CALLISTO PHARMACEUTICALS INC
Form 10-K
March 31, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

(Mark one)
x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED: DECEMBER 31, 2005

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

For the transition period from _____ to _____

Commission file number 001-32325

CALLISTO PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	13-3894575
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

420 Lexington Avenue, Suite 1609, New York, New York 10170
(Address of Principal Executive Offices) (Zip Code)

(212) 297-0010
(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	American Stock Exchange

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

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 o No þ

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

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 þ No o

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

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

Large accelerated filer o Accelerated filer o Non-accelerated filer þ

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of March 30, 2006, based on the closing sale price on such date, was $50,615,700.

As of March 30, 2006 the registrant had a total of 37,713,264 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Report, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Shareholders to be held in 2006, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

CALLISTO PHARMACEUTICALS, INC.

FORM 10-K

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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, 2005, 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 on the development of drugs to treat relapsed (re-occurrence of active disease) or refractory acute leukemia, multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow), and advanced carcinoid cancer patients. Our lead drug candidate, L-Annamycin, a drug from the anthracycline family (chemotherapy drugs which are derived from antibiotics), earlier completed an initial Phase I/IIa clinical trial in relapsed or refractory leukemia patients with a prior sponsor. L-Annamycin, originally developed by scientists at The University of Texas M.D. Anderson Cancer Center to address the clinical limitations associated with anthracycline drugs such as Adriamycin (doxorubicin) to treat cancer, began a 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. This single-arm, open label trial will enroll 12 patients in a dose escalation Phase I portion, followed by 10 patients in a final fixed dose in the Phase II portion. We plan to treat up to 34 patients. We also expect to commence two additional trials of L-Annamycin in 2006, a single agent trial in pediatric relapsed or refractory ALL patients and a combination therapy trial with Ara-C (cytosine arabinoside) in relapsed or refractory acute myeloid leukemia (AML) patients.

Our second drug candidate, Atiprimod, is an orally administered drug with antiproliferative and antiangiogenic activity. Atiprimod commenced a Phase I/IIa clinical trial in relapsed 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 being performed at four sites, The University of Texas M.D. Anderson Cancer Center (Houston, TX), the Dana-Farber Cancer Institute (Boston, MA), the St. Vincent's Comprehensive Cancer Center (New York, NY) and the Roswell Park Cancer Institute (Buffalo, NY). 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. Two patients exhibited stable disease, with one patient having a 34% decrease in M protein (measure of tumor burden) over 3 months of treatment. It was also noted that two patients reported a subjective decrease in bone pain. We plan to continue this trial at higher dose levels until the maximum tolerated dose is reached and then treat 10 additional patients at that level.

On March 15, 2005 we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The new trial is entitled: "An Open Label Study of the Safety and Efficacy of Atiprimod Treatment for Patients with Advanced Cancer", and is currently being conducted at the University of Texas M.D. Anderson Cancer Center. On February 28, 2006, we announced plans to launch an additional indication for clinical development of Atiprimod based on encouraging clinical results from the advanced cancer clinical trial that showed a clear response in a patient with advanced carcinoid cancer plus additional encouraging clinical data on other carcinoid patients. Based on these

new clinical data, we plan to initiate a new Phase I/II clinical trial of Atiprimod in carcinoid cancer patients with advanced metastatic tumors at several clinical sites in the next few months.

RECENT DEVELOPMENTS

On February 3, 2006, we 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 gross proceeds of approximately $5.14 million. Net proceeds, after fees and expenses, was $4.6 million. We 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. In addition, we agreed to use our commercially reasonable efforts to cause the registration statement to be declared effective within 120 days after closing.

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 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 the 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.

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.

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/m2. No cardiotoxicity was seen on biopsy of heart tissue of four patients studied. The maximum tolerated dose (MTD) for L-Annamycin in solid tumor patients was found to be 190 mg/m2. A second Phase II study of L-Annamycin was performed in 13 women with doxorubicin-resistant breast cancer. The median number of prior chemotherapy regimes was two, and six patients had two or more organ sites of involvement. L-Annamycin was administered at 190-250 mg/m2 as a single i.v. infusion over 1-2 h every 3 weeks. Of the 13 patients, 12 had clear

deterioration and new tumor growth after one or two courses.

The potential of a less cardiotoxic drug that was active against multi-drug resistant tumors led to a third trial in relapsed leukemia patients (both AML and ALL). The trial involved 20 patients with relapsed/refractory AML (n=17) or ALL (n=3). L-Annamycin was infused at a starting dose of 190 mg/m2/day x 3 days with escalation to 230, 280, and 350 mg/m2/day x 3 days. Notably, this dosing regime gave cumulative dosages that were 4 to 5-fold greater than was achieved in solid tumor patients. L-Annamycin was generally well tolerated with no observed cardiotoxicity. The MTD was determined at 280 mg/m2/day x 3 days with grade 3/4 hepatotoxicity, or liver toxicity, and mucositis, or inflammation and lesions of the oral mucosa, observed at the highest dose levels of 350 mg/m2/day x 3 days. Of the 20 treated patients, two achieved complete remission (1 AML at 280 mg/m2/day x 3 days who had failed prior induction therapy, and 1 ALL at 350 mg/m2/day x 3 days). Importantly, fifty percent of all patients cleared their immature white blood cells, or blasts circulating in their blood stream and 43% cleared the blasts in their bone marrow. The conclusions drawn from the trial were that L-Annamycin was safe, well tolerated and showed 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 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. This single-arm, open label trial will enroll 12 patients in a dose escalation Phase I portion, followed by 10 patients in a final fixed dose in the Phase II portion. We plan to treat up to 34 patients. We also expect to commence two additional trials with L-Annamycin in 2006, a single agent trial of L-Annamycin in pediatric relapsed ALL patients, and a combination trial of L-Annamycin in combination with Ara-C in adult relapsed or refractory AML patients.

MANUFACTURING

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. Upon the conclusion of our Phase IIb clinical trials, the agreement provides that the parties will negotiate in good faith towards a commercial supply agreement for Annamycin.

ATIPRIMOD TO TREAT MULTIPLE MYELOMA AND 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.

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 first 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 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 white blood cell, 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

On May 26, 2004 we commenced a Phase I/IIa clinical trial of Atiprimod in relapsed multiple myeloma patients at two sites, the Dana-Farber Cancer Institute (Boston) and The University of Texas M.D. Anderson Cancer Center (Houston). On January 31, 2005, we announced the opening of two additional sites for the Phase I/IIa clinical trial of Atiprimod, the Roswell Park Cancer Institute in Buffalo, New York, and the St. Vincent's Comprehensive Cancer Center in New York, New York. The 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. Two patients exhibited stable disease, with one patient having a 34% decrease in M protein (measure of tumor burden) over 3 months of treatment. It was also noted that two patients reported a subjective decrease in bone pain. We plan to continue this trial at higher dose levels until the maximum tolerated dose is reached and then treat 10 additional patients at that level.

On March 15, 2005 we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The new 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. The trial is currently being conducted at the University of Texas M.D. Anderson Cancer Center.

On February 28, 2006, we announced plans to launch an additional indication for clinical development of Atiprimod based on encouraging clinical results from the advanced cancer patient clinical trial that showed a clear response in a patient with advanced carcinoid cancer plus additional encouraging clinical data on other carcinoid patients. Based on these new clinical data, we plan to initiate a new Phase I/II clinical trial of Atiprimod in carcinoid cancer patients with advanced metastatic tumors at several clinical sites in the next few months.

MANUFACTURING

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. We plan to enter into a supply contract for Atiprimod with a commercial supplier by the end of 2007 or after confirming activity of the drug candidate in our current human clinical trials.

ORPHAN DRUG STATUS

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 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. 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.

GUANYLATE CYCLASE RECEPTOR AGONIST TECHNOLOGY

Our guanylate cyclase receptor agonist (GCRA) program is based on control of cyclic guanosine monophosphate (“cyclic GMP”), an important second messenger involved in key cellular processes, which are essential for maintenance of the balance between proliferation and cellular death (apoptosis). Uroguanylin, a hormone produced by and secreted by specialized cells in the human GI tract, helps to maintain this balance by activating synthesis of cyclic GMP through activation of guanylate cyclase receptor. Recent findings suggest a role of cyclic GMP in gastrointestinal (GI)

inflammatory diseases.

We have successfully developed a potent analog (synthetic molecule) of uroguanylin called Guanilib (formerly called SP304). Guanilib has been demonstrated to be superior to uroguanylin in its biological activity, protease stability and pH characteristics. Guanilib is currently undergoing pre-clinical animal studies as a treatment for gastrointestinal or GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of Pittsburgh. Recent results from his laboratory showed that Guanilib was efficacious in treatment of ulcerative colitis in mice. A patent allowance covering therapeutic applications of Guanilib in colon cancer and GI inflammatory diseases has recently been granted by the U.S. Patent and Trademark Office.

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. We plan to work closely with scientists at the University of Texas M.D. Anderson Cancer Center during 2006 to bring forward a pre-clinical candidate for development in the clinic.

SUPERANTIGEN-BASED BIOTERORRISM DEFENSE

On August 20, 1996, we entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University ("Rockefeller") licensed patents covering peptides and antibodies useful in treating toxic shock syndrome and septic shock. In addition, on July 25, 2001, we entered into a license agreement for two additional patents related to the regulation of exoproteins in staphylococcus aureus.

We have designed both a monoclonal antibody and a peptide that prevent the unregulated activation of T-cells (human white blood cells) by a wide range of bacterial toxins (superantigens). This form of T-cell activation leads to a lethal condition called toxic shock syndrome, and is typically generated by bacteria from the class of staphylococcus aureus and streptococcus pyogenes. These bacteria provide a potential opportunity for bioterrorists, and, in particular, the toxin from staphylococcus enterotoxin B is listed as a Category B bioterrorism agent by the Centers for Disease Control Emergency Preparedness and Response program. We are exploring the development of the monoclonal antibody as a therapeutic agent to prevent, treat and control superantigen-mediated bioweapons. Our goal is to demonstrate therapeutic utility of this agent in an animal model in which toxic shock is induced by an aerosolized superantigen toxin. The research work involves a collaboration with Dr. Sina Bavari, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD. We are also exploring strategic alternatives regarding further development of the Superantigen program, including spin-off or strategic partnership.

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 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 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, 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 are 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 Bioenvision 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 $6,154,254 for the year ended December 31, 2005, compared to $2,817,387 and $1,369,985 for the twelve months ended December 31, 2004 and 2003, respectively.

On October 7, 2003 we were 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, our Chief Executive Officer, and Dr. Kenneth C. Anderson, Director of the Jerome Lipper Multiple Myeloma Center of the Dana-Farber Cancer Institute, respectively. The studies, which began in early 2004 and were completed in November 2004, utilized unique in vitro and in vivo methods and animal models at the Dana-Farber Cancer Institute and at our in-house laboratory facilities to explore Atiprimod's pharmacological activity and mechanism of action. Funding for the total amount of this grant was received during 2004 as expenses were incurred and $265,697 has been reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grant".

On April 1, 2005 we were 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. The Principal Investigator of the grant entitled: "Peptide and Antibodies as Antidotes for Superantigens" is Dr. Kunwar Shailubhai, Senior Vice President, Drug Discovery for Synergy Pharmaceuticals Inc., our wholly-owned subsidiary. The grant will also fund a key collaboration with Dr. Sina Bavari of the U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD, to evaluate our monoclonal antibody and antagonist peptide agents in animal models. During the twelve months ended December 31, 2005 we received $226,119 which has been reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grant".

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 March 20, 2006, 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 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 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, and as amended on May 23, 2003, Synergy entered into a worldwide license agreement with AnorMED to research, develop, sell and commercially exploit the Atiprimod patent rights. The license agreement provides 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. In addition the agreement requires Synergy to pay AnorMED royalties on net sales. Commencing on January 1, 2004 and on January 1 of each subsequent year Synergy is obligated to pay AnorMED a maintenance fee of $200,000 until the first commercial sale of the product. The three annual maintenance fee payments under this agreement were made in January 2004, 2005 and 2006 and were recorded as research and development expense. Pursuant to the license agreement, failure to pay the maintenance fee is a material breach of the license agreement. The license agreement will terminate in 2018.

On July 25, 2001, we entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University licensed patents covering the regulation of exoprotein in staphylococcus aureus. We agreed to pay Rockefeller a $7,500 annual maintenance fee until the first commercial sale of the product, plus royalties of 2% and 0.75% of net sales of product depending on whether the product is covered by a claim under the licensed patents or derived from a claim under the licensed patents and will pay Rockefeller 15% of any sublicense fee paid by sublicensees. The agreement will terminate in November 2016. Rockefeller may terminate the license agreement if we are more than 30 days late in paying Rockefeller any amounts due under the license agreement or if we breach the license agreement. We have paid the annual maintenance fee for the year ended July 25, 2002, and have accrued but not paid the annual maintenance fee for the twelve months ended July 25, 2003, 2004 and 2005 pending our evaluation as to the applicability of the patents licensed under this agreement to our ongoing toxic shock syndrome and septic shock development program under the August 20, 1996 agreement.

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 sublicensees. The licensed patents

under this agreement are the subject of research being funded by the NIAID grant awarded to us on April 1, 2005 for $885,641over two years. The license agreement will terminate upon the expiration of the related patents.

EMPLOYEES

As of March 20, 2006, we had 9 full-time and 3 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 Callisto Pharma, GmbH (Germany); and we own one inactive subsidiary, IgX, Ltd (Ireland). 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 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/IIa and Phase IIb clinical trials that our two product candidates, Atiprimod for the treatment of relapsed multiple myeloma and advanced carcinoid cancer and L-Annamycin for the treatment of relapsed acute leukemia, respectively, 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, 2005 and 2004, we had an accumulated deficit of $45,140,654 and $33,361,197, respectively. We have incurred losses in each year since our inception in 1996. We incurred a net loss of $11,779,457, $7,543,467 and $13,106,247 for the twelve months ended December 31, 2005, 2004 and 2003, respectively. These losses, among other things, 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, 2005 have been prepared under the assumption that we will continue as a going concern for the year ending December 31, 2006. Our independent registered public accounting firm has issued a report dated March 29, 2006 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 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 lead product candidates, Atiprimod for the treatment of multiple myeloma and advanced carcinoid cancer and L-Annamycin for the treatment of acute leukemia;
- continue the development of our other product candidates;
- finance our general and administrative expenses;
- prepare regulatory approval applications and seek approvals for Atiprimod 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.

In 2005, our cash used in operating activities increased significantly over 2004 and we expect that our cash used in operating activities will increase significantly for the next several years. For the year ended December 31, 2005, we used approximately $8,700,000, or approximately $725,000 per month in operating activities, as compared to approximately $4,700,000 and $2,000,000 for the twelve months ended December 31, 2004 and 2003, 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, 2005, 2004 and 2003 was approximately $4,800,000, $6,100,000 and $3,800,000 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 AGREEMENTS WITH ANORMED INC. OR THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER TERMINATE, OUR BUSINESS WOULD BE ADVERSELY AFFECTED.

Our business is dependent on rights we have licensed from AnorMED Inc. and The University of Texas M.D. Anderson Cancer Center. Under the terms of the AnorMED license agreement, we are obligated to make a maintenance fee payment of $200,000 on January 1 of each year for the term of the license agreement. Pursuant to the license agreement, failure to pay the maintenance fee is a material breach of the agreement. We do not anticipate failing to pay the maintenance fee, however in the event we cannot pay the maintenance fee, AnorMED may terminate the license agreement and we would not be able to further develop and commercialize Atiprimod which would have an adverse effect on our business. Under the terms of The University of Texas M.D. Anderson Cancer Center license agreement for L-Annamycin, 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. 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 CANCER 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 $3,000,000 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, 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, 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, our Chief Executive Officer and Donald Picker, our Executive Vice President, R&D. The loss of services of Drs. Jacob, Picker 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.

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. We currently do not have any intentions to acquire another company.

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 many need to raise additional funds through public or private debt or equity financing to make acquisitions, which may result in dilution to stockholders and the incurrence of indebtedness that may include restrictive covenants.

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

We are a small company with 9 full-time and 3 part-time employees as of March 20, 2006. 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 March 20, 2006, 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 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.

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. In December 2005 our lease for laboratory space in New Jersey terminated and research activities, directed by Dr. Kunwar Shailubhai, were relocated to Doylestown, PA,

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.

We are not a party to any pending legal proceedings.

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

Our Annual Meeting of Stockholders was held on October 20, 2005 and we disclosed the results of the matters voted on in our Quarterly Report on Form 10-Q filed on November 14, 2005.

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. From May 21, 2003 to October 22, 2004, our common stock was quoted on the OTC Bulletin Board under the symbol "CLSP.OB." Prior to May 21, 2003, our common stock was quoted on the OTC Bulletin Board under the symbol "WEBR.OB" but never traded. The following table shows the reported high and low closing prices per share for our common stock as reported on the American Stock Exchange and the OTC Bulletin Board. With respect to the OTC Bulletin Board quotes, these quotations reflect inter-dealer prices, without markup, markdown or commissions and may not necessarily represent actual transactions or a liquid trading market.

2005	HIGH	LOW
Fourth Quarter	$1.53	$1.01
Third Quarter	1.42	0.97
Second Quarter	1.50	0.95
First Quarter	1.98	1.30

2004	HIGH	LOW

Fourth Quarter	$2.08	$1.50
Third Quarter	2.01	1.15
Second Quarter	3.70	1.95
First Quarter	4.25	3.25

NUMBER OF STOCKHOLDERS

As of March 29, 2006, there were 163 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.

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, 2005, 2004 and 2003 and the balance sheet data at December 31, 2005 and 2004 are derived from our audited financial statements which are included elsewhere in this Form 10-K. The statement of operations data for the year ended December 31, 2001 and the balance sheet data at December 31, 2002 and 2001 are derived from our audited financial statements which are not included in this Form 10-K. The 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 Years Ended December 31,				
	2005	2004	2003	2002	2001
Consolidated Statements of Operations Data:					
Revenues	$ -0-	$ -0-	$ -0-	$ -0-	$ -0-
Operating expenses:					
Research and development	6,154	2,817	1,370	491	653
Government grant	(226)	(266)	—	—	—
Purchased in process research and development	—	210	6,735	—	—
Stock-based compensation - research and development	276	1,508	434	—	—
General and administrative	3,714	2,363	1,398	1,228	939
Stock-based compensation - general and administrative	2,143	1,224	3,400	—	22
Loss from operations	(12,062)	(7,857)	(13,337)	(1,719)	(1,614)
Other income	177	229	222	—	—
Interest and investment income	105	84	9	34	182
Net loss	$ (11,780)	$ (7,544)	$ (13,106)	$ (1,685)	$ (1,432)
Net loss per common share — basic and diluted	$ (0.37)	$ (0.26)	$ (0.61)	$ (0.10)	$ (0.08)
Weighted average number of common shares outstanding — basic and diluted	31,527	28,485	21,358	17,319	17,319

	As of December 31,				
	2005	2004	2003	2002	2001
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 1,421	$ 5,323	$ 3,956	$ 2,223	$ 3,627
Total assets	1,684	5,470	4,119	2,272	3,651
Total current liabilities	2,017	1,220	1,264	440	138
Accumulated deficit during development stage	(45,141)	(33,361)	(25,818)	(12,711)	(11,027)
Total stockholders' equity (deficit)	$ (333)	$ 4,249	$ 2,855	$ 1,829	$ 3,513

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, 2005, we have sustained cumulative net losses of $45,140,654. Our losses have resulted primarily from expenditures incurred in connection with clinical development of licensed products, the purchase of in-process research and development, stock based compensation expense, patent filing and maintenance, outside accounting and legal services and regulatory consulting fees.

From inception through December 31, 2005 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.

To date, our sources of cash have been primarily limited to the sale of our equity securities. On February 3, 2006, we 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 gross proceeds of approximately $5.14 million, for which net proceeds were $4.6 million. On August 22, 2005, we closed a private placement of 1,869,203 shares of common stock to certain existing stockholders. The shares were sold at a price of $0.97 per share for aggregate gross proceeds of approximately $1.8 million, for which net proceeds were $1.6 million. On March 9, 2005, we completed a private placement of an aggregate 1,985,791 shares of our common stock at a per share price of $1.52, for aggregate gross proceeds of $3.02 million and for which net proceeds were $2.99 million. We have devoted substantially all of our capital resources to the in-licensing and development of our product candidates.

Our research and development expenses consist primarily of costs associated with an in-house research and development laboratory, salaries and staff, 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. 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 service 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

PLAN OF OPERATIONS

Our plan of operations for the next year is to focus primarily on the development of two drugs to treat leukemia, multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow) and advanced carcinoid tumors. Our lead drug in development for leukemia, L-Annamycin, earlier completed a Phase I/IIa trial in relapsed or refractory acute leukemia patients. On December 1, 2005 we initiated a clinical trial in adult relapsed or refractory acute lymphocytic leukemia patients. Our second drug candidate, Atiprimod, is presently in a Phase I/IIa clinical trial in multiple myeloma patients, and in a Phase I/IIa clinical trial in advanced cancer patients. The drug is an orally available drug with antiproliferative and antiangiogenic activity.

Our plan of research studies include further pre-clinical work on Guanilib, in preclinical development for gastrointestinal inflammation, a drug exploratory program focused on a class of anticancer compounds called Degrasyns, and a monoclonal antibody and vaccine candidate that are being explored as biodefense agents against staphylococcal and streptococcal bioterrorism agents.

L-Annamycin

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, an anthacycline 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 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 Annamycin.

L-Annamycin was discovered by scientists at The University of Texas M.D. Anderson Cancer Center and initially evaluated in a Phase I clinical trial in 36 patients with relapsed solid tumors, a Phase II clinical trial in 13 patients with doxorubicin-resistant breast cancer, and a Phase I/IIa trial in 20 patients with relapsed or refractory acute myeloid leukemia (AML) or relapsed or refractory acute lymphocytic leukemia (ALL). We began a 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. This single-arm, open label trial will enroll 12 patients in a dose escalation Phase I portion, followed by 10 patients in a final fixed dose in the Phase II portion. We plan to treat up to 34 patients. We also expect to commence two additional trials with L-Annamycin in 2006, a single agent trial of L-Annamycin in pediatric relapsed or refractory ALL patients, and a combination trial of L-Annamycin in combination with Ara-C in adult relapsed or refractory AML patients.

Atiprimod

On August 28, 2002, and as amended on May 23, 2003, Synergy entered into a worldwide license agreement with AnorMED to research, develop, sell and commercially exploit the Atiprimod patent rights. The license agreement provides 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. In addition the agreement requires Synergy to pay AnorMED royalties on net sales. Commencing on January 1, 2004 and on January 1 of each subsequent year, Synergy is obligated to pay AnorMED a maintenance fee of $200,000 until the first commercial sale of the product. The first two annual maintenance fee payments under this agreement were made in January 2004 and 2005 and were recorded as research and development expense. The license agreement will terminate in 2018.

On May 26, 2004 we commenced a Phase I/IIa clinical trial of Atiprimod in relapsed or refractory multiple myeloma patients at two sites, the Dana-Farber Cancer Institute (Boston) and The University of Texas M.D. Anderson Cancer Center (Houston). On January 31, 2005, we announced the opening of two additional sites for the Phase I/IIa clinical trial of Atiprimod, the Roswell Park Cancer Institute in Buffalo, New York, and the St. Vincent's Comprehensive Cancer Center in New York, New York. The 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 an update on 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. Two patients exhibited stable disease, with one patient having a 34% decrease in M protein (measure of tumor burden) over 3 months of treatment. It was also noted that two patients reported a subjective decrease in bone pain. We plan to continue this trial

at higher dose levels until the maximum tolerated dose is reached and then treat 10 additional patients at that level.

On March 15, 2005 we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The new 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. The trial is currently being conducted at the University of Texas M.D. Anderson Cancer Center. On February 28, 2006, we announced plans to launch an additional indication for clinical development of Atiprimod based on encouraging clinical results from the advanced cancer clinical trial that showed a clear response in a patient with advanced carcinoid cancer plus additional encouraging clinical data on other carcinoid patients. Based on these new clinical data, we plan to initiate a new Phase I/II clinical trial of Atiprimod in carcinoid cancer patients with advanced metastatic tumors at several clinical sites in the next few months.

GUANYLATE CYCLASE RECEPTOR AGONIST TECHNOLOGY (GUANILIB)

Our guanylate cyclase receptor agonist (GCRA) program is based on control of cyclic GMP, an important second messenger involved in key cellular processes, which are essential for maintenance of the balance between proliferation and cellular death (apoptosis). Uroguanylin, a hormone produced by and secreted by specialized cells in the human GI tract, helps to maintain this balance by activating synthesis of cyclic GMP through activation of guanylate cyclase receptor. Recent findings suggest roles of cyclic GMP in GI inflammatory diseases.

We have successfully developed a potent analog (synthetic molecule) of uroguanylin called Guanilib (formerly called SP304). Guanilib has been demonstrated to be superior to uroguanylin in its biological activity, protease stability and pH characteristics. Guanilib is currently undergoing pre-clinical animal studies as a treatment for GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of Pittsburgh. Recent results from his laboratory showed that Guanilib was efficacious in treatment of colitis in mice. A patent allowance covering therapeutic applications of Guanilib in colon cancer and GI inflammatory diseases has recently been granted by the U.S. Patent and Trademark Office.

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. We plan to work closely with scientists at the University of Texas M.D. Anderson Cancer Center during 2006 to bring forward a pre-clinical candidate for development in the clinic.

SUPERANTIGEN-BASED BIOTERORRISM DEFENSE

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 sublicensees.

The licensed patents under this agreement are the subject of research being funded by the NIAID grant awarded to us on April 1, 2005 for $885,641 over two years. The license agreement will terminate upon the expiration of the related patents.

On July 25, 2001, we entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University licensed patents covering the regulation of exoprotein in staphylococcus aureus. We agreed to pay Rockefeller a $7,500 annual maintenance fee until the first commercial sale of the product, plus royalties of 2% and 0.75% of net sales of product depending on whether the product is covered by a claim under the licensed patents or derived from a claim under the licensed patents and will pay Rockefeller 15% of any sublicense fee paid by sublicensees. The agreement will terminate in November 2016. Rockefeller may terminate the license agreement if we are more than 30 days late in paying Rockefeller any amounts due under the license agreement or if we breach the license agreement. We have paid the annual maintenance fee for the year ended July 25, 2002, and have accrued but not paid the annual maintenance fee for the twelve months ended July 25, 2003, 2004 and 2005, pending our evaluation as to the applicability of the patents licensed under this agreement to our ongoing toxic shock syndrome and septic shock development program under the August 20, 1996 agreement.

We are exploring the development of a monoclonal antibody as a therapeutic agent to prevent, treat and control superantigen-mediated bioweapons. Our goal is to demonstrate therapeutic utility of this agent in an animal model in which toxic shock is induced by an aerosolized superantigen toxin. The research work involves collaboration with Dr. Sina Bavari, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD. We are also exploring strategic alternatives regarding further development of the superantigen program, including spin-off or strategic partnership.

MANUFACTURING

An improved manufacturing method for Annamycin has been developed at Antibioticos S.p.A., our commercial supplier of Good Manufacturing Practice, or GMP, drug substance. GMP material is currently being produced in sufficient quantity for all three anticipated Phase I/II trials. Currently, Antibioticos S.p.A. is our sole supplier of Annamycin for our clinical trials. Our agreement with Antibioticos provides that Antibioticos S.p.A. will provide 400 grams of GMP drug substance (Annamycin) for our L-Annamycin clinical trials. Upon the conclusion of our Phase IIb clinical trials, the agreement provides that the parties will negotiate in good faith towards a commercial supply agreement for Annamycin. 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.

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. We plan to enter into a supply contract for Atiprimod with a commercial supplier by the end of 2007 or after confirming activity of the drug candidate in our current human clinical trials.

EMPLOYEES

Our plan is to use contract research organizations (“CRO”) for most of our development efforts, including monitoring of clinical trial results, thus
minimizing the need to hire full time employees. As of March 20, 2006, we had 9 full-time and 3 part-time employees.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of December 31, 2005.

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, 2005. 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.

Accounting for stock based compensation: We have adopted Statement of Financial Accounting Standard No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). As provided for by SFAS 123, we have also elected to account for our stock-based compensation programs according to the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25")." Accordingly, compensation expense has been recognized based on the intrinsic value of stock issued or options granted to employees and directors for services rendered. Other stock based compensation associated with grants to non-employees, as well as Directors who perform services outside of their Board duties, is measured using the fair value method. 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, 2005 stock based compensation expense totaled $13,770,967 or approximately 31% of our accumulated deficit.

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

The single most significant factor impacting our operating results is the price of our stock which is used in the computation of stock-based compensation expense, particularly for variable options. Our stock price fluctuated from $3.95 per share as of December 31, 2003 to $1.38 per share as of December 31, 2005. As of December 31, 2005, 803,500 of our non-employee options required variable accounting treatment in accordance with FASB Interpretation No. 44 “Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25” (“FIN 44”). Our stock-based compensation expense associated with these non-employee variable options during the twelve months ended December 31, 2005 was $75,110. During the twelve months ended December 31, 2003 we recorded $1,108,817 of stock-based compensation expense associated with these non-employee variable options and we reversed $816,865 of this expense during the twelve month ended December 31, 2004.

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, 2005 AND DECEMBER 31, 2004

We had no revenues during the twelve months ended December 31, 2005 and 2004 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 approximately $3,336,867, or 118%, to $6,154,254 for the twelve months ended December 31, 2005 from $2,817,387 for the twelve months ended December 31, 2004. The single most significant factor contributing to this increase in research and development expense was our L-Annamycin project where our program expenses increased to approximately $2,500,000 during the twelve months ended December 31, 2005. We started our work on L-Annamycin in the latter part of 2004, and incurred approximately $300,000 in expenses during the twelve months ended December 31, 2004, primarily limited to a $100,000 initial license fee, $31,000 in patent related legal fees paid to The University of Texas M. D. Anderson Cancer Center and approximately $85,000 incurred with our clinical consultant to begin the process of developing protocols and obtaining investigational review board (“IRB”) approvals to start our trials.

Atiprimod clinical trial expenses which include patient costs, drug formulation and tableting, data collection, monitoring, insurance, and FDA consultants increased approximately $500,000, or 35% to approximately $1,900,000 during the twelve months ended December 31, 2005 as compared to approximately $1,400,000 for the twelve months ended December 31, 2004. Also contributing to this increase in research and development expense in the twelve months ended December 31, 2005 were salaries and wages in the amount of $750,000 compared to $450,000 during the twelve months ended December 31, 2004, increasing approximately $300,000, or 67%. The increase was a result of hiring a chief medical officer, an in-house patent agent and several clinical trial associates to manage our clinical activities.

Stock-based compensation - research and development recorded during the twelve months ended December 31, 2005, totaled $276,252 as compared to $1,508,588 recorded during the twelve months ended December 31, 2004. This decrease was primarily attributable to the restructuring of Dr. Kunwar M. Shailubhai’s employment agreement during 2004, which resulted in additional stock-based compensation expense of approximately $1,100,000 during the twelve months ended December 31, 2004 (see Footnote 8 to our Consolidated Financial Statements).

Government grant funding for the twelve months ended December 31, 2005 was $226,119 as compared to $265,697 for the twelve months ended December 31, 2004. Our 2005 funding was for work on a biodefense partnership grant from the National Institute of Allergy and Infectious Diseases to develop a monoclonal antibody and vaccine against bacterial superantigen toxins under our August 20, 1996 license with Rockefeller University. Our 2004 funding was from a grant from the National Institutes of Health for studies on Atiprimod. We request grant funding to reimburse research and development expenses as incurred and this reimbursement has been reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grant".

General and administrative expenses for the twelve months ended December 31, 2005 were $3,714,082, an increase of $1,351,309 or 57%, from $2,362,773 for the twelve months ended December 31, 2004. The increase was due primarily to approximately (i) $500,000 of increased investor relations costs, (ii) $270,000 in higher consulting fees for strategic planning and capital markets advice,(iii) $250,000 in higher personnel expenses primarily employee group insurance, payroll taxes and recruitment fees associated with staffing growth and (iv) $90,000 in higher costs related to our work on compliance with the Sarbanes-Oxley Act of 2002.

Stock-based compensation - general and administrative recorded during the twelve months ended December 31, 2005, totaled $2,143,442 as compared to $1,224,182 recorded during the twelve months ended December 31, 2004. This increase was primarily attributable to the expense associated with warrants we issued to Trilogy Capital Partners to

purchase 1,793,322 shares of our Common Stock at an exercise price of $1.03 per share. The fair value of the warrants using the Black-Scholes methodology is $1,469,431 which is being recorded as stock-based compensation expense over the twelve month term of the service agreement entered into on July 18, 2005. During the twelve months ended December 31, 2005 the amortization of the Trilogy warrant stock-based compensation totaled $734,995.

Purchased in-process research and development was $0 and $209,735 for the twelve months ended December 31, 2005 and 2004 respectively. The 2004 expense was primarily in connection with the acquisition of rights to two key patents from Houston Pharmaceuticals, Inc.

During December 2005 and 2004 Synergy sold certain New Jersey State tax loss carry forwards under a state economic development program for cash of approximately $177,000 and $233,000, respectively, the proceeds of which were used to support research and development activities in New Jersey. This state tax benefit was recorded as Other Income during the fourth quarters ended December 31, 2005 and 2004. As of December 31, 2005 we have no remaining New Jersey State tax loss carry forwards available for sale.

Net loss for the twelve months ended December 31, 2005 was $11,779,457 compared to a net loss of $7,543,467 reported for the twelve months ended December 31, 2004. The increased net loss is primarily the result of higher research, development, general and administrative expenses discussed above net of lower stock based compensation and purchased in-process R&D.

YEARS ENDED DECEMBER 31, 2004 AND DECEMBER 31, 2003.

The results of operations of Synergy are included in the consolidated statements of operations since the Merger on April 30, 2003.

We had no revenues during the twelve months ended December 31, 2004 and 2003 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 approximately $1,447,402, or 106%, to $2,817,387 for the twelve months ended December 31, 2004 from $1,369,985 for the twelve months ended December 31, 2003. The single most significant factor contributing to this increase in research and development expense was approximately $500,000 in higher costs associated with the commencement of our Phase I/IIa clinical trials of Atiprimod in May of 2004. These clinical trial expenses included patient costs, drug formulation and tableting, data collection, monitoring, insurance, and FDA consultants. During the twelve months ended December 31, 2003 our Atiprimod project expenses were pre-clinical in nature, associated with preparing our IND application. Also contributing to this increase in research and development expense in the twelve months ended December 31, 2004 were our payments of the first annual $200,000 maintenance fee to AnorMED, Inc. for the Atiprimod license. In addition personnel costs increased approximately $300,000 as we retained two Synergy executive staff scientists, Drs. Picker and Shailubhai, subsequent to the Merger and we incurred $137,000 of costs to develop a new GMP certified commercial production capacity for future trials of Atiprimod. The remainder of the increase was primarily attributable to $160,000 of higher expenses paid to outside collaborating institutions under our government research grant for Atiprimod.

Our L-Annamycin project, which started in the latter part of 2004, incurred expenses primarily limited to a $100,000 initial license fee and $31,000 in patent related legal fees paid to The University of Texas MD Anderson Cancer Center and approximately $85,000 incurred with our clinical consultant to begin the process of developing protocols and obtaining investigational review board (“IRB”) approvals to start our trials. Until the latter part of 2004 our lead drug candidate was Atiprimod and almost all of our resources were devoted to that project. Concurrently with the license of L-Annamycin we began implementing a project cost management system which became effective January 1, 2005. This system captures all of our outside variable project cost (e.g. patient costs, drug formulation and tableting, data collection, monitoring, insurance, and FDA consultants) associated with the clinical development of each of our drug candidates. With regard to our relatively fixed and smaller research and development overhead expenses, principally salaries and facilities, we are not able to accurately and meaningfully determine project allocations at this time. We do believe however that these internal fixed resources are expended on projects approximately in proportion to our outside variable costs.

Stock-based compensation - research and development recorded during the twelve months ended December 31, 2004, totaled $1,508,588 as compared to $434,187 recorded during the twelve months ended December 31, 2003. This increase was primarily attributable to restructuring of Dr. Kunwar M. Shailubhai’s employment agreement, which resulted in deferred compensation cost associated with 225,000 cancelled options of $706,813 as of the date of cancellation being charged to stock-based compensation expense during the twelve months ended December 31, 2004 (see Footnote 8 to our Consolidated Financial Statements). In addition our stock-based compensation - research and development recorded during the twelve months ended December 31, 2004 reflects a full twelve months of expense attributable to options granted to our scientific staff at mid-year 2003 subsequent to the Merger with Synergy in April 2003.

Government grant funding for the twelve months ended December 31, 2004 was $265,697 as compared to $0 for the twelve months ended December 31, 2003. We request grant funding to reimburse research and development expenses as incurred.

General and administrative expenses for the twelve months ended December 31, 2004 were $2,362,773, an increase of $964,683 or 69%, from $1,398,090 for the twelve months ended December 31, 2003. The increase was due primarily to approximately (i) $300,000 of increased personnel costs principally as a result of the Merger and recruitment costs related to hiring personnel, (ii) $220,000 in higher facilities and office overhead related to the move into our new corporate headquarters in New York City during the quarter ended December 31, 2003, (iii) $340,000 in higher outside services associated with being a public company including outside directors, transfer agent fees and investor relations and (iv) $80,000 in higher business travel principally attending investor, professional and medical conferences in the United States, England, Italy and Germany.

Stock-based compensation - general and administrative recorded during the twelve months ended December 31, 2004, totaled $1,224,182 as compared to $3,399,759 recorded during the twelve months ended December 31, 2003. This decrease was primarily attributable to a decrease in our stock price from $3.95 as of December 31, 2003 to $1.98 per share as of December 31, 2004. This share price decrease resulted in the recapture during 2004 of stock based compensation recorded on certain variable options granted to non-employees during 2003. The stock-based compensation expense associated with these variable options during the twelve months ended December 31, 2003 was $1,108,817, whereas we reversed $816,865 of this expense during the twelve months ended December 31, 2004.

Purchased in-process research and development was $209,735 for the twelve months ended December 31, 2004, primarily in connection with the acquisition of rights to two key patents covering a novel cancer platform technology from Houston Pharmaceuticals, Inc. During the twelve months ended December 31, 2003 we recorded $6,734,818 of purchased in-process research and development expense in connection with the Merger.

During December 2004 and 2003, Synergy sold certain New Jersey State tax loss carry forwards under a state economic development program for cash of approximately $233,000 and $222,000 respectively , the proceeds of which were used to support research and development activities in New Jersey. This state tax benefit was recorded as Other Income during the fourth quarters ended December 31, 2004 and 2003.

Net loss for the twelve months ended December 31, 2004 was $7,543,467 compared to a net loss of $13,106,247 incurred for the twelve months ended December 31, 2003. The decreased net loss is primarily the result of the lower purchased in-process research and development expenses, partially offset by higher research, development, general and administrative expenses discussed above. In addition we recorded lower stock based compensation expense of $2,732,770 during the twelve months ended December 31, 2004, as compared to $3,833,946 recorded during the same period ended December 31, 2003.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2005 we had $1,420,510 in cash and cash equivalents, compared to $5,323,384 as of December 31, 2004. This decrease in cash of $3,902,874 during the twelve months ended December 31, 2005 was principally the result of cash used in operating activities of $8,686,902 during the twelve months ended December 31, 2005. Cash used in operating activities was primarily for research and development and general and administrative expenses discussed above, partially offset by government grant funding, the sale of tax loss carry forwards and interest and investment income. We financed these net operating cash expenditures from existing cash balances, by completing two private placements of common stock yielding net proceeds of $4,655,278, and from the exercise of common stock warrants totaling $128,750.

On February 3, 2006, we 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 $5,140,402. We paid an aggregate $468,340 and issued an aggregate 390,284 warrants to certain selling agents. The selling agent warrants are exercisable at $1.25 per share and will expire three years after closing. We also incurred $30,000 in legal fees directly associated with the closing. The net proceed were from this private placement were $4,641,870.

On August 22, 2005, we closed a private placement of 1,869,203 shares of common stock to certain of our existing stockholders. The shares were sold at a price of $0.97 per share for aggregate proceeds of approximately $1.8 million. We paid an aggregate $151,250 to certain selling agents.

On March 9, 2005 we sold and issued in a private placement an aggregate 1,985,791 shares of common stock at a per share price of $1.52, for aggregate gross proceeds of approximately $3.02 million. Because this transaction was completed with certain existing institutional shareholders and certain members of our management we paid no fees to selling agents, and legal fees were $25,000.

On April 1, 2005 we were awarded a biodefense partnership grant from the National Institute of Allergy and Infectious Diseases (NIAID) to develop a monoclonal antibody and vaccine against bacterial superantigen toxins, in the amount of $885,641 over two years. Work on the NIAID superantigen grant started in July 2005 and funding totaled $226,119 during the twelve months ended December 31, 2005.

Our capital resources are focused primarily on the clinical development and regulatory approval of L-Annamycin for acute leukemia and Atiprimod for multiple myeloma, advanced carcinoid cancer, and bone resorption disease, a major complication associated with multiple myeloma. Our product development efforts are thus in their early stages and we cannot make estimates of the costs or the time it will take to complete. The risk of completion of any program is high because of the long duration of clinical testing, extended regulatory approval and review cycles and uncertainty of the costs. Net cash inflows from any products developed may take several years to achieve. We will need additional funding to complete these activities. We could however receive grants, contracts or technology licenses in the short-term. The amount and timing of these inflows, if any, is not known.

Our consolidated financial statements as of December 31, 2005 have been prepared under the assumption that we will continue as a going concern for the year ending December 31, 2006. Our independent registered public accounting firm has issued a report dated March 29, 2006 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. 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.

To date, our sources of cash have been primarily limited to the sale of our equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct 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.

Our current plan of operations envisions expenditures that will require additional funding, and we have developed a contingency plan reflecting scaled back operations which uses only existing resources to fund our operations for the next twelve months.

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, 2005, and is based on information appearing in the Notes to Consolidated Financial Statements.

	Total	Less than 1 Year	1-2 Years	3-5 Years	More than 5 Years
Operating leases - facilities	$ 854,541	$ 148,553	$ 306,079	$ 318,444	$ 81,464
Purchase obligation- principally consulting services	513,298	393,298	60,000	60,000	(3)
Minimum spending obligations (1)	2,212,714	534,874	1,069,747	608,093	(3)
License royalty payments (2)	1,342,500	407,500	440,000	495,000	(3)
Total obligations	$ 4,923,053	$ 1,484,225	$ 1,875,826	$ 1,481,537	$ 81,464

(1) We have licensed patents from other companies and institutions under certain license agreements. This line item represents our minimum obligations to spend monies for product development and commercialization as set forth in each license.

(2) This line item represents our minimum license fee payments to (i) AnorMED, Inc. for our Atiprimod license, (ii) the University of Texas M.D. Anderson Cancer Center for our Degrasyns license and (iii) Rockefeller University for the license of several patents related to our superantigen-based bioterrorism defense program. 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.

RECENT ACCOUNTING PRONOUNCEMENTS:

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 will be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS 123R also addresses transactions in which an entity incurs liabilities in exchange for goods or services that are based on the fair value of 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 this standard on January 1, 2006. This statement does not change the accounting guidance for share based payment transactions with parties other than employees as set forth in SFAS 123 and EITF 96-18 “*Accounting for Equity Instruments Issued to Other than Employees, for Acquiring, or in connection with selling Goods or Services”*.

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*" in adopting this standard.

In March 2005 the SEC issued Staff Accounting Bulletin No. 107 ("SAB 107") which discusses the SEC's interpretation of SFAS 123R and the related valuation on share-based compensation for public entities. We are assessing the requirements of SFAS 123R and SAB 107 and the impact that they will have on our consolidated financial statements. While we cannot precisely determine the impact on net loss and loss per share we anticipate the adoption of these standards will affect our results of operations to an extent similar to that presented SFAS 123 proforma disclosure included in Note 3 to the accompanying audited consolidated financial statements.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets An Amendment of APB Opinion No. 29", which is effective for fiscal periods beginning after June 15, 2005. SFAS No.153 amends APB 29, "Accounting for Nonmonetary Transactions", which is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB 29 included certain exceptions to that principle. SFAS No. 153 amends APB 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. Our adoption of this statement on July 1, 2005 did not have a material effect on our financial position or results of operations.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections," which changes the requirements for accounting for and reporting of a change in accounting principle. SFAS No. 154 requires retrospective application to prior periods' financial statements of a voluntary change in accounting principle unless it is impracticable. SFAS No. 154 also requires that a change in method of depreciation, amortization, or depletion for long-lived, nonfinancial assets be accounted for as a change in accounting estimate that is affected by a change in accounting principle. SFAS No. 154 is effective for accounting changes and a correction of errors made in fiscal years beginning after December 15, 2005, but does not change the transition provisions of any existing accounting pronouncements, including those that are in a transition phase as of the effective date of SFAS No. 154. The adoption of SFAS No. 154 will not have a material effect on our results of operations or our financial position.

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

At December 31, 2005 and 2004, 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). 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, 2005 and 2004 and for the fiscal years ended December 31, 2005, 2004 and 2003 and for the period from June 5, 1996 (inception) to December 31, 2005, 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.

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, 2005, our Chief Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were not effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms. Our Chief Executive Officer and Principal Financial Officer also concluded that, as of December 31, 2005, our disclosure controls and procedures were not effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the relationship between the benefit of desired controls and procedures and the cost of implementing new controls and procedures.

In that context and in order to ensure the effectiveness of our disclosure controls in the future we are taking the following actions:

(i) form a Disclosure Committee, comprising members of our senior management and corporate counsel, charged with the task of discussing and reviewing all transactions occurring during each quarter prior to filing our periodic reports with the SEC;

(ii) tighten our policy regarding review and approval of all contractual obligations;

(iii) inclusion of our Chief Business Officer and our Principal Financial and Accounting Officer in all Board of Directors meetings;

(iv) segregate financial reporting and accounting duties more effectively between our Chief Business Officer and our Principal Financial and Accounting Officer in preparing all periodic reports filed with the SEC; and

(v) retain a third party GAAP advisor to assist the Principal Financial and Accounting Officer, as well as advise the Audit Committee from time to time.

The consolidated financial statements include all adjustments identified as a result of the evaluation performed.

Except for the above, there were no changes in our internal controls over financial reporting that could significantly affect internal controls over financial reporting during the quarter ended December 31, 2005.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

Information required by Item 10 of Part III is included in our Proxy Statement relating to our 2006 Annual Meeting of Stockholders, and is incorporated herein by reference. Information relating to our Code of Business Conduct and Ethics and to compliance with Section 16(a) of the 1934 Act is set forth in our Proxy Statement relating to our 2006 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

Information required by Item 11 of Part III is included in our Proxy Statement relating to our 2006 Annual Meeting of Stockholders and is incorporated herein by reference.

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

Information required by Item 12 of Part III is included in our Proxy Statement relating to our 2006 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Information required by Item 13 of Part III is included in our Proxy Statement relating to our 2006 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required by Item 14 of Part III is included in our Proxy Statement relating our 2006 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

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

(1) *Index to Consolidated Financial Statements:*

Report of BDO Seidman LLP, Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of December 31, 2005 and 2004
Consolidated Statements of Operations for each of the three years in the period ended December 31, 2005 and for the period from June 5, 1996 (inception) to December 31, 2005
Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period from June 5, 1996 (inception) to December 31, 2005
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2005 and for the period from June 5, 1996 (inception) to December 31, 2005
Notes to Consolidated Financial Statements

(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*

E x h i b i t Number	**Description**
3.1	Certificate of Incorporation (Incorporated by reference to Exhibit 99.1 filed with the Company's Current Report on Form 8-K filed on May 28, 2003)

3.2 Certificate of Amendment to the Certificate of Incorporation of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2005)

3.3 Bylaws (Incorporated by reference to Exhibit 99.2 filed with the Company's Current Report on Form 8-K filed on May 28, 2003)

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)

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 Employment Agreement dated June 13, 2003 by and between Callisto Pharmaceuticals, Inc. and Donald H. Picker (Incorporated by reference to Exhibit 10.3 filed with the Company's Current Report on Form 10-QSB filed on November 14, 2003)*

10.4 Amendment to Employment Agreement dated April 6, 2004 by and between Callisto Pharmaceuticals, Inc. and Donald H. Picker (Incorporated by reference to Exhibit 10.6 filed with the Company's Annual Report on Form 10-KSB filed on April 14, 2004)*

10.5 License Agreement dated as of August 28, 2002 by and between Synergy Pharmaceuticals Inc. and AnorMED Inc.(Incorporated by reference to Exhibit 10.4 filed with the Company's Current Report on Form 10-QSB filed on November 14, 2003)**

10.6 Employment Agreement dated January 15, 2004 by and between Callisto Pharmaceuticals, Inc and Bernard Denoyer (Incorporated by reference to Exhibit 10.6 filed with the Company's Annual Report on Form 10-KSB on April 14, 2004)*

10.7 Form of Registration Rights Agreement dated as of January 21, 2004 by and among the Registrant and the Purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on January 28, 2004)

10.8 Common Stock Purchase Agreement dated as of April 19, 2004, by and between Callisto Pharmaceuticals, Inc. and the Purchasers set forth on Exhibit A thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on April 19, 2004)

10.9 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)**

10.10 Consulting Agreement dated as of December 27, 2004 between the Registrant and Gabriele M. Cerrone (Incorporated by reference to Exhibit 10.10 filed with the Company’s Annual Report on Form 10-KSB filed on March 30, 2005) *

10.11 Common Stock Purchase Agreement dated as of March 8, 2005 by and between Callisto Pharmaceuticals, Inc. and the Purchasers set forth on Exhibit A thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on March 5, 2005)

10.12 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)

10.13 Agreement among Davos Chemical Corporation, Callisto Pharmaceuticals, Inc. and Antibioticos S.p.A. dated July 28, 2004 (Incorporated by reference to Exhibit 10.15 filed with the Company's Annual Report on Form 10-K filed on June 6, 2005)

10.14 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)*

10.15 Extension and Severance Compensation Agreement dated June 9, 2005 between Callisto Pharmaceuticals, Inc. and Donald S. Picker (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on June 15, 2005)*

10.16 Letter of Engagement between Trilogy Capital Partners, Inc. and Callisto Pharmaceuticals, Inc. dated July 18, 2005 (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on July 22, 2005)

10.17 Common Stock Purchase Agreement dated as of August 22, 2005 between Callisto Pharmaceuticals, Inc. and the investors listed on Exhibit A thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on August 26, 2005)

10.18 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)*

10.19 Amendment dated October 19, 2005 to the Employment Agreement dated as of September 23, 2003, as amended April 6, 2004 by and between Callisto Pharmaceuticals, Inc. and Donald H. Picker (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on October 21, 2005)*

10.20 Amendment dated October 19, 2005 to the Employment Agreement dated as of January 15, 2004 by and between Callisto Pharmaceuticals, Inc. and Bernard Denoyer (Incorporated by reference to Exhibit 10.4 filed with the Company's Current Report on Form 8-K filed on October 21, 2005)*

10.21 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)*

10.22 Patent and Technology License Agreement dated January 10, 2006 between The University of Texas M.D. Anderson Cancer Center and Callisto Pharmaceuticals, Inc. **

10.23 Securities Purchase Agreement dated February 3, 2006 between Callisto Pharmaceuticals, Inc. and the investors listed on Schedule A thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's

	Current Report on Form 8-K filed on February 9, 2006)
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
99.1	Power of Attorney (included on page 36)

* 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 31, 2006

By: /s/ Gary S. Jacob

Gary S. Jacob,
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned officers or directors of the Registrant, by virtue of their signatures to this report, appearing below, hereby constitute and appoint Gabriele M. Cerrone and Gary S. Jacob, or any one of them, with full power of substitution, as attorneys-in-fact in their names, places and stead to execute any and all amendments to this report in the capacities set forth opposite their names and hereby ratify all that said attorneys-in-fact do by virtue hereof.

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

SIGNATURE	TITLE	DATE
/s/ Gary S. Jacob Gary S. Jacob	Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2006
/s/ Bernard F. Denoyer Bernard F. Denoyer	Vice President, Finance (Principal Financial and Accounting Officer)	March 31, 2006
/s/ Gabriele M. Cerrone Gabriele M. Cerrone	Chairman of the Board	March 31, 2006
/s/ Riccardo Dalla-Favera Riccardo Dalla-Favera	Director	March 31, 2006
/s/ John P. Brancaccio John P. Brancaccio	Director	March 31, 2006
/s/ Stephen K. Carter Stephen K. Carter	Director	March 31, 2006
/s/ Christoph Bruening Christoph Bruening	Director	March 31, 2006
/s/ Randall K. Johnson	Director	March 31, 2006

Randall K. Johnson

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

Index to Consolidated Financial Statements

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, 2005 and 2004, the related consolidated statements of operations and cash flows for each of the three years in the period ended December 31, 2005 and for the period from June 5, 1996 (inception) to December 31, 2005 and the related consolidated statement of stockholders' equity (deficit) for the period from June 5, 1996 (inception) to December 31, 2005. 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, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 and for the period from June 5, 1996 (inception) to December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

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

/s/ BDO Seidman, LLP

New York, New York
March 29, 2006

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

	AS OF DECEMBER 31,	
	2005	**2004**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,420,510	$ 5,323,384
Prepaid expenses and other	181,284	45,231
	1,601,794	5,368,615
Property and equipment - net	—	18,856
Security deposits	82,196	82,196
	$ 1,683,990	$ 5,469,667
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,424,612	$ 984,486
Accrued expenses	592,297	235,803
	2,016,909	1,220,289
Stockholders' equity (deficit):		
Common stock, par value $.0001, 100,000,000 shares authorized, 33,233,096 and 29,219,102 outstanding at December 31, 2005 and 2004, respectively.	3,323	2,922
Additional paid-in capital	46,387,875	39,910,187
Unamortized deferred stock based compensation	(1,583,463)	(2,302,534)
Deficit accumulated during development stage	(45,140,654)	(33,361,197)
	(332,919)	4,249,378
	$ 1,683,990	$ 5,469,667

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,
	2005	2004	2003	2005
Revenues	$ —	$ —	$ —	$ —
Costs and expenses:				
Research and development	6,154,254	2,817,387	1,369,985	13,874,002
Government grant	(226,119)	(265,697)	—	(491,816)
Purchased in process research and development	—	209,735	6,734,818	6,944,553
Stock-based compensation (research and development)	276,252	1,508,588	434,187	2,219,027
General and administrative	3,714,082	2,362,773	1,398,090	12,326,327
Stock-based compensation (general and administrative)	2,143,442	1,224,182	3,399,759	11,551,940
Loss from operations	(12,061,911)	(7,856,968)	(13,336,839)	(46,424,033)
Interest and investment income	105,303	84,081	8,768	654,984
Other income	177,151	229,420	221,824	628,395
Net loss	$ (11,779,457)	$ (7,543,467)	$ (13,106,247)	$ (45,140,654)
Weighted average shares outstanding: basic and diluted	31,527,060	28,485,227	21,357,659	
Net loss per common share: basic and diluted	$ (0.37)	$ (0.26)	$ (0.61)	

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 period					
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

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

	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance at inception, June 5, 1996	—	—	—
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

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

	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

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

	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 period	—	—	—	—	—	—	(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	39,910,187	(2,302,534)	(33,361,197)	4,249,378

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

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

	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	$ 39,910,187	($2,302,534)	($33,361,197)	$ 4,249,378
Net loss for the year	—	—	—	—	(11,779,457)	(11,779,457)
Deferred stock-based compensation - new grants	—	—	1,571,772	(1571,772)	—	—
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

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,
	2005	2004	2003	2005
Cash flows from operating activities:				
Net loss	$ (11,779,457)	$ (7,543,467)	$ (13,106,247)	$ (45,140,654)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	18,856	27,632	27,755	84,637
Stock based compensation expense	2,419,694	2,732,770	3,833,946	13,770,967
Purchased in-process research and development (non-cash portion)	—	106,235	6,734,818	6,841,053
Changes in operating assets and liabilities:				
Prepaid expenses	(136,053)	7,413	(24,188)	(181,284)
Security deposit	—	(19,216)	(62,980)	(82,196)
Accounts payable and accrued expenses	790,058	(43,481)	581,008	1,770,418
Total adjustments	3,092,555	2,811,353	11,090,359	22,203,595
Net cash used in operating activities	(8,686,902)	(4,732,114)	(2,015,888)	(22,937,059)
Cash flows from investing activities:				
Acquisition of equipment	—	—	(54,462)	(84,637)
Net cash used in investing activities	—	—	(54,462)	(84,637)
Cash flows from financing activities:				
Issuance of common and preferred stock, net of repurchases	4,831,528	6,533,144	4,164,999	25,285,463
Finders fees and expenses	(176,250)	(434,132)	(361,625)	(972,007)
Exercise of common stock warrants	128,750	—	—	128,750
Net cash provided by financing activities	4,784,028	6,099,012	3,803,374	24,442,206
Net (decrease) increase in cash and cash equivalents	(3,902,874)	1,366,898	1,733,024	1,420,510
Cash and cash equivalents at beginning of period	5,323,384	3,956,486	2,223,462	—
Cash and cash equivalents at end of period	$ 1,420,510	$ 5,323,384	$ 3,956,486	$ 1,420,510
Supplementary disclosure of cash flow information:				
Cash paid for taxes	$ 46,643	$ 2,921	$ 23,834	$ 109,606
Cash paid for interest	$ —	$ —	$ —	$ —

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

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, 2005, Callisto has sustained cumulative net losses of $45,140,654. 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. From inception through December 31, 2005, 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 it 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 but inactive subsidiary, Callisto Pharma, GmbH (Germany)) and (2) Synergy Pharmaceuticals Inc. ("Synergy", including its wholly owned but inactive subsidiary IgX, Ltd (Ireland)), 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, 2005. All intercompany balances and transactions have been eliminated (see footnote 4).

The consolidated financial statements as of December 31, 2005 have been prepared under the assumption that Callisto will continue as a going concern for the twelve months ending December 31, 2006. 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.

In 2005, Callisto's cash used in operating activities increased significantly over 2004 and it is expected that Callisto's cash used in operating activities will increase significantly for the next several years. For the twelve months ended December 31, 2005, Callisto used approximately $8,700,000, or approximately $725,000 per month in operating activities, as compared to approximately $4,700,000 and $2,000,000 for the twelve months ended December 31, 2004 and 2003 respectively.

During the year ended December 31, 2005 Callisto incurred a net loss of approximately $11.8 million and as of that date current liabilities exceeded current assets by approximately $415,000 and we have a deficit accumulated during the development stage of approximately $45 million.

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, 2005, 2004 and 2003 was approximately $4,800,000, $6,100,000 and $3,800,000 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 license or otherwise dispose of rights to technologies, product candidates or products that Callisto would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Our current plan of operations envisions expenditures that will require additional funding, and we have developed a contingency plan reflecting scaled back operations which uses only existing resources to fund our operations for the next twelve months.

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

Fair value of financial instruments - 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, 2005 and 2004 are on deposit with two major money center financial institutions. Deposits at any point in time may exceed federally insured limits.

Accounting for stock based compensation - Callisto has adopted Statement of Financial Accounting Standard ("SFAS") No. 123, "Accounting for Stock-Based Compensation." As provided for by SFAS 123, Callisto has also elected to continue to account for its stock-based compensation programs according to the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees ("APB 25")." Accordingly, compensation expense has been recognized to the extent of employee or director services rendered based on the intrinsic value of stock options granted under the plans.

In December 2002, the Financial Accounting Standards Board issued SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of FASB Statement No. 123," to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this statement amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results.

Had compensation cost for stock options granted to employee and directors been determined based upon the fair value at the grant date for awards, consistent with the methodology prescribed under SFAS 123 and SFAS 148, Callisto's net loss would have been as follows:

	Years Ended December 31,		
	2005	2004	2003
Net loss, as reported	$ (11,779,457)	$ (7,543,467)	$ (13,106,247)
Add: Stock-based employee compensation expense recorded under APB No. 25 intrinsic method	1,530,417	1,317,108	1,996,890
Deduct: Stock-based employee compensation expense determined under Fair Value based method for all awards	(2,526,419)	(2,916,720)	(2,510,721)
Pro forma net loss	$ (12,775,459)	$ (9,143,079)	$ (13.620,078)
Net loss per share:			
Basic and diluted - as reported	$ (0.37)	$ (0.26)	$ (0.61)
Basic and diluted -pro forma	$ (0.41)	$ (0.32)	$ (0.64)
Range of Fair Value per share for options granted	$0.75 to $1.34	$1.35 to $3.15	$0.58 to $5.50
Black-Scholes Methodology Assumptions:			
Dividend yield	0%	0%	0%
Risk free interest rate	4.25%	2.87% to 4.5%	2.87% to 4.5%
Expected lives of options	3 to 7 years	7 to 10 years	7 to 10 years

Volatility of 0% was used until Callisto's common stock began to trade publicly on June 16, 2003. From June 16, 2003 through December 31, 2004 Callisto used 100% volatility to determine fair value of options granted to employees. During the twelve months ended December 31, 2005 Callisto used a 79% volatility factor, based on more recent historical volatility.

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 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. As of December 31, 2005, 2004 and 2003, Callisto had 8,008,210, 7,322,060 and 4,853,560 stock options outstanding, respectively. In addition Callisto had 2,567,317 and 758,995 common stock warrants outstanding as of December 31, 2005 and 2004, respectively, and none as of December 31, 2003.

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

Government Grants - Callisto requests cash funding under approved grants as expenses are incurred (not in advance) and reports these receipts on the consolidated statements of operations as a separate line item entitled "Government Grant". The corresponding expenses are included in research and development. On April 1, 2005, Callisto was awarded a biodefense partnership grant from the National Institute of Allergy and Infectious Diseases (NIAID) to develop a monoclonal antibody and vaccine against bacterial superantigen toxins, in the amount of $885,641 over two years. Work on the NIAID superantigen grant started in July 2005 and funding totaled $226,119 during the twelve months ended December 31, 2005. Callisto received a research grant from the National Institutes of Health (“NIH”) for studies on Atiprimod with funding totaling $265,697 during the year ended December 31, 2004 and received no government grants during 2003.

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.

RECENT ACCOUNTING PRONOUNCEMENTS:

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 will be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS 123R also addresses transactions in which an entity incurs liabilities in exchange for goods or services that are based on the fair value of 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 this standard January 1, 2006 for the first quarter of 2006. This statement does not change the accounting guidance for share based payment transactions with parties other than employees as set forth in SFAS 123 and EITF 96-18 “*Accounting for Equity Instruments Issued to Other than Employees, for Acquiring, or in connection with selling Goods or Services”,* which is effective for fiscal periods beginning after June 15, 2005

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*” in adopting this standard.

In March 2005 the SEC issued Staff Accounting Bulletin No. 107 (“SAB 107”) which discusses the SEC’s interpretation of SFAS 123R and the related valuation on share-based compensation for public entities. Callisto is assessing the requirements of SFAS 123R and SAB 107 and the impact that they will have on Callisto’s consolidated financial statements. While Callisto cannot precisely determine the impact on net loss and loss per share management anticipates the adoption of these standards share-based payment standards will affect Callisto’s results of operations to an extent similar to that presented the SFAS 123 proforma disclosure above.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets - An Amendment to APB Opinion No. 29", which is effective for fiscal periods beginning after June 15, 2005. SFAS No. 153 amends APB 29, "Accounting for Nonmonetary Transactions", which is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB 29 included certain exceptions to that principle. SFAS No. 153 amends APB 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The Company’s adoption of this statement on July 1, 2005 did not have a material effect on Callisto’s financial position or results of operations.

In May 2005, the FASB issued SFAS No. 154, “Accounting Changes and Error Corrections,” which changes the requirements for accounting for and reporting of a change in accounting principle. SFAS No. 154 requires retrospective application to prior periods’ financial statements of a voluntary change in accounting principle unless it is impracticable. SFAS No. 154 also requires that a change in method of depreciation, amortization, or depletion for long-lived, nonfinancial assets be accounted for as a change in accounting estimate that is affected by a change in accounting principle. SFAS No. 154 is effective for accounting changes and a correction of errors made in fiscal years beginning after December 15, 2005, but does not change the transition provisions of any existing accounting pronouncements, including those that are in a transition phase as of the effective date of SFAS No. 154. The adoption of SFAS No. 154 will not have a material effect on Callisto’s results of operations or financial position.

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.

The results of operations of Synergy are included in the consolidated financial statements since May 1, 2003. The following combined pro forma results of operations for the twelve months ended December 31, 2003 have been prepared as if the Merger with Synergy had occurred at January 1, 2003.

Revenues	$	—
Net loss		($13,513,820)
Net loss per common share - basic and diluted		(0.58)
(23,296,920 common shares in 2003)		

In addition, Callisto assumed liabilities in excess of Synergy assets acquired at April 30, 2003 as follows:

Cash	$	9,501
Accounts receivable		258,928
Rent deposit		44,746
Fixed assets		38,343
Total assets acquired		351,518
Accounts payable and other liabilities assumed		(591,446)
Net liabilities assumed in excess of assets acquired		(239,928)
Fair value of shares issued to Synergy shareholders		(6,335,799)
Total consideration paid by Callisto to acquire Synergy	$	(6,575,727)

5. Stockholders' equity (deficit):

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

On October 5, 2005, Trilogy Capital Partners, Inc. exercised 125,000 common stock warrants at an exercise price of $1.03 per share for aggregate proceeds of $128,750. (Note 8)

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 of the company for services performed in the year 1999. Based on the most recent private placement of common stock during the fourth quarter of 1999, the value of these shares was determined to be $0.70 per share and Callisto recorded $3,168,832 as stock based compensation expense.

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

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

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

6. Stock option plan:

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 5,128,372 options granted to date under the Plan is ten years from date of grant. The Plan terminated 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 and there were 5,000,000 option shares available for future grants as of December 31, 2005.

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 and there are 970,000 option shares available for future grants as of December 31, 2005.

The Company recognizes deferred compensation expense for the intrinsic value of unvested stock options granted to employees. Deferred stock-based compensation is amortized to stock-based compensation expense over the vesting period of the stock option. During the twelve months ended December 31, 2005, 2004, and 2003 and for the period from June 5, 1996 (inception) to December 31, 2005 Callisto recognized $2,419,694, $2,732,770, $3,833,946 and $13,770,967, respectively, as stock-based compensation expense related to issuance of stock and stock options. At December 31, 2005, there was $1,583,463 remaining in unamortized deferred compensation.

The following represent options outstanding for the years since June 5, 1996 (inception) through December 31, 2005.

	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

Included in the balance at December 31, 2005 were 2,849,838 Non-Plan options, of which 2,370,128 were exercisable.

Options are exercisable as follows at December 31, 2005:

	Options Outstanding		Options Exercisable
Ranges of	Number		Number

Exercise Prices	Outstanding	Weighted Average Remaining Contractual Life		Weighted Average Exercise Price	Exercisable		Weighted Average Exercise Price
$0.75 - $1.10	1,992,823	6.6 years	$	0.95	1,141,499	$	0.91
$1.17 - $1.75	3,716,055	7.9 years	$	1.48	2,172,721	$	1.44
$1.95 - $3.60	2,137,666	7.3 years	$	2.84	924,166	$	2.59
$4.90 - $6.75	161,666	4.4 years	$	5.32	61,666	$	6.00
Total	8,008,210	7.4 years	$	1.79	4,300,052	$	1.61

6. Stock option plan (continued):

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 the Company. The stock options are immediately exercisable at $3.20 per share and stock-based compensation 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.

On June 29, 2004, Callisto's Compensation Committee recommended and the Board of Directors approved the grant of 400,000 stock options to Donald Picker, Executive Vice President, R&D as additional compensation. The stock options are exercisable at $3.00 per share. 50,000 options vest on each of June 1, 2005 and June 1, 2006 and 75,000 options vest on June 1, 2007. The remaining 225,000 options vest upon the achievement of performance milestones associated with the successful advancement and development of Callisto’s drug candidates through various stages of clinical trials. 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 200,000 stock options to Mr. Picker as additional compensation. The stock options are exercisable at $1.01 per share. 75,000 options vest on each of July 6, 2006 and 2007 and 50,000 options vest on July 6, 2008.

7. Income taxes:

At December 31, 2005 and 2004, Callisto had available Federal net operating tax loss carry forwards of approximately $22,000,000 and $13,000,000, respectively, expiring through 2025 to offset future taxable income. The net deferred tax asset has been fully offset by a valuation allowance due to uncertainties regarding realization of benefits from these future tax deductions. As a result of the change in control provisions of Internal Revenue Code Section 382, a significant portion of these net operating loss carry forwards may be subject to limitation on future utilization.

During the twelve months ended December 31, 2005, 2004, and 2003, Synergy sold certain New Jersey State tax loss carry forwards under a state economic development program for cash of approximately $177,000, $233,000 and $222,000, respectively. The proceeds of economic development funds have and will be 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, 2004 and 2003. As of December 31, 2005 Callisto had no remaining New Jersey State tax loss carry forwards available for sale.

8. Commitments and contingencies:

License agreements:

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. 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. In addition on September 28, 2005 Callisto agreed with HPI that HPI would repurchase certain patent rights in exchange for forfeiting the 1,170,000 performance based stock options. Accordingly the 1,170,000 options granted to HPI were cancelled.

On August 28, 2002, and as amended on May 23, 2003, Synergy entered into a worldwide license agreement with AnorMED, Inc. (“AnorMED”) to research, develop, sell and commercially exploit the Atiprimod patent rights. The license agreement provides 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. In addition the agreement requires Synergy to pay AnorMED royalties on net sales. Commencing on January 1, 2004 and on January 1 of each subsequent year Synergy is obligated to pay AnorMED a maintenance fee of $200,000 until the first commercial sale of the product. The first two annual maintenance fee payments under this agreement were made in January 2004 and 2005 and these were recorded as research and development expense. The license agreement will terminate in 2018.

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. The licensed patents under this agreement are the subject of research being funded by the NIAID grant awarded to Callisto on April 1, 2005 for $885,641over two years. The license agreement will terminate upon the expiration of the related patents.

On July 25, 2001, Callisto entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University licensed patents covering the regulation of exoprotein in staphylococcus aureus. Callisto agreed to pay Rockefeller a $7,500 annual maintenance fee until the first commercial sale of the product, plus royalties of 2% and 0.75% of net sales of product depending on whether the product is covered by a claim under the licensed patents or derived from a claim under the licensed patents and will pay Rockefeller 15% of any sublicense fee paid by sublicensees. The agreement will terminate in November 2016. Rockefeller may terminate the license agreement if Callisto is more than 30 days late in paying Rockefeller any amounts due under the license agreement or if Callisto breaches the license agreement. Callisto has paid the annual maintenance fee for the twelve months ended July 25, 2002, and have accrued but not paid the annual maintenance fee for the twelve months ended July 25, 2003, 2004 and 2005, pending Callisto’s evaluation as to the applicability of the patents licensed under this agreement to ongoing toxic shock syndrome and septic shock development program under the August 20, 1996 agreement.

Employment and Consulting Agreements:

On October 10, 2005 Callisto entered into an employment agreement with Dan D’Agostino to serve as Callisto's Chief Business Officer. Pursuant to the employment agreement, Callisto will employ Mr. D’Agostino for a period of one year commencing October 10, 2005 which term will be automatically renewed for successive one year periods until written notice not to renew is delivered by either Callisto or Mr. D’Agostino. Mr. D’Agostino will be paid an annual base salary of $175,000 ("Base Salary"). In addition, Mr. D’Agostino will be eligible to earn an annual cash bonus up to 15% of his annual Base Salary annually, plus up to $25,000 based on meeting performance objectives and bonus criteria, specifically surrounding Callisto's corporate development plans to expand its technology and product portfolio.

Mr. D’Agostino was granted an aggregate 400,000 incentive stock options pursuant to Callisto's stock option plan with an exercise price of $1.53 per share. 300,000 of such options will vest pursuant to the following schedule: 100,000 options will vest on October 10, 2006; 100,000 options will vest on October 10, 2007; and 100,000 options will vest on October 10, 2008. The remaining 100,000 options will vest upon the successful in-licensing of certain drug candidates.

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 $734,695 during the year ended December 31, 2005. On October 5, 2005 Trilogy exercised 125,000 common stock warrants for cash totaling $128,750.

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. In addition, per the Agreement Consultant was granted 375,000 ten year non-qualified stock options at an exercise price of $1.70 per share, which was the stock price on December 27, 2004 (date of execution of the Agreement), one half of such options vest on each of the first two anniversaries of the date of the Agreement. The stock-based compensation expense associated with these option grants during the year ended December 31, 2005 was $212,619. This expense was based on an initial Black-Scholes fair value of $1.52 per share on the date of grant and subsequently marked to market quarterly as required by Financial Accounting Standards Board Interpretation No. 44 ("FIN 44"). Accordingly the measurement date will be the earlier of the second anniversary of the agreement (fully vested) or the accelerated vesting date if Mr. Cerrrone is terminated without cause or good reason.

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.

On December 22, 2004, the Board of Directors of Callisto, acting upon advice of its Compensation Committee, awarded Mr. Cerrone a cash bonus of $200,000 in recognition of his contributions to the Company including negotiation and acquisition of certain intellectual property licenses during 2004. Accordingly this bonus was charged to research and development expense during 2004. Mr. Cerrone’s cash bonus for the year ended December 31, 2005 was $30,750 per his Agreement and based on his role in strategic planning and capital markets consulting for the Company during 2005 this bonus was charged to general and administrative expense.

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 the Company's Scientific Advisory Board. As consideration for consulting and advisory services Dr. Perez-Soler shall receive a $30,000 per year consulting fee and 44,000 shares of restricted common stock. These shares were recorded as stock based compensation expense during the 12 months ended December 31, 2004 for a total 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.

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 unvested options were forfeited.

The new grant of 100,000 options will be subject to variable accounting because it was deemed that his agreement was a continuation of employment with a wholly owned subsidiary of Callisto. 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 January 15, 2004, Callisto entered into an employment agreement with Bernard Denoyer, its Vice President, Finance. Mr. Denoyer's employment agreement is for a term of 12 months beginning January 15, 2004 and is

automatically renewable for successive one year periods at the end of the term. Mr. Denoyer's salary is $90,000 per year and he is 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 23, 2003, Callisto entered into an employment agreement with Donald H. Picker, Ph.D., to serve as Vice President, Drug Development. The employment agreement is for a term of 18 months beginning September 23, 2003 and is automatically renewable for successive one year periods at the end of the term. Dr. Picker's salary is $175,000 per year and he is 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 years ended December 31, 2005 and 2004, Dr. Picker earned a bonus of $20,000 and $37,500, respectively, based on achievement of certain milestones. The balance of the annual bonus Dr. Picker is eligible to receive will be paid only if and when certain other milestones are reached.

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 is automatically renewable for successive one year periods at the end of the term. As of March 17, 2006, pursuant to Compensation Committee approval, Dr. Jacob's salary was increased to $300,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. In connection with his employment agreement, Dr. Jacob received a grant of 500,000 stock options which vest over a three year period and are exercisable at $1.50 per share. During the years ended December 31, 2005 and 2004, Dr. Jacob was paid a bonus of $33,750 during each year as per his employment agreement.

Callisto has various consulting agreements with members of its scientific advisory board to provide services. Fees are based and paid on services provided.

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 the Company did not 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, 2005, 2004 and 2003 and for the period from June 5, 1996 (inception) to December 31, 2005, total rent expense was $244,531, $217,297, $67,261 and $649,110, respectively. Total annual commitments under the remaining New York City lease for each of the years ended December 31, are as follows:

2006	$ 148,553
2007	151,524
2008	154,555
2009	157,646
2010	160,799
2011	81,464
Total	$ 854,541

Other:

In April 2003, Callisto settled legal fees totaling approximately $352,000, accrued as of December 31, 2002, for approximately $100,000. The balance was reversed into general and administrative expense in the second quarter of 2003.

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, 2005, 2004, 2003 and from June 5, 1996 (inception) to December 31, 2005 was $18,856, $27,632, $27,755, and $84,637, respectively.

	December 31,	
	2005	2004
Equipment	$ 46,294	$ 46,294
Furniture and fixtures	38,343	38,343
Less - Accumulated depreciation	(84,637)	(65,781)
Property and equipment, net	$ 0	$ 18,856

10. Selected Quarterly Financial Data (Unaudited):

	(Amounts in dollars)				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Year Ended December 31, 2004					

Net loss	($1,827,913)	($1,909,797)	($1,605,686)	($2,200,071)	($7,543,467)
Net income per share:					
Basic and diluted	($0.07)	($0.07)	($0.06)	($0.08)	($0.26)
Year Ended December 31, 2005					
Net loss	($2,594,131)	($2,610,677)	($3,320,569)	($3,254,081)	($11,779,457)
Net loss per share:					
Basic and diluted	($0.09)	($0.08)	($0.10)	($0.10)	($0.37)

11. Subsequent events:

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 $5,140,402. The Company paid an aggregate $468,340 and issued an aggregate 390,284 warrants to certain selling agents. The selling agent warrants are exercisable at $1.25 per share and will expire three years after closing. Callisto also incurred $30,000 in legal fees directly associated with the closing. The net proceeds from this private placement were $4,641,870.

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. In addition, Callisto agreed to use commercially reasonable efforts to cause the registration statement to be declared effective within 120 days after closing.

Had this private placement been completed on December 31, 2005 pro forma selected balance sheet items would have been as follows:

	As reported 2005	Pro forma 2005
Cash and cash equivalents	$ 1,420,510	$ 6,062,379
Stockholders' equity (deficit)	$ (332,919)	$ 4,308,951
Common shares outstanding	33,233,096	37,516,764

As provided for by Emerging Issues Task Force Issue 00-19: *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* (“EITF 00-19”) the warrants will be classified as permanent equity. The fair value of the investor warrants on February 3, 2006, the date of grant was $662,680 using Black Scholes assumptions of 79% volatility, a risk free interest rate of 4.25%, no dividend, an expected life of 18 months and a stock price on that date of $1.59 per share. This fair value allocated to the investor warrants will be recorded as additional paid in capital during the quarter ended March 31, 2006.

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 the Company is developing the Degrasyns platform of compounds in all indications.

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 upon execution of this agreement 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.

Index to Exhibits

Exhibit Number	Description
3.1	Certificate of Incorporation (Incorporated by reference to Exhibit 99.1 filed with the Company's Current Report on Form 8-K filed on May 28, 2003)
3.2	Certificate of Amendment to the Certificate of Incorporation of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2005)
3.3	Bylaws (Incorporated by reference to Exhibit 99.2 filed with the Company's Current Report on Form 8-K filed on May 28, 2003)
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)
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	Employment Agreement dated June 13, 2003 by and between Callisto Pharmaceuticals, Inc. and Donald H. Picker (Incorporated by reference to Exhibit 10.3 filed with the Company's Current Report on Form 10-QSB filed on November 14, 2003)*

10.4 Amendment to Employment Agreement dated April 6, 2004 by and between Callisto Pharmaceuticals, Inc. and Donald H. Picker (Incorporated by reference to Exhibit 10.6 filed with the Company's Annual Report on Form 10-KSB filed on April 14, 2004)*

10.5 License Agreement dated as of August 28, 2002 by and between Synergy Pharmaceuticals Inc. and AnorMED Inc.(Incorporated by reference to Exhibit 10.4 filed with the Company's Current Report on Form 10-QSB filed on November 14, 2003)**

10.6 Employment Agreement dated January 15, 2004 by and between Callisto Pharmaceuticals, Inc and Bernard Denoyer (Incorporated by reference to Exhibit 10.6 filed with the Company's Annual Report on Form 10-KSB on April 14, 2004)*

10.7 Form of Registration Rights Agreement dated as of January 21, 2004 by and among the Registrant and the Purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on January 28, 2004)

10.8 Common Stock Purchase Agreement dated as of April 19, 2004, by and between Callisto Pharmaceuticals, Inc. and the Purchasers set forth on Exhibit A thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on April 19, 2004)

10.9 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)**

10.10 Consulting Agreement dated as of December 27, 2004 between the Registrant and Gabriele M. Cerrone (Incorporated by reference to Exhibit 10.10 filed with the Company's Annual Report on Form 10-KSB filed on March 30, 2005) *

10.11 Common Stock Purchase Agreement dated as of March 8, 2005 by and between Callisto Pharmaceuticals, Inc. and the Purchasers set forth on Exhibit A thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on March 5, 2005)

10.12 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)

10.13 Agreement among Davos Chemical Corporation, Callisto Pharmaceuticals, Inc. and Antibioticos S.p.A. dated July 28, 2004 (Incorporated by reference to Exhibit 10.15 filed with the Company's Annual Report on Form 10-K filed on June 6, 2005)

10.14 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)*

10.15 Extension and Severance Compensation Agreement dated June 9, 2005 between Callisto Pharmaceuticals, Inc. and Donald S. Picker (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on June 15, 2005)*

10.16 Letter of Engagement between Trilogy Capital Partners, Inc. and Callisto Pharmaceuticals, Inc. dated July 18, 2005 (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on July 22, 2005)

10.17 Common Stock Purchase Agreement dated as of August 22, 2005 between Callisto Pharmaceuticals, Inc. and the investors listed on Exhibit A thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on August 26, 2005)

10.18 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)*

10.19 Amendment dated October 19, 2005 to the Employment Agreement dated as of September 23, 2003, as amended April 6, 2004 by and between Callisto Pharmaceuticals, Inc. and Donald H. Picker (Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on October 21, 2005)*

10.20 Amendment dated October 19, 2005 to the Employment Agreement dated as of January 15, 2004 by and between Callisto Pharmaceuticals, Inc. and Bernard Denoyer (Incorporated by reference to Exhibit 10.4 filed with the Company's Current Report on Form 8-K filed on October 21, 2005)*

10.21	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)*
10.22	Patent and Technology License Agreement dated January 10, 2006 between The University of Texas M.D. Anderson Cancer Center and Callisto Pharmaceuticals, Inc. **
10.23	Securities Purchase Agreement dated February 3, 2006 between Callisto Pharmaceuticals, Inc. and the investors listed on Schedule A thereto (Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on February 9, 2006)
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

99.1 Power of Attorney (included on page 36)

* 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.