CALLISTO PHARMACEUTICALS INC
Form 10-K/A
June 06, 2005

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K/A

(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, 2004
|_| 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 Exchange Act:

Title of each class	Name of each exchange on which registered
Common Stock, $.0001 par value	American Stock Exchange

Securities registered under Section 12(g) of the Exchange Act:

Title of class
None

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.

|X| Yes |_| No

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). | | Yes |X| No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2004, based on the closing sale price on such date, was $45,660,790.

As of March 24, 2005 the registrant had a total of 31,228,893 shares of Common Stock outstanding.

EXPLANATORY NOTE

This Form 10-K/A to our Annual Report on Form 10-KSB for the year ended December 31, 2004 is being filed for the purposes of responding to comments received by us from the Staff of the Securities and Exchange Commission. This Amendment speaks as of the original filing date of our Annual Report on Form 10-KSB and has not been updated to reflect events occurring subsequent to the original filing date.

CALLISTO PHARMACEUTICALS, INC.

FORM 10-K

INDEX

PART I		PAGE
Item 1.	Business	3
Item 2.	Properties	18
Item 3.	Legal Proceedings	18
Item 4.	Submission of Matters to a Vote of Security Holders	18
PART II		
Item 5.	Market for Common Equity and Related Stockholder Matters	18
Item 6.	Selected Financial Data	19
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	19
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	25
Item 8.	Financial Statements	25
Item 9.	Changes in and Disagreements with Accountants On Accounting and Financial Disclosure	25
Item 9A.	Controls and Procedures	25
PART III		

Item 10.	Directors and Executive Officers of the Registrant	26
Item 11.	Executive Compensation	30
Item 12.	Security Ownership of Certain Beneficial Owners and Management	33
Item 13.	Certain Relationships and Related Transactions	34
Item 14.	Principal Accountant Fees and Services	35
PART IV		
Item 15.	Exhibits	35
	Signatures	38

PART I

This Form 10-K/A 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/A for the year ended December 31, 2004, as filed with the Securities and Exchange Commission, including the uncertainties associated with product development, the risk that products that appeared promising in early clinical trials do not demonstrate efficacy in larger-scale clinical trials, the risk that we will not obtain approval to market our products, the risks associated with dependence upon key personnel and the need for additional financing. We do not assume any obligation to update forward-looking statements as circumstances change.

ITEM 1. BUSINESS.

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

We are a biopharmaceutical company focused on the development of drugs to treat relapsed (failure of prior therapy) acute leukemia, multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow), other cancers and osteolytic bone disease (bone disease caused by white blood cells). Our lead drug candidate, Annamycin, a drug from the anthracycline family (chemotherapy drugs which are also antibiotics), earlier completed a Phase I/IIa trial in leukemia patients with residual leukemic cells (refractory) in their bodies. Annamycin, originally developed by scientists at The University of Texas M.D. Anderson Cancer Center to address the clinical limitations associated with anthracycline drugs such as Adriamycin (doxorubicin) to treat cancer, is planned to begin a trial at The University of Texas M.D. Anderson Cancer Center in adult relapsed acute lymphocytic leukemia (ALL) patients in mid-2005 which will include an initial evaluation of a small number of patients (2 cohorts totaling approximately 6 patients) in a Phase I/IIa trial that will be rolled into a

larger Phase IIb trial. We also expect to commence two additional trials of Annamycin in 2005, a single agent trial in pediatric relapsed ALL patients and in combination with Ara-C (cytosine arabinoside) in relapsed acute myeloid leukemia (AML) patients.

Our second drug candidate, Atiprimod, is an orally available drug with antiproliferative and antiangiogenic activity. Atiprimod commenced a Phase I/IIa clinical trial in relapsed multiple myeloma patients on May 26, 2004. These are patients that no longer respond to chemotherapy, and are in advanced stages of the disease. The Phase I/IIa clinical trial is currently being enrolled at four sites, The University of Texas M.D. Anderson Cancer Center (Houston, TX), the Dana-Farber Cancer Institute (Boston, MA), the St. Vincent's Comprehensive Cancer Center (New York, NY) and the Roswell Park Cancer Institute (Buffalo, NY).

On January 6, 2004, we announced that the Office of Orphan Products Development of the United States Food and Drug Administration (FDA) granted orphan drug designation to Atiprimod for the treatment of multiple myeloma.

RECENT DEVELOPMENTS

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 have agreed to file a registration statement covering resale of the shares within 30 days of the closing.

On March 15, 2005 we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The new trial is entitled: "An Open Label Study of the Safety and Efficacy of Atiprimod Treatment for Patients with Advanced Cancer". An open label trial is a trial where the physicians and patients are aware of the amount of drug each patient receives. The trial protocol received institutional review board, or IRB, approval on February 22, 2005 at The University of Texas M.D. Anderson Cancer Center. Site initiation was completed on March 3, 2005, and patient screening and dosing is anticipated to begin in April, 2005.

HISTORY

In March 2002, Callisto Pharmaceuticals, Inc. ("Old Callisto") 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.

ANNAMYCIN TO TREAT RELAPSED 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 Annamycin patent rights. 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 encapsulated in a lipid preparation (liposomal) 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 liposomal Annmycin 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 or suppression of the body's immune response, was noted in mice at a single intravenous dose of 15.7 mg/kg liposomal Annamycin. With weekly intravenous doses of 5.2 mg/kg liposomal Annamycin for 6 weeks, or 3.1 and 4.2 mg/kg liposomal Annamycin for 10 weeks in mice, the cardiotoxicity (toxicity to heart tissue) of liposomal 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 liposomal Annamycin was well tolerated, with no clinically significant adverse effects, hematological or chemical changes, or pathological changes.

COMPLETED CLINICAL STUDIES

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, liposomal 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 liposomal Annamycin in solid tumor patients was found to be 190 mg/m2. A second Phase II study of liposomal 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. Liposomal 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). Annamycin was infused at a starting dose of 190 mg/m2/day x 3 days with escalation to 230, 280, and 350 mg/m2/day x 3 days. Notably, this dosing regime gave cumulative dosages that were 4 to 5-fold greater than was achieved in solid tumor patients. Annamycin was generally well tolerated with no observed cardiotoxicity. The MTD was determined at 280 mg/m2/day x 3 days with grade 3/4 hepatotoxicity, or liver toxicity, and mucositis, or inflammation and lesions of the oral mucosa, observed at the highest dose levels. Of the 20 treated patients, two achieved complete remission (1 AML at 280 mg/m2/day x 3 days who had failed prior induction therapy, and 1 ALL at 350 mg/m2/day x 3 days). Importantly, fifty percent of all patients cleared their immature white blood

cells, or blasts circulating in their blood stream and 43% cleared the blasts in their bone marrow. The conclusions drawn from the trial were that liposomal Annamycin was safe, well tolerated and showed clinical activity in patients with acute leukemias, and that further evaluation of this novel anthracycline in patients with hematopoietic, or blood borne, malignancies was clearly warranted.

DEVELOPMENT STRATEGY

We expect to commence a trial of liposomal Annamycin in adult relapsed ALL patients at The University of Texas M.D. Anderson Cancer Center in mid-2005 which will include an initial evaluation of a small number of patients (2 cohorts totaling approximately 6 patients) in a Phase I/IIa trial that will be rolled into a larger Phase IIb trial. The clinical trial protocol was submitted to the institutional review board for approval in February 2005. We also expect to commence two additional trials with liposomal Annamycin in 2005, a single agent trial of liposomal Annamycin in pediatric relapsed ALL patients, and a combination trial of liposomal Annamycin in combination with Ara-C in adult relapsed AML patients.

MANUFACTURING

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

ATIPRIMOD TO TREAT MULTIPLE MYELOMA

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 chemical cell signaling 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. Forty-three patients entered the study and remained on the drug as long as 12 months. Clinical laboratory results for all patients were unremarkable, in particular liver enzyme levels remained within the normal range in all patients throughout the study period.

DEVELOPMENT STRATEGY

On May 26, 2004 we commenced a Phase I/IIa clinical trial of Atiprimod in relapsed multiple myeloma patients at two sites, the Dana-Farber Cancer Institute (Boston) and The University of Texas M.D. Anderson Cancer Center (Houston). On January 31, 2005, we announced the opening of two additional sites for the Phase I/IIa clinical trial of Atiprimod, the Roswell Park Cancer Institute in Buffalo, New York, and the St. Vincent's Comprehensive Cancer Center in New York, New York. The clinical trial is an open label study, with the primary objective of assessing safety of drug and identifying the maximum tolerated dose. The secondary objectives are to measure the pharmacokinetics, evaluate the response in patients with refractory disease and to identify possible surrogate responses to the drug to better determine the mechanism of

drug action. The duration of this clinical study depends on the enrollment rate, how well the drug is tolerated, and on drug response, with final results not anticipated until the end of 2005. If Atiprimod produces positive responses, we intend to initiate a Phase IIb trial in relapsed multiple myeloma patients in 2006.

On March 15, 2005 we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The new trial is entitled: "An Open Label Study of the Safety and Efficacy of Atiprimod Treatment for Patients with Advanced Cancer." The primary objective is to assess the safety and determine the maximum tolerated dose of Atiprimod in advanced cancer patients. The secondary objectives are to measure the pharmacokinetics of Atiprimod and evaluate the response in a variety of relapsed solid tumors and hematological malignancies. The trial protocol received IRB approval on February 22, 2005 at The University of Texas M.D. Anderson Cancer Center with Dr. Razelle Kurzrock as the Principal Investigator. Site initiation was completed on March 3, 2005, and patient screening and dosing is anticipated to begin in April, 2005. The duration of this study is expected to depend on the enrollment rate, how well the drug is tolerated and on drug response.

MANUFACTURING

A practical, efficient and cost effective method for producing Atiprimod on a commercial scale was originally developed by SKB. In the course of this work, a new dimaleate salt form was developed. A portion of the 7 kilos of Atiprimod drug substance, available from SKB, was used as the source for generating the Atiprimod dimaleate drug product presently being used in the Phase I/IIa clinical study. Several lots of drug substance were re-qualified to meet current FDA approved release specifications. The full package of fully validated analytical methods developed by SKB was transferred to a contract research organization used by us to perform all analytical tests. One large-scale GMP production run of Atiprimod dimaleate led to the successful release of 10 Kg of material available for future Phase II clinical studies. We plan to enter into a supply contract for Atiprimod with a commercial supplier by the end of 2005.

ORPHAN DRUG STATUS

On January 6, 2004, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of multiple myeloma. 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.

SITE DIRECTED INTERCALATION TECHNOLOGY

On February 24, 2004, we entered into an agreement with Houston Pharmaceuticals,

Inc. ("HPI") to sublicense the rights to a key patent covering a technology platform for site-directed DNA intercalation and we acquired the rights to a patent covering new anthracycline analogs.

The lead inventor on both patents, Dr. Waldemar Priebe, a Professor of Medicinal Chemistry at The University of Texas M.D. Anderson Cancer Center, is an expert in the synthesis of novel anti-cancer compounds. The first patent covers a technology platform for site-directed DNA intercalation, or a compound's ability to insert between the base pairs in DNA. This approach to target intercalator drug candidates to new sites on DNA can potentially provide a new way to attack cancer targets not achievable with older technologies. The second patent covers new anthacycline analogs with increased potency and reduced toxicity. The site-directed intercalation technology is exemplified by the identification of a lead drug candidate, WP760, for melanoma that shows remarkable selectivity for human melanoma cancer cell lines. WP760 is presently being pre-clinically evaluated as a potential drug to treat melanoma.

GUANYLYL CYCLASE RECEPTOR AGONIST TECHNOLOGY

Our guanylyl cyclase receptor agonist (GCRA) program is focused on the control of cyclic GMP, an important second messenger involved in key cellular functions that are tied to inflammation, anti-tumorigenic responses and/or cellular death (apoptosis). Uroguanylin, a hormone produced by and secreted by specialized cells in the human gastrointestinal tract, activates synthesis of cyclic GMP, leading to apoptosis, an important event in the turnover of cells lining the gastrointestinal (GI) tract. Production of uroguanylin is dramatically suppressed in colon cancer patients, and there is increasing evidence that uroguanylin may have GI antiinflammatory properties.

Our GCRA program has resulted in the development of SP304, a biologically functional analog of uroguanylin that has demonstrated superior activity, enhanced temperature and protease stability and superior pH characteristics relative to human uroguanylin. SP304 is currently undergoing pre-clinical evaluation as a treatment for GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of Pittsburgh.

SUPERANTIGEN-BASED BIOTERORRISM DEFENSE

On July 25, 2001, 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.

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

GOVERNMENT REGULATION

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

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

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

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

COMPETITION

The biopharmaceutical industry is characterized by rapidly evolving technology and intense competition. Our competitors include major pharmaceutical and biotechnology companies, most of which 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 $2,817,387 for the year ended December 31, 2004, compared to $1,369,985 for the year ended December 31, 2003 and $491,430 for the year ended December 31, 2002. We expect our research and development expenses to increase in 2005 as our products move into more expensive later stages of development.

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".

PROPRIETARY RIGHTS

We are able to protect our technology from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents or is effectively maintained as a trade secret. Accordingly, patents or other proprietary rights are an essential element of our business. We are the assignee or exclusive licensee of three pending patent applications and 12 issued patents in the United States, and in most cases corresponding patents/applications in foreign countries that we have deemed desirable. 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 liposomal Annamycin and Atiprimod expire in 2008 and 2009, respectively. Our formulation patents for liposomal Annamycin and Atiprimod expire in 2019 and 2018, respectively.

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

On August 28, 2002, Synergy entered into a worldwide license agreement with AnorMED to research, develop, sell and commercially exploit the Atiprimod patent rights. The license agreement provides for aggregate milestone payments of up to $14 million based upon achieving certain regulatory submissions and approvals for an initial indication, and additional payments of up to $16 million for each additional indication based on achieving certain regulatory submissions and approvals. In addition the agreement requires Synergy to pay AnorMED royalties on net sales. Commencing on January 1, 2004 and on January 1 of each subsequent year Synergy is obligated to pay AnorMED a maintenance fee of $200,000 until the

first commercial sale of the product. The first of these annual maintenance fee payments under this agreement was made on January 22, 2004. 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 February 24, 2004, we entered into an agreement with HPI to sublicense the rights to a key patent covering a technology platform for site-directed DNA intercalation and we acquired the rights to a patent covering new anthracycline analogs. We issued to HPI 25,000 shares of common stock at a fair value of $56,250 and reimbursed HPI approximately $103,500 for various costs and expenses. In addition, we granted to HPI 1,170,000 performance based stock options, exercisable at $3.50 per share, which vest upon the achievement of certain milestones. We also agreed to pay HPI royalties of 2% on net sales from any products resulting from commercializing the site-directed DNA intercalation. Pursuant to the sublicense agreement, in the event our Board of Directors determines to abandon its development and commercialization of the site-directed DNA intercalation, HPI shall have the right to terminate the sublicense agreement.

On July 25, 2001, 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 will pay Rockefeller a $7,500 annual maintenance fee until the first commercial sale of the product, plus royalties of 2% and 0.75% of net sales of product depending on whether the product is covered by a claim under the licensed patents or derived from a claim under the licensed patents and will pay Rockefeller 15% of any sublicense fee paid by sublicensees. The agreement will terminate on July 25, 2021. Rockefeller may terminate the license agreement if we are more than 30 days late in paying Rockefeller any amounts due under the license agreement or if we breach the license agreement.

EMPLOYEES

As of March 24, 2005, we had 4 full-time and 2 part-time employees. We believe our employee relations are satisfactory.

AVAILABLE INFORMATION

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

We maintain a site on the world wide web at http://www.callistopharma.com; however, information found on our website is not incorporated by reference into this report. We make available free of charge through our website our Securities and Exchange Commission, or SEC, filings, including our annual report on Form 10-K/A, 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.

RISK FACTORS

YOU SHOULD CAREFULLY CONSIDER THE FOLLOWING RISK FACTORS AND THE OTHER INFORMATION INCLUDED HEREIN AS WELL AS THE INFORMATION INCLUDED IN OTHER REPORTS AND FILINGS MADE WITH THE SEC BEFORE INVESTING IN OUR COMMON STOCK. IF ANY OF

THE FOLLOWING RISKS ACTUALLY OCCURS, OUR BUSINESS, FINANCIAL CONDITION OR RESULTS OF OPERATIONS COULD BE HARMED. THE TRADING PRICE OF OUR COMMON STOCK COULD DECLINE DUE TO ANY OF THESE RISKS, AND YOU MAY LOSE PART OR ALL OF YOUR INVESTMENT.

RISKS RELATED TO OUR BUSINESS

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

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

- demonstration in Phase I/IIa and Phase IIb clinical trials that our two product candidates, Atiprimod for the treatment of relapsed multiple myeloma and 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 Annamycin for the treatment of acute leukemia is expected to enter clinical trials in mid-2005. Our other product candidates are in preclinical development. As a result, if we do not successfully develop and commercialize Atiprimod or 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, 2004, we had an accumulated deficit of $33,361,197. We have incurred losses in each year since our inception in 1996. We incurred a net loss of $7,543,467, $13,106,247 and $1,684,965 for the years ended December 31, 2004, 2003 and 2002, 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, initiate our clinical trials of 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.

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 Annamycin for the treatment of acute leukemias;
- continue the development of our other product candidates;
- finance our general and administrative expenses;
- prepare regulatory approval applications and seek approvals for Atiprimod and Annamycin and our other product candidates;
- license or acquire additional technologies;

- launch and commercialize our product candidates, if any such product candidates receive regulatory approval; and
- develop and implement sales, marketing and distribution capabilities.

In 2004, our cash used in operations increased significantly over 2003 and we expect that our cash used in operations will increase significantly for the next several years. Over the past 12 months, we have spent approximately $4.7 million or approximately $400,000 per month. We expect that our existing capital resources will be sufficient to fund our operations for at least the next 12 months. We will be required to raise additional capital to complete the development and commercialization of our current product candidates. 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. 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 The University of Texas M.D. Anderson Cancer Center license agreement, we are required to make certain good faith expenditures towards the clinical development of at least one licensed product within the two year period after March 2005. In addition, at any time after 5 years from August 12, 2004, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or we are actively and effectively attempting to commercialize Annamycin. 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 have 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. We commenced in May 2004 a Phase I/IIa trial of Atiprimod for the treatment of multiple myeloma. We expect to commence a Phase IIb clinical trial of Annamycin for the treatment of acute leukemias in the first half of 2005. 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, Annamycin. These compounds include Adriamycin(R) and Ellence(R) which are marketed by Pfizer and Cerubidine(R) which is marketed by Boehringer Ingelheim. These drugs have been approved by the FDA and are currently being marketed as opposed to 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 RELATIONSHIPS WITH OUR CONTRACT MANUFACTURER FOR ANNAMYCIN TERMINATES, OR THEIR FACILITIES ARE DAMAGED OR DESTROYED, WE MAY BE UNABLE TO DEVELOP OR COMMERCIALIZE ANNAMYCIN.

Currently, Antibioticos S.p.A. is our sole supplier of Annamycin for our clinical trials. 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 Annamycin, entail higher costs, and could result in our being unable to commercialize 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 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 $2,000,000 annual aggregate limit for up to 40 patients participating in our Atiprimod and prospective Annamycin clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

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

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

restrictions and criminal prosecution. Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing and marketing these products.

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

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

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

a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

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

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

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

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

To date, we have in-licensed or acquired the rights to each of our product candidates. As part of our growth strategy, in addition to developing our current product candidates, we intend to license or acquire additional products and product candidates for development and commercialization. Because we have limited internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license products to us. The success of this strategy depends upon our ability to identify, select and acquire the right pharmaceutical product candidates and products. We currently do not have any intentions to acquire another company.

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

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

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

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

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

We are a small company with 4 full-time and 2 part-time employees as of March 24, 2005. 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 approximately four employees who we expect to assist us with our clinical programs. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

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

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

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

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

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription

drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subject the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products.

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

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

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

As of March 24, 2005, we own 4 issued United States patents and have licensed rights to 8 issued United States patents and 78 issued foreign patents, and to 3 pending United States patent applications and 39 pending foreign patent applications. We do not and have not had any control over the filing or prosecution of these patents or patent applications. We may file additional patent applications and extensions. The issued United States patents we own and license primarily are composition of matter and formulation patents related to Atiprimod and liposomal Annamycin. Our composition of matter patents for

liposomal Annamycin and Atiprimod expire in 2008 and 2009, respectively. Our formulation patents for liposomal Annamycin and Atiprimod expire in 2019 and 2018, respectively.

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;
- 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 you may not be able to resell your shares at or above the price you paid for your shares. In addition, the stock markets in general, and the markets for biotechnology and biopharmaceutical stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock.

WE ARE AT RISK OF SECURITIES CLASS ACTION LITIGATION.

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

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

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

ITEM 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.

Additionally, we currently lease 2,120 square feet of laboratory space located at 7 Deer Park Drive, Suite N, Monmouth Junction, New Jersey through November 2005.

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

ITEM 3. LEGAL PROCEEDINGS.

We are not a party to any pending legal proceedings.

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

There were no matters submitted to a vote of security holders during the three months ended December 31, 2004.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

MARKET INFORMATION

Our common stock has been quoted on the American Stock Exchange under the symbol "KAL" since October 25, 2004. From May 21, 2003 to October 22, 2004, our common stock was quoted on the OTC Bulletin Board under the symbol "CLSP.OB." Prior to May 21, 2003, our common stock was quoted on the OTC Bulletin Board under the symbol "WEBR.OB" but never traded. The following table shows the reported high and low closing prices per share for our common stock as reported on the American Stock Exchange and the OTC Bulletin Board. With respect to the OTC Bulletin Board quotes, these quotations reflect inter-dealer prices, without markup, markdown or commissions and may not necessarily represent actual transactions or a liquid trading market.

2004	HIGH	LOW
Fourth Quarter	$2.08	$1.50

Third Quarter	2.01	1.15
Second Quarter	3.70	1.95
First Quarter	4.25	3.25

2003	HIGH	LOW
Fourth Quarter	$4.05	$3.95
Third Quarter	5.30	3.00
Second Quarter (beginning May 21, 2003)	5.80	4.50

NUMBER OF STOCKHOLDERS

As of March 24, 2005, there were 195 holders of record of our common stock.

DIVIDEND POLICY

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

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K/A. The statements of operations data for the years ended December 31, 2004, 2003 and 2002 and the balance sheet data at December 31, 2004 and 2003 are derived from our audited financial statements which are included elsewhere in this Form 10-K/A. The statement of operations data for the year ended December 31, 2001 and the balance sheet data at December 31, 2002 and 2001 are derived from our audited financial statements which are not included in this Form 10-K/A. The statement of operations data for the year ended December 31, 2000 and the balance sheet data at December 31, 2000 are derived from our unaudited financial statements not included in this Form 10-K/A. The historical results are not necessarily indicative of results to be expected for future periods. The following information is presented in thousands, except per share data.

	FOR THE YEAR ENDIN		
	2004	2003	2002
CONSOLIDATED STATEMENTS OF OPERATIONS DATA:			
Revenues	$ -0-	$ -0-	$ -0-
Operating expenses:			
Research and development	2,817	1,370	491
Government grant	(266)	--	--
Purchased in process research and development	210	6,735	--

Stock-based compensation - research and development	1,508	434	--
General and administrative	2,363	1,398	1,228
Stock-based compensation - general and administrative	1,224	3,400	--
Loss from operations	(7,857)	(13,337)	(1,719
Other income	229	222	--
Interest income	84	9	34
Net loss	$ (7,544)	$ (13,106)	$ (1,685
Net loss per common share -- basic and diluted	$ (0.26)	$ (0.61)	$ (0.10
Weighted average number of common shares outstanding -- basic and diluted	28,485	21,358	17,319

			AS OF DECEMB
	2004	2003	2002
CONSOLIDATED BALANCE SHEET DATA:			
Cash and cash equivalents	$ 5,323	$ 3,956	$ 2,223
Total assets	5,470	4,119	2,272
Total current liabilities	1,220	1,264	440
Accumulated deficit during development stage	(33,361)	(25,818)	(12,711
Total stockholders' equity	$ 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, 2004, we have sustained cumulative net losses of $33,361,197. Our losses have resulted primarily from expenditures incurred in connection with clinical development of licensed products, the purchase of in-process research and development, stock based compensation expense, patent filing and maintenance, outside accounting and legal services and regulatory consulting fees.

From inception through December 31, 2004 we have not generated any revenue from operations. We expect to incur substantial and increasing losses for the next several years as we develop our product candidates, expand our clinical development team and prepare for the commercial launch of our product candidates. We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all.

To date, our sources of cash have been primarily limited to the sale of our equity securities. On March 9, 2005, we completed a private placement of an aggregate 1,985,791 shares of our common stock at a per share price of $1.52, for net proceeds of $2,993,402. The financing was led by certain current institutional shareholders and included certain members of our management. We

have devoted substantially all of our capital resources to the in-licensing and development of our product candidates.

Our research and development expenses consist primarily of costs associated with an in-house research and development laboratory, salaries and staff, application and filing for regulatory approval of our proposed products, purchase of in-process research and development, regulatory and scientific consulting fees, contract research and royalty payments to outside suppliers, facilities and universities as well as legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products. We expense all research and development costs as they are incurred. We expect our research and development expenses to increase significantly in the future as we develop our product candidates.

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

HISTORY

In March 2002, Callisto Pharmaceuticals, Inc. ("Old Callisto") 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 development of two drugs to treat leukemia and multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow). Our lead drug in development for leukemia, Annamycin, earlier completed a Phase I/IIa trial in refractory leukemia patients. We plan to initiate clinical trials in relapsed (failure of prior therapy) leukemia patients in 2005. Our second drug candidate, Atiprimod, is presently in a Phase I/IIa clinical trial in multiple myeloma patients, and is an orally available drug with antiproliferative and antiangiogenic activity. We also have three drugs in preclinical development, WP760, for melanoma, SP304 for gastrointestinal inflammation, and a monoclonal antibody that is being explored as a biodefensive agent against staphylococcal and streptococcal bioweapons.

ANNAMYCIN

On August 12, 2004, we entered into a world-wide license agreement with The University of Texas M.D. Anderson Cancer Center to research, develop, sell and commercially exploit the patent rights for Annamycin, an anthacycline cancer drug for leukemia therapy. Consideration paid for this license amounted to $31,497 for reimbursement of out-of-pocket costs for filing, enforcing and maintaining the Annamycin patent rights and a $100,000 initial license fee. We also agreed to pay The University of Texas M.D. Anderson Cancer Center royalties based on net sales from any licensed products, plus aggregate milestone payments of up to $750,000 based upon achieving certain regulatory submissions and

approvals. The term of the agreement is from August 12, 2004 until November 2, 2019. Under the terms of the license agreement, we are required to make certain good faith expenditures towards the clinical development of at least one licensed product within the two year period after March 2005. In addition, at any time after 5 years from August 12, 2004, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or we are actively and effectively attempting to commercialize Annamycin.

Annamycin was discovered by scientists at The University of Texas M.D. Anderson Cancer Center and initially evaluated in a Phase I clinical trial in 36 patients with relapsed solid tumors, a Phase II clinical trial in 13 patients with doxorubicin-resistant breast cancer, and a Phase I/IIa trial in 20 patients with relapsed/refractory acute myeloid leukemia, or AML and acute lymphocytic leukemia, or ALL. We expect to commence a trial of Annamycin in adult relapsed ALL patients at The University of Texas M.D. Anderson Cancer Center in mid-2005 which will include an initial evaluation of a small number of patients (2 cohorts totaling approximately 6 patients) in a Phase I/IIa trial that will be rolled into a larger Phase IIb trial. The clinical trial protocol was submitted to the institutional review board for approval in February 2005. We also expect to commence two additional trials with Annamycin in 2005, a single agent trial of Annamycin in pediatric relapsed ALL patients, and a combination trial of Annamycin in combination with Ara-C in adult relapsed AML patients.

ATIPRIMOD

On August 28, 2002, Synergy entered into a worldwide license agreement with AnorMED to research, develop, sell and commercially exploit the Atiprimod patent rights. The license agreement provides for aggregate milestone payments of up to $14 million based upon achieving certain regulatory submissions and approvals for an initial indication, and additional payments of up to $16 million for each additional indication based on achieving certain regulatory submissions and approvals. In addition the agreement requires Synergy to pay AnorMED royalties on net sales. Commencing on January 1, 2004 and on January 1 of each subsequent year, Synergy is obligated to pay AnorMED a maintenance fee of $200,000 until the first commercial sale of the product. The first of these annual maintenance fee payments under this agreement was made on January 22,

2004. 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 May 26, 2004, we commenced a Phase I/IIa clinical trial of Atiprimod in relapsed multiple myeloma patients at two sites, the Dana-Farber Cancer Institute (Boston) and The University of Texas M.D. Anderson Cancer Center (Houston). On January 31, 2005, we announced the opening of two additional sites for the Phase I/IIa clinical trial of Atiprimod, the Roswell Park Cancer Institute in Buffalo, New York, and the St. Vincent's Comprehensive Cancer Center in New York, NY. The clinical trial is an open label study, with the primary objective of assessing the safety of the 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 drug to better determine the mechanism of drug action. The duration of this clinical study depends on the enrollment rate, how well the drug is tolerated, and on drug response, with final results not anticipated until the end of 2005. If Atiprimod produces positive responses, we intend to initiate a Phase IIb trial in relapsed multiple myeloma patients in 2006.

On March 15, 2005 we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The new trial is entitled: "An Open Label Study of the Safety and Efficacy of Atiprimod Treatment for Patients with Advanced Cancer". The primary objective is to assess the safety and determine the maximum tolerated dose (MTD) 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 hematologic malignancies. The trial protocol received institutional review board (IRB) approval on February 22, 2005 at The University of Texas M.D. Anderson Cancer Center with Dr. Razelle Kurzrock as the Principal Investigator. Site initiation was completed on March 3, 2005, and patient screening and dosing began in April, 2005. The duration of this study will depend on the enrollment rate, how well the drug is tolerated and on drug response.

SITE DIRECTED INTERCALATION TECHNOLOGY

On February 24, 2004, we entered into an agreement with HPI to sublicense the rights to a key patent covering a technology platform for site-directed DNA intercalation and we acquired the rights to a patent covering new anthracycline analogs. We issued to HPI 25,000 shares of common stock at a fair value of $56,250 and reimbursed HPI approximately $103,500 for various costs and expenses. The total consideration of $159,750 was allocated in full to the HPI patent rights, which have not yet reached technological feasibility, and having no alternative use, was accounted for as purchased in-process research and development expense during the quarter ended March 31, 2004. The fair value of the common stock issued to HPI was $2.25, based on the price per share paid in the April 2004 private placement, which closed on April 19, 2004.

In addition, we granted to HPI 1,170,000 performance based stock options, exercisable at $3.50 per share, which vest upon the achievement of certain milestones. If the milestones are achieved, we will record additional purchased in-process research and development expense based upon the fair value of the options at that time. We also agreed to pay HPI royalties of 2% on net sales from any products resulting from commercializing the site-directed DNA intercalation. Pursuant to the sublicense agreement, in the event our Board of Directors determines to abandon its development and commercialization of the site-directed DNA intercalation, HPI shall have the right to terminate the sublicense agreement. The technology platform for site-directed DNA intercalation is exemplified by the identification of a lead drug candidate, WP760, for melanoma that shows remarkable selectivity for human melanoma cancer cell lines. We are presently evaluating this drug pre-clinically in animal models of human melanoma, and based on these results plan to make a decision in 2005 on further development of WP760.

GUANYLYL CYCLASE RECEPTOR AGONIST TECHNOLOGY

Our GCRA program has resulted in the development of SP304, a biologically functional analog that has demonstrated superior biological activity, enhanced temperature and protease stability and superior pH characteristics relative to human uroguanylin. SP304 is currently undergoing pre-clinical evaluation as a treatment for GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of Pittsburgh. Based on these animal studies, we plan in 2005 to make a decision on moving this drug forward into the clinic.

SUPERANTIGEN-BASED BIOTERORRISM DEFENSE

On July 25, 2001, 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 will pay Rockefeller a $7,500 annual maintenance fee until the

first commercial sale of the product, plus royalties of 2% and 0.75% of net sales of product depending on whether the product is covered by a claim under the licensed patents or derived from a claim under the licensed patents and will pay Rockefeller 15% of any sublicense fee paid by sublicensees. The agreement will terminate on July 25, 2021. Rockefeller may terminate the license agreement if we are more than 30 days late in paying Rockefeller any amounts due under the license agreement or if we breach the license agreement.

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

MANUFACTURING

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

provides that the parties will negotiate in good faith towards a commercial supply agreement for Annamycin. If our relationship with this contract manufacturer, or any other contract manufacturer we might use, terminates or if any of their facilities are damaged for any reason, including fire, flood, earthquake or other similar event, we may be unable to obtain supply of Annamycin. If any of these events were to occur, we may need to find alternative manufacturers or manufacturing facilities. The number of contract manufacturers with the expertise, required regulatory approvals and facilities to manufacture Annamycin on a commercial scale is extremely limited, and it would take a significant amount of time to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must approve these manufacturers' facilities and processes prior to our use, which would require new testing and compliance inspections. In addition, we may not have the intellectual property rights, or may have to share intellectual property rights, to any improvements in the current manufacturing processes or any new manufacturing processes for Annamycin. Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of Annamycin, entail higher costs, and could result in our being unable to commercialize Annamycin successfully.

One large-scale GMP production run of Atiprimod dimaleate led to the successful release of 10 Kg of material available for future Phase II clinical studies. We plan to enter into a supply contract for Atiprimod with a commercial supplier by the end of 2005.

EMPLOYEES

Our plan is to use contract research organizations (CROs) for most of our development efforts, including monitoring of clinical trial results, thus minimizing the need to hire full time employees. As of March, 24, 2005, we had 4

full-time and 2 part-time employees.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of December 31, 2004.

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/A for the fiscal year ended December 31, 2004. The financial statements are prepared in accordance with accounting principles generally accepted in the United States of America, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Accounting for stock based compensation: We have adopted Statement of Financial Accounting Standard No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). As provided for by SFAS 123, we have also elected to account for our stock-based compensation programs according to the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25")." Accordingly, compensation expense has been recognized based on the intrinsic value of stock issued or options granted to employees and directors for services rendered. Other stock based compensation associated with grants to non-employees, as well as Directors who perform services outside of their Board duties, is measured using the fair value method. We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options is designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage. Since inception through December 31, 2004 stock based compensation expense totaled $11,351,272, or approximately one third of our accumulated deficit.

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

The single most significant factor impacting our operating results is the price of our stock which is used in the computation of stock-based compensation expense, particularly for variable options. Our stock price fluctuated from $3.95 per share as of December 31, 2003 to $1.98 per share as of December 31, 2004. As of December 31, 2004, 428,500 of our non-employee options required variable accounting treatment in accordance with FASB Interpretation No. 44 "Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25" ("FIN 44"). Our stock-based compensation expense associated with these non-employee variable options during the twelve months ended December 31, 2003 was $1,108,817, whereas we reversed $816,865 of this expense during the twelve months ended December 31, 2004 due entirely to the fluctuation in our stock price.

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, 2004 AND DECEMBER 31, 2003.

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

We had no revenues during the twelve months ended December 31, 2004 and 2003 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses increased approximately $1,447,402, or 106%, to $2,817,387 for the twelve months ended December 31, 2004 from $1,369,985 for the twelve months ended December 31, 2003. The single most significant factor contributing to this increase in research and development expense was approximately $500,000 in higher costs associated with the commencement of our Phase I/IIa clinical trials of Atiprimod in May of 2004. These clinical trial expenses included patient costs, drug formulation and tableting, data collection, monitoring, insurance, and FDA consultants. During the twelve month period ended December 31, 2003 our Atiprimod project expenses were pre-clinical in nature, associated with preparing our IND application. Also contributing to this increase in research and development expense in the twelve months ended December 31, 2004 were our payments of the first annual $200,000 maintenance fee to AnorMED, Inc. for the Atiprimod license In addition personnel costs increased approximately $300,000 as we retained two Synergy executive staff scientists, Drs. Picker and Shailubhai, subsequent to the Merger and we incurred $137,000 of costs to develop a new GMP certified commercial production capacity for future trials of Atiprimod. The remainder of the increase was primarily attributable to $160,000 of higher expenses paid to outside collaborating institutions under our government research grant for Atiprimod.

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

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

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

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

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

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

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

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

the twelve months ended December 31, 2004, as compared to $3,833,946 recorded during the same period ended December 31, 2003.

YEARS ENDED DECEMBER 31, 2003 AND DECEMBER 31, 2002.

We had no revenues during the twelve months ended December 31, 2003 and December 31, 2002 because we did not have any commercial biopharmaceutical products.

Research and development expenses increased $878,555 or 179% to $1,369,985 for the twelve months ended December 31, 2003 from $491,430 for the same period in 2002. The results of operations of Synergy for the period May 1, 2003 through December 31, 2003 are included in the consolidated statement of operations for the year ended December 31, 2003, and are not included in the results of 2002. Of this increase in research and development expense, approximately 63% or $556,000 was attributable to costs associated with preparing and filing our IND application for

Atiprimod in September of 2003. These IND application related costs included quantitative analysis and synthesis, as well as pre-clinical management consulting fees paid to contract research organizations to develop and advise on IND application requirements, proposed clinical trial protocols, site selection and principal investigator contracting. Also contributing to this increase in research and development expense were higher salaries and wages, which increased approximately $200,000 as we retained two key executive staff scientists from Synergy. The remainder of this increase in research and development was primarily due to the acquisition of the Synergy research laboratory facility in conjunction with the Merger. No such expenses were incurred in 2002. Our research and development expenses were primarily incurred negotiating and doing due diligence in anticipation of the Merger and maintaining our existing superantigen-based bioterrorism defense patents licensed from Rockefeller University.

During the twelve months ended December 31, 2003 we also incurred $6,734,818 of net purchased in-process research and development expense related to the Merger. There was no such expense during the twelve months ended December 31, 2002.

General and administrative expenses for the twelve months ended December 31, 2003 of $1,398,090 increased $170,391 or 14% from the $1,227,699 we incurred for the twelve months ended December 31, 2002. During 2002, we recorded a charge of $400,000 associated with the purchase of Webtronics. Excluding this $400,000 charge in 2002, the increase in general and administrative expenses was $570,391 or 69% from 2002 to 2003 primarily from higher legal, accounting and professional fees incurred in connection with the Merger, regulatory filings, insurance and travel associated with fund raising activities during 2003.

Stock-based compensation expense recorded during the twelve months ended December 31, 2003, totaled $3,833,946 as compared to $332 recorded during the twelve months ended December 31, 2002. This increase was primarily attributable to options issued in connection with the Merger, to retain several key Synergy scientists, at approximately the same time our shares of common stock commenced trading on the OTC Bulletin Board on June 17, 2003. The remaining balance of unamortized deferred stock based compensation expense, presented in the stockholder's equity section of our December 31, 2003 Balance Sheet, totaled $5,480,007.

During December 2003 Synergy sold certain New Jersey State tax loss carry forwards under a state economic development program for cash of approximately $222,000, the proceeds of which have been and will be used to support research

and development activities in New Jersey. This state tax benefit was recorded as Other Income during the fourth quarter ended December 31, 2003 and there was no such benefit in 2002.

Net loss for the twelve months ended December 31, 2003 was $13,106,247 compared to a net loss of $1,684,965 incurred for the twelve months ended December 31, 2002.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2004 we had $5,323,384 in cash and cash equivalents, compared to $3,956,486 as of December 31, 2003. This increase in cash of $1,366,898 during the twelve months ended December 31, 2004 was principally the result of completing two private placements of common stock yielding net proceeds of $6,099,012. This was partially offset by cash used in operating activities of $4,732,114 during the twelve months ended December 31, 2004. Cash used in operating activities was primarily for research and development and general and administrative expenses discussed above totaling $5,180,160, less $265,697 in government grant funding and $233,382 in cash received from the sale of certain New Jersey State tax loss carry forwards under a state economic development program.

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 have agreed to file a registration statement covering resale of the shares within 30 days of closing.

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

In January 2004, we completed a private placement begun in late 2003 and issued 1,128,766 shares of common stock at an issue price of $1.50 for aggregate proceeds of $1,693,149, less $139,891 in fees to various selling agents. In addition, we incurred and issued 31,467 shares of common stock and an aggregate 370,543 warrants to purchase common stock to such selling agents. The warrants are immediately exercisable at $1.90 per share and will expire five years after issuance.

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 studies began in early 2004 and were completed in November 2004. Funding for the total amount of this grant was received during 2004 and has been reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grant".

Our capital resources will be focused primarily on the clinical development and regulatory approval of Annamycin for acute leukemia and Atiprimod for multiple myeloma and bone resorption disease, a major complication associated with multiple myeloma disease. 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.

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. 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 expect that our existing capital resources will be sufficient to fund our operations for at least the next 12 months.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following is a summary of our significant contractual cash obligations for the periods indicated that existed as of December 31, 2004, 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 t 5 Yea
Operating leases - facilities	$1,048,092	$ 193,552	$ 300,077	$ 312,200	$242,2
Minimum spending obligations(1)	5,045,000	1,009,000	2,018,000	2,018,000	
License royalty payments (2)	1,037,500	207,500	415,000	415,000	
Total obligations	$7,130,592	$1,410,052	$2,733,077	$2,745,200	$242,2

(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 annual royalty payments of $200,000 to AnorMED, Inc. for our Atiprimod license and $7,500 to Rockefeller University for our superantigen-based bioterrorism defense patents. 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.

(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 royalty payments will cease

RECENT ACCOUNTING PRONOUNCEMENTS:

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard ("SFAS") No. 123 (Revised 2004), "Share-Based Payment." SFAS No 123R is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation" and supersedes Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees" and its related implementation guidance. SFAS No. 123R focuses primarily on accounting for transactions in which an entity obtains employee services through share-based payment transactions. SFAS No 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 cost will be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS No. 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. While we cannot precisely determine the impact on net loss as a result of the adoption of SFAS No 123R, estimated compensation expense related to prior periods can be found in footnote 3 to our audited consolidated financial statements.

In December 2004, the FASB issued SFAS 153, "Exchanges of Nonmonetary Assets", which is effective for fiscal years beginning after June 15, 2005. SFAS 153 amends APB 29, "Accounting for Nonmonetary Transactions", which is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB 29 included certain exceptions to that principle. SFAS 153 amends APB 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The adoption of this statement is not expected to have a material effect on our financial position or results of operations.

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

At December 31, 2004 and 2003, a substantial portion of our cash and cash equivalents consists of short term, highly liquid investments in a money market fund managed by a large money center bank (JPMorganChase). Maturities of fund investments are all less than three months.

ITEM 8. FINANCIAL STATEMENTS.

The full text of our audited consolidated financial statements as of December 31, 2004 and 2003 and for the fiscal years ended December 31, 2004, 2003 and 2002 begins on page F-1 of this Annual Report on Form 10-K/A.

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

Not applicable

25

ITEM 9A. CONTROLS AND PROCEDURES.

Our Chief Executive Officer and Principal Financial Officer, based on 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, 2004, have concluded that our disclosure controls and procedures were effective to ensure

the timely collection, evaluation and disclosure of information relating to our company that would potentially be subject to disclosure under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated there under.

There were no significant change in our internal controls over financial reporting that could significantly affect internal controls over financial reporting during the quarter ended December 31, 2004.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The following table sets forth certain information regarding the directors and executive officers of Callisto Pharmaceuticals, Inc. as of March 24, 2005:

Name	AGE	POSITIONS
Gabriele M. Cerrone	33	Chairman of the Board
Gary S. Jacob	58	Chief Executive Officer, Chief Scientific Officer and Director; Chairman of Synergy Pharmaceuticals Inc.
Donald H. Picker	59	Executive Vice President, R&D
Bernard F. Denoyer	57	Vice President, Finance
Kunwar Shailubhai	47	Senior Vice President, Drug Discovery of Synergy Pharmaceuticals Inc.
Christoph Bruening	37	Director
Iain G. Ross	51	Director
Edwin Snape	65	Director
John P. Brancaccio	57	Director
Stephen K. Carter	66	Director
Randall Johnson	58	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.

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.

Donald H. Picker, Ph.D. has served as our Executive Vice President, R&D since April 2004. From May 2003 until March 2004, Dr. Picker served as Senior Vice President, Drug Development. Dr. Picker was Chief Executive Officer and President of Synergy Pharmaceuticals Inc. and a member of its board of directors

from September 1999 to April 2003. From February 1997 to September 1999, Dr. Picker was President and Chief Operating Officer of LXR Biotechnology Inc., an apoptosis drug development company. From 1991 to 1997, he was Senior Vice President of Research and Development at Genta Inc., an antisense drug development company. Dr. Picker is also a director of Xenomics, Inc., a public medical diagnostics company.

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. 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. Mr. Denoyer is also Vice President, Controller of Xenomics, Inc., a public medical diagnostics company.

Kunwar Shailubhai, Ph.D., has served as Senior Vice President, Drug Discovery of Synergy Pharmaceuticals Inc. since April 2004. From May 2003 until March 2004, Dr. Shailubhai served as our Executive Vice President. From 2001 to April 2003, Dr. Shailubhai held the position of Vice

President, Drug Discovery at Synergy Pharmaceuticals Inc. Between 1993 and 2000, he was affiliated with Monsanto Company as Group Leader of the cancer chemoprevention group during which time he was involved in several cancer research projects.

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 and is a director of Xenomics, Inc., a public medical diagnostics company.

Iain G. Ross has served as a Director of our company since June 2003. Mr. Ross has been Chairman of Biomer Technology Ltd., SR Pharma plc and Ozone Industries Ltd since January 2003, July 2004 and March 2005, respectively, and serves as a director of a number of healthcare technology companies including Angle plc, Eden Biopharm Group, Swedish DIA (Sweden) AB and Procognia Ltd. Mr. Ross is an advisor to Apax Partners and PPM Ventures in London. From 2001 to 2002, Mr. Ross was Chairman and Chief Executive Officer of Allergy Therapeutics Ltd. and from 1995 to 2000, Mr. Ross was Chief Executive Officer of Quadrant Healthcare plc, which was sold to Elan Corporation in 2000.

Edwin Snape, Ph.D. has served as a Director of our company since May 2003. Dr. Snape has been a principal at New England Partners, a private equity firm since 1999. Previously, he was Managing General Partner of the Vista Group, an international private equity firm. Dr. Snape is Chairman of Memry Corporation and a director of Deltex Medical Holdings, Inc. and Diomed, Inc.

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

companies. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. Mr. Brancaccio is currently a director of Alfacell Corporation.

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

Each of our directors is entitled to receive a cash payment of $5,750 per calendar quarter. Messrs. Cerrone, Snape and Jacob have waived their right to such payments. Upon their appointment to the Board of Directors, each of our directors received a grant of 75,000 stock options to purchase common stock which vest over a period of three years from the date of grant.

AUDIT COMMITTEE

The Audit Committee currently consists of John Brancaccio, chairman of the Audit Committee, and Christoph Bruening. 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 Audit Committee met four times in 2004. 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 the Company's web site www.callistopharma.com

The Audit Committee's responsibilities include: (i) reviewing the independence, qualifications, services, fees, and performance of the independent auditors, (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.

COMPENSATION COMMITTEE

We have a Compensation Committee currently consisting of Iain Ross, 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 Compensation Committee met three times in 2004. 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 the Company's web site www.callistopharma.com.

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 the Company; assuring that the executive officers are compensated effectively in a manner consistent with the stated compensation strategy of the Company; 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 the Company's incentive plans and benefit programs and monitoring of compliance with the legal prohibition on loans to directors and executive officers of the Company.

27

CORPORATE GOVERNANCE/NOMINATING COMMITTEE

We have a Corporate Governance/Nominating Committee currently consisting of Stephen Carter, 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 Corporate Governance/ Nominating Committee was designated by the Board of Directors in January 2005 and did not meet in 2004. 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 the Company's web site www.callistopharma.com.

As set forth in the Corporate Governance/Nominating Committee charter, 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.

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:

Robert A. Kyle, M.D. Dr. Kyle is the Chairman of our scientific advisory board and is Professor of Medicine and Laboratory Medicine at Mayo Medical School. He served as the William H. Donner Professor of Medicine at Mayo Medical School. He was previously Section Head of the Division of Hematology and subsequently, Chairman of the Division of Hematology at Mayo Clinic, and served as Secretary-General of the International Society of Hematology. He is currently on

the Board of Directors and is Chairman of the Scientific Advisory Board of the International Myeloma Foundation. Dr. Kyle's research interests include the biology and management of multiple myeloma, amyloidosis and monoclonal gammopathy of undetermined significance. Dr. Kyle has received a number of awards including the Waldenstrom Award for Myeloma Research, Henry S. Plummer Distinguished Internist Award and the Distinguished Clinician Award from Mayo Clinic.

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.

Moshe Talpaz, M.D. Dr. Talpaz currently holds the titles of 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.

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 2004, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with.

CODE OF BUSINESS CONDUCT AND ETHICS

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

ITEM 11. EXECUTIVE COMPENSATION.

SUMMARY COMPENSATION TABLE

The following summary compensation table sets forth certain information concerning compensation paid to our Chief Executive Officer and our two most highly paid executive officers (the "Named Executive Officers") for services rendered in all capacities as of December 31, 2004.

		Annual Compensation		Long Term Compensation
Name and Principal Position	Year	Salary ($)	Bonus ($)	Securities Underlying Options (#)
Gary S. Jacob Chief Executive Officer and Chief Scientific Officer	2004 2003	$225,000 $144,792	$33,750 $0	275,000 500,000
Donald H. Picker Executive Vice President, R&D	2004 2003	$191,875 $126,661	$37,500 $10,000	400,000 325,000
Kunwar Shailubhai Senior Vice President, Drug Discovery of Synergy Pharmaceuticals, Inc.	2004 2003	$155,333 $110,833	$0 $0	100,000(1) 350,000(2)

(1) On April 6, 2004, Dr. Shailubhai entered int o an employment agreement with Synergy Pharmaceuticals Inc. and was granted 100,000 stock options exercisable at $1.50 per share, 50,000 of such stock options vest in June 2004 and the remainder vest in December 2004.

(2) All of such stock options were granted on June 13, 2003 pursuant to an employment agreement entered into with us at that time. On April 6, 2004, the employment agreement was terminated and 325,000 unvested stock options were canceled.

OPTION GRANTS IN FISCAL YEAR 2004

The following table sets forth certain information concerning grants of stock options to the Named Executive Officers during the fiscal year ended December 31, 2004.

	Number of Shares	Percent of Total

Name	Underlying Options Granted	Options Granted to Employees in 2004	Exercise Price Per Share	Exp
Gary S. Jacob Chief Executive Officer and Chief Scientific Officer	275,000 (1)	29.4%	$3.00	6/
Donald H. Picker Executive Vice President, R&D	400,000 (2)	42.8%	$3.00	6/
Kunwar Shailubhai Senior Vice President, Drug Discovery of Synergy Pharmaceuticals, Inc.	100,000 (3)	10.7%	$1.50	4/

(1) 25,000 options vest on 6/1/2005; 25,000 options vest on 6/1/2006 and 50,000 options vest on 6/1/2007. The remaining 175,000 options vest based on the achievement of certain performance milestones.

(2) 50,000 options vest on 6/1/2005; 50,000 options vest on 6/1/2006 and 75,000 options vest on 6/1/2007. The remaining 225,000 options vest based on the achievement of certain performance milestones.

(3) 50,000 of such stock options vested in June 2004 and the remainder vested in December 2004.

On April 26, 2004, we granted 100,000 stock options to Gabriele M. Cerrone, Chairman of the Board, in recognition of his efforts during the past year on behalf of the company. The stock options are immediately exercisable at $3.20 per share.

AGGREGATED OPTION EXERCISES IN 2004 AND YEAR END OPTION VALUES

The following table provides certain information with respect to the Named Executive Officers concerning the exercise of stock options during the fiscal year ended December 31, 2004 and the value of unexercised stock options held as of such date.

	Number of Shares Underlying Options at December 31, 2004		Value of Unexercised In the Money Options at December 31, 2004(1)	
Name	Exercisable	Unexercisable	Exercisable	Unexercisable
Gary S. Jacob Chief Executive Officer and Chief Scientific Officer	150,000	625,000	$72,000	$168,000
Donald H. Picker Executive Vice President, R&D	83,333	641,667	$40,000	$116,000
Kunwar Shailubhai	125,000	0	$60,000	--

Senior Vice President,
Drug Discovery of Synergy
Pharmaceuticals, Inc.

During the fiscal year ended December 31, 2004, no options were exercised.

(1) Amounts calculated by subtracting the exercise price of the options from the market value of the underlying common stock using the closing sale price on the American Stock Exchange of $1.98 per share on December 31, 2004.

MANAGEMENT AGREEMENTS

On June 13, 2003, we entered into an employment agreement with Gary S. Jacob, Ph.D., to serve as our Chief Executive Officer and Chief Scientific Officer. Dr. Jacob's employment agreement is for a term of 18 months beginning June 13, 2003 and is automatically renewable for successive one year periods at the end of the term. Dr. Jacob's salary is $225,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. In connection with his employment agreement, Dr. Jacob received a grant of 500,000 stock options which vest over a three year period and are exercisable at $1.50 per share.

On September 23, 2003, we entered into an employment agreement with Donald H. Picker, Ph.D., to serve as Vice President, Drug Development. The employment agreement is for a term of 18 months beginning September 23, 2003 and is automatically renewable for successive one year periods at the end of the term. Dr. Picker's salary is $175,000 per year and he is eligible to receive a cash bonus of up to $45,000 per year upon the achievement of certain performance milestones. In connection with his employment agreement, Dr. Picker received a grant of 325,000 stock options which vest over a three year period and are exercisable at $1.50 per share. On April 6, 2004, Dr. Picker's employment agreement was amended to change his title to Executive Vice President, R&D and his salary was increased to $200,000 per year and certain milestones were added upon which cash bonuses of up to $92,500 over a 12 month period may be paid. During the twelve months ended December 31, 2004, Dr. Picker was paid a bonus $37,500 based on certain milestones he achieved during 2004. The balance of the annual bonus Dr. Picked is eligible to receive will be paid only if and when certain other milestones are reached.

On January 15, 2004, we entered into an employment agreement with Bernard Denoyer, our Vice President, Finance. Mr. Denoyer's employment agreement is for a term of 12 months beginning January 15, 2004 and is automatically renewable for successive one year periods at the end of the term. Mr. Denoyer's salary is $90,000 per year and he is eligible to receive a cash bonus of up to 10% of his salary per year. Mr. Denoyer received a grant of 100,000 stock options which vest over a three year period and are exercisable at $3.60 per share.

On April 6, 2004, Kunwar Shailubhai, Ph.D. entered into an employment agreement with Synergy in which he agreed to serve as Senior Vice President, Drug Discovery. Dr. Shailubhai's employment agreement is for a term of 12 months beginning April 6, 2004 and is automatically renewable for successive one year periods at the end of the term. Dr. Shailubhai's salary is $150,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. Dr. Shailubhai received a grant of 100,000 stock options which are exercisable at $1.50 per share. 50,000 of such stock options vest in June 2004 and the remainder vest in December 2004. We previously had an employment agreement dated June 13, 2003 with Kunwar Shailubhai, Ph.D. to serve as Executive Vice President and Head of Research and Development for a term of 18 months beginning June 13, 2003. Dr. Shailubhai's salary was $170,000 per year and he was eligible to receive a cash bonus of up to 15% of his salary per year. In connection with his employment agreement, Dr. Shailubhai received a grant of 25,000 stock options which were fully vested and have an exercise price of $1.50 per share. Dr.

Shailubhai also received a grant of 325,000 stock options which were to have vested over a three year period and were exercisable at $1.50 per share. This employment agreement was terminated on April 6, 2004 and unvested options were forfeited. The new grant of 100,000 options will be subject to variable accounting because it was deemed that his agreement was a continuation of employment with a wholly owned subsidiary of Callisto.

On December 27, 2004, we entered into a consulting agreement with Gabriele M. Cerrone, our Chairman of the Board and a principal stockholder. The duties of Mr. Cerrone pursuant to the agreement will consist of business development, strategic planning, capital markets and corporate financing consulting advice. The term of the agreement commenced on January 10, 2005 and continues until December 31, 2006 with automatic renewal for successive one year periods unless either party gives notice to the other not to renew the agreement.

We will pay Mr. Cerrone an annual fee of $205,000 on a monthly basis. In addition, Mr. Cerrone received a grant of 375,000 ten year non-qualified stock options pursuant to our Stock Option Plan at an exercise price of $1.70 per share. One half of such options will vest on each of the first two anniversaries of the date of the agreement

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 December 22, 2004 our Board of Directors, acting upon advice of the Compensation Committee, awarded Mr. Cerrone a cash bonus of $200,000 in recognition of his contributions to the company including negotiation and acquisition of certain intellectual property licenses during 2004.

STOCK OPTION PLAN

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.

The stock option plan authorizes the grant of stock options to 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.

As of December 31, 2004, options for 3,177,222 shares were outstanding under our stock option plan, and options for 6,822,778 shares remain available for future grants. The options we grant under the 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. The stock option plan is not a qualified deferred compensation plan under Section 401(a) of the Code, and is not subject to the provisions of the Employee Retirement Income Security Act of 1974, as amended (ERISA). In addition, as of December 31, 2004, we have granted 4,144,838 stock options not subject to the stock option plan.

The following table summarizes information about our equity compensation plans as of December 31, 2004.

EQUITY COMPENSATION PLAN INFORMATION

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options
	(a)	(b)
Equity Compensation Plans Approved by Stockholders	3,177,222	$2.27
Equity Compensation Plans Not Approved by Stockholders	4,144,838	$2,14
Total	7,322,060	$2.19

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of March 24, 2005 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	2,976,237(2)	9.3%
Gary S. Jacob Chief Executive Officer, Chief Scientific Officer and Director	274,745(3)	*
Donald H. Picker Executive Vice President, R&D	172,037(4)	*
Kunwar Shailubhai Senior Vice President, Drug Discovery of Synergy Pharmaceuticals Inc.	125,000(5)	*
Iain G. Ross Director	25,000(6)	*
Edwin Snape Director	939,402(7)	3.0%
Stephen Carter Director	0	
Christoph Bruening Director	460,699(8)	1.5%
John Brancaccio Director	25,000(9)	*
Randall K. Johnson Director	10,000(10)	*
All Directors and Executive Officers as a group (11 persons)	5,038,120(11)	15.5%
Donald G. Drapkin	1,766,059(12)	5.6%
Panetta Partners Ltd.	2,101,237	6.7%

* less than 1%

(1) Applicable percentage ownership as of March 24, 2005 is based upon 31,228,893 shares of common stock outstanding. Beneficial ownership is determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended. Under Rule 13d-3, shares issuable within 60 days upon exercise of outstanding options, warrants, rights or conversion privileges ("Purchase

Rights") are deemed outstanding for the purpose of calculating the number and percentage owned by the holder of such Purchase Rights, but not deemed outstanding for the purpose of calculating the percentage owned by any other person. "Beneficial ownership" under Rule 13d-3 includes all shares over which a person has sole or shared dispositive or voting power.

(2) Consists of 875,000 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone and 2,101,237 shares held by Panetta Partners, Ltd. Mr. Cerrone is the sole general partner of Panetta and in such capacity only exercises voting and dispositive control over securities owned by Panetta. As such, Mr. Cerrone may be deemed, solely for purposes of Section 13(d) of the Securities Exchange Act of 1934 as amended, to "beneficially" own securities in which he has no pecuniary interest and he therefore disclaims such beneficial interest.

(3) Includes 150,000 shares of common stock issuable upon exercise of stock options.

(4) Includes 83,333 shares of common stock issuable upon exercise of stock options.

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

(6) Consists of 25,000 shares of common stock issuable upon exercise of stock options.

(7) Includes 25,000 shares of common stock issuable upon exercise of stock options. 914,402 of such shares are held by NEGF II, L.P. and New England Partners Capital, L.P.. Mr. Snape is a principal of NEGF II, L.P. and New England Partners Capital, L.P.

(8) Includes 25,000 shares of common stock issuable upon exercise of stock options.

(9) Consists of 25,000 shares of common stock issuable upon exercise of stock options.

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

(11) Includes 1,373,333 shares of common stock issuable upon exercise of stock options.

(12) Includes 250,000 shares of common stock issuable upon exercise of stock options held by Mr. Drapkin and 916,059 shares of common stock held by the Drapkin Family Charitable Foundation.

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. The agreement and its 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 report.

On March 9, 2005 certain members of management, in addition to certain current institutional investors, purchased an aggregate 1,985,791 shares of our common stock in a private placement. The shares were sold at a price of $1.52 per share for aggregate proceeds of approximately $3.02 million. Panetta Partners, Ltd., a principal shareholder and limited partnership, of which Mr. Cerrone is the sole managing partner, purchased 25,000 shares in the private placement. In such

capacity Mr. Cerrone exercises voting and dispositive control over shares owned by Panetta in which he has no pecuniary interest. In addition, Gary S. Jacob, our Chief Executive Officer purchased 16,448 shares in the private placenment and Christoph Bruening, a director, purchased 20,000 shares in the private placement. Each did so at the specific request of the institutional investors.

In connection with the sale of our common stock to certain members of management in the private placement, our Audit Committee determined that participation by such members of management in the private placement (i) did not constitute a conflict of interest under our Code of Business Conduct and Ethics and (ii) was on term no less favorable to the company than terms offered to third parties.

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.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

AUDIT FEES.

The aggregate fees billed and unbilled for the fiscal year ended December 31, 2004 for professional services rendered by our principal accountants for the audits of our annual financial statements and the review of our financial statements included in our quarterly reports on Form 10-QSB were $95,000. The aggregate fees billed and unbilled for the fiscal year ended December 31, 2003 for professional services rendered by our principal accountants for the audit of our annual financial statements, the reaudit of the 2002 and 2001 financial statements, and the review of our financial statements included in our quarterly reports on Form 10-QSB were $153,000.

AUDIT-RELATED FEES.

The aggregate fees billed for the fiscal year ended December 31, 2004 and 2003 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 $2,500 in each period.

TAX AND OTHER FEES.

There were no aggregate fees billed for the fiscal years ended December 31, 2004 and 2003 as there were no tax related or other services rendered by our principal accountants in connection with the preparation of our federal and state tax returns.

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

audit and permissible non-audit services provided by our principal accountants. Our Audit Committee pre-approves these services by category and service. Our Audit Committee has pre-approved all of the services provided by our principal accountants.

ITEM 15. EXHIBITS.

(a) Exhibits

Exhibit Number	Description
2.1	Agreement and Plan of Merger by and among Callisto Pharmaceuticals, Inc., Webtronics, Inc., Callisto Acquisition Corp., Synergy Pharmaceuticals Inc. and Synergy Acquisition Corp. dated as of March 10, 2003 (1)
2.2	Amendment to Agreement and Plan of Merger dated as of April 4, 2003 (2)
3.1	Certificate of Incorporation (3)
3.2	Bylaws (4)
4.1	1996 Incentive and Non-Qualified Stock Option Plan (5)
4.2	Form of Warrant to purchase shares of common stock issued in connection with the sale of common stock (6)
10.1	Employment Agreement dated June 13, 2003 by and between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (7)*
10.2	Employment Agreement dated April 6, 2004 by and between Synergy Pharmaceuticals Inc. and Kunwar Shailubhai (8)*
10.3	Employment Agreement dated June 13, 2003 by and between Callisto Pharmaceuticals, Inc. and Donald H. Picker (9)*
10.4	Amendment to Employment Agreement dated April 6, 2004 by and between Callisto Pharmaceuticals, Inc. and Donald H. Picker (10)*
10.5	License Agreement dated as of August 28, 2002 by and between Synergy Pharmaceuticals Inc. and AnorMED Inc.(11)**
10.6	Employment Agreement dated January 15, 2004 by and between Callisto Pharmaceuticals, Inc and Bernard Denoyer (12)*
10.7	Form of Registration Rights Agreement dated as of January 21, 2004 by and among the Registrant and the Purchasers set forth on the signature page thereto (13)
10.8	Common Stock Purchase Agreement dated as of April 19, 2004, by and between Callisto Pharmaceuticals, Inc. and the Purchasers set forth on Exhibit A thereto. (14)

Exhibit Number	Description
10.9	Patent and Technology License Agreement dated August 12, 2004 by and between The Board of Regents of the University of Texas System, on behalf of The University of Texas M. D. Anderson Cancer Center and Callisto Pharmaceuticals, Inc. (15)**
10.10	Consulting Agreement dated as of December 27, 2004 between the Registrant and Gabriele M. Cerrone. *+
10.11	Common Stock Purchase Agreement dated as of March 8, 2005 by and between Callisto Pharmaceuticals, Inc. and the Purchasers set forth on Exhibit A thereto. (16)
10.12	License Agreement between Callisto Pharmaceuticals, Inc. and The Rockefeller University effective as of July 25, 2001.
10.13	Asset Purchase Agreement dated as of February 24, 2004 between Callisto Pharmaceuticals, Inc. and Houston Pharmaceuticals, Inc.
10.14	Sublicense Agreement dated as of February 24, 2004 between Callisto Pharmaceuticals, Inc. and Houston Pharmaceuticals, Inc.
10.15	Agreement among Davos Chemical Corporation, Callisto Pharmaceuticals, Inc. and Antibioticos S.p.A. dated July 28, 2004.
14	Code of Business Conduct and Ethics (17)
21	List of Subsidiaries+
23	Consent of BDO Seidman, LLP
31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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

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

\+ Previously filed.

(1) Incorporated by reference to Exhibit 2.1 filed with the Company's Current Report on Form 8-K filed on March 19, 2003.

(2) Incorporated by reference to Exhibit 2.2 filed with the Company's Current Report on Form 8-K filed on April 30, 2003.

(3) Incorporated by reference to Exhibit 99.1 filed with the Company's Current Report on Form 8-K filed on May 28, 2003.

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

(5) Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on May 15, 2003.

(6) Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on January 28, 2004.

(7) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 10-QSB filed on August 20, 2003.

(8) Incorporated by reference to Exhibit 10.2 filed with the Company's Annual Report on Form 10-KSB on April 14, 2004.

(9) Incorporated by reference to Exhibit 10.3 filed with the Company's Current Report on Form 10-QSB filed on November 14, 2003.

(10) Incorporated by reference to Exhibit 10.6 filed with the Company's Annual Report on Form 10-KSB filed on April 14, 2004.

(11) Incorporated by reference to Exhibit 10.4 filed with the Company's Current Report on Form 10-QSB filed on November 14, 2003.

(12) Incorporated by reference to Exhibit 10.6 filed with the Company's Annual Report on Form 10-KSB on April 14, 2004.

(13) Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on January 28, 2004.

(14) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on April 19, 2004.

(15) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on September 7, 2004.

(16) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on March 5, 2005.

(17) Incorporated by reference to Exhibit 14 filed with the Company's Annual Report on Form 10-KSB filed on April 14, 2004.

SIGNATURES

Pursuant to the requirements of Section 13 or 15D 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.

Date: June 6, 2005 Callisto Pharmaceuticals, Inc.

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)	June 6, 2005
/s/ Bernard F. Denoyer --- Bernard F. Denoyer	Vice President, Finance (Principal Accounting Officer)	June 6, 2005
/s/ Gabriele M. Cerrone --- Gabriele M. Cerrone	Chairman of the Board	June 6, 2005
/s/ Edwin Snape --- Edwin Snape	Director	June 6, 2005
/s/ John P. Brancaccio --- John P. Brancaccio	Director	June 6, 2005
/s/ Stephen K. Carter --- Stephen K. Carter	Director	June 6, 2005
/s/ Christoph Bruening --- Christoph Bruening	Director	June 6, 2005
/s/ Randall K. Johnson --- Randall K. Johnson	Director	June 6, 2005

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

PAGE

Report of Independent Registered Public Accounting Firm F-2

Consolidated Balance Sheets as of December 31, 2004 and 2003 F-3

Consolidated Statements of Operations for the three years in the period ended December 31, 2004 and for the period from June 5, 1996 (inception) to December 31, 2004 F-4

Consolidated Statement of Changes in Stockholders' Equity for the period from June 5, 1996 (inception) to December 31, 2004 F-5

Consolidated Statements of Cash Flows for the three years in the period ended December 31, 2004 and for the period from June 5, 1996 (inception) to December 31, 2004 F-6

Notes to Consolidated Financial Statements F-7

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, 2004 and 2003, the related consolidated statements of operations and cash flows for each of the three years in the period ended December 31, 2004 and for the period from June 5, 1996 (inception) to December 31, 2004 and the related consolidated statement of stockholders' equity for the period from June 5, 1996 (inception) to December 31, 2004. 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 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 audit 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, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 and for the period from June 5, 1996 (inception) to December 31, 2004, in conformity with accounting principles generally accepted in the United States.

/s/ BDO Seidman, LLP

New York, New York
March 14, 2005

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

AS OF DECEMBER 31

	AS OF DECEMBER 31,	
	2004	2003
Current Assets:		
Cash and cash equivalents	$ 5,323,384	$ 3,956,486
Prepaid expenses	45,231	52,644
	5,368,615	4,009,130
Property and equipment, net	18,856	46,488
Security deposits	82,196	62,980
	$ 5,469,667	$ 4,118,598
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 984,486	$ 842,520
Accrued expenses	235,803	79,625
Selling agent fees payable related to private placement	--	341,625
	1,220,289	1,263,770
Stockholders' equity:		
Common stock, $.0001 par value, authorized 75,000,000 shares, 29,219,102 and 25,928,760 outstanding at December 31, 2004 and December 31, 2003, respectively	2,922	2,590
Additional paid-in-capital	39,910,187	34,149,975
Unamortized deferred stock based compensation	(2,302,534)	(5,480,007)
Deficit accumulated during the development stage	(33,361,197)	(25,817,730)
	4,249,378	2,854,828
	$ 5,469,667	$ 4,118,598

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,		
	2004	2003	20
Revenues	$ --	$ --	$
Costs and Expenses:			
Research and development	2,817,387	1,369,985	4
Government grant	(265,697)	--	
Purchased in-process research and development	209,735	6,734,818	
Stock-based compensation - research and development	1,508,588	434,187	
General and administrative	2,362,773	1,398,090	1,2
Stock-based compensation - general and administrative	1,224,182	3,399,759	
Loss from operations	(7,856,968)	(13,336,839)	(1,7
Interest income	84,081	8,768	
Other income	229,420	221,824	
Net loss	$ (7,543,467)	$(13,106,247)	$ (1,6
Weighted average shares outstanding:			
Basic and diluted	28,485,227	21,357,659	17,3
Net loss per common share: basic and diluted	$ (0.26)	$ (0.61)	$

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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Preferred Shares	Preferred Stock, Par Value	Common Shares	Comm Stock, Val
Balance at inception, June 5, 1996	--	--	--	
Net loss for the period				
Issuance of founder shares	--	--	2,642,500	
Common stock issued	--	--	1,356,194	
Common stock issued via private placement	--	--	1,366,667	
Balance, December 31, 1996	--	--	5,365,361	
Net loss for the year	--	--	--	
Common stock issued via private placement	--	--	1,442,666	
Balance, December 31, 1997	--	--	6,808,027	
Net loss for the year				
Amortization of Stock based	--	--	--	
Compensation	--	--	--	
Common stock issued via private placement	--	--	1,416,667	
Common stock issued for services	--	--	788,889	
Common stock repurchased and cancelled	--	--	(836,792)	
Balance, December 31, 1998	--	--	8,176,791	
Net loss for the year	--	--	--	
Deferred Compensation - stock options	--	--	--	
Amortization of Stock based Compensation	--	--	--	
Common stock issued for services	--	--	--	
Common stock issued via private placement	--	--	346,667	
Balance, December 31, 1999	--	--	8,523,458	
Net loss for the year	--	--	--	
Amortization of Stock based Compensation	--	--	--	
Common stock issued	--	--	4,560,237	
Other	--	--	--	
Preferred shares issued	3,485,299	348	--	
Preferred stock issued for services	750,000	75	--	
Balance, December 31, 2000	4,235,299	423	13,083,695	
Net loss for the year	--	--	--	
Deferred Compensation - stock Options	--	--	--	
Amortization of Stock based Compensation	--	--	--	
Balance, December 31, 2001	4,235,299	423	13,083,695	
Net loss for the year	--	--	--	
Amortization of Stock based Compensation	--	--	--	
Balance, December 31, 2002	4,235,299	$423	13,083,695	$

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (CONTINUED)

	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance at inception, June 5, 1996	--	--	--
Net loss for the year		(404,005)	(404,005)
Issuance of founder shares	--	--	792
Common stock issued	--	--	408
Common stock issued via private placement	--	--	1,025,000
Balance, December 31, 1996	--	(404,005)	622,195
Net loss for the year	--	(894,505)	(894,505)
Common stock issued via private placement	--	--	1,081,999
Balance, December 31, 1997	--	(1,298,510)	809,689
Net loss for the year	--	(1,484,438)	(1,484,438)
Amortization of Stock based Compensation	--	--	52,778
Common stock issued			1,062,500
Common stock issued for services	--	--	-- 591,667
Common Stock repurchased and cancelled	--	--	(97,000)
Balance, December 31, 1998	--	(2,782,948)	935,196
Net loss for the year	--	(4,195,263)	(4,195,263)
Deferred Compensation - stock options	(9,946)	--	--
Amortization of Stock based Compensation	3,262	--	3,262
Common stock issued for services	--	--	3,168,832
Common stock issued via private placement	--	--	260,000
Balance, December 31, 1999	(6,684)	(6,978,211)	172,027
Net loss for the year		(2,616,261)	(2,616,261)
Amortization of Stock based Compensation	4,197	4,197	
Common stock issue	--	--	251,344
Other	--	--	432
Preferred shares issued	--	--	5,986,650
Preferred stock issued for services	--	--	1,125,000
Balance, December 31, 2000	(2,487)	(9,594,472)	4,923,389
Net loss for the year	--	(1,432,046)	(1,432,046)
Deferred Compensation - stock options	(20,000)	--	--
Amortization of Stock based Compensation	22,155	--	22,155
Balance, December 31, 2001	(332)	(11,026,518)	3,513,498

Net loss for the year	--	(1,684,965)	(1,684,965)
Amortization of Stock based Compensation	332	--	332
Balance, December 31, 2002	--	($12,711,483)	$1,828,865

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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (CONTINUED)

	Preferred Stock	Preferred Stock Par Value	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamor Defe Stock Compen
Balance December 31, 2002	4,235,299	$423	13,083,695	$1,307	$14,538,618	
Net loss for the year	--	--	--	--	--	
Conversion of preferred stock in connection with the Merger	(4,235,299)	(423)	4,235,299	423	--	
Common stock issued to former Synergy stockholders	--		4,329,927	432	6,494,458	
Common stock issued in exchange for Webtronics common stock	--		1,503,173	150	(150)	
Deferred Compensation - stock options	--		--	--	9,313,953	(9,3
Amortization of deferred Stock based Compensation	--		--	--	--	3,8
Private placement of common stock, net	--	--	2,776,666	278	3,803,096	
Balance, December 31, 2003	--	--	25,928,760	2,590	34,149,975	(5,4
Net loss for the period	--	--	--	--	--	
Amortization of deferred Stock-based compensation expense	--	--	--	--	--	3,0
Variable accounting for						

stock options	--	--	--	--	(816,865)	
Stock-based compensation net of forfeitures	--	--	--	--	240,572	
Common stock issued via private placements, net	--	--	3,311,342	331	6,098,681	
Warrant and stock-based compensation for services in connection with the Merger	--	--	--	--	269,826	
Common stock returned from former Synergy stockholders	--	--	(90,000)	(9)	(159,083)	
Common stock issued for patent rights	--	--	25,000	3	56,247	
Common stock issued for services	--	--	44,000	7	70,833	
Balance, December 31, 2004	--	$ --	29,219,102	$2,922	$39,910,187	($2,3

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

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

	For the years ended December 31,		
	2004	2003	
Cash flows from operating activities:			
Net loss	$(7,543,467)	$(13,106,247)	$(1,6
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	27,632	27,755	
Stock based compensation expense	2,732,770	3,833,946	
Purchased in-process research and development (non-cash portion)	106,235	6,734,818	
Changes in operating assets and liabilities:			
Prepaid expenses	7,413	(24,188)	
Security deposit	(19,216)	(62,980)	
Accounts payable and accrued expenses	(43,481)	581,008	3

Total adjustments	2,811,353	11,090,359	3
Net cash used in operating activities	(4,732,114)	(2,015,888)	(1,3
Cash flows from investing activities:			
Acquisition of equipment	--	(54,462)	(
Net cash used in investing activities	--	(54,462)	(
Cash flows from financing activities:			
Net proceeds from issuance of common and preferred stock, net of repurchases	6,099,012	3,803,374	
Net cash provided by financing activities	6,099,012	3,803,374	
Net increase (decrease) in cash and cash equivalents	1,366,898	1,733,024	(1,4
Cash and cash equivalents at beginning of year	3,956,486	2,223,462	3,6
Cash and cash equivalents at end of year	$5,323,384	$3,956,486	$2,2
Supplementary disclosure of cash flow information:			
Cash paid for taxes	$2,921	$23,834	$

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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Business overview:

Callisto Pharmaceuticals, Inc. ("Callisto") is a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. See footnote 4 for a complete description of Merger and consolidation. Since inception in June of 1996 our efforts have been principally devoted to research and development, securing and protecting our patents and raising capital. From inception through December 31, 2004, Callisto has sustained cumulative net losses of $33,361,197. Callisto's losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of our proposed products, stock based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees. From inception through December 31, 2004, Callisto has not generated any revenue

from operations, expects to incur additional losses to perform further research and development activities and does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all.

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

2. Basis of presentation:

The accompanying consolidated financial statements of Callisto which include its wholly owned subsidiaries: (1) Callisto Research Labs, LLC.(including its wholly owned but inactive subsidiary, Callisto Pharma, GmbH (Germany)) and (2) Synergy Pharmaceuticals Inc. ("Synergy" , including its wholly owned but inactive subsidiary IgX, Ltd (Ireland)), have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The results of operations of Synergy are included in the consolidated statement of operations for the twelve months ended December 31, 2004 and since May 1, 2003 in the period from June 5, 1996 (inception) to December 31, 2004 and for the twelve months ended December 31, 2003. All significant intercompany balances and transactions have been eliminated (see footnote 4).

3. Summary of significant accounting policies

Use of Estimates - The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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

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

Business concentrations and credit risks - All of Callisto's cash and cash equivalents as of December 31, 2004 and 2003 are on deposit with two major money center financial institutions. Deposits at any point in time may exceed federally insured limits.

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

In December 2002, the Financial Accounting Standards Board issued SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment

of FASB Statement No. 123," to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this statement amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual (see below) and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results.

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

	Years Ended December 31,		
	2004	2003	200
Net loss, as reported	$(7,543,467)	$(13,106,247)	$(1,684,96
Add: Stock-based employee compensation expense recorded under APB No. 25 intrinsic method	1,317,108	1,996,890	-
Deduct: Stock-based employee compensation expense determined under Fair Value based method for all employee awards	(2,916,720)	(2,510,721)	-
Pro forma net loss	$(9,143,079)	$(13,620,078)	$(1,684,96
Net loss per share:			
Basic and diluted -as reported	$(0.26)	$(0.61)	$(0.1
Basic and diluted -pro forma	$(0.32)	$(0.64)	$(0.1
Range of Fair Value per share for options granted to employees	$1.35 to $3.15	$0.58 to $5.50	$0.00 to $
Black-Scholes Methodology Assumptions:			
Dividend yield	0%	0%	
Risk free interest rate	2.87% to 4.0%	2.87% to 4.5%	2.87% to
Expected lives of options	7 to 10 years	7 to 10 years	7 to 10 y

Volatility of 0% was used until Callisto's common stock began to trade publicly on June 16, 2003. Since June 13, 2003 through December 31, 2004 Callisto has used 100% volatility to determine Fair Value of options granted to employees.

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

determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares since the inclusion of issuable shares pursuant to the exercise of stock options and warrants, would have been antidilutive. As of December 31, 2004, 2003 and 2002, Callisto had 7,322,060, 4,853,560 and 2,991,505 stock options outstanding, respectively. In addition Callisto had 758,995 common stock warrants outstanding as of December 31, 2004 and none as of December 31, 2003.

Research and development - Callisto does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all and therefore, research and development costs are expensed as incurred. These include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of our proposed products, patent filing and maintenance expenses, purchase of in-process research and development, regulatory and scientific consulting fees as well as contract research and royalty payments to licensors, patient costs, drug formulation and tableting, data collection, monitoring, insurance, and FDA consultants.

Government Grants - Callisto requests cash funding under approved grants as expenses are incurred (not in advance) and records the receipt as an offset to research and development expense. During 2004 Callisto had a research grant from the National Institutes of Health for studies on Atiprimod. This amount totaled $265,697 during the year ended December 31, 2004 and has been reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grant".

Income taxes - Income taxes are accounted for under the asset and liability method prescribed by Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes." Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or the entire deferred tax asset will not be realized. F-8

RECENT ACCOUNTING PRONOUNCEMENTS:

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard ("SFAS") No. 123 (Revised 2004), "Share-Based Payment." SFAS No 123R is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation" and supersedes Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees" and its related implementation guidance. SFAS No. 123R focuses primarily on accounting for transactions in which an entity obtains employee services through share-based payment transactions. SFAS No 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 cost will be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS No. 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. While Callisto cannot precisely determine the impact on net loss as a result of the adoption of SFAS No 123R, estimated compensation expense related to prior periods can be found above in this footnote.

In December 2004, the FASB issued SFAS 153, "Exchanges of Nonmonetary Assets", which is effective for fiscal years beginning after June 15, 2005. SFAS 153

amends APB 29, "Accounting for Nonmonetary Transactions", which is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB 29 included certain exceptions to that principle. SFAS 153 amends APB 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The adoption of this statement is not expected to have a material effect on our financial position or results of operations.

4. Merger and consolidation:

In March 2002, Callisto Pharmaceuticals, Inc. ("Old Callisto") purchased 99.7% of the outstanding common shares of Webtronics, Inc., ("Webtronics") a public company for $400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations during the year ended December 31, 2002. The purchase price of Webtronics was treated as a cost of becoming a public company, however because there was no capital raised at the time, the amount was charged to general and administrative expense during the 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. In connection with the Merger Webtronics issued 17,318,994 shares of its common stock in exchange for outstanding Old Callisto common stock and an additional 4,395,684 shares in exchange for outstanding Synergy common stock. Subsequently, 171,818 shares of common stock issued to former Synergy shareholders were returned to Callisto under the terms of certain indemnification agreements. The Merger was accounted for as a recapitalization of Old Callisto by an exchange of Webtronics common stock for the net assets of Old Callisto consisting primarily of cash and fixed assets. Old Callisto then changed its name to Callisto Research Labs, LLC and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware. Callisto remains the continuing legal entity and registrant for Securities and Exchange Commission reporting purposes.

The merged companies are considered to be in the development stage. No revenues have been realized since inception and all activities have been concentrated in research and development of biopharmaceutical products not yet approved by the Food and Drug Administration. The fair value of the net shares issued to former Synergy shareholders in the Merger totaled $6,335,799 through December 31, 2004. The fair value per share of $1.50, used to determine this amount, was the value per share Callisto sold common stock in a private placement. The total consideration was allocated in full to the Synergy research and development projects which had not yet reached technological feasibility and having no alternative use was charged to purchased in-process research and development expense during the year ended December 31, 2003.

The results of operations of Synergy are included in the consolidated statement of operations for the twelve months ended December 31, 2004 and since May 1, 2003 in the period from June 5, 1996 (inception) to December 31, 2004 and for the twelve months ended December 31, 2003. The following combined pro forma results of operations for the year ended December 31, 2003 have been prepared as if the merger with Synergy had occurred at January 1, 2003.

Revenues	$--
Net loss	($13,513,820)
Net loss per common share - basic and diluted	(0.58)

(23,296,920 common shares in 2003)

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

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

5. Stockholders' equity:

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

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

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

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

During 2000, the Board of Directors approved an increase in the authorized common shares from 35,000,000 shares to 60,000,000 shares and a one-for-three reverse split of the common stock. All share and per share information has been

adjusted to reflect the stock split as if it had occurred at the beginning of the earliest period presented. In May 2003, as part of the Merger, the authorized common shares were increased to 75,000,000 shares.

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

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

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

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

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

6. Stock option plan:

In 1996, Callisto adopted an incentive and non-qualified stock option plan (the "Plan") for employees, consultants and outside directors to purchase up to 2,000,000 shares of common stock. The Plan was amended in December 2002 to increase the number of shares authorized under the Plan to 10,000,000. The option term for options granted under the Plan is ten years from date of grant

and there were 6,822,778 option shares available for future grants as of December 31, 2004.

The Company recognizes deferred compensation expense for the intrinsic value of unvested stock options granted to employees. Deferred stock-based compensation is amortized to stock-based compensation expense over the vesting period of the stock option. During the twelve months ended December 31, 2004, 2003 and for the period from June 5, 1996 (inception) to December 31, 2004 Callisto recognized $2,732,770, $3,833,946 and $11,351,272, respectively, as stock-based compensation expense related to issuance of stock and stock options. At December 31, 2004, there was $2,302,534 remaining in unamortized deferred compensation.

The following represent options outstanding for the years since June 5, 1996 (inception) through December 31, 2004.

	Number of Shares	Exercise Price Per Share	Weighted Average Exercise Price
Balance, June 5, 1996 (inception)	0	$0.00	$0.00
1996: Granted	66,668	$0.75	$0.75
Balance, December 31, 1996	66,668	$0.75	$0.75
1997: Granted	166,668	$0.75	$0.75
Balance, December 31, 1997	233,336	$0.75	$0.75
1998: Granted	264,169	$0.75	$0.75
Balance, December 31, 1998	497,505	$0.75	$0.75
1999: Granted	633,334	$0.75 - $4.90	$1.92
Balance, December 31, 1999	1,130,839	$0.75 - $4.90	$1.41
2000: Granted	815,666	$2.85 - $6.75	$3.83
Forfeitures	(15,000)	$0.75	$0.75
Balance, December 31, 2000	1,931,505	$0.75 - $6.75	$2.44
2001: Granted	730,000	$1.25 - $6.50	$2.77
Balance, December 31, 2001	2,661,505	$0.75 - $6.75	$2.53
2002: Granted	330,000	$4.50 - $6.50	$5.50
Balance, December 31, 2002	2,991,505	$0.75 - $6.75	$2.86
2003: Granted	3,013,555	$1.10 - $2.50	$1.48
Forfeitures	(1,151,500)	$2.85 - $6.75	$4.51

Balance, December 31, 2003	4,853,560	$0.75 - $6.75	$1.61
2004: Granted	2,853,500	$1.50 - $3.60	$3.11
Forfeitures	(385,000)	$1.50 - $2.50	$1.66
Balance, December 31, 2004	7,322,060	$0.75 - $6.75	$2.19

Included in the balance at December 31, 2004 were 4,144,838 Non-Plan options, of which 2,356,338 were exercisable.

Options are exercisable as follows at December 31, 2004:

	Options Outstanding			Opt
Exercise Price	Number of Shares	Weighted Average Remaining Life	Weighted Average Exercise Price	Number of Shares
$0.75 - $1.10	1,115,839	5.3 years	$0.91	1,115,839
$1.25 - $1.75	2,603,555	8.2 years	$1.44	1,626,888
$1.95 - $3.60	3,441,000	8.5 years	$3.03	957,500
$4.90 - $6.75	161,666	5.4 years	$5.32	61,666
All options:				
$0.75 - $6.75	7,322,060	7.8 years	$2.19	3,761,893

6. Stock option plan (continued):

On April 26, 2004, Callisto's Board of Directors granted 100,000 stock options to Gabriele M. Cerrone, Chairman of the Board, in recognition of his efforts during the past year on behalf of the company. The stock options are immediately exercisable at $3.20 per share and stock-based compensation expense of $286,918 was recorded in connection with the grant, based on a Black-Scholes fair value of $2.87 per share.

On June 29, 2004, Callisto's Compensation Committee recommended and the Board of Directors approved the grant of 275,000 stock options to Gary Jacob, Chief Executive Officer, as additional compensation. The stock options are exercisable at $3.00 per share. 25,000 options vest on each of June 1, 2005 and June 1, 2006 and 50,000 options vest on June 1, 2007. The remaining 175,000 options vest upon the achievement of performance milestones associated with the successful in-licensing, advancement and development of certain drug candidates. If the milestones are achieved Callisto will record stock-based compensation expense based on the intrinsic value of the options at that time.

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

stages of clinical trials. If the milestones are achieved Callisto will record stock-based compensation expense based on the intrinsic value of the options at that time.

7. Income taxes:

At December 31, 2004 and 2003, Callisto had available Federal net operating tax loss carry forwards of approximately $16,000,000 and $14,000,000, respectively, expiring through 2024 to offset future taxable income. The net deferred tax asset has been fully offset by a valuation allowance due to uncertainties regarding realization of benefits from these future tax deductions. As a result of the change in control provisions of Internal Revenue Code Section 382, a significant portion of these net operating loss carry forwards may be subject to limitation on future utilization.

During the years ended December 31, 2004, 2003 and 2002, Synergy sold certain New Jersey State tax loss carry forwards under a state economic development program for cash of approximately $233,000, $222,000 and $0, respectively. The proceeds of economic development funds have and will be used to support research and development activities in New Jersey. This state tax benefit was recorded as Other Income during the fourth quarter ended December 31, 2004 and 2003.

8. Commitments and contingencies:

License agreements:

On August 12, 2004, Callisto entered into a world-wide license agreement with The University of Texas M. D. Anderson Cancer Center to research, develop, sell and commercially exploit the patent rights for Annamycin, an anthracycline cancer drug for leukemia therapy. Consideration paid for this license amounted to $31,497 for reimbursement of out-of-pocket costs for filing, enforcing and maintaining the Annamycin patent rights and a $100,000 initial license fee. Annamycin has not reached technological feasibility and having no alternative use these costs were recorded as research and development expense. Callisto also agreed to pay The University of Texas M. D. Anderson Cancer Center royalties based on net sales from any licensed products, plus aggregate milestone payments of up to $750,000 based upon achieving certain regulatory submissions and approvals. The term of the agreement is from August 12, 2004 until November 2, 2019. Under the terms of the license agreement, Callisto is required to make certain good faith expenditures towards the clinical development of at least one licensed product within the two year period after March 2005. In addition, at any time after 5 years from August 12, 2004, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if Callisto fails to provide evidence within 90 days of written notice that it has commercialized or it is actively and effectively attempting to commercialize Annamycin.

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

In addition, Callisto granted to HPI 1,170,000 performance based stock options, exercisable at $3.50 per share, which vest upon the achievement of certain milestones. Callisto also agreed to pay HPI royalties of 2% on net sales from any products resulting from commercializing the site-directed DNA intercalation. Pursuant to the sublicense agreement, in the event Callisto's Board of Directors determines to abandon its development and commercialization of the site-directed DNA intercalation, HPI shall have the right to terminate the sublicense agreement.

On August 28, 2002, Synergy entered into a worldwide license agreement with AnorMED, Inc. ("AnorMED") to research, develop, sell and commercially exploit the Atiprimod patent rights. The license agreement provides for aggregate milestone payments of up to $14 million based upon achieving certain regulatory submissions and approvals for an initial indication, and additional payments of up to $16 million for each additional indication based on achieving certain regulatory submissions and approvals. In addition the agreement requires Synergy to pay AnorMED royalties on net sales. Commencing on January 1, 2004 and on January 1 of each subsequent year Synergy is obligated to pay AnorMED a maintenance fee of $200,000 until the first commercial sale of the product. The first of these annual maintenance fee payments under this agreement was made on January 22, 2004 and was recorded as research and development expense in 2004. Pursuant to the license agreement, failure to pay the maintenance fee is a material breach of the license agreement. The license agreement will terminate in 2018.

On July 25, 2001, Callisto entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University licensed patents covering peptides and antibodies useful in treating toxic shock syndrome and septic shock. Callisto will pay Rockefeller a $7,500 annual maintenance fee until the first commercial sale of the product, plus royalties of 2% and 0.75% of net sales of product depending on whether the product is covered by a claim under the licensed patents or derived from a claim under the licensed patents and will pay Rockefeller 15% of any sublicense fee paid by sublicensees. The agreement will terminate on July 25, 2021. During the twelve months ended December 31, 2004 and 2003, Callisto made no payments to Rockefeller University. Prior to 2003, $7,500 in total payments had been made under this license agreement. Rockefeller may terminate the license agreement if Callisto is more than 30 days late in paying Rockefeller any amounts due under the license agreement or if Callisto breachs the license agreement.

Employment and Consulting Agreements:

On December 27, 2004, Callisto entered into a consulting agreement (the "Agreement") with Gabriele M. Cerrone, Callisto's Chairman of the Board (the "Consultant"). The duties of the Consultant and the obligations of Callisto to pay compensation commenced on January 10, 2005 (the "Start Date"). The duties of the Consultant pursuant to the Agreement will consist of business development, strategic planning, capital markets and corporate financing consulting advice. The term of the Agreement will commence upon the Start Date and continue until December 31, 2006 with automatic renewal for successive one year periods unless either party gives notice to the other not to renew the Agreement. No compensation expense was recorded during the year ended December 31, 2004.

Callisto will pay Consultant the annual sum of $205,000 (the "Base Compensation") at the rate of $17,083.33 per month commencing on the Start Date. In addition, Consultant was granted 375,000 ten year non-qualified stock options at an exercise price of $1.70 per share. One half of such options vest on each of the first two anniversaries of the date of the Agreement. Stock-based compensation expense associated with these option grants will be recorded based on an initial Black-Scholes Fair Value of $1.52 per share and marked to market quarterly from January 10, 2005 until the measurement date is known. The measurement date in this case will be the earlier of the second anniversary of

the agreement or the accelerated vesting date if Mr. Cerrrone is terminated without cause or good reason.

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

On December 22, 2004 the Board of Directors of Callisto, acting upon advice of its Compensation Committee, awarded Mr. Cerrone a cash bonus of $200,000 in recognition of his contributions to the Company including negotiation and acquisition of certain intellectual property licenses during 2004. Accordingly this bonus was charged to research and development expense during 2004.

On August 12, 2004, in connection with the Annamycin license, Callisto entered into a consulting agreement with Roman Perez-Soler, M.D., for a term concurrent with the Annamycin license agreement. In connection therewith Dr. Perez-Soler agreed to be appointed to the Company's Scientific Advisory Board. As consideration for consulting and advisory services Dr. Perez-Soler shall receive a $30,000 per year consulting fee and, 44,000 shares of restricted common stock. These shares were recorded as stock based compensation expense during the 12 months ended December 31, 2004 for a total of $70,840 based on the closing stock price of $1.61 on August 23, 2004. In addition, Callisto granted to Dr. Perez-Soler an option to purchase 468,500 shares of common stock at an exercise price of $3.00 per share. The option shares vest upon achievement of specific milestones related to future development of Annamycin, at which time stock-based compensation expense will be recorded based upon the fair value of the options at that time.

On April 6, 2004, Kunwar Shailubhai, Ph.D. entered into an employment agreement with Synergy in which he agreed to serve as Senior Vice President, Drug Discovery. Dr. Shailubhai's employment agreement is for a term of 12 months beginning April 6, 2004 and is automatically renewable for successive one year periods at the end of the term. Dr. Shailubhai's salary is $150,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. Dr. Shailubhai received a grant of 100,000 stock options which are exercisable at $1.50 per share. 50,000 of such stock options vest in June 2004 and the remainder vest in December 2004.

Callisto previously had an employment agreement dated June 13, 2003 with Kunwar Shailubhai, Ph.D. to serve as Executive Vice President and Head of Research and Development for a term of 18 months beginning June 13, 2003. Dr. Shailubhai's salary was $170,000 per year and he was eligible to receive a cash bonus of up to 15% of his salary per year. In connection with his employment agreement, Dr. Shailubhai received a grant of 25,000 stock options which were fully vested and have an exercise price of $1.50 per share. Dr. Shailubhai also received a grant of 325,000 stock options which were to have vested over a three year period and were exercisable at $1.50 per share. This employment agreement was terminated on April 6, 2004 and unvested options were forfeited.

The new grant of 100,000 options will be subject to variable accounting because it was deemed that his agreement was a continuation of employment with a wholly

owned subsidiary of Callisto. The unamortized deferred compensation cost associated with the 225,000 cancelled options of $706,813 as of the date of cancellation, was charged to stock-based compensation expense during the quarter ended June 30, 2004. The remaining deferred balance, based on the original intrinsic value, associated with the remaining 100,000 options of $314,139, was expensed over the vesting period of the new grant (e.g. April 7, 2004 through December 31, 2004).

8. Commitments and contingencies (Continued):

On January 15, 2004, Callisto entered into an employment agreement with Bernard Denoyer, its Vice President, Finance. Mr. Denoyer's employment agreement is for a term of 12 months beginning January 15, 2004 and is automatically renewable for successive one year periods at the end of the term. Mr. Denoyer's salary is $90,000 per year and he is eligible to receive a cash bonus of up to 10% of his salary per year. Mr. Denoyer received a grant of 100,000 stock options which vest over a three year period and are exercisable at $3.60 per share.

On September 23, 2003, Callisto entered into an employment agreement with Donald H. Picker, Ph.D., to serve as Vice President, Drug Development. The employment agreement is for a term of 18 months beginning September 23, 2003 and is automatically renewable for successive one year periods at the end of the term. Dr. Picker's salary is $175,000 per year and he is eligible to receive a cash bonus of up to $45,000 per year upon the achievement of certain performance milestones. In connection with his employment agreement, Dr. Picker received a grant of 325,000 stock options which vest over a three year period and are exercisable at $1.50 per share. On April 6, 2004 the employment agreement of Donald H. Picker, Callisto's Executive Vice President, R&D was amended. Dr, Picker's salary was increased from $175,000 to $200,000 per year and certain milestones were added upon which cash bonuses of up to $92,500 over a 12 month period may be paid. During the twelve months ended December 31, 2004, Dr. Picker was paid a bonus $37,500 based on certain milestones he achieved during 2004. The balance of the annual bonus Dr. Picked is eligible to receive will be paid only if and when certain other milestones are reached.

On June 13, 2003, Callisto entered into an employment agreement with Gary S. Jacob, Ph.D., to serve as our Chief Executive Officer and Chief Scientific Officer. Dr. Jacob's employment agreement is for a term of 18 months beginning June 13, 2003 and is automatically renewable for successive one year periods at the end of the term. Dr. Jacob's salary is $225,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. In connection with his employment agreement, Dr. Jacob received a grant of 500,000 stock options which vest over a three year period and are exercisable at $1.50 per share.

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

Lease agreements:

On August 20, 2003, Callisto entered into a five year lease for its corporate headquarters in New York City with an approximate rent of $100,000 annually through August 2008. On June 7, 2004 Callisto extended its lease for its corporate headquarters in New York City three additional years through June 30, 2011, and increased its space. This increased average annual rent to approximately $150,000. On November 4, 2003, Synergy entered a two year lease for laboratory space in New Jersey, principally to support combined Callisto and Synergy research efforts, with an approximate rent of $50,000 annually through November 2005. During the years ended December 31, 2004, 2003 and 2002 and for the period from June 5, 1996 (inception) to December 31, 2004, total rent expense was $217,297, $67,261, $51,856 and $404,579, respectively. Total annual commitments under these leases for each of the twelve months ended December 31,

are as follows:

2005	193,552
2006	148,553
2007	151,524
2008	154,555
2009	157,646
2010	160,799
2011	81,464
Total	$1,048,093

Other:

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

9. Property and equipment:

Equipment consists of laboratory, testing and computer equipment and furniture and fixtures consists of office furniture, both stated at cost, with useful lives ranging from 2-4 years, depreciated on a straight line basis. Depreciation expense for the years ended December 31, 2004, 2003 and 2002 and from June 5, 1996 (inception) to December 31, 2004 was $27,632, $27,755, $6,778 and $65,781, respectively.

	December 31	
	2004	2003
Equipment	$46,294	$46,294
Furniture and fixtures	38,343	38,343
Less - Accumulated depreciation	(65,781)	(38,149)
Property and equipment, net	$18,856	$46,488

10. Subsequent event:

On March 9, 2005 Callisto completed a private placement of an aggregate 1,985,791 shares of its common stock at a per share price of $1.52, for aggregate gross proceeds of approximately $3.02 million. The financing was led by certain current institutional shareholders and included certain members of the Callisto's management; therefore no selling agent fees were incurred. Callisto has agreed to file a registration statement covering resale of the shares within 30 days of closing.

Had this private placement been completed on December 31, 2004 pro forma selected balance sheet items would have been as follows:

	As reported	Pro forma

	2004	2004
Cash and cash equivalents	$5,323,384	$8,343,384
Stockholders' equity	$4,249,278	$7,269,278
Common shares outstanding	29,219,102	31,218,102

Index to Exhibits

Exhibit Number	Description
2.1	Agreement and Plan of Merger by and among Callisto Pharmaceuticals, Inc., Webtronics, Inc., Callisto Acquisition Corp., Synergy Pharmaceuticals Inc. and Synergy Acquisition Corp. dated as of March 10, 2003 (1)
2.2	Amendment to Agreement and Plan of Merger dated as of April 4, 2003 (2)
3.1	Certificate of Incorporation (3)
3.2	Bylaws (4)
4.1	1996 Incentive and Non-Qualified Stock Option Plan (5)
4.2	Form of Warrant to purchase shares of common stock issued in connection with the sale of common stock (6)
10.1	Employment Agreement dated June 13, 2003 by and between Callisto Pharmaceuticals, Inc. and Gary S. Jacob (7)*
10.2	Employment Agreement dated April 6, 2004 by and between Synergy Pharmaceuticals Inc. and Kunwar Shailubhai (8)*
10.3	Employment Agreement dated June 13, 2003 by and between Callisto Pharmaceuticals, Inc. and Donald H. Picker (9)*
10.4	Amendment to Employment Agreement dated April 6, 2004 by and between Callisto Pharmaceuticals, Inc. and Donald H. Picker (10)*
10.5	License Agreement dated as of August 28, 2002 by and between Synergy Pharmaceuticals Inc. and AnorMED Inc. (11)**
10.6	Employment Agreement dated January 15, 2004 by and between Callisto Pharmaceuticals, Inc and Bernard Denoyer (12)*
10.7	Form of Registration Rights Agreement dated as of January 21, 2004 by and among the Registrant and the Purchasers set fourth on the signature page thereto (13)
10.8	Common Stock Purchase Agreement dated as of April 19, 2004, by and between Callisto Pharmaceuticals, Inc. and the Purchasers set forth on Exhibit A thereto. (14)

10.9	Patent and Technology License Agreement dated August 12, 2004 by and between The Board of Regents of the University of Texas System, on behalf of The University of Texas M. D. Anderson Cancer Center and Callisto Pharmaceuticals, Inc. (15)**
10.10	Consulting Agreement dated as of December 27, 2004 between the Registrant and Gabriele M. Cerrone. *+
10.11	Common Stock Purchase Agreement dated as of March 9, 2005 by and between Callisto Pharmaceuticals, Inc. and the Purchasers set forth on Exhibit A thereto. (16)
10.12	License Agreement between Callisto Pharmaceuticals, Inc. and The Rockefeller University effective as of July 25, 2001.
10.13	Asset Purchase Agreement dated as of February 24, 2004 between Callisto Pharmaceuticals, Inc. and Houston Pharmaceuticals, Inc.
10.14	Sublicense Agreement dated as of February 24, 2004 between Callisto Pharmaceuticals, Inc. and Houston Pharmaceuticals, Inc.
10.15	Agreement among Davos Chemical Corporation, Callisto Pharmaceuticals, Inc. and Antibioticos S.p.A. dated July 28, 2004.
14	Code of Business Conduct and Ethics (17)
22	List of Subsidiaries+
23	Consent of BDO Seidman, LLP

31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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

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

\+ Previously filed.

(1) Incorporated by reference to Exhibit 2.1 filed with the Company's Current Report on Form 8-K filed on March 19, 2003.

(2) Incorporated by reference to Exhibit 2.2 filed with the Company's Current Report on Form 8-K filed on April 30, 2003.

(3) Incorporated by reference to Exhibit 99.1 filed with the Company's Current Report on Form 8-K filed on May 28, 2003.

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

(5) Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on May 15, 2003.

(6) Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on January 28, 2004.

(7) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 10-QSB filed on August 20, 2003.

(8) Incorporated by reference to Exhibit 10.2 filed with the Company's Annual Report on Form 10-KSB on April 14, 2004.

(9) Incorporated by reference to Exhibit 10.3 filed with the Company's Current Report on Form 10-QSB filed on November 14, 2003.

(10) Incorporated by reference to Exhibit 10.6 filed with the Company's Annual Report on Form 10-KSB filed on April 14, 2004.

(11) Incorporated by reference to Exhibit 10.4 filed with the Company's Current Report on Form 10-QSB filed on November 14, 2003.

(12) Incorporated by reference to Exhibit 10.6 filed with the Company's Annual Report on Form 10-KSB on April 14, 2004.

(13) Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on January 28, 2004.

(14) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on April 19, 2004.

(15) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on September 7, 2004.

(16) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on March 5, 2005.

(17) Incorporated by reference to Exhibit 14 filed with the Company's Annual Report on Form 10-KSB filed on April 14, 2004.