	\$ 0.75 - 1.60	\$ 1.24	
Balance, December 31, 2007	8,241,207	\$ 0.47 - 6.75	\$ 1.70	\$ 0.00
Exercisable as of December 31, 2007	5,815,707	\$ 0.75 - 6.75	\$ 1.65	\$ 0.00

FAS 123R requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to Callisto's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Had compensation cost for stock options granted to employees and directors prior to January 1, 2006 been determined based upon the fair value at the grant date for awards, consistent with the methodology prescribed under SFAS 123, Callisto's net loss for the twelve months ended December 31, 2005 would have been as follows:

	2005
Net loss applicable to common stockholders, as reported	\$ (11,779,457)
Add: Stock-based employee compensation expense recorded under APB No. 25 intrinsic method	1,530,417
Deduct: Stock-based employee compensation expense determined under Fair Value based method for all awards	(2,526,419)
	\$ (12,775,459)
<b>Net loss per share:</b>	
Basic and diluted as reported	\$ (0.37)
	\$ (0.41)
Basic and diluted pro forma	\$ (0.41)
	\$ 0.93
<b>Weighted average fair value per share for options granted</b>	
<b>Black-Scholes Methodology Assumptions:</b>	
Expected stock volatility	79%
Dividend yield	0%
Risk free interest rate	4.25%
Expected lives of options	3 to 7 years

*Research and development* Callisto does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all and therefore, because the benefits are uncertain, and occur only when research leads to a commercial product, research and development costs are expensed as incurred as prescribed by SFAS No. 2. These 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, purchase of in-process research and development, regulatory and scientific consulting fees as well as contract research and royalty payments to licensors, patient costs, drug formulation and tableting, data collection, monitoring, insurance, and FDA consultants.

*Income taxes* Income taxes are accounted for under the asset and liability method prescribed by SFAS No. 109, "Accounting for Income Taxes." Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or the entire deferred tax asset will not be realized.

In July 2006, the FASB issued Interpretation 48, *Accounting for Uncertainty in Income Taxes* an interpretation of SFAS No. 109 ("FIN 48"). FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The interpretation applies to all tax positions related to income taxes subject to SFAS 109. FIN 48 is effective for fiscal years beginning after December 15, 2006. The adoption of FIN 48 on January 1, 2007 did not have a material effect on Callisto's financial statements for the year ended and as of December 31, 2007.

*Net Loss per Share* Basic and diluted net loss per share is presented in conformity with SFAS No. 128, "Earnings per Share," for all periods presented. In accordance with SFAS No. 128, basic and

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

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 since the inclusion of issuable shares pursuant to the exercise of stock options and warrants, would have been antidilutive.

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

	<u>December 31, 2007</u>	<u>December 31, 2006</u>	<u>December 31, 2005</u>
Common Shares outstanding	46,943,161	39,194,996	33,233,096
Potentially dilutive common shares issuable upon:			
Exercise of warrants	45,162,920	15,841,154	2,567,317
Exercise of stock options	8,241,207	8,053,375	8,008,210
Conversion of Series A Convertible Preferred Stock	4,373,500	7,658,000	
Conversion of Series B Convertible Preferred Stock	22,941,000		
<b>Total fully diluted</b>	<b>127,661,788</b>	<b>70,747,525</b>	<b>43,808,623</b>

*Government Grants* On October 7, 2003 Callisto was awarded a \$265,697 Small Business Technology Transfer Research grant from the National Institutes of Health 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 \$260,853, \$352,649 and \$226,119 during the twelve months ended December 31, 2007, 2006 and 2005, respectively and have been reported on our Condensed Consolidated Statements of Operations as a separate line item entitled "Government Grant". In addition as of December 31, 2006 Callisto has received approximately \$294,000 of cash advances under the NIAID grant for which it had not yet incurred any expenses and this amount is included in a segregated cash account and in current liabilities. During October 2006 Callisto used approximately \$75,000 of this cash, to pay operating expenses not specifically related to the work on the biodefense program, until the proceeds from the sale of Series A Convertible Preferred Stock were received during the quarter ended December 31, 2006. Funding for this program has been extended one year through April, 2008 and as of December 31, 2007 Callisto had approximately \$34,000 of funding remaining in a segregated cash account and in current liabilities. Because the bioterrorism program is not a core activity Callisto plans to terminate in-house work on this program upon expiration of the research grant in April, 2008

*Reclassifications* Certain prior year account balances, associated with stock based compensation expense, have been reclassified to be consistent with current year reporting treatment.

RECENT ACCOUNTING PRONOUNCEMENTS:

In December 2007, the FASB ratified Emerging Issues Task Force ("EITF") Issue No. 07-1, "Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property," ("EITF 07-1"), which provides guidance on how the parties to a collaborative

agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure requirements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. The Company is continuing to evaluate the impact of adopting the provisions EITF 07-1; however, it does not anticipate that adoption will have a material effect on the Company's consolidated results of operations or financial position.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an amendment of ARB No. 51*. SFAS No. 160 requires all entities to report noncontrolling (minority) interests in subsidiaries as equity in the consolidated financial statements. Its intention is to eliminate the diversity in practice regarding the accounting for transactions between an entity and noncontrolling interests. This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. We do not expect that adoption of this Statement will have a material effect on our financial condition or results of operations.

In December 2007, the FASB issued SFAS No. 141(R), a revised version of SFAS No. 141, *Business Combinations*. The revision is intended to simplify existing guidance and converge rulemaking under U.S. GAAP with international accounting rules. This statement applies prospectively to business combinations where the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. We do not expect that adoption of this Statement will have a material effect on our financial condition or results of operations.

In June 2007, the EITF of the FASB reached a consensus on Issue No. 07-3, *"Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities"* ("EITF 07-3"). EITF 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts would be recognized as an expense. This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2007 and earlier application is not permitted. This consensus is to be applied prospectively for new contracts entered into on or after the effective date and is not expected to have a material effect on Callisto's financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No.159, "The Fair Value Option for Financial Assets and Financial Liabilities, including an Amendment to SFAS 115" ("SFAS 159"). The fair value option established by SFAS 159 permits all entities to measure all eligible items at fair value at specified election dates. A business entity shall report all unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. The provisions of SFAS 159 are effective for fiscal years beginning after November 15, 2007. Callisto is currently evaluating the impact, if any, of the provisions of SFAS 159.

In September 2006, the FASB issued Statement of Financial Accounting Standards No.157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 does not require any new fair value measurements. SFAS 157 emphasizes a "market-based" as opposed to an "entity-specific" measurement perspective, establishes a hierarchy of fair value measurement methods and expands disclosure requirements about fair value measurements including methods and assumptions and the impact on earnings. Originally, SFAS 157 was to be effective January 1, 2008 and applied prospectively. In February 2008, the FASB issued a Staff Position that partially defers the effective date of SFAS 157 for one year for certain nonfinancial assets and nonfinancial liabilities. Callisto is currently evaluating the impact, if any, of the provisions of SFAS 157.



**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. and changed its state of incorporation from Florida to Delaware. Callisto remains the continuing legal entity and registrant for Securities and Exchange Commission reporting purposes.

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

**5. Stockholders' equity (deficit):**

On 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 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.

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.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

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

As per Emerging Issues Task Force ("EITF") Issue 00-19, "*Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, Company Stock*", ("EITF 00-19") Callisto has

determined that the fair value of the Series B Warrants issued to the Lead Investors should be treated as a liability upon issuance and reclassified to permanent equity based on the fair value upon expiration of the Put Option. The change in fair value of the Series B Lead Investor warrant from the date of issuance through the expiration of the Put Option was recorded as other income totaling \$2,591,005 during the three and nine months ended September 30, 2007. Callisto has determined that the warrants issued to other than Lead Investors should be treated as "permanent equity."

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

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

On July 18, 2007 Callisto submitted a plan, advising AMEX of the actions it has taken, or will take, that would bring it into compliance with Section 1003(a)(ii) of the Company Guide by April 3, 2008. On August 29, 2007, the Company received a letter from the AMEX that it had reviewed the Company's plan of compliance to meet the AMEX's continued listing standards and will continue the Company's listing while the Company seeks to regain compliance with Sections 1003 (a)(i) and 1003 (a)(ii) of the Company Guide during the period ending April 3, 2008.

On June 18, 2007, Callisto received notice from the staff of the American Stock Exchange ("AMEX") indicating that it is not in compliance with certain continued listing standards, specifically, Section 1003(a) (ii) of the Company Guide with shareholders' equity of less than \$4,000,000 and losses from continuing operations and/or net losses in three of its four most recent fiscal years. As of December 31, 2007 the Company had stockholders' equity of \$1,793,350, and there have been no financing events since that date which would increase stockholder's equity.

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 antidilution rights for the twelve month period beginning on the effective date of the registration statement registering the shares of common stock underlying the warrants. Callisto (i) paid aggregate fees and expenses of \$485,308 (\$448,908 prior to December 31, 2006) in cash and (ii) issued an aggregate 11,775 shares of Series A Convertible

Preferred Stock and 1,228,761 warrants to purchase common stock, to certain selling agents. The warrants are immediately exercisable at \$0.75 per share, will expire five years after issuance and have the same anti-dilutive rights as the investor warrants. The fair value of the selling agent warrants on the date of grant was \$640,481 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.60%, no dividend, an expected life of 5 years and a stock price on the dates of grant of \$0.88 per share. This fair value was accounted for as a cost of capital.

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

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

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

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

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

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

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

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

As per EITF 00-27, Callisto evaluated the Series A Convertible Preferred Stock transaction and accordingly found that there was an embedded beneficial conversion feature. The fair value of the detachable warrants on the date of grant was \$3,557,872 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.57% to 4.84%, no dividend, an expected life of 5 years and a stock price on that dates of grant ranging from \$0.88 to \$0.75 per share. The conversion rights of the Series A Convertible Preferred Stock issued during the twelve months ended December 31, 2006 contained a beneficial conversion feature totaling \$2,384,485. This beneficial conversion feature was

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

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

During the twelve months ended December 31, 2007, 36,125 shares of Series A Convertible Preferred Stock were converted to 481,666 shares of common stock prior to August 2, 2007 at 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 conversion price of \$0.50 per share.

On November 2, 2006 Callisto submitted a plan advising AMEX of the actions it had taken, or would take, to bring it into compliance with Section 1003(a) (iv) of the Company Guide by April 3, 2007 and with Section 1003(a) (i) of the Company Guide by April 3, 2008. The plan was approved January 24, 2007 and Callisto may maintain its listing during the plan period of up to 18 months, during which time Callisto will be subject to periodic review to determine if it is making progress consistent with the plan.

On October 3, 2006, Callisto received notice (the "Deficiency Letter") from the staff AMEX indicating that it was not in compliance with certain continued listing standards, specifically, Section 1003(a)(i) of the Company Guide with shareholders' equity of less than \$2,000,000 and losses from continuing operations and/or net losses in two of its three most recent fiscal years and Section 1003(a)(iv) of the Company Guide in that it has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the Exchange, as to whether it will be able to continue operations and/or meet its obligations as they mature.

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

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

warrants. During October and November 2006 Callisto entered into the Amendment and Lock-up Agreements with each Investor pursuant to which Callisto issued 740,065 shares of common stock and 2,086,988 New Warrants. \$153,797 in cash liquidated damages, payable to these Investors as of September 30, 2006, was concurrently waived.

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

On February 3, 2006, Callisto closed a private placement of 4,283,668 shares of common stock and 1,070,917 common stock purchase warrants to certain accredited investors. The warrants are exercisable for 18 months from closing at an exercise price of \$1.60 per share. The securities were sold at a price of \$1.20 per share for aggregate proceeds of \$5,140,210 and Callisto paid an aggregate transaction related fees and expenses of \$561,808, yielding net proceeds of \$4,578,402. In addition Callisto issued an aggregate 390,284 warrants to certain selling agents, which are exercisable at \$1.25 per share and will expire three years after closing.

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

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

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

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

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

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

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

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

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

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

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

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
	<hr/>	<hr/>	<hr/>
Total	4,572,668		\$ 3,429,499
	<hr/>		<hr/>

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

#### 6. Stock option plans:

In 1996, Callisto adopted an 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. The 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 4,148,374 options outstanding 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 adopted 2005 Equity Compensation Incentive Plan ("2005 Equity 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, there were 1,582,000 options outstanding and there were 3,418,000 options available for future grants as of December 31, 2007.

On October 20, 2005, Callisto also adopted the Callisto 2005 Directors' Stock Option Plan ("2005 Director's Plan"). The maximum number of shares of common stock with respect to which awards may be granted under the 2005 Director's Plan is 1,000,000. The option term for options granted under the 2005 Director's Plan is ten years from date of grant, there were 158,500 options outstanding, and there were 841,500 options available for future grants as of December 31, 2007.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

The following represent options outstanding for the years since June 5, 1996 (inception) through December 31, 2007.

	Number of options outstanding	Exercise Price Per Share	Weighted Average Exercise Price Per Share
Balance, June 5, 1996 (inception)	0	\$ 0.00	\$ 0.00
1996: Granted	66,668	\$ 0.75	\$ 0.75
Balance, December 31, 1996	66,668	\$ 0.75	\$ 0.75
1997: Granted	166,668	\$ 0.75	\$ 0.75
Balance, December 31, 1997	233,336	\$ 0.75	\$ 0.75
1998: Granted	264,169	\$ 0.75	\$ 0.75
Balance, December 31, 1998	497,505	\$ 0.75	\$ 0.75
1999: Granted	633,334	\$ 0.75 - 4.90	\$ 1.92
Balance, December 31, 1999	1,130,839	\$ 0.75 - 4.90	\$ 1.41
2000: Granted	815,666	\$ 2.85 - 6.75	\$ 3.83
Forfeitures	(15,000)	\$ 0.75	\$ 0.75
Balance, December 31, 2000	1,931,505	\$ 0.75 - 6.75	\$ 2.44
2001: Granted	730,000	\$ 1.25 - 6.50	\$ 2.77
Balance, December 31, 2001	2,661,505	\$ 0.75 - 6.75	\$ 2.53
2002: Granted	330,000	\$ 4.50 - 6.50	\$ 5.50
Balance, December 31, 2002	2,991,505	\$ 0.75 - 6.75	\$ 2.86
2003: Granted	3,013,555	\$ 1.10 - 2.50	\$ 1.48
Forfeitures	(1,151,500)	\$ 2.85 - 6.75	\$ 4.51
Balance, December 31, 2003	4,853,560	\$ 0.75 - 6.75	\$ 1.61
2004: Granted	2,853,500	\$ 1.50 - 3.60	\$ 3.11
Forfeitures	(385,000)	\$ 1.50 - 2.50	\$ 1.66
Balance, December 31, 2004	7,322,060	\$ 0.75 - 6.75	\$ 2.19
2005: Granted	2,174,484	\$ 0.97 - 1.70	\$ 1.34
Forfeitures	(1,488,334)	\$ 1.50 - 3.50	\$ 3.12
Balance, December 31, 2005	8,008,210	\$ 0.75 - 6.75	\$ 1.79
2006: Granted	978,500	\$ 0.77 - 1.64	\$ 1.48
Forfeitures	(933,335)	\$ 0.75 - 3.00	\$ 1.78
Balance, December 31, 2006	8,053,375	\$ 0.75 - 6.75	\$ 1.75
2007: Granted	784,500	\$ 0.47 - 0.96	\$ 0.78
Forfeitures	(596,668)	\$ 0.75 - 1.60	\$ 1.24
Balance, December 31, 2007	8,241,207	\$ 0.47 - 6.75	\$ 1.70

Included in the balance at December 31, 2007 were 2,352,333 Non-Plan options, of which 1,883,833 were exercisable at a weighted average exercise price of \$1.40 per share.

The weighted average remaining term of all options outstanding decreased from 6.6 years at December 31, 2006 to 5.9 years at December 31, 2007. The weighted average remaining term of exercisable options decreased from 5.7 years at December 31, 2006 to 5.3 years at December 31, 2007.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

On April 26, 2004, Callisto's Board of Directors granted 100,000 stock options to Gabriele M. Cerrone, Chairman of the Board, in recognition of his efforts during the past year on behalf of Callisto. The stock options are immediately exercisable at \$3.20 per share and stock-based compensation

F-29

---

expense of \$286,918 was recorded in connection with the grant, based on a Black-Scholes fair value of \$2.87 per share.

On June 29, 2004, Callisto's Compensation Committee recommended and the Board of Directors approved the grant of 275,000 stock options to Gary Jacob, Chief Executive Officer, as additional compensation. The stock options are exercisable at \$3.00 per share. 25,000 options vest on each of June 1, 2005 and June 1, 2006 and 50,000 options vest on June 1, 2007. The remaining 175,000 options vest upon the achievement of performance milestones associated with the successful in-licensing, advancement and development of certain drug candidates. If the milestones are achieved Callisto will record stock-based compensation expense based on the intrinsic value of the options at that time. At this date, the milestones have not yet been achieved. On July 6, 2005, Callisto's Compensation Committee recommended and the Board of Directors approved the grant of 350,000 stock options to Mr. Jacob as additional compensation. The stock options are exercisable at \$1.01 per share. 100,000 options vest on each of July 6, 2006 and 2007 and 150,000 options vest on July 6, 2008.

#### **7. Income taxes:**

At December 31, 2007, Callisto has net operating loss carryforwards ("NOLs") of approximately \$40,000,000, which, if not used, expire through 2027. The utilization of these NOLs may be subject to limitations based on past and future changes in ownership of Callisto pursuant to Internal Revenue Code Section 382. Callisto has determined that an ownership change had occurred as of April 30, 2003 (see Note 4 above "Merger") and Callisto believes that the changes in ownership to date will restrict its ability to use pre-merger Synergy NOLs within the carryforward period. Callisto records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Due to the significant doubt related Callisto's ability to continue as a going concern and utilize its deferred tax assets, a valuation allowance for the full amount of the deferred tax assets has been established at December 31, 2007. As a result of this valuation allowance there are no income tax benefits reflected in the accompanying consolidated statements of operations to offset pre tax losses.

The provisions of FIN 48 were adopted by Callisto on January 1, 2007 and had no effect on Callisto's financial position, cash flows or results of operations upon adoption, as Callisto did not have any unrecognized tax benefits. Callisto also evaluated its tax positions as of December 31, 2007 and reached the same conclusion. Callisto does not currently expect any significant changes to unrecognized tax benefits during the fiscal year ended December 31, 2008. Callisto's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. As of January 1, 2007 and December 31, 2007, Callisto had no accrued interest or penalties. Callisto has no uncertain tax positions subject to examination by the relevant tax authorities as of December 31, 2007. Callisto files U.S. and state income tax returns in jurisdictions with varying statutes of limitations. The 2004 through 2007 tax years generally remain subject to examination by federal and most state tax authorities.

During the twelve months ended December 31, 2005 Synergy sold certain New Jersey State tax loss carry forwards under a state economic development program for cash of approximately \$177,000. The proceeds of this economic development funding was used to support research and development activities in New Jersey. This state tax benefit was recorded as Other Income during the fourth quarter ended December 31, 2005. As of December 31, 2005 Callisto had no remaining New Jersey State tax loss carry forwards available for sale and no such benefits were realized since that date.

#### **8. Commitments and contingencies:**

##### **License agreements:**

On December 31, 2007, Callisto 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 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 incurred an upfront fee which was expensed in 2007. 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. The Amended and Restated License Agreement will terminate upon the later of (i) seven years from the first commercial sale of Atiprimod or, (ii) the expiration of the licensed patents.

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 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.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

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.

### **Employment and Consulting Agreements:**

#### ***Gabriele M. Cerrone***

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

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

In the event the Agreement is terminated without cause or for good reason, the Consultant will receive a cash payment equal to the aggregate amount of Base Compensation for the then remaining term of the Agreement and all unvested stock options will immediately vest and the exercise period of such options will be extended to the later of the longest period permitted by Callisto's stock option plans or ten years following termination. In the event a change of control of Callisto occurs, Consultant shall be entitled to such compensation upon the subsequent termination of the Agreement within two years of the change in control unless such termination is the result of the Consultant's death, disability or retirement or the Consultant's termination for cause. Had Mr. Cerrone been terminated without cause or good reason on December 31, 2007 he would have been eligible for total compensation of \$673,750 for the time remaining under the Extension and Amendment Agreement.

On January 25, 2007, Callisto entered into an Extension and Amendment Agreement with Mr. Cerrone. The agreement extends the term of the consulting agreement between us and

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

In conjunction with the Extension and Amendment Agreement, Mr. Cerrone was granted 225,000 ten year non-qualified stock options at an exercise price of \$0.96 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. Stock-based compensation expense associated with these option grants is being recorded in accordance with EITF 96-18 and accordingly (i) the measurement date will be the earliest of December 31, 2009 (when "performance commitment is completed") or the accelerated vesting date if Mr. Cerrone is terminated without cause or good reason prior to December 31, 2009 and (ii) the fair value of these options is being "marked to market" quarterly until the measurement date is determined. Stock-based compensation expense associated with these options during the twelve months ended December 31, 2007 was \$13,851. As of December 31, 2007 the unrecognized fair value of all Mr. Cerrone's unvested options was \$30,758.

***Gary S. Jacob, Ph.D***

On June 13, 2003, Callisto entered into an employment agreement with Gary S. Jacob, Ph.D., to serve as Chief Executive Officer and Chief Scientific Officer. Dr. Jacob's employment agreement is for a term of 18 months beginning June 13, 2003 and was automatically renewable for successive one year periods at the end of the term. In connection with his employment agreement, Dr. Jacob received a grant of 500,000 stock options which vested over a three year period through June 13, 2006 and are exercisable at \$1.50 per share. On March 17, 2006, pursuant to Compensation Committee approval, Dr. Jacob's salary was increased to \$300,000 per year; he became eligible to receive a cash bonus of up to 15% of his salary per year and received a grant of 150,000 stock options which vest over a three year period which are exercisable at \$1.64 per share. During the years ended December 31, 2007, 2006 and 2005, Dr. Jacob earned a bonus of \$78,750, \$48,125, and \$33,750, respectively.

On February 16, 2007, Dr. Jacob entered into an Extension and Amendment Agreement with Callisto as approved by the Compensation Committee which extended the term under his employment agreement to June 30, 2009. In addition, pursuant to the Extension and Amendment Agreement, Dr. Jacob was granted 225,000 ten year stock options exercisable at \$0.81 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. His salary and other compensation were unchanged. As of December 31, 2007 the unrecognized fair value of all Dr. Jacob's unvested options was \$147,471.

***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 is for a term of 12 months beginning April 6, 2004 and is automatically renewable for successive one year periods at the end of the term. Dr. Shailubhai's salary is \$150,000 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 stock options which are exercisable at \$1.50 per share. 50,000 of such stock options vested in June 2004 and 50,000 options vested in December 2004.

Callisto previously had an employment agreement dated June 13, 2003 with Kunwar Shailubhai, Ph.D. to serve as Executive Vice President and Head of Research and Development for a term of



18 months beginning June 13, 2003. Dr. Shailubhai's salary was \$170,000 per year and he was eligible to receive a cash bonus of up to 15% of his salary per year. In connection with his employment agreement, Dr. Shailubhai received a grant of 25,000 stock options which were fully vested and have an exercise price of \$1.50 per share. Dr. Shailubhai also received a grant of 325,000 stock options which were to have vested over a three year period and were exercisable at \$1.50 per share. This employment agreement was terminated on April 6, 2004 and all unvested options were forfeited.

The new grant of 100,000 options was not subject to variable accounting under FIN 44 because it was deemed that Dr. Shailubhai continued as an employee within a consolidated group and there were no change in the exercise price. The unamortized deferred compensation cost associated with the 225,000 cancelled options of \$706,813 as of the date of cancellation, was charged to stock-based compensation expense during the quarter ended June 30, 2004. The remaining deferred balance, based on the original intrinsic value, associated with the remaining 100,000 options of \$314,139, was expensed over the vesting period of the new grant (e.g. April 7, 2004 through December 31, 2004). On April 12, 2007, Dr. Shailubhai was granted 125,000 ten year incentive stock options exercisable at \$0.66 per share of which 41,667 vest on each of April 12, 2008, 2009 and 41,666 vest April 12, 2010

#### ***Bernard F. Denoyer***

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

On December 10, 2007, Callisto entered into an Amended and Restated Employment Agreement (the "Amendment Agreement") with Mr. Denoyer which extends the term of the employment agreement between the Company and the Executive dated as of January 15, 2004, as amended October 19, 2005, to December 1, 2008. Among other things, the Amendment Agreement increases the Executive's salary from \$120,000 to \$162,000 per year (the "Base Salary"), he was promoted to Senior Vice President and he shall be eligible to earn a cash bonus of up to 15% of the Base Salary for each twelve month period during the term of the Amendment Agreement at the discretion of the Compensation Committee of the Company's Board of Directors. During the years ended December 31, 2007, 2006 and 2005, Mr. Denoyer earned a bonus of \$12,000, \$10,461, and \$6,563, respectively. On April 12, 2007, Mr. Denoyer was granted 75,000 ten year incentive stock options exercisable at \$0.66 per share of which 25,000 vest on each of April 12, 2008, 2009 and 2010.

#### ***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 (Guanilib) 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. As of December 31, 2007 such milestones had not been achieved and the escrow had not been established.

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 (Guanilib), Callisto's proprietary compound to treat gastrointestinal 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.

In accordance with EITF Emerging Issues Task Force Issue 96-18: "*Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*" ("EITF 96-18"), the measurement date for purposes of recording stock based compensation on these warrants will be the earliest of the fourth anniversary of the agreement (when "performance commitment is completed") or the accelerated vesting date if a change of control occurs. Accordingly the fair value of the 900,000 warrants which vest over time is being "marked to market" quarterly until the measurement date is determined. The fair value of these 900,000 warrants as of December 31, 2007 was \$260,603 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 3.70%, no dividend, an expected term of 6.7 years and a stock price of \$0.47 per share. Stock based compensation expense associated with these warrants was \$17,314 during the twelve months ended December 31, 2007. The fair value of the 250,000 warrants which vest upon a change of control will not be measured until that milestone event occurs and thus no compensation expense has been recorded as of December 31, 2007.

***Dr. Moshe Talpaz***

On January 31, 2006, Callisto 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 common stock at \$1.60 per share. Such options vest based on milestones related to the Degrasyns compounds being developed towards FDA approval. The term of the agreement is for the length of time Callisto is developing the Degrasyns platform of compounds in all indications. As of December 31, 2007 none of the milestones related to the Degrasyns compounds has been achieved and no stock based compensation has been recorded in connection with Dr. Talpaz's options.

***Roman Perez-Soler, M.D***

On August 12, 2004, in connection with the L-Annamycin license, Callisto 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 has earned a \$30,000 per year consulting fee and received 44,000 shares of restricted common stock. These shares were recorded as stock based compensation expense during the 12 months ended December 31, 2004 for a total expense of \$70,840 based on the closing stock price of \$1.61 on August 23, 2004. In addition, Callisto granted to Dr. Perez-Soler an option to purchase 468,500 shares of common stock at an exercise price of \$3.00 per share. The option shares vest upon achievement of specific milestones related to future development of L-Annamycin, at which time stock-based compensation expense will be recorded based upon the fair value of the options at that time. As of December 31, 2007 none of the milestones related to future development of L-Annamycin has been achieved and no stock based compensation has been recorded in connection with Dr. Perez-Soler's options.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

Callisto has various consulting agreements with scientific advisors, contract research organizations and other professionals. Fees are based and paid on services provided.

### *Other Employees and Consultants (inactive)*

On April 24, 2007, Callisto entered into a services agreement with Barretto Pacific Corporation ("Barretto") to provide, beginning May 1, 2007, investor relations services. Callisto agreed to pay Barretto a fee of \$120,000 over a seven month period and issue 80,000 shares of restricted common stock. On August 2, 2007 Callisto and Barretto entered into a Termination and Release Agreement cancelling any further obligations and Barretto returned the 80,000 shares of common stock. During the twelve months ended December 31, 2007 Callisto incurred \$40,000 in cash consulting fees and \$36,800 of stock based expense associated with this agreement.

### *Trilogy Capital Partners, Inc.*

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

Pursuant to the Agreement, Callisto issued warrants to Trilogy to purchase 1,793,322 shares of Common Stock of Callisto at an exercise price of \$1.03 per share (the "Warrants"). The Warrants issued to Trilogy are exercisable upon issuance and expire 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 is being 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 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.

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.

**Lease agreements:**

On August 20, 2003, Callisto entered into a five year lease for its corporate headquarters in New York City with an approximate rent of \$100,000 annually through August 2008. On June 7, 2004 Callisto extended its lease for its corporate headquarters in New York City three additional years through June 30, 2011, and increased its space to 3,886 rentable square feet. This increased average annual rent to approximately \$150,000. On November 4, 2003, Synergy entered a two year lease for laboratory space in New Jersey, principally to support combined Callisto and Synergy research efforts, with an approximate rent of \$50,000 annually through November 2005, at which time Callisto did not

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

renew its lease, because its research group moved to laboratory and office space in Doylestown PA, funded in full by the NIAID biodefense grant. During the twelve months ended December 31, 2007, 2006 and 2005 total rent expense was \$197,224, \$181,036 and \$244,531, respectively. Total annual commitments under the remaining New York City lease for each of the years ended December 31, are as follows:

2008	154,555
2009	157,646
2010	160,799
2011	81,464
<b>Total</b>	<b>\$ 554,464</b>

**9. 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, 2007, 2006, 2005 and from June 5, 1996 (inception) to December 31, 2007 was \$3,142, \$2,151, \$18,856 and \$89,930, respectively.

	December 31,	
	2007	2006
Equipment	\$ 54,896	\$ 54,896
Furniture and fixtures	38,343	38,343
Leasehold Improvements	11,799	
Less Accumulated depreciation	(89,930)	(86,788)
<b>Property and equipment, net</b>	<b>\$ 15,108</b>	<b>\$ 6,451</b>

**10. Selected Quarterly Financial Data (Unaudited):**

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
(Amounts in dollars)					
Year Ended December 31, 2007					
Net loss applicable to common stockholders	\$ (1,949,623)	\$ (2,046,277)	\$ (12,963,642)	\$ (3,927,886)	\$ (20,887,428)
Net loss per share:					
Basic and diluted	\$ (0.05)	\$ (0.05)	\$ (0.31)	\$ (0.09)	\$ (0.50)
Year Ended December 31, 2006					
Net loss applicable to common stockholders	\$ (4,374,628)	\$ (3,416,171)	\$ (1,930,146)	\$ (5,582,769)	\$ (15,303,714)
Net loss per share:					
Basic and diluted	\$ (0.12)	\$ (0.09)	\$ (0.05)	\$ (0.14)	\$ (0.40)

**11. Subsequent events:**

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 to two unaffiliated entities in connection with the Settlement 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. The Company is currently evaluating these modifications in accordance with SFAS 123R and any associated stock based compensation expense will be record during the quarter ended March 31, 2008. As of March 25, 2008 the Company had not reassigned the warrants.

## Index to Exhibits

Exhibit Number	Description
3.1	Certificate of Incorporation, as amended
3.2	Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed on October 27, 2006)
3.3	Certificate of Amendment to Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.2 filed with the Company's Current Report on Form 8-K filed on December 27, 2006)
3.4	Certificate of Amendment to Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.2 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
3.5	Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series B Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
3.6	Bylaws, as amended (Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed on June 4, 2007)
4.1	1996 Incentive and Non-Qualified Stock Option Plan (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on May 15, 2003)
4.2	Form of Warrant to purchase shares of common stock issued in connection with the sale of common stock (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on January 28, 2004)
4.3	Form of Warrant issued to Trilogy Partners, Inc. (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on July 22, 2005)
4.4	2005 Equity Compensation Incentive Plan (Incorporated by reference to Appendix B filed with the Company's Definitive Proxy Statement on Schedule 14A filed on August 31, 2005)
4.5	2005 Directors' Stock Option Plan (Incorporated by reference to Appendix C filed with the Company's Definitive Proxy Statement on Schedule 14A filed on August 31, 2005)
4.6	Form of Warrant to purchase Common Stock issued in connection with the sale of Common Stock (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on February 9, 2006)
4.7	Form of Warrant to purchase Common Stock issued to certain selling agents in connection with the sale of Common Stock (Incorporated by reference to Exhibit 4.2 filed with the Company's Current Report on Form 8-K filed on February 9, 2006)
4.8	Form of Warrant issued pursuant to the Letter Agreement dated September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on September 14, 2006)
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 Common Stock Purchase Warrant to purchase 1,150,000 shares of common stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on October 1, 2007)

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

- 10.1 Employment Agreement dated June 13, 2003 by and between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (Incorporated by reference to Exhibit 10.1 filed with the Company's Quarterly Report on Form 10-QSB filed on August 20, 2003)\*
  - 10.2 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)\*
  - 10.3 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.\*\*
  - 10.5 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)\*\*
  - 10.6 License Agreement between Callisto Pharmaceuticals, Inc. and The Rockefeller University effective as of July 25, 2001 (Incorporated by reference to Exhibit 10.12 filed with the Company's Annual Report on Form 10-K filed on June 6, 2005)
  - 10.7 Extension and Severance Compensation Agreement dated June 9, 2005 between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on June 15, 2005)\*
  - 10.10 Amendment dated October 19, 2005 to the Employment Agreement dated as of June 13, 2003 by and between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on October 21, 2005)\*
  - 10.12 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)\*
  - 10.13 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.)\*\*
  - 10.15 Form of Letter Agreement dated September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on September 14, 2006)
  - 10.16 Form of Amendment Agreement dated as of September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on September 14, 2006)
  - 10.18 Form of Securities Purchase Agreement dated October 23, 2006 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on October 27, 2006)
  - 10.19 Form of Registration Rights Agreement dated October 23, 2006 by and among Callisto Pharmaceuticals, Inc. and the purchaser's signatory thereto (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on October 27, 2006)
  - 10.20 Form of Securities Purchase Agreement dated December 20, 2006 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on December 27, 2006)
-

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

- 10.21 Form of Securities Purchase Agreement dated January 10, 2007 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on January 17, 2007)
  - 10.22 Extension and Amendment Agreement dated January 25, 2007 between Callisto Pharmaceuticals, Inc. and Gabriele M. Cerrone (Incorporated by reference to Exhibit 10.23 filed with the Company's Annual Report on Form 10-K filed on April 17, 2007)\*
  - 10.23 Extension and Amendment Agreement dated February 16, 2007 between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (Incorporated by reference to Exhibit 10.22 filed with the Company's Annual Report on Form 10-K filed on April 17, 2007)\*
  - 10.24 Form of Securities Purchase Agreement dated August 2, 2007 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
  - 10.25 Form of Registration Rights Agreement dated August 2, 2007 by and among Callisto Pharmaceuticals, Inc. and the purchaser's signatory thereto (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on August 7, 2007)
  - 10.26 Amended and Restated Employment Agreement dated December 10, 2007 by and between Callisto Pharmaceuticals, Inc and Bernard Denoyer\*
    - 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
- 

\*

Management contract or compensatory plan or arrangement required to be filed as an Exhibit to this form pursuant to Item 601 of Regulation S-K.

\*\*

Confidential treatment has been requested with respect to deleted portions of this agreement.

---



QuickLinks

CALLISTO PHARMACEUTICALS, INC. FORM 10-K INDEX

PART I

ITEM 1. BUSINESS.

ITEM 1A. RISK FACTORS

ITEM 1B. UNRESOLVED STAFF COMMENTS.

ITEM 2. PROPERTIES.

ITEM 3. LEGAL PROCEEDINGS.

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

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

ITEM 6. SELECTED FINANCIAL DATA

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

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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

ITEM 9A CONTROLS AND PROCEDURES.

ITEM 9A(T) CONTROLS AND PROCEDURES.

ITEM 9B. OTHER INFORMATION

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

ITEM 11. EXECUTIVE COMPENSATION.

SUMMARY COMPENSATION TABLE

GRANTS OF PLAN-BASED AWARDS

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

DIRECTOR COMPENSATION

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

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

Index to Exhibits

SIGNATURES

CALLISTO PHARMACEUTICALS, INC. (A Development Stage Company) Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

CALLISTO PHARMACEUTICALS, INC. (A Development Stage Company) CONSOLIDATED BALANCE SHEETS

CALLISTO PHARMACEUTICALS, INC. (A Development Stage Company) CONSOLIDATED STATEMENTS OF OPERATIONS

CALLISTO PHARMACEUTICALS, INC. (A Development Stage Company) CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-K

CALLISTO PHARMACEUTICALS, INC. (A Development Stage Company) CONSOLIDATED STATEMENTS OF CASH FLOWS

CALLISTO PHARMACEUTICALS, INC. (A Development Stage Company) NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Index to Exhibits