CALLISTO PHARMACEUTICALS INC
Form S-8
December 27, 2005

As filed with the Securities and Exchange Commission on December 27, 2005
Registration No. 333-_____

UNITED STATES
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)	(IRS Employer Identification No.)

420 Lexington Avenue, Suite 1609
New York, New York 10170
(Address of principal executive offices) (Zip Code)

1996 INCENTIVE AND NON-QUALIFIED STOCK OPTION PLAN
2005 EQUITY COMPENSATION INCENTIVE PLAN
2005 DIRECTORS' STOCK OPTION PLAN
AND NON-PLAN EMPLOYEE OPTIONS
(Full title of Plan)

Gary S. Jacob, Ph.D., Chief Executive Officer
420 Lexington Avenue, Suite 1609
New York, New York 10170
(Name and address of agent for service)

(212) 297-0010
(Telephone number, including area code, of agent for service)

With a copy to:

Jeffrey J. Fessler, Esq.
Sichenzia Ross Friedman Ference LLP
1065 Avenue of Americas
New York, NY 10018

(212) 930-9700
Fax (212) 930-9725

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Proposed Maximum Amount to be Registered (1)	Proposed Maximum Offering Price Per Share	Aggregate Offering Price	Amount of Registration Fee
Common Stock, $.0001 par value	10,000 (2)	$ 1.80 (7)	$ 3,179,459	$ 340
	10,000 (2)	1.75 (7)		
	375,000 (2)	1.70 (7)		
	45,000 (2)	1.60 (7)		
	200,000 (2)	1.54 (7)		
	475,000 (2)	1.53 (7)		
	145,000 (2)	1.50 (7)		
	75,000 (2)	1.38 (7)		
	50,000 (2)	1.10 (7)		
	225,000 (2)	1.03 (7)		
	550,000 (2)	1.01 (7)		
	76,984 (2)	1.00 (7)		
	25,000 (2)	0.97 (7)		
	30,000 (3)	1.17 (7)		
	22,500 (3)	1.45 (7)		
	45,000 (4)	1.50 (7)		
Common Stock, $.0001 par value	5,000,000 (5)	1.43 (8)	7,150,000	765
Common Stock, $.0001 par value	1,447,500 (6)	1.43 (8)	2,069,925	222
Total:	8,806,984		$ 12,399,384	$ 1,327

(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 issuable upon exercise of options outstanding pursuant to our 1996 Incentive and Non-Qualified Stock Option Plan.

(3) Consists of shares of common stock issuable upon exercise of options outstanding pursuant to our 2005 Directors' Stock Option Plan.

(4) Consists of shares of common stock issuable upon exercise of outstanding non-Plan employee options.

(5) Consists of shares of common stock issuable upon exercise of options available for grant pursuant to our 2005 Equity Compensation Incentive Plan.

(6) Consists of shares of common stock issuable upon exercise of options available for grant pursuant to our 2005 Directors' Stock Option Plan.

(7) Pursuant to Rule 457(h) under the Securities Act, the proposed maximum offering price per share was calculated for an aggregate of 2,261,984 shares of common stock issuable upon exercise of outstanding options granted under the 1996 Plan, for an aggregate of 52,500 shares of common stock issuable upon exercise of outstanding options granted under the 2005 Directors' Stock Option Plan, and 45,000 shares of common stock issuable upon exercise of outstanding non-Plan options, based on the per share exercise prices of such options, as set forth in the Calculation of Registration Fee table.

(8) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, using the average of the high and low price as reported on the American Stock Exchange on December 23, 2005.

EXPLANATORY NOTE

This Registration Statement is being filed in accordance with the requirements of Form S-8 in order to register an aggregate of 8,806,984 shares of our common stock, par value $0.0001 per share, consisting of (i) 2,261,984 shares of common stock issuable upon exercise of options outstanding pursuant to our 1996 Incentive and Non-Qualified Stock Option Plan, (ii) 5,000,000 shares of common stock issuable upon exercise of options available for grant pursuant to our 2005 Equity Compensation Incentive Plan, (iii) 1,447,500 shares of common stock issuable upon exercise of options available for grant pursuant to our 2005 Directors' Stock Option Plan, (iv) 52,500 shares of common stock issuable upon exercise of options outstanding pursuant to our 2005 Directors' Stock Option Plan and (v) 45,000 shares of common stock issuable upon exercise of outstanding non-plan employee options.

In addition, the Prospectus filed as part of this Registration Statement has been prepared in accordance with the requirements of Form S-3 and may be used for reofferings and resales of up to an aggregate of 2,089,484 shares of our common stock, consisting of (i) 2,036,984 shares issuable upon exercise of options previously granted by us to our officers and directors under our 1996 Incentive and Non-Qualified Stock Option Plan, and (ii) 52,500 shares issuable upon exercise of options previously granted by us to our directors under our 2005 Directors' Stock Option Plan.

PART I

Item 1. Plan Information.

The documents containing the information specified in Item 1 will be sent or given to participants in the 1996 Incentive and Non-Qualified Stock Option Plan, the 2005 Equity Compensation Incentive Plan and the 2005 Directors' Stock Option Plan as specified by Rule 428(b)(1) of the Securities Act of 1933, as amended (the "Securities Act"). Such documents are not required to be and are not filed with the Securities and Exchange Commission (the "SEC") either as part of this Registration Statement or as prospectuses or prospectus supplements pursuant to Rule 424. These documents and the documents incorporated by reference in this Registration Statement pursuant to Item 3 of Part II of this Form S-8, taken together, constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act.

Item 2. Registrant Information and Employee Plan Annual Information.

Upon written or oral request, any of the documents incorporated by reference in Item 3 of Part II of this Registration Statement (which documents are incorporated by reference in this Section 10(a) Prospectus), other documents required to be delivered to eligible employees, non-employee directors and consultants, pursuant to Rule 428(b) are available without charge by contacting:

Gary S. Jacob, Ph.D., Chief Executive Officer
420 Lexington Avenue, Suite 1609
New York, New York 10170
(212) 297-0010

Prospectus

Callisto Pharmaceuticals, Inc.

2,089,484 SHARES OF COMMON STOCK

1996 Incentive and Non-Qualified Stock Option Plan
2005 Directors' Stock Option Plan

This prospectus relates to the sale of up to 2,089,484 shares of common stock Callisto Pharmaceuticals, Inc. offered by certain holders of our securities, including up to (i) 2,036,984 shares issuable upon exercise of options previously granted by us to our officers and directors under our 1996 Incentive and Non-Qualified Stock Option Plan, and (ii) 52,500 shares issuable upon exercise of options previously granted by us to our directors under our 2005 Directors' Stock Option Plan. The shares may be offered by the selling stockholders from time to time in regular brokerage transactions, in transactions directly with market makers or in certain privately negotiated transactions. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution." We will not receive any of the proceeds from the sale of the shares by the selling stockholders.

Our common stock trades on the American Stock Exchange under the symbol "KAL." On December 23, 2005, the closing sale price of the common stock was $1.45 per share.

The securities offered hereby are speculative and involve a high degree of risk and substantial dilution. Only investors who can bear the risk of loss of their entire investment should invest. See "Risk Factors" beginning on page 9.

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

The date of this prospectus is December 27, 2005

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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

Overview

We are a biopharmaceutical company focused on the development of drugs to treat relapsed (re-occurrence of active disease) acute leukemia, multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow), other cancers and osteolytic bone disease (bone disease caused by white blood cells). Our lead drug candidate, L-Annamycin, a drug from the anthracycline family (chemotherapy drugs which are derived from antibiotics), earlier completed an initial Phase I/IIa clinical trial in relapsed or refractory leukemia patients with a prior sponsor. L-Annamycin, originally developed by scientists at The University of Texas M.D. Anderson Cancer Center to address the clinical limitations associated with anthracycline drugs such as Adriamycin (doxorubicin) to treat cancer, began a clinical trial at The University of Texas M.D. Anderson Cancer Center in adult relapsed acute lymphocytic leukemia (ALL) patients on December 1, 2005. This single-arm, open label trial will enroll 12 patients in a dose escalation Phase I portion, followed by 10 patients in a final fixed dose in the Phase II portion. We plan to treat up to 34 patients. We also expect to commence two additional trials of L-Annamycin in 2006, a single agent trial in pediatric relapsed ALL patients and a combination therapy trial with Ara-C (cytosine arabinoside) in relapsed acute myeloid leukemia (AML) patients.

Our second drug candidate, Atiprimod, is an orally administered drug with antiproliferative and antiangiogenic activity. Atiprimod commenced a Phase I/IIa clinical trial in relapsed multiple myeloma patients on May 26, 2004. These are patients that have a re-occurrence of active disease, and no longer respond to approved therapies. The Phase I/IIa clinical trial is being performed at four sites, The University of Texas M.D. Anderson Cancer Center (Houston, TX), the Dana-Farber Cancer Institute (Boston, MA), the St. Vincent's Comprehensive Cancer Center (New York, NY) and the Roswell Park Cancer Institute (Buffalo, NY). In Dcember 2005, we announced an update on interim results from this trial performed in relapsed or refractory multiple myeloma patients which consisted of 15 patients treated with Atiprimod, including 3 patients at the highest dose level of 180 mg/day. Two patients exhibited stable disease, with one patient having a 34% decrease in M protein (measure of tumor burden) over 3 months of treatment. It was also noted that two patients reported a subjective decrease in bone pain. We plan to continue this trial at higher dose levels until the maximum tolerated dose is reached and then treat 10 additional patients at that level.

On March 15, 2005 we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The new trial is entitled: "An Open Label Study of the Safety and Efficacy of Atiprimod Treatment for Patients with Advanced Cancer". The trial is currently being conducted at the University of Texas M.D. Anderson Cancer Center.

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.

This Offering

Shares of common stock outstanding prior to this offering	33,233,096 (1)
Shares of common stock issuable upon exercise of outstanding options which may be offered pursuant to this prospectus	2,089,484
Use of proceeds	We will not receive any proceeds from the sale of the shares of common stock offered in this prospectus. 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 9.
American Stock Exchange Symbol	KAL

(1) As of December 23, 2005. Does not include shares of common stock issuable upon exercise of outstanding options or warrants.

RISK FACTORS

Investment in our common stock involves a high degree of risk. You should consider the following discussion of risks as well as other information in this prospectus. The risks and uncertainties described below are not the only ones. If any of the following risks actually occur, our business could be harmed. In such case, the trading price of our common stock could decline.

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 L-Annamycin for the treatment of relapsed acute leukemia, respectively, are safe and effective;
- the successful development of our other product candidates;
- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;
- the successful commercialization of our product candidates; and
- market acceptance of our products.

All of our existing product candidates will require extensive additional clinical evaluation, regulatory review, significant marketing efforts and substantial investment before they could provide us with any revenue. For example, Atiprimod for the treatment of multiple myeloma entered Phase I/IIa clinical trials in May 2004 and L-Annamycin for the treatment of acute leukemia entered clinical trials in December 2005. Our other product candidates are in preclinical development. As a result, if we do not successfully develop and commercialize Atiprimod or L-Annamycin, we will be unable to generate any revenue for many years, if at all. We do not anticipate that we will generate revenue for several years, at the earliest, or that we will achieve profitability for at least several years after generating material revenue, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

WE HAVE INCURRED SIGNIFICANT LOSSES SINCE INCEPTION AND ANTICIPATE THAT WE WILL INCUR CONTINUED LOSSES FOR THE FORESEEABLE FUTURE.

As of September 30, 2005 and December 31, 2004, we had an accumulated deficit of $41,886,574 and $33,361,197, respectively. We have incurred losses in each year since our inception in 1996. We incurred a net loss of $8,525,377 for the nine months ended September 30, 2005 and $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 L-Annamycin for the treatment of acute leukemias, acquire or license technologies, advance our other product candidates into clinical development, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock will likely decline.

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 L-Annamycin for the treatment of acute leukemia;
- continue the development of our other product candidates;
- finance our general and administrative expenses;
- prepare regulatory approval applications and seek approvals for Atiprimod and L-Annamycin and our other product candidates;
- license or acquire additional technologies;
- launch and commercialize our product candidates, if any such product candidates receive regulatory approval; and
- develop and implement sales, marketing and distribution capabilities.

In 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. For the nine months ended September 30, 2005, we have spent approximately $6.5 million or approximately $722,000 per month. As of September 30, 2005, we had $3,541,265 in cash and cash equivalents. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of our current product candidates and to continue to fund operations at the current cash expenditure levels. Our future funding requirements will depend on many factors, including, but not limited to:

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

To date, our sources of cash have been primarily limited to the sale of our equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

- seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and
- relinquish, license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

IF OUR AGREEMENTS WITH ANORMED INC. OR THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER TERMINATE, OUR BUSINESS WOULD BE ADVERSELY AFFECTED.

Our business is dependent on rights we have licensed from AnorMED Inc. and The University of Texas M.D. Anderson Cancer Center. Under the terms of the AnorMED license agreement, we are obligated to make a maintenance fee payment of $200,000 on January 1 of each year for the term of the license agreement. Pursuant to the license agreement, failure to pay the maintenance fee is a material breach of the agreement. We do not anticipate failing to pay the maintenance fee, however in the event we cannot pay the maintenance fee, AnorMED may terminate the license agreement and we would not be able to further develop and commercialize Atiprimod which would have an adverse effect on our business. Under the terms of The University of Texas M.D. Anderson Cancer Center license agreement, we are required to make certain good faith expenditures towards the clinical development of at least one

licensed product within the two year period after March 2005. In addition, at any time after 5 years from August 12, 2004, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we

fail to provide evidence within 90 days of written notice that we have commercialized or we are actively and effectively attempting to commercialize L-Annamycin. If we fail to fulfill these obligations or other material obligations, The University of Texas M.D. Anderson Cancer Center license agreement may be terminated and our business would be adversely affected.

CLINICAL TRIALS INVOLVE A LENGTHY AND EXPENSIVE PROCESS WITH AN UNCERTAIN OUTCOME, AND RESULTS OF EARLIER STUDIES AND TRIALS MAY NOT BE PREDICTIVE OF FUTURE TRIAL RESULTS.

In order to receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive clinical trials to demonstrate safety and efficacy of these product candidates. Clinical testing is expensive, can take many years to complete and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

DELAYS IN CLINICAL TESTING COULD RESULT IN INCREASED COSTS TO US AND DELAY OUR ABILITY TO GENERATE REVENUE.

While to date there has been no delays in our clinical trials, enrollment in our Atiprimod Phase I/IIa trial in multiple myeloma was slower than anticipated due to limited availability of relapsed multiple myeloma patients. In the future, we may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval to conduct a trial at a prospective site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new drugs approved for the conditions we are investigating. Prescribing physicians will also have to decide to use our product candidates over existing drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and delay our ability to generate revenue.

WE MAY BE REQUIRED TO SUSPEND OR DISCONTINUE CLINICAL TRIALS DUE TO UNEXPECTED SIDE EFFECTS OR OTHER SAFETY RISKS THAT COULD PRECLUDE APPROVAL OF OUR PRODUCT CANDIDATES.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

IF WE ARE UNABLE TO SATISFY REGULATORY REQUIREMENTS, WE MAY NOT BE ABLE TO COMMERCIALIZE OUR PRODUCT CANDIDATES.

We need FDA approval prior to marketing our product candidates in the United States of America. We commenced in May 2004 a Phase I/IIa trial of Atiprimod for the treatment of multiple myeloma. In addition, we commenced a Phase I/IIa clinical trial of L-Annamycin for the treatment of acute lymphocytic leukemia in December 2005. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States of America and we will not generate any revenue.

This regulatory review and approval process, which includes evaluation of preclinical studies and clinical trials of a product candidate as well as the evaluation of our manufacturing process and our contract manufacturers' facilities, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that the product candidate is both safe and effective for each indication where approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might submit for regulatory review any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use.

The FDA has substantial discretion in the approval process and may either refuse to file our application for substantive review or may form the opinion after review of our data that our application is insufficient to allow approval of our product candidates. If the FDA does not file or approve our application, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to abandon our applications for approval, which might cause us to cease operations.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing the product in those countries. The approval process varies from country to country and the time needed to secure approval may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country.

IF OUR PRODUCT CANDIDATES ARE UNABLE TO COMPETE EFFECTIVELY WITH MARKETED CANCER DRUGS TARGETING SIMILAR INDICATIONS AS OUR PRODUCT CANDIDATES, OUR COMMERCIAL OPPORTUNITY WILL BE REDUCED OR ELIMINATED.

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize cancer drugs that are safer, more effective, have fewer side effects or are less expensive than our product candidates. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring

technologies and technology licenses complementary to our programs or advantageous to our business.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our products and manufacturing processes and other related product technology;
- attract and retain key personnel;
- develop relationships with physicians prescribing these products; and
- build an adequate sales and marketing infrastructure for our product candidates.

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to existing cancer drugs. If we are unable to compete effectively in the cancer drug market and differentiate our products from currently marketed cancer drugs, we may never generate meaningful revenue.

Numerous pharmaceutical and biotechnology companies have developed anthracycline drugs used to treat acute leukemias similar to our compound, L-Annamycin. These compounds include Adriamycin® and Ellence® which are marketed by Pfizer and Cerubidine® which is marketed by Boehringer Ingelheim. These drugs have been approved by the FDA and are currently being marketed as opposed to L-Annamycin which is in clinical development. Atiprimod, our drug candidate for relapsed multiple myeloma, works through a different mechanism of action than Velcade which is currently marketed by Millenium Pharmaceuticals and other drugs in development, such as Celgene Corporation's Revlimid.

WE CURRENTLY HAVE NO SALES AND MARKETING ORGANIZATION. IF WE ARE UNABLE TO ESTABLISH A DIRECT SALES FORCE IN THE UNITED STATES TO PROMOTE OUR PRODUCTS, THE COMMERCIAL OPPORTUNITY FOR OUR PRODUCTS MAY BE DIMINISHED.

We currently have no sales and marketing organization. If any of our product candidates are approved by the FDA, we intend to market that product directly to hospitals in the United States of America through our own sales force. We will incur significant additional expenses and commit significant additional management resources to establish this sales force. We may not be able to establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If we elect to rely on third parties to sell our product candidates in the United States, we may receive less revenue than if we sold our products directly. In addition, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third party to sell our product candidates, we may not be able to commercialize our product candidates which would negatively impact our ability to generate revenue.

WE MAY NEED OTHERS TO MARKET AND COMMERCIALIZE OUR PRODUCT CANDIDATES IN INTERNATIONAL MARKETS.

In the future, if appropriate regulatory approvals are obtained, we intend to commercialize our product candidates in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. Currently, we do not have any plans to enter international markets. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

IF OUR RELATIONSHIP WITH OUR CONTRACT MANUFACTURER FOR L-ANNAMYCIN TERMINATES, OR THEIR FACILITIES ARE DAMAGED OR DESTROYED, WE MAY BE UNABLE TO DEVELOP OR COMMERCIALIZE L-ANNAMYCIN.

Currently, Antibioticos S.p.A. is our sole supplier of Annamycin (drug substance that is the active component of the final formulated L-Annamycin drug product). If our relationship with this contract

manufacturer, or any other contract manufacturer we might use, terminates or if any of their facilities are damaged for any reason, including fire, flood, earthquake or other similar event, we may be unable to obtain supply of Annamycin. If any of these events were to occur, we may need to find alternative manufacturers or manufacturing facilities. The number of contract manufacturers with the expertise, required regulatory approvals and facilities to manufacture Annamycin on a commercial scale is extremely limited, and it would take a significant amount of time to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must approve these manufacturers' facilities and processes prior to our use, which would require new testing and compliance inspections. In addition, we may not have the intellectual property rights, or may have to share intellectual property rights, to any improvements in the current manufacturing processes or any new manufacturing processes for Annamycin. Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of L-Annamycin, entail higher costs, and could result in our being unable to commercialize L-Annamycin successfully. Furthermore, if our contract manufacturers fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we were unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for L-Annamycin and we would lose potential revenue.

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

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

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

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

- decreased demand for our product candidates;

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

We have "clinical trial" liability insurance with a $3,000,000 annual aggregate limit for up to 40 patients participating in our Atiprimod and L-Annamycin clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

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

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

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

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

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

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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, Donald Picker, our Executive Vice President, R&D and Pamela Harris, our Chief Medical Officer. The loss of services of Drs. Jacob, Picker, Harris or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidates.

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

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

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

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

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

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

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

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

We are a small company with 10 full-time and 4 part-time employees as of December 23, 2005. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Over the next 12 months depending on the progress of our planned clinical trials, we plan to add approximately four employees who we expect to assist us with our clinical programs. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

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

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

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

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

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

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

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

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

As of December 23, 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. Our issued United States patents we own and license primarily are composition of matter and formulation patents related to Atiprimod and L-Annamycin. Our composition of matter patents for L-Annamycin and Atiprimod expire in 2008 and 2009, respectively. Our formulation patents for L-Annamycin and Atiprimod dimeleate (preferred salt form) expire in 2019 and 2018, respectively.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The biotechnology patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our licensed patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are competitive with our product candidates but that are not covered by the claims of our licensed patents, or for which we are not licensed under our license agreements;
- we or our licensors might not have been the first to make the inventions covered by our pending patent application or the pending patent applications and issued patents of our licensors;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent application or one or more of the pending patent applications of our licensors will not result in issued patents;

- the issued patents of our licensors may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use

reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

WE MAY INCUR SUBSTANTIAL COSTS AS A RESULT OF LITIGATION OR OTHER PROCEEDINGS RELATING TO PATENT AND OTHER INTELLECTUAL PROPERTY RIGHTS AND WE MAY BE UNABLE TO PROTECT OUR RIGHTS TO, OR USE, OUR TECHNOLOGY.

If we choose to go to court to stop someone else from using the inventions claimed in our licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States of America may be maintained in secrecy until the patents are issued, because patent applications in the United States of America and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our licensors' issued patents or our pending applications or our licensors' pending applications or that we or our licensors were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our or our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the United States Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

RISKS RELATED TO OUR COMMON STOCK

MARKET VOLATILITY MAY AFFECT OUR STOCK PRICE AND THE VALUE OF YOUR INVESTMENT.

The market prices for securities of biopharmaceutical companies in general have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing process or sales and marketing activities;
- regulatory developments in the United States of America and foreign countries;
- the success of our development efforts and clinical trials;
- the success of our efforts to acquire or in-license additional products or product candidates;
- any intellectual property infringement action, or any other litigation, involving us;
- announcements concerning our competitors, or the biotechnology or biopharmaceutical industries in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- our ability to maintain listing requirements on the American Stock Exchange;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders; and
- the loss of any of our key scientific or management personnel.

The occurrence of one or more of these factors may cause our stock price to decline, and 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. 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.

SELLING STOCKHOLDERS

The table below sets forth information concerning the resale of the shares of common stock by the selling stockholders. We will not receive any proceeds from the resale of the common stock by the selling stockholders. We will receive proceeds from the exercise of the options.

The following table also sets forth the name of each person who is offering the resale of shares of common stock by this prospectus, the number of shares of common stock beneficially owned by each person, the number of shares of common stock that may be sold in this offering and the number of shares of common stock each person will own after the offering, assuming they sell all of the shares offered which they beneficially own as of the date hereof.

	Shares Beneficially Owned Prior to the Offering (1)			Shares Beneficially Owned After the Offering (1)	
Name	Number	Percent (2)	Total Shares Offered	Number	Percent (2)
Riccardo Dalla-Favera	—	—	81,000	—	—
Stephen Carter	28,287 (3)	*	19,861	25,000	*
John Brancaccio	30,707 (4)	*	31,123	25,000	*
Randall Johnson	35,000 (5)	*	94,000	—	—
Pamela Harris	—	—	350,000	—	—
Gary S. Jacob	449,745 (6)	1.3%	350,000	449,745	1.3%
Donald Picker	315,370 (7)	*	200,000	315,370	*
Bernard Denoyer	30,000 (8)	*	75,000	30,000	*
Kunwar Shailubhai	125,000 (9)	*	75,000	125,000	*
Daniel D'Agostino	16,448 (10)	*	400,000	16,448	*
Christoph Bruening	534,032 (11)	1.6%	38,500	525,699	1.6%
Gabriele M. Cerrone	3,214,237 (12)	9.4%	375,000	3,026,737	8.8%

* Less than one percent.

(1) The number and percentage of shares beneficially owned is determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rule, beneficial ownership includes any shares as to which the selling stockholder has sole or shared voting power or investment power and also any shares, which the selling stockholder has the right to acquire within 60 days.

(2) Based upon 33,233,096 shares issued and outstanding as of December 23, 2005.

(3) Consists of shares of common stock issuable upon exercise of stock options.

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

(5)

	Consists of shares of common stock issuable upon exercise of stock options.
(6)	Consists of (i) 124,745 shares of common stock, and (ii) 325,000 shares of common stock issuable upon exercise of stock options.
(7)	Consists of (i) 73,704 shares of common stock and (ii) 241,666 shares of common stock issuable upon exercise of stock options.

(8) Consists of common stock issuable upon exercise of stock options.

(9) Consists of common stock issuable upon exercise of stock options.

(10) Consists of shares of common stock.

(11) Consists of (i) 475,699 shares of common stock and (ii) 58,333 shares of common stock issuable upon exercise of stock options.

(12) Consists of (i) 1,087,500 shares of common stock issuable upon exercise of stock options and (ii) 2,126,737 shares of common stock held by Panetta Partners, Ltd. Mr. Cerrone is the sole managing partner of Panetta and in such capacity only exercises voting and dispositive control over securities owned by Panetta.

PLAN OF DISTRIBUTION

Sales of the shares may be effected by or for the account of the selling stockholders from time to time in transactions (which may include block transactions) on the American Stock Exchange, in negotiated transactions, through a combination of such methods of sale, or otherwise, at fixed prices that may be changed, at market prices prevailing at the time of sale or at negotiated prices. The selling stockholders may effect such transactions by selling the shares directly to purchasers, through broker-dealers acting as agents of the selling stockholders, or to broker-dealers acting as agents for the selling stockholders, or to broker-dealers who may purchase shares as principals and thereafter sell the shares from time to time in transactions (which may include block transactions) on the American Stock Exchange, in negotiated transactions, through a combination of such methods of sale, or otherwise. In effecting sales, broker-dealers engaged by a selling stockholder may arrange for other broker-dealers to participate. Such broker-dealers, if any, may receive compensation in the form of discounts, concessions or commissions from the selling stockholders and/or the purchasers of the shares for whom such broker-dealers may act as agents or to whom they may sell as principals, or both (which compensation as to a particular broker-dealer might be in excess of customary commissions).

The selling stockholders and any broker-dealers or agents that participate with the selling stockholders in the distribution of the shares may be deemed to be "underwriters" within the meaning of the Securities Act of 1933. Any commissions paid or any discounts or concessions allowed to any such persons, and any profits received on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act of 1933.

We have agreed to bear all expenses of registration of the shares other than legal fees and expenses, if any, of counsel or other advisors of the selling stockholders. The selling stockholders will bear any commissions, discounts, concessions or other fees, if any, payable to broker-dealers in connection with any sale of their shares.

We have agreed to indemnify the selling stockholders, or their transferees or assignees, against certain liabilities, including liabilities under the Securities Act of 1933 or to contribute to payments the selling stockholders or their respective pledgees, donees, transferees or other successors in interest, may be required to make in respect thereof.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Sichenzia Ross Friedman Ference LLP, 1065 Avenue of the Americas, 21st Floor, New York, NY 10018. Sichenzia Ross Friedman Ference LLP owns an aggregate of 22,000 shares of our 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.

INFORMATION INCORPORATED BY REFERENCE

The Securities and Exchange Commission allows us to incorporate by reference certain of our publicly-filed documents into this prospectus, which means that such information is considered part of this prospectus. Information that we file with the SEC subsequent to the date of this prospectus will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under all documents subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until the selling stockholders have sold all of the shares offered hereby or such shares have been deregistered.

The following documents filed with the SEC are incorporated herein by reference:

- Reference is made to the Registrant’s quarterly report on Form 10-Q for the period ending September 30, 2005, as filed with the SEC on November 14, 2005, which is hereby incorporated by reference.

- Reference is made to the Registrant’s quarterly report on Form 10-Q for the period ending June 30, 2005, as filed with the SEC on August 8, 2005, which is hereby incorporated by reference.

- Reference is made to the Registrant’s quarterly report on Form 10-Q for the period ending March 31, 2005, as filed with the SEC on May 16, 2005, which is hereby incorporated by reference.

- Reference is made to the Registrant’s annual report on Form 10-KSB for the period ending December 31, 2004, as filed with the SEC on March 30, 2005, which is hereby incorporated by reference.

- Reference is made to the Registrant’s annual report on Form 10-K/A for the period ending December 31, 2004, as filed with the SEC on June 6, 2005, which is hereby incorporated by reference.

- Reference is made to Registrant's 8-Ks filed with the SEC on February 3, 7, and 14, 2005, March 15 and 30, 2005, April 8, 2005, June 15, 2005, July 7 and 22, 2005, August 26, 2005, October 21, 2005, December 6, 2005 and December 12, 2005, each of which are hereby incorporated by reference.

- Reference is made to the description of the Registrant's common stock as contained in Item 1 of its Registration Statement on Form 8-A, filed with the Commission on October 22, 2004, including all amendments and reports filed with the Commission for the purpose of updating such description, which is hereby incorporated by reference.

We will provide without charge to each person to whom a copy of this prospectus has been delivered, on written or oral request a copy of any or all of the documents incorporated by reference in this prospectus, other than exhibits to such documents. Written or oral requests for such copies should be directed to Gary S. Jacob.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Our 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 our 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, our 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.

ADDITIONAL INFORMATION AVAILABLE TO YOU

This prospectus is part of a Registration Statement on Form S-8 that we filed with the SEC. Certain information in the Registration Statement has been omitted from this prospectus in accordance with the rules of the SEC. We file annual, quarterly and special reports, proxy statements and other information with the SEC. You can inspect and copy the Registration Statement as well as reports, proxy statements and other information we have filed with the SEC at the public reference room maintained by the SEC at 100 F Street N.E. Washington, D.C. 20549, You can obtain copies from the public reference room of the SEC at 100 F Street N.E. Washington, D.C. 20549, upon payment of certain fees. You can call the SEC at 1-800-732-0330 for further information about the public reference room. We are also required to file electronic versions of these documents with the SEC, which may be accessed through the SEC's World Wide Web site at http://www.sec.gov. No dealer, salesperson or other person is authorized to give any information or to make any representations other than those contained in this prospectus, and, if given or made, such information or representations must not be relied upon as having been authorized by us. This prospectus does not constitute an offer to buy any security other than the securities offered by this prospectus, or an offer to sell or a solicitation of an offer to buy any securities by any person in any jurisdiction where such offer or solicitation is not authorized or is unlawful. Neither delivery of this prospectus nor any sale hereunder shall, under any circumstances, create any implication that there has been no change in the affairs of our company since the date hereof.

CALLISTO PHARMACEUTICALS, INC.

2,089,484 SHARES OF COMMON STOCK

PROSPECTUS

December 23, 2005

PART II

INFORMATION REQUIRED IN THE REGISTRATION STATEMENT

Item 3. Incorporation of Documents by Reference.

The Registrant hereby incorporates by reference into this Registration Statement the documents listed below. In addition, all documents subsequently filed pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), prior to the filing of a post-effective amendment which indicates that all securities offered have been sold or which deregisters all securities then remaining unsold, shall be deemed to be incorporated by reference into this Registration Statement and to be a part hereof from the date of filing of such documents:

- Reference is made to the Registrant’s quarterly report on Form 10-Q for the period ending September 30, 2005, as filed with the SEC on November 14, 2005, which is hereby incorporated by reference.

- Reference is made to the Registrant’s quarterly report on Form 10-Q for the period ending June 30, 2005, as filed with the SEC on August 8, 2005, which is hereby incorporated by reference.

- Reference is made to the Registrant’s quarterly report on Form 10-Q for the period ending March 31, 2005, as filed with the SEC on May 16, 2005, which is hereby incorporated by reference.

- Reference is made to the Registrant’s annual report on Form 10-KSB for the period ending December 31, 2004, as filed with the SEC on March 30, 2005, which is hereby incorporated by reference.

- Reference is made to the Registrant’s annual report on Form 10-K/A for the period ending December 31, 2004, as filed with the SEC on June 6, 2005, which is hereby incorporated by reference.

- Reference is made to Registrant's 8-Ks filed with the SEC on February 3, 7, and 14, 2005, March 15 and 30, 2005, April 8, 2005, June 15, 2005, July 7 and 22, 2005, August 26, 2005, October 21, 2005, December 6, 205 and December 12, 2005, each of which are hereby incorporated by reference.

- Reference is made to the description of the Registrant's common stock as contained in Item 1 of its Registration Statement on Form 8-A, filed with the Commission on October 22, 2004, including all amendments and reports filed with the Commission for the purpose of updating such description, which is hereby incorporated by reference.

Item 4. Description of Securities.

Not Applicable.

Item 5. Interests of Named Experts and Counsel.

The validity of the shares of common stock offered hereby will be passed upon for the Registrant by Sichenzia Ross Friedman Ference LLP, 1065 Avenue of Americas, 21st flr., New York, NY 10018. Sichenzia Ross Friedman Ference LLP owns an aggregate of 22,000 shares of the Registrant’s common stock.

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 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 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, 2005 Equity Compensation Incentive 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.

Item 8. Exhibits.

EXHIBIT NUMBER	**EXHIBIT**
4.1	1996 Incentive and Non-Qualified Stock Option Plan (1)
4.2	2005 Equity Compensation Incentive Plan (2)
4.3	2005 Directors' Stock Option Plan (3)
4.4	Form of Non-Plan Stock Option Agreement (4)
5.1	Opinion of Sichenzia Ross Friedman Ference LLP.
23.1	Consent of Sichenzia Ross Friedman Ference LLP is contained in Exhibit 5.1.
23.2	Consent of BDO Seidman, LLP.
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.
(2) Incorporated by reference to Appendix B filed with the Company's Definitive Proxy Statement on Schedule 14A filed on August 31, 2005.

(3) Incorporated by reference to Appendix C filed with the Company's Definitive Proxy Statement on Schedule 14A filed on August 31, 2005.
(4) Incorporated by reference to Exhibit 4.3 filed with the Company's Registration Statement on Form S-8 filed on October 4, 2004.

Item 9. Undertakings.

(a) 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:

(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 (1)(i), and (1)(ii) do not apply if the Registration Statement is on Form S-8 and if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission 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 under the Securities Act of 1933, 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) 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.

(4) 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 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.

(5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(A) Each prospectus filed by a Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i),

(vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which the prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(6) That, for the purpose of determining liability of a Registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, each undersigned Registrant undertakes that in a primary offering of securities of an undersigned Registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of an undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of an undersigned Registrant or used or referred to by an undersigned Registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about an undersigned Registrant or its securities provided by or on behalf of an undersigned Registrant; and

(iv) Any other communication that is an offer in the offering made by an undersigned Registrant to the purchaser.

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 Securities 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

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-8 and has duly caused this Form S-8 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on December 27, 2005.

CALLISTO PHARMACEUTICALS, INC.

By: /s/ Gary S. Jacob

Gary S. Jacob,
Chief Executive Officer

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 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 Form S-8 has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Gary S. Jacob Gary S. Jacob	Chief Executive Officer and Director (Principal Executive Officer)	December 27, 2005
/s/ Bernard Denoyer Bernard Denoyer	Vice President, Finance (Principal Financial and Accounting Officer)	December 27, 2005
/s/ Gabriele M. Cerrone Gabriele M. Cerrone	Chairman of the Board	December 27, 2005
/s/ Christoph Bruening Christoph Bruening	Director	December 27, 2005

/s/ John P. Brancaccio	Director	December 27, 2005
John P. Brancaccio		
/s/ Stephen Carter	Director	December 27, 2005
Stephen Carter		
/s/ Randall K. Johnson	Director	December 27, 2005
Randall K. Johnson		
	Director	December ___, 2005
Riccardo Dalla-Favera		

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4.3	2005 Directors' Stock Option Plan (3)
4.4	Form of Non-Plan Stock Option Agreement (4)
5.1	Opinion of Sichenzia Ross Friedman Ference LLP.
23.1	Consent of Sichenzia Ross Friedman Ference LLP is contained in Exhibit 5.1.
23.2	Consent of BDO Seidman, LLP.
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.
(2) Incorporated by reference to Appendix B filed with the Company's Definitive Proxy Statement on Schedule 14A filed on August 31, 2005.
(3) Incorporated by reference to Appendix C filed with the Company's Definitive Proxy Statement on Schedule 14A filed on August 31, 2005.
(4) Incorporated by reference to Exhibit 4.3 filed with the Company's Registration Statement on Form S-8 filed on October 4, 2004.