CALLISTO PHARMACEUTICALS INC
Form 10-K
April 17, 2007

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, 2006

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 x

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 x

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 x 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. o

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 x

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $42,841,562 on June 30, 2006 (based on $1.20 per share, the closing price on the American Stock Exchange that day).

As of April 16, 2007 the registrant had a total of 39,194,996 shares of Common Stock outstanding.

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, 2006, 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 neuroendocrine cancer (including advanced carcinoid cancer), acute leukemia (a disease of the white blood cells), and multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow). Our lead drug candidate, Atiprimod, is an orally administered drug with antiproliferative and antiangiogenic activity. Atiprimod is presently in three clinical trials in neuroendocrine cancer, relapsed or refractory multiple myeloma and advanced cancer patients at a number of clinical sites in the U.S. On November 7, 2006, we announced the initiation of a multi-center, open-label Phase II clinical trial of Atiprimod in low to intermediate grade neuroendocrine carcinomas, including advanced carcinoid cancer patients. This trial is based on earlier encouraging clinical results from an ongoing trial of Atiprimod in advanced cancer patients that showed a clear response in a patient with advanced carcinoid cancer plus additional encouraging clinical data on other carcinoid patients. Atiprimod is also in a multi-center, dose-escalation Phase I/IIa clinical trial in relapsed or refractory multiple myeloma patients. In 2006, we amended the protocol to continue the trial at higher dose levels and currently have this trial underway at 4 clinical sites in the U.S.

Our second lead drug candidate, L-Annamycin, earlier completed an initial Phase I/IIa clinical trial in relapsed or refractory leukemia patients with a prior sponsor. L-Annamycin is a novel compound from the anthracycline family of proven anti-cancer drugs which has a novel therapeutic profile, including activity against drug-resistant tumors and significantly reduced cardiotoxicity, or damage to the heart. L-Annamycin was in-licensed by Callisto in October, 2004 and is presently in a Phase I/IIa clinical trial in adult relapsed or refractory acute lymphocytic leukemia (ALL) patients at three clinical sites in the U.S. On February 22, 2007, we announced the opening of a Phase I clinical trial of L-Annamycin in pediatric relapsed or refractory ALL or pediatric relapsed or refractory acute myeloid leukemia (AML) patients.

Our plan of operations for the next twelve months is to focus primarily on the clinical development of our two drugs, Atiprimod to treat neuroendocrine carcinoma and multiple myeloma and L-Annamycin to treat adult and pediatric acute leukemia.

RECENT DEVELOPMENTS

From October 2006 until January 2007, we placed 602,350 shares of Series A Convertible Preferred Stock and 8,031,333 warrants to certain investors for aggregate gross proceeds of $6,023,500. As of December 31, 2006 we had closed on 574,350 shares of such Series A Convertible Preferred Stock for aggregate gross proceeds of $5,743,500. The final traunche of this financing closed January 10, 2007 when we placed 28,000 shares of such Series A Convertible Preferred Stock for aggregate gross proceeds of $280,000. The shares of Series A Convertible Preferred Stock are convertible into shares of common stock at a conversion price of $0.75 per share. The investors also are parties to a Registration Rights Agreement, dated as of October 23, 2006 pursuant to which we agreed to file, within 60 days of closing, a registration statement with the Securities and Exchange Commission (the SEC) covering the resale of the shares of common stock underlying the Series A Convertible Preferred Stock and the warrants issued to the investors. The warrants are immediately exercisable at $0.75 per share, will expire five years from the date of issuance, and have certain antidilution rights for the twelve month period beginning on the effective date of the registration statement registering the shares of common stock underlying the warrants. We paid aggregate fees and expenses of $485,308 ($448,908 prior to December 31, 2006) in cash, issued an aggregate 11,775 shares of Series A Convertible Preferred Stock and 1,228,761warrants to purchase common stock to certain selling agents. The warrants are immediately exercisable at $0.75 per share, will expire five years after issuance and have the same anti-dilutive rights as the investor warrants. On January 12, 2007 we filed a registration statement on Form S-3 covering the common stock issuable upon (i) the conversion of the all Series A Convertible Preferred Stock, (ii) the exercise of all related investor warrants and (iii) the exercise of all selling agent warrants. On February 15, 2007 Amendment No.1 to this registration statement was declared effective by the SEC.

HISTORY

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

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

ATIPRIMOD TO TREAT ADVANCED CARCINOID CANCER PATIENTS AND MULTIPLE MYELOMA

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 cells that break down bone, function. The drug appears to be selectively toxic for activated osteoclasts, displaying a negligible effect on bone marrow stromal cells.

COMPLETED CLINICAL STUDIES

Atiprimod successfully completed single and multiple dose Phase I clinical trials in patients with rheumatoid arthritis (RA). In the initial Phase I study, 28 patients were given single escalating doses of drug (0.002 - 1.0 mg/kg), with a 4-month follow-up. Atiprimod was well tolerated, displaying no clinically relevant changes in any laboratory parameters. In particular, liver function tests remained in the normal range. The second Phase I study involved a 28-day multiple-dose-rising study in 35 RA patients. The study evaluated the effect of food on bioavailability, or the concentration of drug in the body, as well as the safety and pharmacokinetics of repeat dosing. Dosages included 0.1, 1.0, 5.0, and 10 mg/day plus a 14-day cohort at 30 mg/day, with 4-month follow-up. All doses were well tolerated and clinical tests were unremarkable. Significantly, reductions in tender and swollen joint counts were noted in a number of subjects during the course of the dosing period. Individuals from the two Phase I safety studies were also involved in a Phase I open-label extension trial at 5 mg/day dosage. Forty-three patients entered the study and remained on the drug as long as 12 months. Clinical laboratory results for all patients were unremarkable, in particular liver enzyme levels remained within the normal range in all patients throughout the study period.

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DEVELOPMENT STRATEGY

Atiprimod commenced a Phase I/IIa clinical trial in relapsed or refractory multiple myeloma patients on May 26, 2004. These are patients that have a re-occurrence of active disease, and no longer respond to approved therapies. The Phase I/IIa clinical trial is an open label study, with the primary objective of assessing safety of drug and identifying the maximum tolerated dose. The secondary objectives are to measure the pharmacokinetics, evaluate the response in patients with refractory disease and to identify possible surrogate responses to the drug to better determine the mechanism of drug action. In December 2005, we announced interim results from this trial performed in relapsed or refractory multiple myeloma patients which consisted of 15 patients treated with Atiprimod, including 3 patients at the highest dose level of 180 mg/day. 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. In 2006, we amended the protocol to continue the trial at higher dose levels and currently have this trial open at 4 clinical sites in the U.S.

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

On November 7, 2006, we announced the initiation of a multi-center, open-label Phase II clinical trial of Atiprimod in low to intermediate grade neuroendocrine carcinomas, including advanced carcinoid cancer patients. This trial is based on encouraging clinical results from the Phase I clinical trial in advanced cancer patients that showed stable disease and a reduction in disease-related symptoms in patients with advanced carcinoid cancer. The first study site to enter the trial was the Hematology Oncology Services of Arkansas in Little Rock, Arkansas. On January 31, 2007 we announced the opening of a second site for this trial the Dana-Farber Cancer Institute in Boston, MA. Subjects will also be seen at the following facilities: Brigham and Women s Hospital, Massachusetts General Hospital and Beth Israel Deaconess Medical Center. On March 12, 2007 we announced the opening of the third site for this trial The Physician Offices at Mount Sinai Medical Center, NY

The primary objective of the Phase II clinical trial is to evaluate efficacy of Atiprimod in patients with low to intermediate grade neuroendocrine carcinoma who have metastatic or unresectable cancer and who have either symptoms, despite standard therapy (octreotide), or progression of neuroendocrine tumors. Patients, after signing an informed consent, are required to complete two weeks of a symptoms diary to establish their symptoms baseline before commencing Atiprimod dosing. A maximum of 40 evaluable patients will be enrolled in this trial. Efficacy evaluations will include the measure of target lesions (per RECIST), and the quantization of symptom relief.

MANUFACTURING OF ATIPRIMOD

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

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

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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). The conclusions drawn from the trial were that L-Annamycin was safe, well tolerated and showed potential clinical activity in patients with acute leukemias, and that further evaluation of this novel anthracycline in patients with hematopoietic, or blood borne, malignancies was clearly warranted**.**

DEVELOPMENT STRATEGY

We began a Phase I clinical trial at The University of Texas M.D. Anderson Cancer Center in adult relapsed or refractory acute lymphocytic leukemia (ALL) patients on December 1, 2005. Additional sites enrolled in this study include the Roswell Park Cancer Institute (Buffalo, NY) and the Montefiore Medical Center (New York, NY). The single-arm, open-label L-Annamycin trial is designed to enroll patients in a dose escalation Phase I portion followed by 10 patients at a final fixed dose in the Phase II portion once the maximum tolerated dose (MTD) is determined. Up to 34 adult patients can be treated in this single-arm trial.

On February 22, 2007, we announced the opening of a Phase I clinical trial of L-Annamycin in pediatric relapsed or refractory ALL or AML patients. The trial is presently open at two sites in the U.S., Phoenix Children s Hospital, Phoenix, AZ, and the University of Arizona, Tucson, AZ.

MANUFACTURING OF ANNAMYCIN

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

ORPHAN DRUG STATUS OF ATIPRIMOD AND L-ANNAMYCIN

On January 6, 2004, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of multiple myeloma. On September 26, 2006, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of carcinoid tumors. 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 (Guanilib)

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 North Carolina, Chapel Hill, NC. 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 2007 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.

On April 1, 2005 we were awarded a two-year $885,641 biodefense partnership grant from the National Institute of Allergy and Infectious Diseases (NIAID) to develop a monoclonal antibody and vaccine against bacterial superantigen toxins. The goal was to design a monoclonal antibody and vaccine that prevent the unregulated activation of T-cells (human white blood cells) by bacteria from the class of staphylococcus aureus and streptococcus pyogenes. Funding for this program will end in the spring of 2007. Because the bioterrorism program is not a core activity of Callisto, we expect to terminate further development work upon the expiration of the research grant.

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.

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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 $6,031,953 for the twelve months ended December 31, 2006, compared to $6,430,506 and $4,325,975 for the twelve months ended December 31, 2005 and 2004, 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 also funded a 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, 2006 and 2005 we received $352,649 and $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 December 31, 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.

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

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

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

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

LICENSE AGREEMENTS

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

We also agreed to pay The University of Texas M.D. Anderson Cancer Center royalties based on net sales from any licensed products, plus aggregate milestone payments of up to $1,750,000 based upon achieving certain regulatory submissions and approvals. The term of the agreement is from January 10, 2006 until the end of the term for which the patent rights associated with the licensed technology have expired. If the first pending patent is issued, the agreement is projected to expire in 2025. In addition, at any time after 2 years from January 10, 2006, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or are actively and effectively attempting to commercialize the licensed technology.

On August 12, 2004, we entered into a world-wide license agreement with The University of Texas M. D. Anderson Cancer Center to research, develop, sell and commercially exploit the patent rights for L-Annamycin. Consideration paid for this license amounted to $31,497 for reimbursement of out-of-pocket costs for filing, enforcing and maintaining the L-Annamycin patent rights and a $100,000 initial license fee. We also agreed to pay The University of Texas M. D. Anderson Cancer Center royalties based on net sales from any licensed products, plus aggregate milestone payments of up to $750,000 based upon achieving certain regulatory submissions and approvals. The term of the agreement is from August 12, 2004 until November 2, 2019. Under the terms of the license agreement, we are required to make certain good faith expenditures towards the clinical development of at least one licensed product within the two year period after March 2005. In addition, at any time after 5 years from August 12, 2004, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or we are actively and effectively attempting to commercialize L-Annamycin.

On August 28, 2002, 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 annual maintenance fee payments under this agreement were made in January of each year since entering into the license agreement with AnorMED and are

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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 August 20, 1996, we entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University licensed patents covering peptides and antibodies useful in treating toxic shock syndrome and septic shock. We agreed to work toward commercialization of products related to these patents as evidenced by a minimum expenditure of approximately $210,000 per year, plus milestone payments and royalties of between 2% and 3% of annual net sales and will pay Rockefeller 30% of any sublicense fee paid by sublicenses. The licensed patents under this agreement are the subject of research 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 30, 2007, we had 9 full-time and 4 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 (specifically, but not limited to, Item 9A of this annual report) as well as the information included in other reports and filings made with the SEC before investing in our common stock. If any of the following risks actually occurs, our business, financial condition or results of operations could be harmed. The trading price of our common stock could decline due to any of these risks, and you may lose part or all of your investment.

RISKS RELATED TO OUR BUSINESS

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

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

- demonstration in Phase I/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, 2006 and 2005, we had an accumulated deficit of $60,444,368 and $45,140,654, respectively. We have incurred losses in each year since our inception in 1996. We incurred a net loss of $12,919,229, $11,779,457 and $7,543,467 for the twelve months ended December 31, 2006, 2005 and 2004, 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, 2006 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 April 13, 2007 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.

We expect that our cash used in operating activities will increase significantly for the next several years. For the years ended December 31, 2006, 2005 and 2004 we used approximately $8.3 million, $8.7 million and $4.7 million in operating activities, respectively.

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

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

- any future decisions we may make about the scope and prioritization of the programs we pursue;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of regulatory approval;
- the costs of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and
- general market conditions for offerings from biopharmaceutical companies.

To date, our sources of cash have been primarily limited to the sale of our equity securities. Net cash provided by financing activities for the twelve months ended December 31, 2006, 2005 and 2004 was approximately $10.8 million, $4.8 million and $6.1 million, respectively. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms,

we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

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

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

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

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

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

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

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

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

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

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

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

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

We may acquire additional businesses, products or product candidates that complement or augment our existing business. Integrating any newly acquired business or product could be expensive and time-consuming. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Moreover, we 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 30, 2007. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Over the next 12 months depending on the progress of our planned clinical trials, we plan to add additional employees to assist us with our clinical programs. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our development efforts effectively;
- manage our clinical trials effectively;
- integrate additional management, administrative, manufacturing and sales and marketing personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

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

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

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

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

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

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

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

These proposals have included prescription drug benefit proposals for Medicare beneficiaries introduced in Congress. Legislation creating a prescription drug benefit and making certain changes in Medicaid reimbursement has recently been enacted by Congress and signed by the President. Given this legislation s recent enactment, it is still too early to determine its impact on the pharmaceutical industry and our business. Further federal and state proposals are likely. The potential for adoption of these proposals affects or will affect our ability to raise

capital, obtain additional collaborators and market our products. We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. Our results of operations could be adversely affected by future healthcare reforms.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

As of December 31, 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.

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

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

On November 2, 2006 we submitted a plan advising the American Stock Exchange of the actions we have taken, or will take, that would bring us into compliance with Section 1003(a)(iv) of the Company Guide by April 3, 2007 and with Section 1003(a)(i) of the Company Guide by April 3, 2008 . The plan was approved on January 24, 2007. We will continue to maintain our listing during the plan period of up to 18 months, during which time we will be subject to periodic review to determine if we are making progress consistent with the plan. If we are not in compliance with the continued listing standards at the end of the plan period, or we do not make progress consistent with the plan during the plan period, the American Stock Exchange staff may initiate delisting proceedings. There is no guarantee that we will be able to make progress consistent with the plan. While the plan is under periodic review by the American Stock Exchange, we expect that our common stock will continue to trade without interruption on the American Stock Exchange. If we are delisted by the American Stock Exchange you may experience difficulty in trading your shares of our common stock.

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

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

WE ARE AT RISK OF SECURITIES CLASS ACTION LITIGATION.

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None

ITEM 2. PROPERTIES.

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

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

ITEM 3. LEGAL PROCEEDINGS.

On November 2, 2006, Trilogy Capital Partners, Inc. filed suit against us in Superior Court of the State of California, County of Los Angeles, Central District, alleging that we breached a Letter of Engagement dated July 18, 2005 between us and Trilogy by failing to pay certain fees. Additionally, Trilogy alleges that we breached a consulting agreement dated January 1, 2006 between us and MBA Holdings, LLC (later assigned to Trilogy) by failing to pay certain consulting fees. Trilogy is seeking payment in the aggregate amount of $94,027.55 plus interest and attorneys fees. On December 27, 2006, we filed an answer to the Trilogy complaint denying the allegations in the Trilogy complaint and On the same date, we filed a cross-complaint against Trilogy in Superior Court of the State of California, County of Los Angeles, Central District, alleging, among other things, that Trilogy breached the Letter of Engagement with us by failing to provide the agreed-upon services and fraudulently induced us to enter into the Letter of Engagement by misrepresenting its capabilities. We are asking

for unspecified damages plus attorneys fees. On January 23, 2007, Trilogy answered our cross-complaint denying all of the allegations. The court has ordered the parties to mediation to be completed by November 20, 2007.

On December 21, 2006, we filed a complaint against Tapestry Pharmaceuticals, Inc., Leonard P. Shaykin and Kai P. Larson in the Supreme Court of the State of New York alleging that Tapestry used information they obtained pursuant to a confidential disclosure agreement between us and Tapestry to cause Donald Picker, Ph.D., our former Executive Vice President, Research & Development, to resign and accept a position with Tapestry. In addition, we are alleging that Tapestry fraudulently entered into the confidential disclosure agreement with us and intentionally interfered with Dr. Picker s employment agreement with us. We are seeking actual and punitive damages. As of April 9, 2007 the discovery process is ongoing and the defendants have filed a motion to dismiss the complaint against Messrs. Shaykin and Larsen.

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

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

On May 18, 2006, we held a Special Meeting of Stockholders and we disclosed the results of the matter voted on in our Quarterly Report on Form 10-Q filed on August 14, 2006. Our Annual Meeting of Stockholders was held on October 12, 2006 and we disclosed the results of the matters voted on in our Quarterly Report on Form 10-Q filed on November 20, 2006. At a Special Meeting of Stockholders on March 2, 2007, two matters were voted upon. A description of each matter and a tabulation of the votes for each of the matters follow:

1. Proposal to approve the potential issuance of up to 17,448,427 shares of our common stock (issuable upon the conversion of 614,125 shares of Series A Convertible Preferred Stock and the exercise of 9,260,094 common stock purchase warrants) at a price below fair market value issued in connection with a private placement conducted October 2006-January 2007.

Votes

For	Against	Abstain
17,271,006	356,278	8,965,182

2. Proposal to amend our Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock, par value $.0001 per share, from 100,000,000 shares to 150,000,000 shares

Votes

For	Against	Abstain
26,050,328	517,912	37,592

PART II

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

MARKET INFORMATION

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

2006	HIGH	LOW
Fourth Quarter	$ 0.97	$ 0.71
Third Quarter	1.25	0.81
Second Quarter	1.54	1.16
First Quarter	1.70	1.34

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

NUMBER OF STOCKHOLDERS

As of March 30, 2007, we had 145 holders of record of our common stock.

DIVIDEND POLICY

Historically, we have not declared paid any cash dividends to the holders of our common stock and we do not expect to pay any such dividends in the foreseeable future as we expect to retain our future earnings for use in the operation and expansion of our business.

EQUITY COMPENSATION PLAN INFORMATION

The following table summarizes information about our equity compensation plans as of December 31, 2006.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options and warrants (a)	Weighted-Average Exercise Price of Outstanding Options and warrants (b)	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Stockholders	5,701,042	$ 1.76	5,044,000
Equity Compensation Plans Not Approved by Stockholders (1)	18,193,487	$ 1.05	
Total	23,894,529	$ 1.22	5,044,000

(1) Consists of 2,352,333 stock options not subject to any of our stock option plans and 15,841,154 warrants. These non-plan stock options and warrants have been primarily issued in conjunction with our private placements of common stock and consulting services agreements as discussed in Notes 5, 6 and 8 to our consolidated financial statements.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report on Form 10-K. The statements of operations data for the twelve months ended December 31, 2006, 2005 and 2004 and the balance sheet data at December 31, 2006 and 2005 are derived from our audited financial statements which are included elsewhere in this Form 10-K. The statement of operations data for the years ended December 31, 2003 and 2002 and the balance sheet data at December 31, 2004, 2003 and 2002 are derived from our audited financial statements which are not included in this Form 10-K. Our historical results are not necessarily indicative of results to be expected for future periods. The following information is presented in thousands, except per share data.

	For the Twelve Months Ended December 31,				
	2006	**2005**	**2004**	**2003**	**2002**
Consolidated Statements of Operations Data:					
Revenues	$ -0-	$ -0-	$ -0-	$ -0-	$ -0-
Operating expenses:					
Research and development	6,032	6,431	4,325	1,804	491
Government grant	(353)	(226)	(266)		
Purchased in process research and development			210	6,735	
General and administrative	5,113	4,968	3,568	1,611	1,228
Stock-based compensation - non-employees	1,374	889	20	3,187	
Loss from operations	(12,166)	(12,062)	(7,857)	(13,337)	(1,719)
Other income (expense)	(802)	177	229	222	
Interest and investment income	49	105	84	9	34
Net loss	(12,919)	(11,780)	(7,544)	(13,106)	(1,685)
Preferred stock beneficial conversion feature accreted as a dividend	(2,385)				
Net loss available to common stockholders	$ (15,304)	$ (11,780)	$ (7,544)	$ (13,106)	$ (1,685)
Net loss per common share basic and diluted	$ (0.40)	$ (0.37)	$ (0.26)	$ (0.61)	$ (0.10)
Weighted average number of common shares outstanding basic and diluted	37,941	31,527	28,485	21,358	17,319

	As of December 31,				
	2006	**2005**	**2004**	**2003**	**2002**
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 3,904	$ 1,421	$ 5,323	$ 3,956	$ 2,223
Total assets	4,051	1,684	5,470	4,119	2,272
Total current liabilities	3,201	2,017	1,220	1,264	440
Accumulated deficit during development stage	(60,444)	(45,141)	(33,361)	(25,818)	(12,711)
Total stockholders equity (deficit)	$ 850	$ (333)	$ 4,249	$ 2,855	$ 1,829

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, 2006, we have sustained net losses of $58,059,883. Our losses have resulted primarily from expenditures in connection with our 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, 2006 we have not generated any revenue from operations. We expect to incur substantial and increasing losses for the next several years as we develop our product candidates, expand our clinical development team and prepare for the commercial launch of our product candidates. We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all.

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

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

HISTORY

In March 2002, Callisto Pharmaceuticals, Inc. (Old Callisto), a non-public company, purchased 99.7% of the outstanding common shares of Webtronics, Inc., a public company (Webtronics), for $400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations during the year ended December 31, 2002. On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Synergy Pharmaceuticals Inc. (Synergy) and Callisto Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Old Callisto (collectively, the Merger). As a result of the Merger, Old Callisto and Synergy became wholly-owned subsidiaries of Webtronics. Old Callisto changed its name to Callisto Research Labs, LLC and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware.

PLAN OF OPERATIONS

Our plan of operations for the next twelve months is to focus primarily on the clinical development of our two drugs, Atiprimod and L-Annamycin, to treat neuroendocrine carcinomas (including advanced carcinoid cancer), adult and pediatric acute leukemia (a disease of the white blood cells) and multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow).

Our lead drug candidate, Atiprimod, is an orally administered drug with antiproliferative and antiangiogenic activity. We are presently enrolling patients in two clinical trials in low to intermediate grade neuroendocrine cancer and relapsed or refractory multiple myeloma at a number of clinical sites in the U.S. On November 7, 2006, we announced the initiation of a multi-center open-label Phase II clinical trial of Atiprimod in low- to intermediate-grade neuroendocrine cancers, including advanced carcinoid cancer patients. This trial is based on earlier encouraging clinical results from an ongoing trial of Atiprimod in advanced cancer patients that showed stable disease and disease-related symptom relief in patients with advanced carcinoid cancer. Atiprimod is also in a multi-center, dose-escalation Phase I/IIa clinical trial in relapsed or refractory multiple myeloma patients. In December 2005, we announced interim results from this trial on 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. In 2006, we amended the protocol to continue the trial at higher dose levels and currently have this trial underway at clinical sites in the U.S.

Our second lead drug candidate, L-Annamycin, earlier completed an initial Phase I/IIa clinical trial in relapsed or refractory leukemia patients with a prior sponsor. L-Annamycin is a novel compound from the anthracycline family of proven anti-cancer drugs, which has a

novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart. L-Annamycin was in-licensed by Callisto in October, 2004 and is presently in two clinical trials: 1) a Phase I/IIa clinical trial in adult relapsed or refractory acute lymphocytic leukemia (ALL) patients at three clinical sites in the U.S.; and 2) a Phase I clinical trial in children and young adults with relapsed or refractory ALL or AML.

ATIPRIMOD TO TREAT ADVANCED CARCINOID CANCER PATIENTS AND MULTIPLE MYELOMA

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

Atiprimod commenced a Phase I/IIa clinical trial in relapsed or refractory multiple myeloma patients on May 26, 2004. These are patients that have a re-occurrence of active disease, and no longer respond to approved therapies. The Phase I/IIa clinical trial is an open label study, with the primary objective of assessing safety of drug and identifying the maximum tolerated dose. The secondary objectives are to measure the pharmacokinetics, evaluate the response in patients with refractory disease and to identify possible surrogate responses to the drug to better determine the mechanism of drug action. In December 2005, we announced interim results from this trial performed in relapsed or refractory multiple myeloma patients which consisted of 15 patients treated with Atiprimod, including 3 patients at the highest dose level of 180 mg/day. 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. In 2006, we amended the protocol to continue the trial at higher dose levels and currently have this trial open at 4 clinical sites in the U.S.

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

On November 7, 2006, we announced the initiation of a multi-center, open-label Phase II clinical trial of Atiprimod in low to intermediate grade neuroendocrine carcinomas, including advanced carcinoid cancer patients. This trial is based on encouraging clinical results from the Phase I clinical trial in advanced cancer patients that showed stable disease and a reduction in disease-related symptoms in patients with advanced carcinoid cancer. The first study site to enter the trial was the Hematology Oncology Services of Arkansas in Little Rock, Arkansas. On January 31, 2007 we announced the opening of a second site for this trial the Dana-Farber Cancer Institute in Boston, MA. Subjects will also be seen at the following facilities: Brigham and Women s Hospital, Massachusetts General Hospital and Beth Israel Deaconess Medical Center. On March 12, 2007 we announced the opening of the third site for this trial The Physician Offices at Mount Sinai Medical Center, NY

The primary objective of the Phase II clinical trial is to evaluate efficacy of Atiprimod in patients with low to intermediate grade neuroendocrine carcinoma who have metastatic or unresectable cancer and who have either symptoms, despite standard therapy (octreotide), or progression of neuroendocrine tumors. Patients, after signing an informed consent, are required to complete two weeks of a symptoms diary to establish their symptoms baseline before commencing Atiprimod dosing. A maximum of 40 evaluable patients will be enrolled in this trial. Efficacy evaluations will include the measure of target lesions (per RECIST), and the quantization of symptom relief.

MANUFACTURING OF ATIPRIMOD

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

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-

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Annamycin was performed in 13 women with doxorubicin-resistant breast cancer. The median number of prior chemotherapy regimes was two, and six patients had two or more organ sites of involvement. L-Annamycin was administered at 190-250 mg/m2 as a single i.v. infusion over 1-2 h every 3 weeks. Of the 13 patients, 12 had clear deterioration and new tumor growth after one or two courses.

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

DEVELOPMENT STRATEGY

We began a Phase I clinical trial at The University of Texas M.D. Anderson Cancer Center in adult relapsed or refractory acute lymphocytic leukemia (ALL) patients on December 1, 2005. Additional sites enrolled in this study include the Roswell Park Cancer Institute (Buffalo, NY) and the Montefiore Medical Center (New York, NY). The single-arm, open-label L-Annamycin trial is designed to enroll patients in a dose escalation Phase I portion followed by 10 patients at a final fixed dose in the Phase II portion once the maximum tolerated dose (MTD) is determined. Up to 34 adult patients can be treated in this single-arm trial.

On February 22, 2007, we announced the opening of a Phase I clinical trial of L-Annamycin in pediatric relapsed or refractory ALL or AML patients. The trial is presently open at two sites in the U.S., Phoenix Children s Hospital, Phoenix, AZ, and the University of Arizona, Tucson, AZ.

MANUFACTURING OF ANNAMYCIN

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

ORPHAN DRUG STATUS OF ATIPRIMOD AND L-ANNAMYCIN

On January 6, 2004, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of multiple myeloma. On September 26, 2006, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of carcinoid tumors. 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 (Guanilib)

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 North Carolina, Chapel Hill, NC. 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 2007 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.

On April 1, 2005 we were awarded a two-year $885,641 biodefense partnership grant from the National Institute of Allergy and Infectious Diseases (NIAID) to develop a monoclonal antibody and vaccine against bacterial superantigen toxins. The goal was to design a monoclonal antibody and vaccine that prevent the unregulated activation of T-cells (human white blood cells) by bacteria from the class of staphylococcus aureus and streptococcus pyogenes. Funding for this program will end in the spring of 2007. Because the bioterrorism program is not a core activity of Callisto, we expect to terminate further development work upon the expiration of the research grant.

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 30, 2007, we had 9 full-time and 4 part-time employees.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of December 31, 2006.

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, 2006. The financial statements are prepared in accordance with accounting principles generally accepted in the United States of America, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options is designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage. Since inception through December 31, 2006 stock based compensation expense has totaled $16,517,445 or 27% of our total accumulated deficit of $60,444,368.

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

SFAS 123R provides for two transition methods. The modified *prospective* method requires that share-based compensation expense be recorded for any employee options granted after the adoption date and for the unvested portion of any employee options outstanding as of the adoption date. The *modified retrospective* method requires that, beginning in the first quarter of 2006, all prior periods presented be

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restated to reflect the impact of share-based compensation expense consistent with the proforma disclosures previously required under SFAS 123. We have elected to use the modified *prospective* method in adopting this standard.

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

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

For all fair value computations required for employee and non-employee stock-based compensation we use the Black-Scholes option-pricing model which requires assumptions for expected stock price volatility, expected term of the option, risk-free interest rate and expected dividend yield at the grant date. Our stock price fluctuated from $3.95 per share as of December 31, 2003 to $0.86 per share as of December 29, 2006.

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, 2006 AND DECEMBER 31, 2005

We had no revenues during the twelve months ended December 31, 2006 and 2005 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses decreased $398,551, or 6%, to $6,031,953 for the twelve months ended December 31, 2006 from $6,430,504 for the twelve months ended December 31, 2005. The single most significant factor contributing to this decrease in research and development expense was our L-Annamycin project where our program expenses decreased to approximately $1,300,000 during the twelve months ended December 31, 2006. Program expenses, incurred with outside contract research organizations (CROs), include hospital patient costs, blood testing, drug formulation, synthesis, tableting, data collection, clinical monitoring and FDA consultants. This decreased level of expenditure during the twelve months ended December 31, 2006 compared to approximately $2,500,000 during the twelve months ended December 31, 2005 during which period we purchased and expensed a supply of drug substance which was used in our 2006 Annamycin clinical trials. Atiprimod clinical program expenses decreased to approximately $1,700,000 during the twelve months ended December 31, 2006 as compared to approximately $1,900,000 for the twelve months ended December 31, 2005. Partially offsetting this decrease in L-Annamycin and Atiprimod program expenses were higher expenditures for two of our pre-clinical drug candidates, Degrasyns and Guanilib, increasing to approximately $1,200,000 during the twelve months ended December 31, 2006, as compared to approximately $100,000 during the twelve months ended December 31, 2005. Research and development in-house overhead, not allocated to specific clinical programs, totaled approximately $1,700,000, during the twelve months ended December 31, 2006, a decrease of approximately $100,000, or 5%, in line with our overall decrease in program expenses. Partially offsetting these decreases in the above cash-based expenditures was higher stock-based compensation expense associated with grants to research and development employees. During the twelve months ended December 31, 2006 and 2005 stock-based compensation expense totaled $420,683 and $276,250, respectively. This increase was primarily attributable to our adoption of SFAS 123R on January 1, 2006 (see Critical Accounting Policies above).

On April 1, 2005 we received 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 the next two years. Government grant funding under our NIAID grant for the twelve months ended December 31, 2006 and 2005 was $352,649 and $226,119, respectively.

General and administrative expenses for the twelve months ended December 31, 2006 were $5,112,876, an increase of $144,627 or 3%, from $4,968,249 for the twelve months ended December 31, 2005. This increase was entirely due to higher cash-based general and administrative expenses partially offset by lower stock-based compensation expense . Cash-based general and administrative expenses increased approximately $400,000, or 12%, primarily due to approximately $300,000 of increased investor relations costs and $150,000 in higher bonuses, partially offset by lower Sarbanes-Oxley compliance testing services, as a result of regulatory extensions during 2006. Stock-based compensation expense, attributable to general and administrative employees, decreased approximately $300,000, or 24%, to approximately $950,000 during the twelve months ended December 31, 2006.

Stock-based compensation attributable to non-employees recorded during the twelve months ended December 31, 2006 totaled $1,373,991 as compared to $889,277 recorded during the twelve months ended December 31, 2005. This increase of $484,714 or 55% was primarily attributable to the expense associated with 872,188 warrants we issued to certain investor relations consultants. The warrants vested on the date of issuance and the fair value of these warrants using the Black-Scholes methodology was $411,112.

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

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

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

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 $2,104,531 or 49%, to $6,430,506 for the twelve months ended December 31, 2005 from $4,325,975 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 attributable to research and development employees, recorded as research and development expense during the twelve months ended December 31, 2005, totaled $276,250 as compared to $1,508,588 recorded during the twelve months ended December 31, 2004. This decrease of approximately $1,200,000 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.

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 $4,968,249, an increase of $1,401,522 or 39%, from $3,566,727 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 attributable to general and administrative employees, recorded as general and administrative expense during the twelve months ended December 31, 2005, totaled $1,254,167 as compared to $1,203,954 recorded during the twelve months ended December 31, 2004.

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.

Stock-based compensation attributable to non-employee consultants and advisors was $889,277 during the twelve months ended December 31, 2005 as compared to $20,228 for the previous year. 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 was 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, whereas we had no such expense during the twelve months ended December 31, 2004.

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 Synergy had 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.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2006 we had $3,904,232 in cash and cash equivalents, compared to $1,420,510 as of December 31, 2005. This increase in cash of $2,483,722 during the twelve months ended December 31, 2006 was principally the result of approximately $10.8 million of cash provided from fund raising activities, partially offset by cash used in operating activities of $8.3 million during the twelve months ended December 31, 2006.

From October 2006 until January 2007, we placed 602,350 shares of Series A Convertible Preferred Stock and 8,031,333 warrants to certain investors for aggregate gross proceeds of $6,023,500. As of December 31, 2006 we had closed on 574,350 shares of such Series A Convertible Preferred Stock for aggregate gross proceeds of $5,743,500. The final traunche of this financing closed January 10, 2007 when we placed 28,000 shares of such Series A Convertible Preferred Stock for aggregate gross proceeds of $280,000. The shares of Series A Convertible Preferred Stock are convertible into shares of common stock at a conversion price of $0.75 per share. The investors also are parties to a Registration Rights Agreement, dated as of October 23, 2006 pursuant to which we agreed to file, within 60 days of closing, a registration statement with the Securities and Exchange Commission (the SEC) covering the resale of the shares of common stock underlying the Series A Convertible Preferred Stock and the warrants issued to the investors. The warrants are immediately exercisable at $0.75 per share, will expire five years from the date of issuance, and have certain antidilution rights for the twelve month period beginning on the effective date of the registration statement registering the shares of common stock underlying the warrants. We paid aggregate fees and expenses of $485,308 ($448,908 prior to December 31, 2006) in cash, issued an aggregate 11,775 shares of Series A Convertible Preferred Stock and 1,228,761warrants to purchase common stock to certain selling agents. The warrants are immediately exercisable at $0.75 per share,will expire five years after issuance and have the same anti-dilutive rights as the investor warrants. On January 12, 2007 we filed a registration statement on Form S-3 registering the common stock issuable upon (i) the conversion of the all Series A Convertible Preferred Stock, (ii) the exercise of all related investor warrants and (iii) the exercise of all selling agent warrants. On February 15, 2007 Amendment No.1 to this registration statement was declared effective by the SEC.

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 at a price of $1.20 per share for aggregate proceeds of $5,140,210. We paid an aggregate $531,808 in fees and expenses; and issued an aggregate 390,284 warrants to certain selling agents. We also incurred $30,000 in legal fees directly associated with the closing. On April 7, 2006 we had a second closing of the financing described above, in which we sold an additional 666,667 shares of common stock and issued 166,667 common stock purchase warrants at the same terms, for gross proceeds of $800,000, bringing the total gross proceeds of the financing to $5.94 million and net proceeds to $5.34 million. Placement agent fees of $41,000 were paid on this second closing and three year warrants to purchase a total of 66,667 common shares at a per share price of $1.25 were issued to several selling agents

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 July 18, 2005, we entered into a letter of engagement with Trilogy Capital Partners, Inc. 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 provided marketing and financial public relations services to us and assumed the responsibilities of an investor relations officer for us. We were obligated to pay Trilogy $12,500 per month under the agreement. Pursuant to the agreement, we also issued warrants to Trilogy to purchase 1,793,322 shares of our common stock at an exercise price of $1.03 per share, exercisable upon issuance and expiring on July 18, 2008. On July 5, 2006, we terminated this agreement. This agreement is currently the subject of a lawsuit and cross-complaint between the parties discussed in Item 3 of this annual report.

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 $352,649 and $226,119 during the twelve months ended December 31, 2006 and 2005, respectively.

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.

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, 2006 have been prepared under the assumption that we will continue as a going concern for the year ending December 31, 2007. Our independent registered public accounting firm has issued a report dated April 13, 2007 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.

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, 2006, 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	$ 705,988	$ 151,524	$ 312,201	$ 242,263	
Purchase obligation- principally consulting services	1,411,423	473,673	805,750	132,000	
Minimum spending obligations (1)	1,045,000	209,000	418,000	418,000	
License royalty payments (2)	1,145,000	210,000	455,000	480,000	(3)
Total obligations	$ 4,307,411	$ 1,044,197	$ 1,990,951	$ 1,272,263	

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

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

RECENT ACCOUNTING PRONOUNCEMENTS:

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

years beginning after November 15, 2007. We are currently evaluating the impact, if any, of the provisions of SFAS 159.

In December 2006, the Financial Accounting Standards Board (FASB) issued a FASB Staff Position (FSP) Emerging Issues Task Force (EITF) Issue No. 00-19-2 Accounting for Registration Payment Arrangements (FSP 00-19-2) which addresses an issuer s accounting for registration payment arrangements. FSP 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No.5 Accounting for Contingencies . The guidance in FSP 00-19-2 amends FASB Statements No. 133, Accounting for Derivative Instruments and Hedging

Activities , and No.150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity , and FASB Interpretation No.45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others to include scope exceptions for registration payment arrangements. FSP 00-19-2 is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of FSP 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of FSP 00-19-2, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. We have analyzed the provisions of FSP 00-19-2 and determined that it is not likely have a material effect on Callisto s consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No.157, Fair Value Measurements (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact, if any, of the provisions of SFAS 157.

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48) Accounting for Uncertainty in Income Taxes (an interpretation of FASB Statement No. 109) which is effective for fiscal years beginning after December 15, 2006. This interpretation was issued to clarify the accounting for uncertainty in the amount of income taxes recognized in the financial statements by prescribing a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The provisions of FIN 48 are effective January 1, 2007, with the cumulative effect of the change in accounting principle recorded as an adjustment to retained earnings. The Company does not expect the adoption of FIN 48 to have a material impact on its consolidated financial position, results of operations or cash flows.

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 did 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, 2006 and 2005, a substantial portion of our cash and cash equivalents consists of short term, highly liquid investments in a money market fund managed by a large money center bank (JPMorganChase). Original maturities of fund investments are all less than three months.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The full text of our audited consolidated financial statements as of December 31, 2006 and 2005 and for the fiscal years ended December 31, 2006, 2005 and 2004 and for the period from June 5, 1996 (inception) to December 31, 2006, 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, 2006, our Chief Executive Officer and Principal Financial Officer have concluded that, due to the material weakness in the internal control over financial reporting noted below, 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, 2006, 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 disclosures.

In connection with the audit of our financial statements, our independent registered public accountants noted various errors in the calculations in the accounting of the issuance of preferred stock in the fourth quarter of 2006 which led to the recording of material adjustments to our financial statements. Our independent registered public accountants also advised us of various omissions in our financial statement disclosures. The weakness identified is as a result of the fact that we lack sufficient internal accounting personnel and segregation of duties necessary to ensure that an adequate review of the financial statements and notes thereto is performed.

In order to ensure the effectiveness of our disclosure controls in the future we plan to add financial staff resources to our accounting and finance department. 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.

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, 2006.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The following table sets forth certain information regarding the directors and executive officers of Callisto Pharmaceuticals, Inc. as of March 30, 2007:

Name	Age	Positions
Gabriele M. Cerrone	35	Chairman of the Board
Gary S. Jacob	60	Chief Executive Officer, Chief Scientific Officer and Director; Chairman of Synergy Pharmaceuticals Inc.
Bernard F. Denoyer	59	Vice President, Finance and Secretary
Daniel S. D Agostino	40	Chief Business Officer
John P. Brancaccio	59	Director
Christoph Bruening	39	Director
Riccardo Dalla-Favera	54	Director
Stephen K. Carter	68	Director
Randall Johnson	60	Director

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

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

Bernard F. Denoyer, CPA has served as our Vice President, Finance since January 2004. From July 2003 to December 2003, Mr. Denoyer served as an independent consultant to our company providing interim CFO services. From January 2005 to February 2006 Mr. Denoyer also served as Vice President Controller for Xenomics, Inc. In addition to our company, Mr. Denoyer provided interim CFO and other services to emerging technology companies, principally portfolio companies of Marsh & McLennan Capital, LLC, from October 2000 to December 2003. From October 1994 until September 2000, Mr. Denoyer served as Chief Financial Officer and Senior Vice President at META Group, Inc., a public information technology research company. From 1990 to 1993 he was Vice President Finance of Environetics, Inc., a pharmaceutical water diagnostic business.

Daniel S. D Agostino has served as our Chief Business Officer since October 2005 and as a consultant since October 2004. From July 2001 to July 2004 Mr. D Agostino served as a Managing Director of Healthcare Investment Banking of Punk, Ziegel & Company LLP, a boutique healthcare investment bank. Prior to such affiliation, Mr. D Agostino held the position of head of biotechnology investment banking at Gerard Klauer Mattison & Co., a full service investment bank, between June 1999 and July 2001. Prior to that Mr. D Agostino was employed by BT Alex.Brown, Dillon Read & Co., and Wasserstein Perella & Co. all as a member of the investment banking group. Mr. D Agostino has been a Limited Partner of Punk, Ziegel & Company LLP since February 2002.

John P. Brancaccio, a retired CPA, has served as a Director of our company since April 2004. Since April 2004, Mr. Brancaccio has been the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. Mr. Brancaccio is currently a director of Alfacell Corporation as well as a director of each of Xenomics, Inc. and FermaVir Pharmaceuticals, Inc.

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

and funds manager in Germany. From 1997 to 1998, Mr. Bruening was a financial analyst and Head of Research for Value Research GmbH. Mr. Bruening is currently a member of the advisory board of Clarity AG.

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

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

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

COMPENSATION OF DIRECTORS

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

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

AUDIT COMMITTEE

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

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

COMPENSATION COMMITTEE

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

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

Compensation Committee Interlocks and Insider Participation

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

CORPORATE GOVERNANCE/NOMINATING COMMITTEE

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

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

SCIENTIFIC ADVISORY BOARD

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

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

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

Roman Perez-Soler, M.D. Dr. Perez-Soler is currently Gutman Professor of Oncology and Chairman of the Department of Oncology at Montefiore Medical Center as well as Associate Director of Clinical Research at the Albert Einstein Cancer Center and Chief of the Division of Medical Oncology at the Albert Einstein College of Medicine. Dr. Perez-Soler was formerly Professor of Medicine and Deputy Chairman of the

Department of Thoracic/Head and Neck Medical Oncology at The University of Texas M.D. Anderson Cancer Center and Associate Director for Clinical and Translational Research at the Kaplan Cancer Center at New York University. Dr. Perez-Soler is a nationally and

internationally renowned clinical translational researcher in the areas of new anticancer drug development, with a strong emphasis in liposome delivery and thoracic malignancies.

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

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

Based on a review of the copies of such forms received, we believe that during 2006, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with, except that a Form 4 with respect to each of Randall Johnson, Stephen Carter, John Brancaccio, Christoph Bruening and Riccardo Dalla-Favera was filed late.

CODE OF BUSINESS CONDUCT AND ETHICS

We have adopted a formal Code of Business Conduct and Ethics applicable to all Board members, executive officers and employees. A copy of this Code of Business Conduct and Ethics is posted on our website at www.callistopharma.com.

ITEM 11. EXECUTIVE COMPENSATION.

Compensation Committee Report

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

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

Submitted by the Compensation Committee

Christoph Bruening, Chairman

John Brancaccio

Stephen Carter

Compensation Discussion and Analysis

Overview

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

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

Utilizing this philosophy, our compensation programs are designed to:

- be market-based and reflect the competitive environment for personnel;
- stress our pay for performance approach to managing pay levels;
- share risks and rewards with employees at all levels;
- be affordable, within the context of our operating expense model;
- align the interests of our employees with those of our stockholders;
- reflect our values; and
- be fairly and equitably administered.

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

- evolve and modify our programs to reflect the competitive environment and our changing business needs;
- focus on simplicity, flexibility and choice wherever possible;
- openly communicate the details of our programs with our employees and managers to ensure that our

programs and their goals are understood; and

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

Elements of Our Compensation Program

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

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

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

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

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

The four key elements of our compensation structure are:

- base pay;
- variable pay;
- equity-based pay; and
- benefits.

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

Base Pay

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

Variable Pay

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

Equity-Based Rewards

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

Benefits Programs

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

Determining the Amount of Each Element of Compensation

Base Pay. We provide our executive officers and other employees with base salary to compensate them for services rendered during the fiscal year. The Compensation Committee intends to compensate our executive officers competitively within the industry. The Compensation Committee considered the scope of and accountability associated with each executive officer s position and such factors as the performance and experience of each executive officer when setting base salary levels for fiscal year 2006. With respect to executive officers other than Dr. Jacob, who is discussed below, the Compensation Committee targeted base salaries to be competitive with our peers within the biotechnology industry. In some circumstances it is necessary to provide compensation above these levels; these circumstances include the need to retain key individuals, to recognize roles that were larger in scope or accountability than standard market positions and/or to reward individual performance.

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

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

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

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

Timing of Equity Awards

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

Executive Equity Ownership

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

Performance-Based Compensation and Financial Restatement

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

Severance and Change in Control Arrangements

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

Effect of Accounting and Tax Treatment on Compensation Decisions

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

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

Beginning on January 1, 2006, we began accounting for stock-based payments including our stock options in accordance with the requirements of FASB Statement 123(R).

Role of Executives in Executive Compensation Decisions

Our board of directors and our Compensation Committee generally seek input from our Chief Executive Officer, Gary S. Jacob, when discussing the performance of, and compensation levels for executives other than himself. The Compensation Committee also works with Dr. Jacob and our Vice President, Finance evaluating the financial, accounting, tax and retention implications of our various compensation programs. Neither Dr. Jacob nor any of our other executives participates in deliberations relating to his or her own compensation.

Chief Executive Officer Compensation for Fiscal Year 2006

On February 16, 2007, Dr. Jacob entered into an Extension and Amendment Agreement with us as approved by the Compensation Committee which extended the term under his employment agreement to June 30, 2009. In addition, pursuant to the agreement, Dr. Jacob was granted 225,000 ten year incentive stock options exercisable at $0.81 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. The Compensation Committee believes the grant of options to Dr. Jacob is a key component of his compensation and an important means of ensuring that as Chief Executive Officer he continues to share significantly in the success of our business with the other stockholders. The Compensation Committee determined that it was appropriate to grant these options for these reasons and due to Dr. Jacob s performance. Dr. Jacob received a salary of $287,500 for 2006. Dr. Jacob also earned a bonus of $48,125 for 2006. Dr. Jacob s bonus was earned pursuant to this employment agreement and is based on achieving key performance objectives for our company as approved and measured by the Compensation Committee.

SUMMARY COMPENSATION TABLE

The following table provides certain summary information concerning compensation awarded to, earned by or paid to our Chief Executive Officer, Principal Financial Officer and three other highest paid executive officers whose total annual salary and bonus exceeded $100,000 (collectively, the named executive officers) for fiscal year 2006.

Name & Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($) (1)	Total ($)
Gary S. Jacob	2006	287,500	48,125	82,147	417,772
Chief Executive Officer	2005	225,000	33,750		258,750
and Chief Scientific Officer	2004	225,000	33,750		258,750
Bernard F. Denoyer	2006	111,576	10,461		122,037
Vice President, Finance	2005	79,167	6,563		85,730
and Secretary	2004	86,250	9,000		95,250
Gabriele M. Cerrone (2)	2006	213,542	125,855		339,397
Chairman of the Board	2005	191,498	30,750		222,248

Daniel S. D Agostino (3)	2006	175,000	32,814	207,814
Chief Business Officer	2005	138,614		138,614
Donald Picker (4)	2006	210,417		210,417
Executive Vice President,	2005	200,000	20,000	220,000
R&D	2004	191,875	37,500	229,375

(1) Amounts represent stock-based compensation expense for fiscal year 2006 for stock options granted in 2006 under SFAS 123R as discussed in Note 3 Summary of Significant Accounting Policies subheading Share-based payments, of the Notes to our Consolidated Financial Statements included elsewhere in this report.

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

(3) Mr. D Agostino was appointed Chief Business Officer in October 2005. From October 2004 to October 2005, Mr. D Agostino served as a consultant to us.

(4) Mr. Picker resigned as Executive Vice President, R&D on December 19, 2006.

GRANTS OF PLAN-BASED AWARDS

The following table sets forth information regarding stock option awards to our named executive officers under our stock option plans during the fiscal year ended December 31, 2006:

Name	Grant Date	Number of Securities Underlying Options(#)		Exercise or Base Price of Option Awards ($/Share)	Fair Value at Grant Date of Option Awards	
Gary S. Jacob	March 17, 2006	150,000	(1)	$ 1.64	$ 183,386	(2)

(1) 50,000 options vest on each of March 17, 2007, 2008 and 2009.

(2) Amount represents stock-based compensation expense for stock options granted in 2006 under SFAS 123R as discussed in Note 3 Summary of Accounting Policies subheading Share-based payments, of the Notes to our Consolidated Financial Statements included elsewhere in this annual report.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table sets forth information for the named executive officers regarding the number of shares subject to both exercisable and unexercisable stock options, as well as the exercise prices and expiration dates thereof, as of December 31, 2006.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		Option Exercise Price ($)	Option Expiration Date
Gary S. Jacob	500,000			1.50	June 13, 2013
	62,500	212,500	(1)	3.00	June 29, 2014
	100,000	250,000	(2)	1.01	July 6, 2015
	50,000	100,000	(3)	1.64	March 17, 2016
Bernard F. Denoyer	100,000			3.60	January 15, 2014
	25,000	50,000	(4)	1.38	July 29, 2015
Gabriele M. Cerrone	189,167			0.75	May 3, 2008
	27,778			0.75	October 1, 2009
	200,000			1.25	January 18, 2011
	333,055			1.30	April 22, 2013
	75,000			1.50	June 13, 2013
	100,000			3.20	April 26, 2014
	375,000			1.70	January 10, 2015

Daniel S. D Agostino	100,000	300,000	(5) 1.53	October 10, 2015

(1) 50,000 options vest on June 1, 2007 and 12,500 options will vest on June 1, 2007 since we have established a second disease target for Atiprimod. The remaining 150,000 options vest upon certain drug development or licensing benchmarks.

(2) 100,000 options vest on July 6, 2007 and 150,000 options vest on July 6, 2008.

(3) 50,000 options vest on each of March 17, 2008 and 2009.

(4) 25,000 options vest on each of July 29, 2007 and 2008.

(5) 100,000 options vest on each of October 10, 2007 and 2008. The remaining 100,000 options vest upon the successful in-licensing or acquisition of a drug candidate.

DIRECTOR COMPENSATION

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2006 for services to our company.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	Total ($)
Christoph Bruening (2)	30,500	519	31,019
Riccardo Dalla-Favera (3)	15,000	165	15,165
John P. Brancaccio (4)	31,500	546	32,046
Stephen K. Carter (5)	23,000	328	23,328
Randall Johnson (6)	21,000	274	21,274

(1) Amounts represent the expensed fair value for fiscal year 2006 of stock options granted in 2006 under SFAS 123R as discussed in Note 3 Summary of Significant Accounting Policies subheading Share-based payments, of the Notes to Consolidated Financial Statements included in this report.

(2) Stock options for the purchase of an aggregate of 227,000 shares were outstanding as of December 31, 2006, with a grant date fair value of $434,697.

(3) Stock options for the purchase of an aggregate of 88,000 shares were outstanding as of December 31, 2006, with a grant date fair value of $63,729.

(4) Stock options for the purchase of an aggregate of 120,123 shares were outstanding as of December 31, 2006, with a grant date fair value of $224,488.

(5) Stock options for the purchase of an aggregate of 104,861 shares were outstanding as of December 31, 2006, with a grant date fair value of $119,025.

(6) Stock options for the purchase of an aggregate of 103,000 shares were outstanding as of December 31, 2006, with a grant date fair value of $93,097.

EMPLOYMENT AGREEMENTS AND CHANGE IN CONTROL ARRANGEMENTS

We are party to an employment agreement with Gary S. Jacob, Ph.D. dated June 13, 2003, pursuant to which Dr. Jacob serves as our Chief Executive Officer and Chief Scientific Officer. Dr. Jacob s employment agreement, as amended, is in effect until December 31, 2009. Dr. Jacob s salary is $300,000 per year and he is eligible to receive a cash bonus of up to $60,000 per year based on meeting performance objectives and bonus criteria to be mutually identified by Dr. Jacob and the Board of Directors. During 2006, Dr. Jacob earned a bonus of $48,125. On February 16, 2007, Dr. Jacob was granted 225,000 ten year incentive stock options exercisable at $0.81 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. Dr. Jacob is a party to an Extension and Severance Agreement with us dated June 9, 2005 as amended February 16, 2007 which provides that in the event there is a change of control of our company and the executive s employment shall have been terminated within two years after a change in control by him for good reason or by our company and such termination did not occur as a result of (i) the executive s death, (ii) the executive s disability, (iii) the executive s retirement or (iv) the executive s termination for cause, the executive shall be entitled to an amount equal to the compensation due to the executive for the term of his employment under his employment agreement for the time remaining of such employment term. In addition, all of the executive s unvested stock options shall immediately and irrevocably vest and the exercise period of such options will be extended to the later of the longest period permitted by our stock option plans or ten years

following termination. A Change in Control shall be deemed to have occurred if (i) there shall be consummated (A) any consolidation or merger of our company in which we are not the continuing or surviving corporation or pursuant to which shares of our common stock would be converted into cash, securities or other property, other than a merger of our company in which the holders of our common stock immediately prior to the merger have substantially the same proportionate ownership of common stock of the surviving corporation immediately after the merger, or (B) any sale, lease, exchange or other transfer (in

one transaction or a series of related transactions) of all or substantially all the assets of our company; or (ii) the stockholders of our company shall approve any plan or proposal for the liquidation or dissolution of our company, (ii) any person (as such term is used in Sections 13(d) and 14(d)(2) of the Securities Exchange Act of 1934 (the Exchange Act)), other than us or any employee benefit plan sponsored by us, shall become the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act) of our securities representing 20% or more of the combined voting power of our then outstanding securities ordinarily (and apart from rights accruing in special circumstances) having the right to vote in the election of directors, as a result of a tender or exchange offer, open market purchases, privately negotiated purchases or otherwise, or (iv) at any time during a period of two consecutive years, individuals who at the beginning of such period constituted the Board of Directors of our company shall cease for any reason to constitute at least a majority thereof, unless the election or the nomination for election by our stockholders of each new director during such two-year period was approved by a vote of at least two-thirds of the directors then still in office who were directors at the beginning of such two-year period (or in the case that Dr. Jacob is our CEO, in addition if the Board appoints a new CEO during the term of the agreement or substantially reduces the title and authority of Dr. Jacob without his prior consent). Had a Change of Control occurred on December 31, 2006 and the executive had been terminated on that date, Dr. Jacob would have been eligible for total compensation (salary and bonus) for the term of his employment under his employment agreement for the time remaining of such employment term, of $1,080,000.

We are party to an employment agreement with Bernard Denoyer dated January 15, 2004, pursuant to which Mr. Denoyer serves as our Vice President, Finance and Secretary. 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. On January 15, 2004 Mr. Denoyer received a grant of 100,000 stock options which vest over a three year period and are exercisable at $3.60 per share. On July 29, 2005 Mr. Denoyer was granted an additional 75,000 stock options which vest over three years and are exercisable at $1.38 per share. On September 1, 2006 Mr. Denoyer s salary was increased to $120,000 per year and he became eligible for to receive a cash bonus of up to 10% of his salary per year.

On October 10, 2005 we entered into an employment agreement with Dan D Agostino to serve as our Chief Business Officer. Pursuant to the employment agreement, we 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 us or Mr. D Agostino. Mr. D Agostino will be paid an annual base salary of $175,000. In addition, Mr. D Agostino will be eligible to earn an annual cash bonus up to 15% of his annual base salary, plus up to $25,000 based on meeting performance objectives and bonus criteria, specifically surrounding our corporate development plans to expand our technology and product portfolio. In addition, Mr. D Agostino s employment agreement provides that in the event there is a change of control of our company and Mr. D Agostino s employment shall have been terminated within two years after a change in control by him for good reason or by our company and such termination did not occur as a result of (i) death, (ii) disability, (iii) retirement or (iv) termination for cause, Mr. D Agostino shall only be entitled to all of his unvested stock options immediately and irrevocably vesting and the exercise period of such options will be extended to the later of the longest period permitted by our stock option plans or ten years following termination. On October 10, 2005 Mr. D Agostino was granted an aggregate 400,000 incentive stock options pursuant to our 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 vested 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. The fair value of Mr. D Agostino s unvested options as of December 31, 2006, which would have vested had a Change of Control occurred as of December 31, 2006, was $342,172.

CONSULTING AGREEMENTS

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

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

On December 27, 2004, we entered into a consulting agreement with Gabriele M. Cerrone, our Chairman of the Board and a principal stockholder. On January 25, 2007, we entered into an Extension and Amendment Agreement with Mr. Cerrone. The agreement extends the term of the consulting agreement between us and Mr. Cerrone dated as of December 27, 2004 to December 31, 2009. Among other things, the agreement increases Mr. Cerrone s compensation from $205,000 to $275,000 per year. In addition, Mr. Cerrone was granted 225,000 ten year non-qualified stock options at an exercise price of $0.96 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. Additionally, pursuant

to the agreement, in recognition of the services beyond that required of Mr. Cerrone during the period from July 1, 2006 to January 25, 2007, we will accrue a bonus to Mr. Cerrone of $75,000, payable on March 31, 2007. Mr. Cerrone shall be eligible to earn a cash bonus of up to 22.5% of his base compensation for each twelve month period during the term of the agreement based

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on meeting performance objectives and bonus criteria to be mutually identified by Mr. Cerrone and our Board. Under the original agreement, Mr. Cerrone received a grant of 375,000 stock options, all of which have vested.

In the event the agreement is terminated without cause or for good reason, Mr. Cerrone will receive a cash payment equal to the aggregate amount of his annual fee for the then remaining term of the Agreement and all unvested stock options will immediately vest and the exercise period of such options will be extended to the later of the longest period permitted by our stock option plans or ten years following termination. In the event a change of control of the Company occurs, Mr. Cerrone shall be entitled to such compensation upon the subsequent termination of the agreement within two years of the change in control unless such termination is the result of Mr. Cerrone s death, disability or retirement or his termination for cause.

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

STOCK OPTION PLANS

We rely on incentive compensation in the form of stock options to retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options is designed to provide long-term incentives to directors, executive officers, employees and consultants, to encourage them to remain with us and to enable them to develop and maintain an ownership position in our common stock.

In 1996, we adopted the 1996 Incentive and Non-Qualified Stock Option Plan (the Plan) for employees, consultants and outside directors to purchase up to 2,000,000 shares of common stock. This Plan was amended in December 2002 to increase the number of shares authorized under the Plan to 10,000,000. The option term for 4,745,042 options outstanding to date under the Plan is ten years from date of grant. The Plan terminated on January 1, 2006 under its original terms and no further options will be granted under the Plan.

On October 20, 2005, our stockholders approved the 2005 Equity Compensation Incentive Plan. The maximum number of shares of common stock with respect to which awards may be granted under the 2005 Equity Plan is 5,000,000. The option term for options granted under the 2005 Equity Plan is ten years from date of grant and there were 4,150,000 options available for future grants as of December 31, 2006.

On October 20, 2005, our stockholders approved our 2005 Directors Stock Option Plan. The maximum number of shares of common stock with respect to which awards may be granted under the 2005 Directors Plan is 1,000,000. The option term for options granted under the 2005 Directors Plan is ten years from date of grant and there are 894,000 option shares available for future grants as of December 31, 2006.

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

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

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

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of March 30, 2007 by (i) each person know to beneficially own more than 5% of the outstanding common stock, (ii) each of our directors, (iii) the Named Executive Officers and (iv) all directors and executive officers as a group. Except as otherwise indicated, the persons named in the table have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable. Unless otherwise indicated, the address of each beneficial owner listed below is c/o Callisto Pharmaceuticals, Inc., 420 Lexington Avenue, Suite 1609, New York, N.Y. 10170.

Name and Address of Beneficial Owner	Shares of Common Stock Beneficially Owned (1) Number of Shares		Percentage of Class	
Gabriele M. Cerrone Chairman of the Board	3,486,737	(2)	8.6	%
Gary S. Jacob Chief Executive Officer, Chief Scientific Officer and Director	834,745	(3)	2.1	%
Bernard Denoyer Vice President, Finance and Secretary	125,000	(4)	*	
Daniel S. D Agostino Chief Business Officer	116,448	(5)	*	
Riccardo Dalla-Favera Director	27,000	(6)	*	
Stephen Carter Director	62,574	(7)	*	
Christoph Bruening Director	576,865	(8)	1.5	%
John Brancaccio Director	71,415	(9)	*	
Randall K. Johnson Director	65,000	(10)	*	
All Directors and Executive Officers as a group (9 persons)	5,365,784	(11)	12.8	%
Panetta Partners Ltd.	2,186,737		5.6	%

* less than 1%

(1) Applicable percentage ownership as of March 30, 2007 is based upon 39,194,996 shares of common stock outstanding.

(2) Consists of 1,300,000 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone and 2,126,737 shares of common stock, 30,000 shares of common stock issuable upon conversion of 2,250 shares of Series A Convertible Preferred Stock and 30,000 shares of common stock issuable upon exercise of the warrants, each held by Panetta Partners, Ltd. Mr. Cerrone is the sole managing partner of Panetta and in such capacity only exercises voting and dispositive control over securities owned by Panetta, despite him having only a small pecuniary interest in such securities.

(3) Includes 700,000 shares of common stock issuable upon exercise of stock options.

(4) Consists of 125,000 shares of common stock issuable upon exercise of stock options.

(5) Includes 100,000 shares of common stock issuable upon exercise of stock options.

(6) Consists of 27,000 shares of common stock issuable upon exercise of stock options.

(7) Consists of 62,574 shares of common stock issuable upon exercise of stock options.

(8) Includes of 101,166 shares of common stock issuable upon exercise of stock options.

(9) Consists of 71,415 shares of common stock issuable upon exercise of stock options.

(10) Consists of 65,000 shares of common stock issuable upon exercise of stock options.

(11) Includes 2,552,155 shares of common stock issuable upon exercise of stock options, 30,000 shares of common stock issuable upon conversion of 2,250 shares of Series A Convertible Preferred Stock and 30,000 shares of common stock issuable upon exercise of the warrants.

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

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

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

The agreement, the amendment and their respective terms were approved by our Compensation Committee, which consists solely of independent members of the Board. Additional information concerning the terms of the consulting agreement are set forth in Item 9 of this annual report.

CONFLICTS OF INTEREST

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

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

AUDIT FEES.

The aggregate fees billed and unbilled for the fiscal year ended December 31, 2006 for professional services rendered by our principal accountants for the audits of our annual financial statements, the review of our financial statements included in our quarterly reports on Form 10-Q and consultations and consents were approximately $138,750. The aggregate fees billed and unbilled for the fiscal year ended December 31, 2005 for professional services rendered by our principal accountants for the audits of our annual financial statements, the review of our financial statements included in our quarterly reports on Form 10-Q and consultations and consents were approximately $155,000.

AUDIT-RELATED FEES.

The aggregate fees billed for the fiscal year ended December 31, 2006 and 2005 for assurance and related services rendered by our principal accountants related to the performance of the audit or review of our financial statements, specifically accounting research, were approximately $0 and $6,000, respectively.

TAX AND OTHER FEES.

There were no aggregate fees billed for the fiscal years ended December 31, 2006 and 2005 as there were no tax related or other services rendered by our principal accountants in connection with the preparation of our federal and state tax returns.

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

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SUMMARY COMPENSATION TABLE 91

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

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

(2) *Index to Financial Statement Schedules:*

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

(3) *Index to Exhibits*

Index to Exhibits

Exhibit Number	**Description**
3.1	Certificate of Incorporation, as amended
3.2	Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 filed with the Company s Current Report on Form 8-K filed on October 27, 2006)
3.3	Certificate of Amendment to Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.2 filed with the Company s Current Report on Form 8-K filed on December 27, 2006)
3.4	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)
4.8	Form of Warrant issued pursuant to the Letter Agreement dated September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 4.1 filed with the Company s Current Report on Form 8-K filed on September 14, 2006)
4.9	Form of Warrant to purchase shares of Common Stock issued in connection with the sale of the Series A Convertible Preferred Stock (Incorporated by reference to Exhibit 4.1 filed with the Company s Current Report on Form 8-K filed on October 27, 2006)
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	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)**
10.4	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)*
10.5	Patent and Technology License Agreement dated August 12, 2004 by and between The Board of Regents of the University of Texas System, on behalf of The University of Texas M. D. Anderson Cancer Center and Callisto Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.1 filed with the Company s Current Report on Form 8-K filed on September 7, 2004)**
10.6	License Agreement between Callisto Pharmaceuticals, Inc. and The Rockefeller University effective as of July 25, 2001 (Incorporated by reference to Exhibit 10.12 filed with the Company s Annual Report on Form 10-K filed on June 6, 2005)
10.7	Extension and Severance Compensation Agreement dated June 9, 2005 between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (Incorporated by reference to Exhibit 10.1 filed with the Company s Current Report on Form 8-K filed on June 15, 2005)*
10.8	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)
10.9	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)
10.10	Amendment dated October 19, 2005 to the Employment Agreement dated as of June 13, 2003 by and between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (Incorporated by reference to Exhibit 10.1 filed with the Company s Current Report on Form 8-K filed on October 21, 2005)*
10.11	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)*
10.12	Amendment dated October 19, 2005 to the Employment Agreement dated as of April 6, 2004 by and between Synergy Pharmaceuticals Inc. and Kunwar Shailubhai (Incorporated by reference to Exhibit 10.5 filed with the Company s Current Report on Form 8-K filed on October 21, 2005)*

10.13	Patent and Technology License Agreement dated January 10, 2006 between The University of Texas M.D. Anderson Cancer Center and Callisto Pharmaceuticals, Inc. **
10.14	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)
10.15	Form of Letter Agreement dated September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 10.1 filed with the Company s Current Report on Form 8-K filed on September 14, 2006)
10.16	Form of Amendment Agreement dated as of September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 10.2 filed with the Company s Current Report on Form 8-K filed on September 14, 2006)
10.17	Form of Lock-up Agreement dated as of September 8, 2006 between Callisto Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 10.3 filed with the Company s Current Report on Form 8-K filed on September 14, 2006)
10.18	Form of Securities Purchase Agreement dated October 23, 2006 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company s Current Report on Form 8-K filed on October 27, 2006)
10.19	Form of Registration Rights Agreement dated October 23, 2006 by and among Callisto Pharmaceuticals, Inc. and the purchaser s signatory thereto (Incorporated by reference to Exhibit 10.2 filed with the Company s Current Report on Form 8-K filed on October 27, 2006)
10.20	Form of Securities Purchase Agreement dated December 20, 2006 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company s Current Report on Form 8-K filed on December 27, 2006)
10.21	Form of Securities Purchase Agreement dated January 10, 2007 by and among Callisto Pharmaceuticals, Inc. and the purchasers set forth on the signature page thereto (Incorporated by reference to Exhibit 10.1 filed with the Company s Current Report on Form 8-K filed on January 17, 2007)
10.22	Extension and Amendment Agreement dated January 25, 2007 between Callisto Pharmaceuticals, Inc. and Gabriele M. Cerrone*
10.23	Extension and Amendment Agreement dated February 16, 2007 between Callisto Pharmaceuticals, Inc. and Gary S. Jacob*
14	Code of Business Conduct and Ethics (Incorporated by reference to Exhibit 14 filed with the Company s Annual Report on Form 10-KSB filed on April 14, 2004)
21	List of Subsidiaries
23	Consent of BDO Seidman, LLP
31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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

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SUMMARY COMPENSATION TABLE 97

** 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: April 17, 2007 By: /s/ Gary S. Jacob
Gary S. Jacob,
Chief Executive Officer

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

SIGNATURE	**TITLE**	**DATE**
/s/ Gary S. Jacob Gary S. Jacob	Chief Executive Officer and Director (Principal Executive Officer)	April 17, 2007
/s/ Bernard F. Denoyer Bernard F. Denoyer	Vice President, Finance (Principal Financial and Accounting Officer)	April 17, 2007
/s/ Gabriele M. Cerrone Gabriele M. Cerrone	Chairman of the Board	April 17, 2007
/s/ Riccardo Dalla-Favera Riccardo Dalla-Favera	Director	April 17, 2007
/s/ John P. Brancaccio John P. Brancaccio	Director	April 17, 2007
/s/ Stephen K. Carter Stephen K. Carter	Director	April 17, 2007
/s/ Christoph Bruening Christoph Bruening	Director	April 17, 2007
/s/ Randall K. Johnson Randall K. Johnson	Director	April 17, 2007

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, 2006 and 2005, the related consolidated statements of operations and cash flows for each of the three years in the period ended December 31, 2006 and for the period from June 5, 1996 (inception) to December 31, 2006 and the related consolidated statement of stockholders equity (deficit) for the period from June 5, 1996 (inception) to December 31, 2006. 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, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006 and for the period from June 5, 1996 (inception) to December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

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

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

/s/ BDO Seidman, LLP

New York, New York
April 13, 2007
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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)
CONSOLIDATED BALANCE SHEETS

	AS OF DECEMBER 31, 2006	2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,904,232	$ 1,420,510
Prepaid expenses and other	66,741	181,284
	3,970,973	1,601,794
Property and equipment - net	6,451	
Security deposits	73,716	82,196
	$ 4,051,140	$ 1,683,990
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,843,422	$ 1,424,612
Accrued expenses	1,357,600	592,297
	3,201,022	2,016,909
Stockholders equity (deficit):		
Series A convertible preferred stock, par value $0.0001, 700,000 shares authorized, 586,125 shares outstanding at December 31, 2006 with a liquidation preference of $5,861,250.	58	
Common stock, par value $.0001, 100,000,000 shares authorized, 39,194,996 and 33,233,096 shares outstanding at December 31, 2006 and 2005, respectively.	3,919	3,323
Additional paid-in capital	61,290,509	46,387,875
Unamortized deferred stock based compensation		(1,583,463)
Deficit accumulated during development stage	(60,444,368)	(45,140,654)
	850,118	(332,919)
	$ 4,051,140	$ 1,683,990

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,
	2006	2005	2004	2006
Revenues	$	$	$	$
Costs and expenses:				
Research and development	6,031,953	6,430,504	4,325,975	22,037,815
Government grant	(352,649)	(226,119)	(265,697)	(844,465)
Purchased in process research and development			209,735	6,944,553
General and administrative	5,112,876	4,968,249	3,566,727	20,753,740
Stock-based compensation non-employees	1,373,991	889,277	20,228	9,698,561
Loss from operations	(12,166,171)	(12,061,911)	(7,856,968)	(58,590,204)
Interest and investment income	48,632	105,303	84,081	703,616
Other income (expense)	(801,690)	177,151	229,420	(173,295)
Net loss	(12,919,229)	(11,779,457)	(7,543,467)	(58,059,883)
Series A Preferred stock beneficial conversion feature accreted as a dividend	(2,384,485)			(2,384,485)
Net loss available to common stockholders	$ (15,303,714)	$ (11,779,457)	$ (7,543,467)	$ (60,444,368)
Weighted average shares outstanding: basic and diluted	37,941,267	31,527,060	28,485,227	
Net loss per common share: basic and diluted	$ (0.40)	$ (0.37)	$ (0.26)	

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

	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

	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

	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, December31, 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

	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)