CALLISTO PHARMACEUTICALS INC
Form S-8
October 08, 2004

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON OCTOBER 8, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-8
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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 Number)

420 LEXINGTON AVENUE, SUITE 1609
NEW YORK, NEW YORK 10170
(Address of Principal Executive Offices)

CALLISTO PHARMACEUTICALS, INC. 1996 INCENTIVE AND NON-QUALIFIED
STOCK OPTION PLAN AND NON-PLAN EXECUTIVE AND DIRECTOR OPTIONS
(Full Title of Plan)

GARY S. JACOB, PHD.
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)

COPY TO:
JEFFREY J. FESSLER, ESQ.
SILLS CUMMIS EPSTEIN & GROSS, P.C.
ONE RIVERFRONT PLAZA
NEWARK, NEW JERSEY 07102
(973) 643-5974

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(6)	Proposed Aggre Offering

Common Stock, par value $.0001 per share	216,945 shares (2)	$ .75	$5,89
	200,000 shares (2)	$1.25	
	333,055 shares (2)	$1.30	
	1,325,000 shares (3)	$1.50	
	75,000 shares (4)	$1.61	
	675,000 shares (4)	$3.00	
	175,000 shares (5)	$3.20	
	100,000 shares (4)	$3.60	

(1) Pursuant to Rule 416 promulgated under the Securities Act of 1933, as amended, this registration statement covers such indeterminate additional shares of common stock to be offered or issued to prevent dilution as a result of future stock splits, stock dividends or other similar transactions.

(2) Consists of shares of common stock underlying outstanding non-Plan options.

(3) Consists of 950,000 shares of common stock underlying outstanding options granted under the Registrant's 1996 Incentive and Non-Qualified Stock Option Plan (the "1996 Plan") and 375,000 shares of common stock underlying outstanding non-Plan options.

(4) Consists of shares of common stock underlying outstanding options granted under the 1996 Plan.

(5) Consists of 75,000 shares of common stock underlying outstanding options granted under the 1996 Plan and 100,000 shares of common stock underlying outstanding non-Plan options.

(6) Pursuant to Rule 457(h) under the Securities Act, the proposed maximum offering price per share was calculated for an aggregate of 3,100,000 shares of common stock issuable upon exercise of outstanding non-Plan options and outstanding options granted under the 1996 Plan, based on the per share exercise prices of such options, as set forth in the Calculation of Registration Fee table.

EXPLANATORY NOTE

The Registrant has prepared this Registration Statement in accordance with the requirements of Form S-8 under the Securities Act of 1933, as amended (the "Securities Act"), to register (i) 1,875,000 shares of common stock that are issuable upon the exercise of options previously granted under the Registrant's 1996 Incentive and Non-Qualified Stock Option Plan (the "1996 Plan") and (ii) 1,225,000 shares of common stock issuable upon exercise of options granted outside of the 1996 Plan ("non-Plan Options").

This Registration Statement also includes a prospectus (the "REOFFER PROSPECTUS") prepared in accordance with General Instruction C of Form S-8 and in accordance with the requirements of Part I of Form S-3. This REOFFER PROSPECTUS may be used for reofferings or resales on a continuous or delayed basis in the future by affiliates of the Company of an aggregate of 3,100,000 shares of common stock that may be issued upon exercise of 1996 Plan and non-Plan Options previously granted by the Company.

PART I

INFORMATION REQUIRED IN THE SECTION 10(A) PROSPECTUS

ITEM 1. PLAN INFORMATION.
The document(s) containing the information specified in Part I of Form S-8 will be sent or given to participants in the 1996 Plan as specified by Rule 428(b)(1) under the Securities Act of 1933, as amended (the "Securities Act"). Such documents are not being filed with the Securities and Exchange Commission, but constitute, along with the documents incorporated by reference into this Registration Statement, a prospectus that meets the requirements of Section 10(a) of the Securities Act.

ITEM 2. REGISTRANT INFORMATION AND EMPLOYEE PLAN ANNUAL INFORMATION.
The Company will furnish without charge to each person to whom the prospectus is delivered, upon the written or oral request of such person, a copy of any and all of the documents incorporated by reference in Item 3 of Part II of this Registration Statement, other than exhibits to such documents (unless such exhibits are specifically incorporated by reference to the information that is incorporated). Requests should be directed to Callisto Pharmaceuticals, Inc., 420 Lexington Avenue, Suite 1609, New York, New York 10170, Attention: Gary S. Jacob; telephone number (212) 297-0010.

NOTE: The REOFFER PROSPECTUS referred to in the Explanatory Note follows this page.

PROSPECTUS

CALLISTO PHARMACEUTICALS, INC.

3,100,000 shares of Common Stock

Callisto Pharmaceuticals, Inc. 1996 Incentive and Non-Qualified Stock Option Plan and Non-plan Executive and Director Options

This prospectus is being used in connection with the offering from time to time by certain selling stockholders of our company or their successors in interest of shares of the common stock which have been issued under, or may be acquired upon the exercise of, stock options pursuant to our 1996 Incentive and Non-Qualified Stock Option Plan and Non-plan Executive and Director Options (collectively, the "Plans").

The common stock may be sold from time to time by the selling stockholders or by their pledgees, donees, transferees or other successors in interest. Such sales may be made in the over-the-counter market or otherwise at prices and at terms then prevailing or at prices related to the then current market price, or in negotiated transactions. The common stock may be sold by one or more of the following: (a) block trades in which the broker or dealer so engaged will attempt to sell the shares as agent but may position and resell portions of the block as principal to facilitate the transaction; (b) purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus; (c) an exchange distribution in accordance with the rules of such exchange; and (d) ordinary brokerage transactions and transactions in which the broker solicits purchases. In effecting sales, brokers or dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate. Brokers or dealers will receive commissions or discounts from selling stockholders in amounts to be negotiated immediately prior to the sale. Such brokers or dealers and any other participating brokers or dealers may

be deemed to be "underwriters" within the meaning of the Securities Act of 1933, as amended (the "Act") in connection with such sales. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus. We will not receive any of the proceeds from the sale of these shares, although we have paid the expenses of preparing this prospectus and the related registration statement.

On October 7, 2004, the last reported sale price for our common stock on the OTC Bulletin Board was $2.08 per share.

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Prospectus is October 8, 2004.

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NO PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS, OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS, IN CONNECTION WITH THE OFFERING MADE HEREBY, AND, IF GIVEN OR MADE, SUCH INFORMATION OR REPRESENTATION MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY OR ANY OTHER PERSON. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER SHALL UNDER ANY CIRCUMSTANCES CREATE ANY IMPLICATION THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF THE COMPANY SINCE THE DATE HEREOF. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OFFERED HEREBY BY ANYONE IN ANY JURISDICTION IN WHICH SUCH OFFER OR SOLICITATION IS NOT AUTHORIZED OR IN WHICH THE PERSON MAKING SUCH OFFER OR SOLICITATION IS NOT QUALIFIED TO DO SO OR TO ANY PERSON TO WHOM IT IS UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION.

PROSPECTUS SUMMARY

The following summary contains basic information about Callisto Pharmaceuticals, Inc. and this prospectus. It may not contain all of the information that is important to you. For a more complete understanding, we

encourage you to read the entire prospectus and the documents incorporated by reference into this prospectus. In this prospectus, the words "Callisto," "Company," "we," "our" and "us" refer to Callisto Pharmaceuticals, Inc.

THIS OFFERING

Common Stock outstanding before the offering	29,175,102 shares (1)
Common Stock issuable upon exercise of outstanding options which may be offered pursuant to this prospectus	3,100,000 shares
Use of Proceeds	We will not receive any of the proceeds from the sale of common stock by the selling stockholders. We will receive proceeds to the extent that currently outstanding options are exercised for cash. We will use the exercise proceeds, if any, for working capital and general corporate purposes.
Risk Factors	The purchase of our common stock involves a high degree of risk. You should carefully review and consider "Risk Factors" beginning on page 5.
OTC Bulletin Board Trading Symbol	CLSP.OB

(1) As of October 7, 2004. Does not include shares of common stock issuable upon exercise of options or warrants.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports and other information with the Securities and Exchange Commission (the "SEC"). You may read and copy, upon payment of a fee set by the SEC, any documents that we file with the SEC as its public reference room at 450 Fifth Street, N.W., Washington, D.C. You may also call the SEC at 1-800-432-0330 for more information on the public reference rooms. Our filings are also available to the public on the Internet through the SEC's EDGAR database. You may access the EDGAR database at the SEC's website at www.sec.gov.

This prospectus is part of a registration statement on Form S-8 that we have filed with the SEC to register the common stock offered hereby under the Act. As permitted by SEC rules, this prospectus does not contain all of the information contained in the registration statement and accompanying exhibits and schedules that we file with the SEC. You may refer to the registration statement, the exhibits and schedules for more information about us and our common stock. The registration statement, exhibits and schedules are available at the SEC's public reference rooms or through its EDGAR database on the Internet.

You should rely only on the information contained in this prospectus or

any supplement to this prospectus. We have not authorized anyone to provide you with different information.

Our common stock is quoted on the OTC Bulletin Board under the symbol "CLSP.OB."

DOCUMENTS INCORPORATED BY REFERENCE

The following documents filed with the SEC pursuant to the Securities Exchange Act of 1934, as amended, (the "Exchange Act") are incorporated herein by reference:

1. Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003.

2. Quarterly Report on Form 10-QSB for the period ended March 31, 2004.

3. Quarterly Report on Form 10-QSB for the period ended June 30, 2004.

4. Current Reports on Form 8-K filed on January 28 and January 30, 2004, February 27, 2004, April 19, 2004, May 13, 2004 and September 7, 2004.

All documents subsequently filed by the Company pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering shall be deemed to be incorporated by reference in this prospectus and to be a part of this prospectus from the date of filing thereof.

Any statement contained in a document incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute part of this prospectus.

We will provide without charge to each person to whom this prospectus is delivered, upon written or oral request of that person, a copy of all documents incorporated by reference into the registration statement of which this prospectus is a part, other than exhibits to those documents (unless such exhibits are specifically incorporated by reference into such documents). Requests for such documents should be directed to Gary S. Jacob, Chief Executive Officer, Callisto Pharmaceuticals, Inc., 420 Lexington Avenue, Suite 1609, New York, New York 10170, telephone: (212) 297-0010.

THE COMPANY

We are a biopharmaceutical company focused on the development of drugs to treat leukemia, multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow), other cancers and osteolytic bone disease. Our lead drug candidate for multiple myeloma, Atiprimod, is a small-molecule, orally available drug with antiproliferative and antiangiogenic activity.

Atiprimod successfully completed Phase I clinical trials in rheumatoid arthritis patients and in May 2004 we commenced a Phase I/IIa open-label clinical trial of Atiprimod in relapsed multiple myeloma patients. These are patients that no longer respond to chemotherapy, and are in advanced stages of the disease. The Phase I/IIa clinical trial is being performed at two sites, the Dana-Farber Cancer Institute (Boston) and The University of Texas M.D. Anderson Cancer Center (Houston). On January 6, 2004, we announced that the Office of Orphan Products Development of the United States Food and Drug Administration, or FDA, granted orphan drug designation to Atiprimod for the treatment of

multiple myeloma.

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On August 12, 2004, we entered into a worldwide license agreement with The University of Texas M. D. Anderson Cancer Center pursuant to which we licensed Annamycin, an anthracycline drug for leukemia therapy. We intend to initiate a Phase IIb clinical trial in relapsed acute lymphocytic leukemia (ALL) and relapsed acute myeloid leukemia (AML) patients, in the first half of 2005. The trial will be led by co-Principal Investigators Dr. Hagop Kantarjian and Dr. Michael Andreeff of The University of Texas M. D. Anderson Cancer Center. Annamycin earlier completed a Phase I/IIa clinical trial in AML and ALL patients conducted by Dr. Andreeff as Principal Investigator. Relapsed ALL and AML patients are presently an unmet medical need.

Our principal executive office is located at 420 Lexington Avenue, Suite 1609, New York, New York 10170 and our telephone number is (212) 297-0010.

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.

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 clinical trials that our lead product candidate, Atiprimod for the treatment of multiple myeloma, is safe and effective;
- demonstration in Phase IIb clinical trials that Annamycin, for the treatment of leukemia, is effective;
- successful further clinical development of Atipirmod and Annamycin;
- 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, Annamycin for the treatment of leukemia is expected to enter Phase IIb clinical trials in the first half of 2005 and 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 June 30, 2004, we had an accumulated deficit of $29,555,440. We have incurred losses in each year since our inception in 1996. We incurred a net loss of $13,106,247 and $3,737,710 for the year ended December 31, 2003 and the six months ended June 30, 2004, respectively. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development, conduct our clinical trials of Atiprimod, initiate our clinical trials of Annamycin, 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 Atiprimod and Annamycin;
- continue the development of our other product candidates;
- finance our general and administrative expenses;
- prepare regulatory approval applications and seek approvals for Atiprimod for the treatment of multiple myeloma, Annamycin for the treatment of leukemia 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 2003, our cash used in operations increased significantly over 2002 and we expect that our cash used in operations will continue to increase 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 agreement with AnorMED Inc. terminates, we may be unable to continue our business.

Our business is dependent on rights we have licensed from AnorMED Inc. Under the terms of the license agreement, we are obligated to make specified payments. If we fail to fulfill those obligations or other material obligations, the license agreement may be terminated. If AnorMED 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 and we may be forced to cease our operations, 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. We commenced in May 2004 a Phase I/IIa trial of Atiprimod for the treatment of multiple myeloma. 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 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 leukemia 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 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 $2,000,000 annual aggregate limit for up to 40 patients participating in our Atiprimod 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, 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 products could be expensive and time-consuming. We may not be able to integrate any acquired business or products 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 employees as of October 7, 2004. 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 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 payors 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 payors 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 October 7, 2004, we own 4 issued United States patents and have licensed rights to 11 issued United States patents and 91 issued foreign patents, and to 4 pending United States patent applications and 41 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 may be maintained in secrecy until the patents are issued, because patent applications in the United States 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 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.

The ownership interests of our officers, directors and largest stockholders could conflict with the interests of our other stockholders.

As of October 7, 2004, our officers, directors and holders of 5% or more of our outstanding common stock beneficially own approximately 26.9% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

Our common stock may be deemed penny stock with a limited trading market.

Our common stock is currently listed for trading in the OTC Bulletin Board which is generally considered to be a less efficient market than markets such as NASDAQ or other national exchanges, and which may cause difficulty in conducting trades and difficulty in obtaining future financing. Further, our securities are subject to the "penny stock rules" adopted pursuant to Section 15(g) of the Securities Exchange Act of 1934, as amended, or Exchange Act. The penny stock rules apply to non-NASDAQ companies whose common stock trades at less than $5.00 per share or which have tangible net worth of less than $5,000,000 ($2,000,000 if the company has been operating for three or more years). Such rules require, among other things, that brokers who trade "penny stock" to persons other than "established customers" complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade "penny stock" because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. In the event that we remain subject to the "penny stock rules" for any significant period, there may develop an adverse impact on the market, if any, for our securities. Because our securities are subject to the "penny stock rules," investors will find it more difficult to dispose of our securities. Further, for companies whose securities are traded in the OTC Bulletin Board, it is more difficult: (i) to obtain accurate quotations, (ii) to obtain coverage for significant news events because major wire services, such as the Dow Jones News Service, generally do not publish press releases about such companies, and (iii) to obtain needed capital.

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.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants, the market price of our common stock could fall. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. Approximately 21.6 million shares of our restricted common stock is eligible for sale pursuant to Rule 144. In addition, the 3,100,000 shares of common stock issuable pursuant to stock options to be registered will be freely tradable upon effectiveness of the registration statement of which this prospectus is a part.

USE OF PROCEEDS

The shares which may be sold under this prospectus will be sold for the respective accounts of each of the selling stockholders. Accordingly, we will not realize any proceeds from the sale of the shares, except that we will derive proceeds if all of the options currently outstanding are exercised for cash. However, all of such options contain certain provisions for cashless exercise. If exercised for cash, such funds will be available to us for working capital and general corporate purposes. No assurance can be given, however, as to when of if any or all of the options will be exercised. All expenses of the registration of the shares will be paid for by Callisto. See "Selling Stockholders" and "Plan of Distribution."

SELLING STOCKHOLDERS

The following table sets forth (i) the name and relationship to Callisto and its affilitates of each selling stockholder, (ii) the number of outstanding shares of common stock beneficially owned by each selling stockholder prior to this offering; (iii) the number of shares of common stock each selling stockholder may acquire pursuant to the exercise of a previously granted option or options, all of which shares may be sold pursuant to this prospectus; and (iv) the number of shares of common stock beneficially owned by each selling stockholder and (if one percent or more) the percentage of outstanding shares of common stock to be beneficially owned by each selling stockholder assuming the exercise of all options granted and the sale of all shares acquired upon exercise of such options. See "Plan of Distribution."

Selling Stockholder	Shares Beneficially Owned Prior to the Offering	Shares Being Offered	Share Af

			Numbe Shar
Gabriele M. Cerrone Chairman of the Board	2,924,237 (2)	925,000	2,049
Gary S. Jacob Chief Executive Officer and Chief Scientific Officer	258,297 (3)	775,000	108
Donald H. Picker Executive Vice President, R&D	180,741 (4)	725,000	97
Kunwar Shailubhai Senior Vice President, Drug Discovery, Synergy Pharmaceuticals Inc.	75,000 (5)	125,000	
Bernard Denoyer Vice President, Finance	30,000 (6)	100,000	
Christoph Bruening Director	368,199 (7)	75,000	343
Iain G. Ross Director	25,000 (8)	75,000	
Edwin Snape Director	939,402 (9)	75,000	914
Albert Henry Director	1,407,164 (10)	75,000	1,382
John P. Brancaccio Director	-0-	75,000	
Stephen Carter Director	-0-	75,000	

* less than 1%.

(1) Applicable percentage ownership as of October 7, 2004 is based upon 29,175,102 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 2,049,237 shares held by Panetta Partners, Ltd., of which Mr. Cerrone is the sole general partner and in such capacity only exercises voting and dispositive control.

(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 75,000 shares of common stock issuable upon exercise of stock options.

(6) Consists of 30,000 shares of common stock issuable upon exercise of stock options.

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

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

(9) Includes 25,000 shares of common stock issuable upon exercise of stock options held by Mr. Snape. 714,402 shares are held by NEGF II, L.P. and 200,000 shares are held by New England Partners Capital, L.P. Mr. Snape is a principal of NEGF II, L.P. and New England Partners Capital, L.P.

(10) Includes 25,000 shares of common stock issuable upon exercise of stock options held by Mr. Henry. The remaining 1,382,164 shares are held by Henry Venture II Limited. Mr. Henry is the Chairman of Henry Venture II Limited.

PLAN OF DISTRIBUTION

In this section of the prospectus, the term "selling security holder" means and includes: (1) the persons identified in the table above as the Selling Stockholders; and (2) any of their donees, pledgees, distributees, transferees or other successors in interest who may (a) receive any of the shares of our common stock offered hereby after the date of this prospectus and (b) offer or sell those shares hereunder.

The shares of our common stock offered by this prospectus may be sold from time to time directly by the selling security holders. Alternatively, the selling security holders may from time to time offer such shares through underwriters, brokers, dealers, agents or other intermediaries. The selling security holders as of the date of this prospectus have advised us that there were no underwriting or distribution arrangements entered into with respect to the common stock offered hereby. The distribution of the common stock by the selling security holders may be effected: in one or more transactions that may take place on the OTC Bulletin Board (including one or more block transactions) through customary brokerage channels, either through brokers acting as agents for the selling security holders, or through market makers, dealers or underwriters acting as principals who may resell these shares on the OTC Bulletin Board; in privately-negotiated sales; by a combination of such methods; or by other means. These transactions may be effected at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at other negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling security holders in connection with sales of our common stock.

The selling security holders may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In such transactions, broker-dealers may engage in short sales of the shares of our common stock in the course of hedging the positions they assume with the selling

security holders. The selling security holders also may sell shares short and redeliver the shares to close out such short positions. The selling security holders may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of shares of our common stock. The broker-dealer may then resell or otherwise transfer such shares of common stock pursuant to this prospectus.

The selling security holders also may lend or pledge shares of our common stock to a broker-dealer. The broker-dealer may sell the shares of common stock so lent, or upon a default the broker-dealer may sell the pledged shares of common stock pursuant to this prospectus. Any securities covered by this prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus. The selling security holders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities. There is no underwriter or coordinating broker acting in connection with the proposed sale of shares of common stock the selling security holders.

Although the shares of common stock covered by this prospectus are not currently being underwritten, the selling security holders or their underwriters, brokers, dealers or other agents or other intermediaries, if any, that may participate with the selling security holders in any offering or distribution of common stock may be deemed "underwriters" within the meaning of the Act and any profits realized or commissions received by them may be deemed underwriting compensation thereunder.

Under applicable rules and regulations under the Exchange Act, any person engaged in a distribution of shares of the common stock offered hereby may not simultaneously engage in market making activities with respect to the common stock for a period of up to five days preceding such distribution. The selling security holders will be subject to the applicable provisions of the Exchange Act and the rules and regulations promulgated thereunder, including without limitation Regulation M, which provisions may limit the timing of purchases and sales by the selling security holders.

In order to comply with certain state securities or blue sky laws and regulations, if applicable, the common stock offered hereby will be sold in such jurisdictions only through registered or licensed brokers or dealers. In certain states, the common stock may not be sold unless they are registered or qualified for sale in such state, or unless an exemption from registration or qualification is available and is obtained.

We will bear all costs, expenses and fees in connection with the registration of the common stock offered hereby. However, the selling security holders will bear any brokerage or underwriting commissions and similar selling expenses, if any, attributable to the sale of the shares of common stock offered pursuant to this prospectus.

There can be no assurance that the selling securityholders will sell any or all of the securities offered by them hereby.

LEGAL MATTERS

The legality of the common stock to be offered hereby has been passed upon by Sills Cummis Epstein & Gross, P.C., Newark, New Jersey.

EXPERTS

The financial statements incorporated by reference in this Reoffer

Prospectus have been audited by BDO Seidman, LLP, independent registered public accountants, to the extent and for the periods set forth in their reports incorporated herein by reference, and are incorporated herein in reliance upon such reports given upon the authority of said firm as experts in auditing and accounting.

NO PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS, OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS, IN CONNECTION WITH THE OFFERING MADE HEREBY, AND, IF GIVEN OR MADE, SUCH INFORMATION OR REPRESENTATION MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY OR ANY OTHER PERSON. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER SHALL UNDER ANY CIRCUMSTANCES CREATE ANY IMPLICATION THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF THE COMPANY SINCE THE DATE HEREOF. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OFFERED HEREBY BY ANYONE IN ANY JURISDICTION IN WHICH SUCH OFFER OR SOLICITATION IS NOT AUTHORIZED OR IN WHICH THE PERSON MAKING SUCH OFFER OR SOLICITATION IS NOT QUALIFIED TO DO SO OR TO ANY PERSON TO WHOM IT IS UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION.

3,100,000 SHARES

CALLISTO PHARMACEUTICALS, INC.

COMMON STOCK

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P R O S P E C T U S

OCTOBER 8, 2004

PART II

INFORMATION REQUIRED IN REGISTRATION STATEMENT

ITEM 3 INCORPORATION OF DOCUMENTS BY REFERENCE

Included in Part I of this registration statement.

ITEM 4 DESCRIPTION OF SECURITIES

The description of the common stock contained in our Registration Statement (File No. 333-115471) on Form SB-2/A filed with the Commission on August 5, 2004 and declared effective by the Commission on August 12, 2004 is hereby incorporated by reference.

ITEM 5 INTERESTS OF NAMED EXPERTS AND COUNSEL

N/A

ITEM 6 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 the company'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, the company'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.

We have an insurance policy that insures our 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.

Insofar as indemnification for liabilities arising under the Act may be permitted to directors, officers or persons controlling Callisto pursuant to the foregoing provisions, Callisto has been informed that in the opinion of the Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable.

ITEM 7 EXEMPTION FROM REGISTRATION CLAIMED

All shares of common stock registered hereunder for reoffer or resale, have been or will be issued upon exercise of options granted pursuant to the Registrant's 1996 Incentive and Non-Qualified Stock Option Plan, and its Non-Plan Executive and Director Options. The options are non-transferable and the underlying shares were and will be issued in transactions not involving a public offering. Upon exercise of an option, the optionee is required to execute an undertaking not to resell such shares except pursuant to an effective registration statement or other exemption under the Act, a restrictive legend is placed on the certificates for the shares of common stock purchased and transfer stops are placed against such certificates. Such shares may only be reoffered and sold pursuant to registration under the Act or pursuant to an applicable exemption under the Act. As a result, such offers and sales are exempt from the registration requirements of the Act pursuant to the provisions of Section 4(2) of the Act.

INDEX TO EXHIBITS

Exhibit	Description
4.1	1996 Incentive and Non-Qualified Stock Option Plan (1)
4.2	Form of Stock Option Agreement for 1996 Incentive and Non-Qualified Stock Option Plan
4.3	Form of Non-Plan Stock Option Agreement
5.1	Opinion of Sills Cummis Epstein & Gross, P.C.
23.1	Consent of BDO Seidman, LLP
23.2	Consent of Sills Cummis Epstein & Gross, P.C. (included in Exhibit 5.1)
24.1	Power of Attorney (Included on Signature Page).

(1) Incorporated by reference to Exhibit 4.1 filed with the Company's Current Report on Form 8-K filed on April 30, 2003.

ITEM 9: UNDERTAKINGS

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement to:

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

(ii) 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, represents a fundamental change in the information set forth in the registration statement;

(iii) include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement.

Provided, however, that paragraphs (1)(i) and (1)(ii) shall not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability pursuant to the Securities Act, 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 offered at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) 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.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the 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 Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all the requirements for filing on Form S-8 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 this 8th day of October, 2004.

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 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.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Gary S. Jacob Gary S. Jacob	Chief Executive Officer (Principal Executive Officer)	October
/s/ Bernard F. Denoyer Bernard F. Denoyer	Vice President, Finance (Principal Financial Officer)	October
/s/ Gabriele M. Cerrone Gabriele M. Cerrone	Chairman of the Board	October
/s/ Iain G. Ross Iain G. Ross	Director	October
/s/ Edwin Snape Edwin Snape	Director	October
Albert J. Henry	Director	October
/s/ Stephen Carter Stephen Carter	Director	October
/s/ Christoph Bruening	Director	October

Christoph Bruening

/s/ John P. Brancaccio Director October

John P. Brancaccio

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