CALLISTO PHARMACEUTICALS INC
Form S-3
April 05, 2005

As filed with the Securities and Exchange Commission on April 5, 2005

Registration Number 333-_____

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-3
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

CALLISTO PHARMACEUTICALS, INC.
(Name of Small Business Issuer 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
(212) 297-0010
(Address, including zip code, and telephone number, including area code of registrant's principal executive offices)

Gary S. Jacob
Chief Executive Officer
Callisto Pharmaceuticals, Inc.
420 Lexington Avenue, Suite 1609
New York, New York 10170
(212) 297-0010
(Name, address, including zip code, and telephone number, including area code of agent for service)

Copies to:
Jeffrey J. Fessler, Esq.
Sichenzia Ross Friedman Ference LLP
1065 Avenue of the Americas, 21st Floor
New York, New York 10018
(212) 930-9700

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this form are to be offered pursuant to dividend or interest reinvestment plans, please check the following box. [ ]

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. [X]

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. [ ]

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share (1)	Proposed Maximum Aggregate Offering Pr
Common Stock, $.0001 par value	1,985,791	$1.42	$2,819,823

(1) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based upon the average of the high and low price per share of the Registrant's Common Stock on the American Stock Exchange on April 4, 2005.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATE(S) AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION ACTING PURSUANT TO SAID SECTION 8(a) MAY DETERMINE.

The information in this prospectus is not complete and may be changed. The securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

CALLISTO PHARMACEUTICALS, INC.

1,985,791 Shares of Common Stock

The selling stockholders named in this prospectus are offering to sell up to 1,985,791 shares of common stock of Callisto Pharmaceuticals, Inc. which are currently issued and outstanding and were previously issued by us to the selling stockholders in a private placement. We will not receive any proceeds from the resale of shares of our common stock.

Our common stock currently trades on the American Stock Exchange under the symbol "KAL." On April 4, 2005, the last reported sale price for our common stock on the American Stock Exchange was $1.36 per share.

The securities offered in this prospectus involve a high degree of risk. See "Risk Factors" beginning on page 6 of this prospectus to read about factors you should consider before buying shares of our common stock.

The selling stockholders are offering these shares of common stock. The

selling stockholders may sell all or a portion of these shares from time to time in market transactions through any market on which our common stock is then traded, in negotiated transactions or otherwise, and at prices and on terms that will be determined by the then prevailing market price or at negotiated prices directly or through a broker or brokers, who may act as agent or as principal or by a combination of such methods of sale. The selling stockholders will receive all proceeds from the sale of the common stock. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution."

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined whether this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus is April _____, 2005

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You may only rely on the information contained in this prospectus or that we have referred you to. We have not authorized anyone to provide you with different information. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the common stock offered by this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any common stock in any circumstances in which such offer or solicitation is unlawful. Neither the delivery of this prospectus nor any sale made in connection with this prospectus shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus or that the information contained by reference to this prospectus is correct as of any time after its date.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement that we filed on Form S-3 with the Securities and Exchange Commission or SEC. This prospectus does not contain all of the information in the registration statement and the exhibits and schedules that were filed with the registration statement. You should refer to the registration statement for additional information about us and the common stock being offered in this prospectus. Statements made in this prospectus regarding the contents of any contract, agreement or other document that is filed as an exhibit to the registration statement or any document

incorporated by reference into the registration statement are not necessarily complete, and you should review the referenced document itself for a complete understanding of its terms.

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document that we file at the SEC's public reference facilities located at 450 Fifth Street, NW, Room 1024, Washington, DC 20549, and at the SEC's regional offices at 500 West Madison Street, Suite 1400, Chicago, Illinois 60661 and Woolworth Building, 233 Broadway New York, New York. Copies of all or any part of the registration statement may be obtained from the SEC upon payment of the prescribed fee. Information regarding the operation of the public reference rooms may be obtained by calling the SEC at 1-800-SEC-0330. Our SEC filings are also available to you free of charge at the SEC's web site at http://www.sec.gov.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to 'incorporate by reference' the information into this prospectus. This means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information that we incorporate by reference is considered to be part of this prospectus. Because we are incorporating by reference our future filings with the SEC, this prospectus is continually updated and those future filings may modify or supersede some or all of the information included or incorporated in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents listed below and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until the selling stockholders sell all of our common stock registered under this prospectus.

- our annual report on Form 10-KSB for the fiscal year ended December 31, 2004;
- our current reports on Form 8-K filed on February 3, 2005, February 7, 2005, February 14, 2005 and March 30, 2005; and
- the description of our common stock contained in Item 1 of our Registration Statement on Form 8-A, dated October 22, 2004;

The information about us contained in this prospectus should be read together with the information in the documents incorporated by reference. You may request a copy of any or all of these filings, at no cost, by writing or telephoning us at Callisto Pharmaceuticals, Inc., 420 Lexington Avenue, Suite 1609, New York, New York 10170, Telephone: (212) 297-0010

SUMMARY

This summary highlights information contained elsewhere in this prospectus. You should read the entire prospectus carefully, including, the section entitled "Risk Factors" before deciding to invest in our common stock. Callisto Pharmaceuticals, Inc. is referred to throughout this prospectus as "Callisto," "we" or "us."

We are a biopharmaceutical company focused on the development of drugs to treat relapsed acute leukemia, multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow), other cancers and osteolytic bone disease. Our lead drug candidate, Annamycin, a drug from the anthracycline family, earlier completed a Phase I/IIa trial in refractory leukemia patients. 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 Phase IIb trial in adult relapsed acute lymphocytic leukemia (ALL) patients in mid-2005, and in pediatric relapsed ALL patients and in combination with Ara-C (cytosine arabinoside) in relapsed acute myeloid leukemia (AML) patients in 2005.

Our second drug candidate, Atiprimod, is a small-molecule, orally available drug with antiproliferative and antiangiogenic activity. Atiprimod commenced a Phase I/IIa open-label 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". The trial protocol received 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.

Our principal executive office is located at 420 Lexington Avenue, Suite 1609, New York, New York 10170

RISK FACTORS

AN INVESTMENT IN OUR SHARES INVOLVES A HIGH DEGREE OF RISK. BEFORE MAKING AN INVESTMENT DECISION, YOU SHOULD CAREFULLY CONSIDER ALL OF THE RISKS DESCRIBED IN THIS PROSPECTUS. IF ANY OF THE RISKS DISCUSSED IN THIS PROSPECTUS ACTUALLY OCCUR, OUR BUSINESS, FINANCIAL CONDITION AND RESULTS OF OPERATIONS COULD BE MATERIALLY AND ADVERSELY AFFECTED. IF THIS WERE TO HAPPEN, THE PRICE OF OUR SHARES COULD DECLINE SIGNIFICANTLY AND YOU MAY LOSE ALL OR A PART OF YOUR INVESTMENT. THE RISK FACTORS DESCRIBED BELOW ARE NOT THE ONLY ONES THAT MAY AFFECT US. ADDITIONAL RISKS AND UNCERTAINTIES THAT WE DO NOT CURRENTLY KNOW ABOUT OR THAT WE CURRENTLY DEEM IMMATERIAL MAY ALSO ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION AND RESULTS OF OPERATIONS. OUR FORWARD-LOOKING STATEMENTS IN THIS PROSPECTUS ARE SUBJECT TO THE FOLLOWING RISKS AND UNCERTAINTIES. OUR ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE ANTICIPATED BY OUR FORWARD-LOOKING STATEMENTS AS A RESULT OF THE RISK FACTORS BELOW. SEE "FORWARD-LOOKING STATEMENTS."

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 a Phase IIb clinical trial 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 and $13,106,247 for the years ended December 31, 2004 and 2003, respectively. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development, continue our clinical trials of Atiprimod for the treatment of multiple myeloma, 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. 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 license agreements, we are obligated to make specified payments. If we fail to fulfill those obligations or other material obligations, the license agreements may be terminated. If either AnorMED or The University of Texas M.D. Anderson Cancer Center terminates its agreement with us, we will have no further rights to utilize the intellectual property covered by the terminated agreement, we would not be able to commercialize Atiprimod or Annamycin, as the case may be, and our business would be adversely affected, particularly if we do not have rights to other product candidates.

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.

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.

THE COMMERCIAL SUCCESS OF OUR PRODUCT CANDIDATES WILL DEPEND UPON THE DEGREE OF MARKET ACCEPTANCE OF THESE PRODUCTS AMONG PHYSICIANS, PATIENTS, HEALTH CARE PAYORS AND THE MEDICAL COMMUNITY.

Our product candidates have never been commercialized for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe our product candidates, in which case we could not generate revenue or become profitable. Market acceptance of Atiprimod for the treatment of multiple myeloma, Annamycin for the treatment of acute leukemias and our other product candidates by physicians, healthcare payors and patients will depend on a number of factors, including:

- acceptance by physicians and patients of each such product as a safe and effective treatment;
- cost effectiveness;
- adequate reimbursement by third parties;
- potential advantages over alternative treatments;

- relative convenience and ease of administration; and
- prevalence and severity of side effects.

IF OUR PRODUCT CANDIDATES ARE UNABLE TO COMPETE EFFECTIVELY WITH MARKETED CANCER DRUGS, 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.

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

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

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

PRODUCT CANDIDATES.

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

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

We have "clinical trial" liability insurance with a $3,000,000 annual aggregate limit for up to 40 patients participating 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 for 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, we intend to license or acquire additional products and product candidates for development and commercialization. Because we have limited internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license products to us. The success of this strategy depends upon our ability to identify, select and acquire the right pharmaceutical product candidates and products.

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

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

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

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

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

We are a small company with 5 full-time and 2 part-time employees as of March 31, 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. 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 clinical trials effectively;
- manage our development efforts 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 31, 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 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.

FORWARD-LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 (the "Act") provides a safe harbor for forward-looking statements made by us or on our behalf. We and our representatives may from time to time make written or oral statements that are "forward-looking," including statements contained in this prospectus and other filings with the Securities and Exchange Commission, reports to our stockholders and news releases. All statements that express expectations, estimates, forecasts or projections are forward-looking statements within the meaning of the Act. In addition, other written or oral statements which constitute forward-looking statements may be made by us or on our behalf. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," "projects," "forecasts," "may," "should," variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in or suggested by such forward-looking statements. We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Among the important factors on which such statements are based are assumptions concerning our ability to complete ongoing clinical trials, results of our clinical trials, the timing of approval of our products by the United States Food and Drug Administration, our ability to obtain additional financing, our ability to attract and retain key employees, our ability to protect intellectual property, and our ability to adapt to economic, political and regulatory conditions

affecting the healthcare industry.

USE OF PROCEEDS

We will not receive any of the proceeds from the resale of the shares. All proceeds from the sale of these shares will be solely for the accounts of the selling stockholders.

SELLING STOCKHOLDERS

On March 9, 2005, we sold and issued 1,985,791 shares of common stock in a private placement. This prospectus only covers the 1,985,791 shares of common stock issued in the private placement. The following table lists certain information with respect to the selling stockholders as follows: (i) each selling stockholder's name, (ii) the number of outstanding shares of common stock beneficially owned by the selling stockholders prior to this offering; (iii) the number of shares being offered in this offering, (iv) the number of shares of common stock to be beneficially owned by each selling stockholder after the completion of this offering assuming the sale of all of the shares of the common stock offered by each selling stockholder; and (v) if one percent or more, the percentage of outstanding shares of common stock to be beneficially owned by each selling stockholder after the completion of this offering assuming the sale of all of the shares of common stock offered by each selling stockholder. Except as noted, none of the selling stockholders have had any position, office, or other material relationship with us or any of our predecessors or affiliates within the past three years.

The selling stockholders may sell all, or none of their shares in this offering. See "Plan of Distribution."

Selling Stockholder	Number of Shares Beneficially Owned Prior to the Offering	Number of Shares Being Offered	Number of Beneficia
The Pharmaceutical/Medical Technology Fund, L.P.	694,444 (1)	250,000	444,444
Atlas Equity I, Ltd.	700,000	500,000	200,000
Orion Biomedical Fund, L..P	905,572	540,461	365,111
Orion Biomedical Offshore Fund, L..P	196,767	117,434	79,333
Alexandra Global Master Fund Ltd.	750,000	500,000	250,000
Panetta Partners, Ltd. (2)	2,101,237	25,000	2,076,237
Gary S. Jacob (3)	274,745 (4)	16,448	258,297
Christoph Bruening (5)	460,699 (6)	20,000	440,699
Daniel D'Agostino (7)	16,448	16,448	--

* less than 1%.

(1) Includes 444,444 shares of common stock owned by Greenberg Health Care Partners LLC, a related entity.

(2) Gabriele M. Cerrone, our Chairman, 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) Mr. Jacob is our Chief Executive Officer

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

(5) Mr. Bruening is a director of our company.

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

(7) Mr. D'Agostino is a consultant to our company.

PLAN OF DISTRIBUTION

The selling stockholders, or their pledgees, donees, transferees, or any of their successors in interest selling shares received from a named selling stockholder as a gift, partnership distribution or other non-sale-related transfer after the date of this prospectus (all of whom may be selling stockholders) may sell the common stock offered by this prospectus from time to time on any stock exchange or automated interdealer quotation system on which the common stock is listed or quoted at the time of sale, in the over-the-counter market, in privately negotiated transactions or otherwise, at fixed prices that may be changed, at market prices prevailing at the time of sale, at prices related to prevailing market prices or at prices otherwise negotiated. The selling stockholders may sell the common stock by one or more of the following methods, without limitation:

- Block trades in which the broker or dealer so engaged will attempt to sell the common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- An exchange distribution in accordance with the rules of any stock exchange on which the common stock is listed;
- Ordinary brokerage transactions and transactions in which the broker solicits purchases;
- Privately negotiated transactions;
- In connection with short sales of company shares;
- Through the distribution of common stock by any selling stockholder to its partners, members or stockholders;
- By pledge to secure debts of other obligations;

- In connection with the writing of non-traded and exchange-traded call options, in hedge transactions and in settlement of other transactions in standardized or over-the-counter options;

- Purchases by a broker-dealer as principal and resale by the broker-dealer for its account; or

- In a combination of any of the above.

These transactions may include crosses, which are transactions in which the same broker acts as an agent on both sides of the trade. The selling stockholders may also transfer the common stock by gift. We do not know of any arrangements by the selling stockholders for the sale of any of the common stock.

The selling stockholders may engage brokers and dealers, and any brokers or dealers may arrange for other brokers or dealers to participate in effecting sales of the common stock. These brokers or dealers may act as principals, or as an agent of a selling stockholder. Broker-dealers may agree with a selling stockholder to sell a specified number of the stocks at a stipulated price per share. If the broker-dealer is unable to sell common stock acting as agent for a selling stockholder, it may purchase as principal any unsold shares at the stipulated price. Broker-dealers who acquire common stock as principals may thereafter resell the shares from time to time in transactions in any stock exchange or automated interdealer quotation system on which the common stock is then listed, at prices and on terms then prevailing at the time of sale, at prices related to the then-current market price or in negotiated transactions. Broker-dealers may use block transactions and sales to and through broker-dealers, including transactions of the nature described above. The selling stockholders may also sell the common stock in accordance with Rule 144 or Rule 144A under the Securities Act, rather than pursuant to this prospectus. In order to comply with the securities laws of some states, if applicable, the shares of common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers.

From time to time, one or more of the selling stockholders may pledge, hypothecate or grant a security interest in some or all of the shares owned by them. The pledgees, secured parties or person to whom the shares have been hypothecated will, upon foreclosure in the event of default, be deemed to be selling stockholders. The number of a selling stockholder's shares offered under this prospectus will decrease as and when it takes such actions. The plan of distribution for that selling stockholder's shares will otherwise remain unchanged. In addition, a selling stockholder may, from time to time, sell the shares short, and, in those instances, this prospectus may be delivered in connection with the short sales and the shares offered under this prospectus may be used to cover short sales.

To the extent required under the Securities Act, the aggregate amount of selling stockholders' shares being offered and the terms of the offering, the names of any agents, brokers, dealers or underwriters, any applicable commission and other material facts with respect to a particular offer will be set forth in an accompanying prospectus supplement or a post-effective amendment to the registration statement of which this prospectus is a part, as appropriate. Any underwriters, dealers, brokers or agents participating in the distribution of the common stock may receive compensation in the form of underwriting discounts, concessions, commissions or fees from a selling stockholder and/or purchasers of selling stockholders' shares, for whom they may act (which compensation as to a particular broker-dealer might be less than or in excess of customary commissions). Neither we nor any selling stockholder can presently estimate the amount of any such compensation.

The selling stockholders and any underwriters, brokers, dealers or agents that participate in the distribution of the common stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any discounts, concessions, commissions or fees received by them and any profit on the resale of the securities sold by them may be deemed to be underwriting discounts and commissions. If a selling stockholder is deemed to be an underwriter, the selling stockholder may be subject to certain statutory liabilities including, but not limited to Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Exchange Act. Selling stockholders who are deemed underwriters within the meaning of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act. The SEC staff is of a view that selling stockholders who are registered broker-dealers or affiliates of registered broker-dealers may be underwriters under the Securities Act. We will not pay any compensation or give any discounts or commissions to any underwriter in connection with the securities being offered by this prospectus.

A selling stockholder may enter into hedging transactions with broker-dealers and the broker-dealers may engage in short sales of the common stock in the course of hedging the positions they assume with that selling stockholder, including, without limitation, in connection with distributions of the common stock by those broker-dealers. A selling stockholder may enter into option or other transactions with broker-dealers, who may then resell or otherwise transfer those common stock. A selling stockholder may also loan or pledge the common stock offered hereby to a broker-dealer and the broker-dealer may sell the common stock offered by this prospectus so loaned or upon a default may sell or otherwise transfer the pledged common stock offered by this prospectus.

The selling stockholders and other persons participating in the sale or distribution of the common stock will be subject to applicable provisions of the Exchange Act, and the rules and regulations under the Exchange Act, including Regulation M. This regulation may limit the timing of purchases and sales of any of the common stock by the selling stockholders and any other person. The anti-manipulation rules under the Exchange Act may apply to sales of common stock in the market and to the activities of the selling stockholders and their affiliates. Regulation M may restrict the ability of any person engaged in the distribution of the common stock to engage in market-making activities with respect to the particular

common stock being distributed for a period of up to five business days before the distribution. These restrictions may affect the marketability of the common stock and the ability of any person or entity to engage in market-making activities with respect to the common stock.

We have agreed to indemnify the selling stockholders who participated in our March 9, 2005 private placement (the "Private Placement Stockholders") and any brokers, dealers and agents who may be deemed to be underwriters, if any, of the common stock offered by this prospectus, against specified liabilities, including liabilities under the Securities Act. The Private Placement Stockholders have agreed to indemnify us against specified liabilities.

The common stock offered by this prospectus was originally issued to the Private Placement Stockholders pursuant to an exemption from the registration requirements of the Securities Act, as amended. We agreed to register the common stock issued to the Private Placement Stockholders under the Securities Act, and to keep the registration statement of which this prospectus is a part effective until three years after the effective date of the registration statement. We have agreed to pay all expenses incident to the registration of the common stock held by the Private Placement Stockholders in connection with this offering, but

all selling expenses related to the securities registered shall be borne by the individual holders of such securities pro rata on the basis of the number of shares of securities so registered on their behalf.

We cannot assure you that the selling stockholders will sell all or any portion of the common stock offered by this prospectus. In addition, we cannot assure you that a selling stockholder will not transfer the shares of our common stock by other means not described in this prospectus.

LEGAL MATTERS

The validity of the common stock will be passed upon by Sichenzia Ross Friedman Ference LLP, New York, New York. Sichenzia Ross Friedman Ference LLP owns an aggregate of 22,000 shares of Callisto's common stock.

EXPERTS

The financial statements incorporated by reference in this prospectus have been audited by BDO Seidman, LLP, an independent registered public accounting firm, to the extent and for the periods set forth in their report incorporated herein by reference, and are incorporated herein in reliance upon such report given upon the authority of said firm as experts in auditing and accounting.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth an estimate of the costs and expenses payable by Callisto Pharmaceuticals, Inc. in connection with the offering described in this registration statement. All of the amounts shown are estimates except the Securities and Exchange Commission ("SEC") registration fee:

Securities and Exchange Commission Registration Fee	$ 332
Printing and Engraving Expenses	2,500
Accounting Fees and Expenses	5,000
Legal Fees and Expenses	15,000
Miscellaneous	168
Total	$23,000

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Callisto Pharmaceuticals, Inc.'s Certificate of Incorporation provides that to the fullest extent permitted by the Delaware General Corporation Law, a director of the company shall not be personally liable to the company or its stockholders for monetary damages for breach of fiduciary duty as a director. Under current Delaware law, liability of a director may not be limited (i) for any breach of the director's duty of loyalty to the company or its stockholders, (ii) for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, and (iii) for any transaction from which the director derives an improper personal benefit.

The effect of the provision of Callisto's Certificate of Incorporation is to eliminate the rights of the company and its stockholders (through stockholders' derivative suits on behalf of the company) to recover monetary

damages against a director for breach of the fiduciary duty of care as a director (including breaches resulting from negligent or grossly negligent behavior) except in the situations described in clauses (i) through (iii) above. This provision does not limit or eliminate the rights of the company or any stockholder to seek nonmonetary relief such as an injunction or rescission in the event of a breach of a director's duty of care. In addition, Callisto's Certificate of Incorporation provides that the company shall indemnify to the fullest extent permitted by law its directors, officers and employees and any other persons to which Delaware law permits a corporation to provide indemnification against losses incurred by any such person by reason of the fact that such person was acting in such capacity.

Callisto has an insurance policy that insures its directors and officers, within the limits and subject to the limitations of the policy, against certain expenses in connection with the defense of actions, suits or proceedings, and certain liabilities that might be imposed as a result of such actions, suits or proceedings, to which they are parties by reason of being or having been directors or officers.

ITEM 16. EXHIBITS

EXHIBIT NUMBER	DESCRIPTION
5.1	Opinion of Sichenzia Ross Friedman Ference LLP
23.1	Consent of BDO Seidman, LLP
23.2	Consent of Sichenzia Ross Freidman Ference LLP (included in Exhibit 5.1)
24	Power of Attorney (included on Page II-3)*

* Previously filed.

ITEM 17. UNDERTAKINGS

1. The undersigned registrant hereby undertakes to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933.

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the

plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that paragraphs (B)(1)(i) and (B)(1)(ii) of this section do not apply if the registration statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the registration statement.

2. The undersigned registrant hereby undertakes that, for the purpose of determining any liability under the Securities Act of 1933, as amended, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. The undersigned registrant hereby undertakes to remove from registration by means of a post-effective amendment any of the securities being registered that remain unsold at the termination of the offering.

4. The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

5. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers and controlling persons of the undersigned registrant according the foregoing provisions, or otherwise, the undersigned registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, as amended, and will be governed by the final adjudication of such issue.

6. The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1)or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was

declared effective.

(ii) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

In accordance with the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on April 5, 2005.

CALLISTO PHARMACEUTICALS, INC.

By: /s/ Gary S. Jacob

Gary S. Jacob,
CHIEF EXECUTIVE OFFICER

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Gabriele M. Cerrone and Gary S. Jacob, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and any subsequent registration statements pursuant to Rule 462 of the Securities Act of 1933 and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that each of said attorney-in-fact or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

In accordance with the requirements of the Securities Act of 1933, as amended, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE
/s/ Gary S. Jacob Gary S. Jacob	Chief Executive Officer and Director (Principal Executive Officer)
/s/ Bernard Denoyer	Vice President, Finance (Principal Financial and Accounting Officer)

Bernard Denoyer

/s/ Gabriele M. Cerrone Gabriele M. Cerrone	Chairman of the Board
Edwin Snape	Director
/s/ Christoph Bruening Christoph Bruening	Director
/s/ John P. Brancaccio John P. Brancaccio	Director
/s/ Stephen Carter Stephen Carter	Director
/s/ Randall K. Johnson Randall K. Johnson	Director