

CALLISTO PHARMACEUTICALS INC  
Form S-3  
April 16, 2008

As filed with the Securities and Exchange Commission on April 16, 2008

Registration No. 333-

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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**FORM S-3**

**REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

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**Callisto Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**13-3894575**  
(I.R.S. Employer  
Identification No.)

**420 Lexington Avenue, Suite 1609  
New York, New York 10170  
(212) 297-0010**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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**Gary S. Jacob**  
**Chief Executive Officer**

**Callisto Pharmaceuticals, Inc.**  
**420 Lexington Avenue, Suite 1609**

**New York, New York 10170**  
**(212) 297-0010**

(Name, address including zip code, and telephone number, including area code, of agent for service)

**With copies to:**

**Jeffrey J. Fessler, Esq.**  
Sichenzia Ross Friedman Ference LLP  
61 Broadway, 32<sup>nd</sup> Floor

New York, New York 10006  
(212) 930-9700

(212) 930-9725 - Facsimile

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**Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement, as determined by market conditions and other factors.**

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

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of *large accelerated filer*, *accelerated filer* and *smaller reporting company* in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer                       Accelerated filer                       Non-accelerated filer                       Smaller reporting company   
 (do not check if smaller reporting company)

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Security(1)	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee
Common Stock, \$.0001 par value per share	(3)(4)	(3)	(3)	(3)
Preferred Stock, \$.0001 par value per share	(3)(4)	(3)	(3)	(3)
Warrants	(3)(4)	(3)	(3)	(3)
Units	(3)(4)	(3)	(3)	(3)
<b>Total</b>			\$ 25,000,000	\$ 983

- (1) This registration statement includes \$25,000,000 of securities which may be issued by the registrant from time to time in indeterminate amounts and at indeterminate times. Securities registered hereunder may be sold separately, together or as units with other securities registered hereunder. The securities registered hereunder also include such indeterminate number of shares of common stock and preferred stock, warrants or units, respectively, of the registrant.
- (2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) of the Securities Act of 1933, as amended (the Securities Act).
- (3) Not required to be included in accordance with General Instruction II.D. of Form S-3 under the Securities Act.
- (4) Subject to footnote (1), there is also being registered hereunder such indeterminate amount of securities (including shares or other classes of the registrant's stock that may be issued upon reclassification of unissued, authorized stock of the registrant) as may be issued in exchange for or upon conversion of, as the case may be, the preferred stock or warrants registered hereunder. No separate consideration will be received for any securities registered hereunder that are issued in exchange for, or upon conversion of, as the case may be, the preferred stock.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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

**Subject to completion, dated April 16, 2008**

**CALLISTO PHARMACEUTICALS, INC.**

**\$25,000,000**

**Common Stock  
Preferred Stock  
Warrants  
Units**

We may offer and sell, from time to time in one or more offerings, any combination of common stock, preferred stock, warrants, or units having an aggregate initial offering price not exceeding \$25,000,000. When we decide to sell a particular class or series of securities, we will provide specific terms of the offered securities in a prospectus supplement.

We will provide specific terms of the offerings of our securities in supplements to this prospectus. The prospectus supplement may also add, update or change information in this prospectus. You should read this prospectus and any prospectus supplement, as well as the documents incorporated by reference or deemed to be incorporated by reference into this prospectus, carefully before you invest.

**This prospectus may not be used to offer or sell our securities unless accompanied by a prospectus supplement relating to the offered securities.**

Our common stock is traded on the American Stock Exchange under the symbol KAL. On April 14, 2008, the last reported sale price for the common stock was \$0.33 per share. The aggregate market value of the voting and non-voting common equity computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of April 14, 2008 was \$14,663,313. We have not offered any securities during the past twelve months pursuant to General Instruction I.B.6. of Form S-3. Each prospectus supplement will contain information, where applicable, as to any listing on the American Stock Exchange or any other securities exchange covered by the prospectus supplement.

These securities may be sold directly by us, through dealers or agents designated from time to time, to or through underwriters or through a combination of these methods. See Plan of Distribution in this prospectus. We may also describe the plan of distribution for any particular offering of our securities in a prospectus supplement. If any agents, underwriters or dealers are involved in the sale of any securities in respect of

which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in a prospectus supplement. The net proceeds we expect to receive from any such sale will also be included in a prospectus supplement.

**Investing in our securities involves various risks. See Risk Factors on page 4 for more information on these risks. Additional risks will be described in the related prospectus supplements under the heading Risk Factors . You should review that section of the related prospectus supplements for a discussion of matters that investors in our securities should consider.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus or any accompanying prospectus supplement. Any representation to the contrary is a criminal offense.**

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The date of this Prospectus is April , 2008.

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## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the SEC) using a shelf registration process. Under this shelf registration process, we may offer from time to time securities having an aggregate initial offering price of \$25,000,000. Each time we offer securities, we will provide you with a prospectus supplement that describes the specific amounts, prices and terms of the securities we offer. The prospectus supplement also may add, update or change information contained in this prospectus. You should read carefully both this prospectus and any prospectus supplement together with additional information described below under the caption Where You Can Find More Information.

This prospectus does not contain all the information provided in the registration statement we filed with the SEC. For further information about us or our securities offered hereby, you should refer to that registration statement, which you can obtain from the SEC as described below under Where You Can Find More Information.

You should rely only on the information contained or incorporated by reference in this prospectus or a prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell securities, and it is not soliciting an offer to buy securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any prospectus supplement, as well as information we have previously filed with the SEC and incorporated by reference, is accurate as of the date on the front of those documents only. Our business, financial condition, results of operations and prospects may have changed since those dates.

We may sell securities through underwriters or dealers, through agents, directly to purchasers or through a combination of these methods. We and our agents reserve the sole right to accept or reject in whole or in part any proposed purchase of securities. The prospectus supplement, which we will provide to you each time we offer securities, will set forth the names of any underwriters, agents or others involved in the sale of securities, and any applicable fee, commission or discount arrangements with them. See Plan of Distribution.

## OUR BUSINESS

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

We are a biopharmaceutical company focused primarily on the development of drugs to treat neuroendocrine cancer (including advanced carcinoid cancer), acute leukemia and gastrointestinal disorders and diseases. Our lead drug candidate in the clinic, Atiprimod, is an orally administered drug with antiproliferative and antiangiogenic activity. On November 7, 2006, we announced the initiation of a multi-center open-label Phase II clinical trial of Atiprimod for low-to-intermediate grade neuroendocrine cancers, primarily in advanced carcinoid cancer patients. This trial is based on earlier encouraging clinical results from a Phase I trial of Atiprimod in advanced cancer patients that showed stable disease and disease-related symptom relief in patients with advanced carcinoid cancer. On September 20, 2007, we announced that we had completed enrollment of the 40-patient Phase II clinical trial, and that patients had been on drug as long as 11 months. In October 2007, we announced the opening of a Phase II extension trial to permit those patients who had successfully completed a full year in the Phase II advanced carcinoid cancer trial, which only permitted dosing for up to one year, to continue to receive Atiprimod therapy. We are no longer dosing patients in the Phase I clinical trial of Atiprimod in relapsed or refractory multiple myeloma and have no plans at present to continue evaluating the drug in this disease indication, instead focusing on the clinical development of Atiprimod to treat advanced carcinoid cancer.

Our second drug candidate, L-Annamycin, earlier completed an initial Phase I/IIa clinical trial in relapsed or refractory leukemia patients with a prior sponsor. L-Annamycin is a novel compound from the anthracycline family of proven anti-cancer drugs, which has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart. L-Annamycin was in-licensed by us in October

2004 and is presently in two clinical trials: 1) a Phase I/IIa clinical trial in adult relapsed or refractory acute lymphocytic leukemia (ALL) patients at three clinical sites in the U.S.; and 2) a Phase I clinical trial in children and young adults with relapsed or refractory ALL or AML. We recently reached the maximum tolerated dose (MTD) in the adult trial and are currently evaluating its potential at the fixed-dose portion of the trial. We have not yet established the MTD in children. We plan to review future development of this drug once data from the adult trial are available.

In October 2007 we announced a major strategic initiative to develop SP-304 (Guanilib), our guanylyl cyclase C (GC-C) receptor agonist, to treat gastrointestinal disorders, primarily chronic constipation and constipation-predominant irritable bowel syndrome (IBS-C). On April 2, 2008, we filed an investigational new drug (IND) application with the FDA. We plan to initiate a Phase I clinical trial in volunteers upon FDA approval of our IND application. We also plan to open a Phase Ib trial of SP-304 (Guanilib) in late 2008.

Our principal executive office is located at 420 Lexington Avenue, Suite 1609, New York, New York 10170. Our telephone number is (212) 297-0010 and our website address is [www.callistopharma.com](http://www.callistopharma.com). The information on our website is not incorporated by reference into this prospectus.

## **RISK FACTORS**

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information before deciding to invest in our common stock. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently consider immaterial may also adversely affect our business. We have attempted to identify below the major factors that could cause differences between actual and planned or expected results, but we cannot assure you that we have identified all of those factors.

If any of the following risks actually happen, our business, financial condition and operating results could be materially adversely affected. In this case, the trading price of our common stock could decline, and you could lose all or part of your investment.

### **Risks Related to our Business**

#### **We Are at an Early Stage of Development as a Company, Currently have no Source of Revenue and may Never Become Profitable.**

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

- demonstration in Phase I and Phase II clinical trials that our product candidates, Atiprimod for the treatment of advanced carcinoid cancer, L-Annamycin for the treatment of relapsed acute leukemia, and SP-304 (Guanilib) for the treatment of gastrointestinal disorders 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.

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

### **We Have Incurred Significant Losses Since Inception and Anticipate that we will Incur Continued Losses for the Foreseeable Future.**

As of December 31, 2007 we had an accumulated deficit of \$81,331,796. We have incurred losses in each year since our inception in 1996. We incurred net losses available to common stockholders of \$20,887,428, \$15,303,714 and \$11,779,457 for the twelve months ended December 31, 2007, 2006 and 2005, respectively. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development,

continue our clinical trials of Atiprimod for the treatment of multiple myeloma and advanced carcinoid cancer, continue and initiate our clinical trials of L-Annamycin for the treatment of acute leukemias, acquire or license technologies, advance our other product candidates into clinical development, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock will likely decline.

**Our Independent Registered Public Accounting Firm has Expressed Doubt about our Ability to Continue as a Going Concern, which may Hinder our Ability to Obtain Future Financing**

Our consolidated financial statements as of December 31, 2007 have been prepared under the assumption that we will continue as a going concern for the year ending December 31, 2007. Our independent registered public accounting firm has issued a report dated March 25, 2008 that included an explanatory paragraph referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**We Will Need to Raise Substantial Additional Capital Within the Next Year 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 cancer product candidates, Atiprimod for the treatment of advanced carcinoid cancer and L-Annamycin for the treatment of acute leukemia;
- initiate and continue clinical development of SP-304 (Guanilib) to treat gastrointestinal disorders.
- continue development of our other product candidates and the SP-304 (Guanilib) backup and second-generation program;
- finance our general and administrative expenses;
- prepare regulatory approval applications and seek approvals for Atiprimod, SP-304 (Guanilib) and L-Annamycin and our other product candidates;

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

We expect that our cash used in operating activities will increase significantly for the next several years. For the years ended December 31, 2007, 2006 and 2005 we used approximately \$8.4 million, \$8.3 million and \$8.7 million in operating activities, respectively.

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

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

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

To date, our sources of cash have been primarily limited to the sale of our equity securities. Net cash provided by financing activities for the twelve months ended December 31, 2007, 2006 and 2005 was approximately \$10.8 million, \$10.8 million and \$4.8 million, respectively. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

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

**If Our Agreement with the University of Texas M.D. Anderson Cancer Center Terminates, Our Business Would be Adversely Affected.**



Our business is partially dependent on rights we have licensed from The University of Texas M.D. Anderson Cancer Center. Under the terms of The University of Texas M.D. Anderson Cancer Center license agreement for L-Annamycin, at any time after 5 years from August 12, 2004, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or we are actively and effectively attempting to commercialize L-Annamycin. If we fail to fulfill these obligations or other material obligations, The University of Texas M.D. Anderson Cancer Center license agreement may be terminated and our business would be adversely affected.

**Clinical Trials Involve a Lengthy and Expensive Process with an Uncertain Outcome, and Results of Earlier Studies and Trials may not be Predictive of Future Trial Results.**

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

The results of preclinical studies and early clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug

development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

**Delays in Clinical Testing Could Result in Increased Costs to Us and Delay our Ability to Generate Revenue.**

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

**We may be Required to Suspend or Discontinue Clinical Trials Due to Unexpected Side Effects or Other Safety Risks That Could Preclude Approval of our Product Candidates.**

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

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

**If We are Unable to Satisfy Regulatory Requirements, We may not be Able to Commercialize our Product Candidates.**

We need FDA approval prior to marketing our product candidates in the United States of America. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States of America and we will not generate any revenue.

This regulatory review and approval process, which includes evaluation of preclinical studies and clinical trials of a product candidate as well as the evaluation of our manufacturing process and our contract manufacturers' facilities, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that the product candidate is both safe and effective for each indication where approval is sought. Satisfaction of these requirements typically takes several years and the time needed to

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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 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 \$5,000,000 annual aggregate limit for up to 40 patients participating at the same time in our Atiprimod and L-Annamycin clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

**Even if we Receive Regulatory Approval for our Product Candidates, we will be Subject to Ongoing Significant Regulatory Obligations and Oversight.**

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

**We Rely on Third Parties to Conduct our Clinical Trials. If these Third Parties do not Successfully Carry Out Their Contractual Duties or Meet Expected Deadlines, We may not be Able to Seek or Obtain Regulatory Approval for or Commercialize our Product Candidates.**

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

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

**If we Fail to Attract and Keep Senior Management and Key Scientific Personnel, we may be Unable to Successfully Develop our Product Candidates, Conduct our Clinical Trials and Commercialize our Product Candidates.**

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



The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies. We do not carry key person insurance covering any members of our senior management other than \$1,000,000 for Dr. Jacob.

**If we Fail to Acquire and Develop Other Products or Product Candidates, we may be Unable to Grow our Business.**

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

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

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

**We may Undertake Acquisitions in the Future, and Any Difficulties from Integrating These Acquisitions could Damage our Ability to Attain or Maintain Profitability.**

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

**We Will Need to Increase the Size of our Organization, and we May Experience Difficulties in Managing Growth.**

We are a small company with 9 full-time and 2 part-time employees as of April 7, 2008. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Over the next 12 months depending on the progress of our planned clinical trials, we plan to add additional employees to assist us

with our clinical programs. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our development efforts effectively;
- manage our clinical trials effectively;

- integrate additional management, administrative, manufacturing and sales and marketing personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

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

**Reimbursement may not be Available for our Product Candidates, Which Could Diminish our Sales.**

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

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

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

**Legislative or Regulatory Reform of the Healthcare System may Affect our Ability to Sell our Products Profitably.**

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

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

## **Risks Related to our Intellectual Property**

### **It is Difficult and Costly to Protect our Proprietary Rights, and we May not be Able to Ensure Their Protection.**

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

As of December 31, 2007, we own and/or have licensed rights to 15 issued United States patents and 7 United States patent applications. We have approximately 150 issued and/or pending foreign patent applications. We may file additional patent applications and extensions. Our issued United States patents we own and license primarily are composition of matter and formulation patents related to Atiprimod and L-Annamycin. Our composition of matter patents for L-Annamycin and Atiprimod expire in 2017 and 2016, respectively. Our formulation patents for L-Annamycin and Atiprimod dimaleate (preferred salt form) both expire in 2016.

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

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

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



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

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other

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

**We may Incur Substantial Costs as a Result of Litigation or Other Proceedings Relating to Patent and Other Intellectual Property Rights and we may be Unable to Protect our Rights to, or Use, our Technology.**

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

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

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

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

**Risks Related to our Common Stock**

**Market Volatility may Affect our Stock Price and the Value of Your Investment.**

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

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing process or sales and marketing activities;
- regulatory developments in the United States of America and foreign countries;
- the success of our development efforts and clinical trials;
- the success of our efforts to acquire or in-license additional products or product candidates;
- any intellectual property infringement action, or any other litigation, involving us;
- announcements concerning our competitors, or the biotechnology or biopharmaceutical industries in general;
- actual or anticipated fluctuations in our operating results;

- changes in financial estimates or recommendations by securities analysts;
- our ability to maintain listing requirements on the American Stock Exchange;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders; and
- the loss of any of our key scientific or management personnel.
- the potentially dilutive effect of all outstanding dilutive instruments as follows:

	December 31, 2007	December 31, 2006	December 31, 2005
Common Shares outstanding	46,943,161	39,194,996	33,233,096
Potentially dilutive common shares issuable upon:			
Exercise of warrants	45,162,920	15,841,154	2,567,317
Exercise of stock options	8,241,207	8,053,375	8,008,210
Conversion of Series A Convertible Preferred Stock	4,373,500	7,658,000	
Conversion of Series B Convertible Preferred Stock	22,941,000		
Total fully diluted	127, 661,788	70,747,525	43,808,623

The occurrence of one or more of these factors may cause our stock price to decline, and investors may not be able to resell their shares at or above the price that they paid for the shares. In addition, the stock markets in general, and the markets for biotechnology and biopharmaceutical stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock.

**The Liquidity of Your Stock Depends in Part on Continued Listing of our Shares of Common Stock on the American Stock Exchange.**

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

On November 2, 2006 we submitted a plan advising the American Stock Exchange of the actions we have taken, or will take, that would bring us into compliance with Section 1003(a)(iv) of the Company Guide by April 3, 2007 and with Section 1003(a)(i) of the Company Guide by April 3, 2008. The plan was approved on January 24, 2007.

On June 18, 2007, we received notice from the staff of the American Stock Exchange indicating that we are not in compliance with Section 1003(a)(ii) of the Company Guide with shareholders' equity of less than \$4,000,000 and losses from continuing operations and/or net losses in three of our four most recent fiscal years.

We submitted a plan on July 18, 2007, advising the American Stock Exchange of the actions we have taken, or plan to take, that would bring it into compliance with Section 1003(a)(ii) of the Company Guide by April 3, 2008. On August 27, 2007, the American Stock Exchange notified us that they accepted our plan.

On April 7, 2008, we received notice from the staff of the American Stock Exchange of their intent to strike our common stock from the American Stock Exchange by filing a delisting application with the SEC for failure to regain compliance with Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide and falling out of compliance with Section 1003(a)(iii) of the Company Guide with shareholders' equity of less than \$6,000,000 and losses from continuing operations and/or net losses in four of our five most recent fiscal years. We have a limited right to appeal the staff's determination and we have requested such an appeal. If we are delisted by the American Stock Exchange you may experience difficulty in trading your shares of our common stock.

**We Have Identified Material Weaknesses in our Disclosure Controls and Procedures and Have Concluded that Internal Control Over Financial Reporting is Not Effective as of December 31, 2007. In Addition, we may Experience Additional Material Weaknesses in the Future. any Material Weaknesses in our Disclosure Controls and Procedures or our Failure to Remediate such Material Weaknesses Could Result in a Material Misstatement in our Financial Statements not Being Prevented or Detected and Could Affect Investor Confidence in the Accuracy and Completeness of our Financial Statements, as Well as Our Stock Price.**

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We have identified material weaknesses in our disclosure controls and procedures relating to our lack of sufficient internal accounting personnel and segregation of duties necessary to ensure that adequate review of our financial statements and notes thereto is performed and have concluded that our internal control over financial reporting is not effective as of December 31, 2007. These material weaknesses and our remediation plans are described further in ITEM 9A(T) CONTROLS AND PROCEDURES of our Form 10-K for the year ended December 31, 2007. Material weaknesses in our disclosure controls and procedures could result in material misstatements in our financial statements not being prevented or detected. We may experience difficulties or delays in completing remediation or may not be able to successfully remediate material weaknesses at all. Any material weakness or unsuccessful remediation could affect investor confidence in the accuracy and completeness of our

financial statements, which in turn could harm our business and have an adverse effect on our stock price and our ability to raise additional funds.

**We are at Risk of Securities Class Action Litigation.**

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

**We Have not Paid Cash Dividends in the Past and do Not Expect to Pay Cash Dividends in the Future. Any Return on Investment may be Limited to the Value of our Stock.**

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

**DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and any accompanying prospectus supplement, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Exchange Act. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

In some cases, you can identify forward-looking statements by terminology, such as expects, anticipates, intends, estimates, plans, believes, seeks, may, should, could or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus.

You should read this prospectus and any accompanying prospectus supplement and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus is part, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus and any accompanying prospectus supplement is accurate as of the date on the front cover of this prospectus or such prospectus supplement only. Because the risk factors referred to above, as well as the risk factors referred to on page 3 of this prospectus and incorporated herein by reference, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of

the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this prospectus and any accompanying prospectus supplement, and particularly our forward-looking statements, by these cautionary statements.



## USE OF PROCEEDS

Except as otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities offered by this prospectus for general corporate purposes, which may include working capital, capital expenditures, research and development expenditures, regulatory affairs expenditures, clinical trial expenditures, acquisitions of new technologies and investments, and the repayment, refinancing, redemption or repurchase of future indebtedness or capital stock. Additional information on the use of net proceeds from the sale of securities offered by this prospectus may be set forth in the prospectus supplement relating to that offering.

## THE SECURITIES WE MAY OFFER

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize all the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If we indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

We may sell from time to time, in one or more offerings:

- shares of our common stock;
- shares of our preferred stock;
- warrants to purchase any of the securities listed above; and/or
- units consisting of one or more of the foregoing.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

## DESCRIPTION OF CAPITAL STOCK

### General

The following description of common stock and preferred stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus but is not complete. For the complete terms of our common stock and preferred stock, please refer to our certificate of incorporation, as amended, which may be further amended from time to time, any certificates of designation for our preferred stock, and our amended and restated bylaws, as amended from time to time. The Delaware General Corporation Law may also affect the terms of these securities. While the

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terms we have summarized below will apply generally to any future common stock or preferred stock that we may offer, we will describe the particular terms of any series of these securities in more detail in the applicable prospectus supplement. If we so indicate in a prospectus supplement, the terms of any common stock or preferred stock we offer under that prospectus supplement may differ from the terms we describe below.

Our authorized capital stock consists of 225,000,000 shares of common stock, \$0.0001 par value, and 20,000,000 shares of preferred stock, \$0.0001 par value. The authorized and unissued shares of common stock and the authorized and undesignated shares of preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange or automated

quotation system on which our securities may be listed or traded. If the approval of our stockholders is not so required, our board of directors may determine not to seek stockholder approval.

### **Common Stock**

As of April 7, 2008, there were 47,218,161 shares of our common stock outstanding. The holders of our common stock are entitled to such dividends as our board of directors may declare from legally available funds. The holders of our common stock are entitled to one vote per share on any matter to be voted upon by stockholders. Our certificate of incorporation, as amended, and our amended and restated bylaws do not provide for cumulative voting. No holder of our common stock will have any preemptive right to subscribe for any shares of capital stock issued in the future under the Delaware General Corporation Law, our certificate of incorporation, as amended, or our amended and restated bylaws. Upon any voluntary or involuntary liquidation, dissolution, or winding up of our affairs, the holders of our common stock are entitled to receive all of our remaining assets legally available for distribution to the stockholders after payment of all our debts and other liabilities, subject to prior distribution rights of our preferred stock, if any.

Our common stock is quoted on the American Stock Exchange under the symbol KAL. The transfer agent and registrar for our common stock is StockTrans, Inc.

### **Preferred Stock**

We are currently authorized to issue 20,000,000 shares of undesignated preferred stock, with 700,000 designated as Series A Convertible Preferred Stock and 2,500,000 designated as Series B Convertible Preferred Stock. As of April 7, 2008, 214,925 shares of Series A Convertible Preferred Stock and 1,137,050 shares of Series B Convertible Preferred Stock were issued and outstanding. The material terms of the Series A Convertible Preferred Stock consist of:

*Dividends.* Holders of the Series A Convertible Preferred Stock shall not be entitled to receive dividends.

*Voting Rights.* Shares of the Series A Convertible Preferred Stock shall have no voting rights. However, so long as any shares of Series A Convertible Preferred Stock are outstanding, we shall not, without the affirmative vote of a majority in interest of the shares of Series A Convertible Preferred Stock then outstanding, (a) alter or change adversely the powers, preferences or rights given to the Series A Convertible Preferred Stock, (b) authorize or create any class of stock senior or equal to the Series A Convertible Preferred Stock, (c) amend our articles of incorporation or other charter documents, so as to affect adversely any rights of the holders of Series A Convertible Preferred Stock or (d) increase the authorized number of shares of Series A Convertible Preferred Stock.

*Liquidation.* Subject to the rights of the holders of the Series B Convertible Preferred Stock, upon any liquidation, dissolution or winding-up of the company, the holders of the Series A Convertible Preferred Stock shall be entitled to receive an amount equal to the Stated Value per share, which is \$10 per share plus any accrued and unpaid dividends.

*Conversion Rights.* Each share of Series A Convertible Preferred Stock shall be convertible into that number of shares of common stock determined by dividing the Stated Value, currently \$10 per share, by the conversion price, currently \$0.50 per share. The conversion price is subject to adjustment for dilutive issuances.

*Automatic conversion.* Beginning October 24, 2007, if the price of the common stock equals \$1.50 per share for 20 consecutive trading days, and an average of 50,000 shares of common stock per day shall have been traded during the 20 trading days, we shall have the right to deliver a notice to the holders of the Series A Convertible Preferred Stock, to convert any portion of the shares of Series A Convertible Preferred Stock into shares of Common Stock at the conversion price.

The material terms of the Series B Preferred Stock are:

*Dividends.* Holders of the Series B Convertible Preferred Stock shall not be entitled to receive dividends.

*Voting Rights.* The Series B Preferred Stock shall have no voting rights. However, so long as any shares of Series B Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of the shares of the Series B Preferred Stock then outstanding, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the Certificate of Designation (whether by merger, consolidation or otherwise), (b) authorize or create any class of stock ranking as to dividends, redemption or distribution of assets upon a liquidation senior to or otherwise *pari passu* with the Series B Preferred Stock, (c) amend our certificate of incorporation or other charter documents so as to affect adversely any rights of the holders, (d) increase the authorized number of shares of Series B Preferred Stock, or (e) enter into any agreement with respect to the foregoing.

*Liquidation.* Upon any liquidation, dissolution or winding-up of our company, whether voluntary or involuntary, the holders shall be entitled to receive out of our assets, whether such assets are capital or surplus, for each share of Series B Preferred Stock an amount equal to the stated value of \$10.00 per share, plus any accrued and unpaid dividends thereon and any other fees or liquidated damages owing thereon before any distribution or payment shall be made to the holders of any junior securities, and if our assets shall be insufficient to pay in full such amounts, then the entire assets to be distributed to the holders shall be distributed among the holders ratably in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

*Conversions at Option of Holder.* Each share of Series B Preferred Stock shall be convertible into that number of shares of common stock determined by dividing the stated value of \$10.00 of such share of Series B Preferred Stock by \$0.50 (the *Conversion Price* ), at the option of the holder, at any time and from time to time.

*Conversion at the Option of the Company.* Beginning August 2, 2008, provided certain conditions are satisfied, if the volume weighted average price of our common stock equals \$1.00 per share for the 20 consecutive trading days and the average daily volume of the common stock is at least 0.5% of the shares that are being converted, we shall have the right to convert any portion of the Series B Preferred Stock into shares of common stock at the then-effective *Conversion Price*.

*Subsequent Equity Sales.* For the twelve (12) month period beginning on September 27, 2007, if we at any time while Series B Preferred Stock is outstanding, shall sell or grant any option to purchase or otherwise dispose of or issue any common stock or common stock equivalents entitling any person to acquire shares of Common Stock, at an effective price per share less than the then *Conversion Price* (the *Base Conversion Price* ), then, the *Conversion Price* shall be reduced to an amount equal to the *Base Conversion Price*.

Our certificate of incorporation, as amended, provides that our board of directors may by resolution, without further vote or action by the stockholders, establish one or more classes or series of preferred stock having the number of shares and relative voting rights, designation, dividend rates, liquidation, and other rights, preferences, and limitations as may be fixed by them without further stockholder approval. Once designated by our board of directors, each series of preferred stock will have specific financial and other terms that will be described in a prospectus supplement. The description of the preferred stock that is set forth in any prospectus supplement is not complete without reference to the documents that govern the preferred stock. These include our certificate of incorporation, as amended, and any certificates of designation that the board of directors may adopt. Prior to the issuance of shares of each series of preferred stock, the board of directors is required by the

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Delaware General Corporation Law and the certificate of incorporation, as amended, to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware. The certificate of designation fixes for each class or series the designations, powers, preferences, rights, qualifications, limitations and restrictions, including, but not limited to, some or all of the following:

- (a) the number of shares constituting that series and the distinctive designation of that series, which number may be increased or decreased (but not below the number of shares then outstanding) from time to time by action of the board of directors;

- (b) the dividend rate and the times of payment of dividends on the shares of that series, whether dividends shall be cumulative, and, if so, from which date;
- (c) whether that series shall have voting rights, in addition to the voting rights provided by law, and, if so, the terms of such voting rights;
- (d) whether that series shall have conversion privileges, and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the board of directors shall determine;
- (e) whether or not the shares of that series shall be redeemable, and, if so, the terms and conditions of such redemption;
- (f) whether that series shall have a sinking fund for the redemption or purchase of shares of that series, and, if so, the terms and amount of such sinking fund;
- (g) whether or not the shares of the series will have priority over or be on a parity with or be junior to the shares of any other series or class in any respect;
- (h) the rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights or priority, if any, of payment of shares of that series; and
- (i) any other relative rights, preferences and limitations of that series.

All shares of preferred stock offered hereby will, when issued, be fully paid and nonassessable, including shares of preferred stock issued upon the exercise of preferred stock warrants or subscription rights, if any.

Although our board of directors has no intention at the present time of doing so, it could authorize the issuance of a series of preferred stock that could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt.

#### **Options/Warrants**

As of April 7, 2008, there were 8,191,207 shares of common stock reserved underlying stock options granted under our equity compensation plans and there were 4,309,500 shares available for future grants under our 2005 Equity Compensation Incentive Plan and 864,000 shares available for future grants under our 2005 Directors' Stock Option Plan. Additionally, we have reserved 45,162,920 shares of common stock for

issuance upon exercise of outstanding warrants.

#### **DESCRIPTION OF WARRANTS**

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below. If there are differences between that prospectus supplement and this prospectus, the prospectus supplement will control. Thus, the statements we make in this section may not apply to a particular series of warrants. Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement which includes this prospectus.



## General

We may issue warrants for the purchase of common stock and/or preferred stock in one or more series. We may issue warrants independently or together with common stock and/or preferred stock, and the warrants may be attached to or separate from these securities.

We will evidence each series of warrants by warrant certificates that we may issue under a separate agreement. We may enter into the warrant agreement with a warrant agent. Each warrant agent may be a bank that we select which has its principal office in the United States and a combined capital and surplus of at least \$50,000,000. We may also choose to act as our own warrant agent. We will indicate the name and address of any such warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

- the offering price and aggregate number of warrants offered;
- the currency for which the warrants may be purchased;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the warrant agreement under which the warrants will be issued;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
- anti-dilution provisions of the warrants, if any;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire or, if the warrants are not continuously exercisable during that period, the specific date or dates on which the warrants will be exercisable;
- the manner in which the warrant agreement and warrants may be modified;
- the identities of the warrant agent and any calculation or other agent for the warrants;
- federal income tax consequences of holding or exercising the warrants;
- the terms of the securities issuable upon exercise of the warrants;
- any securities exchange or quotation system on which the warrants or any securities deliverable upon exercise of the warrants may be listed; and



- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

### **Exercise of Warrants**

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to 5:00 P.M. eastern time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate, and in the applicable prospectus supplement, the information that the holder of the warrant will be required to deliver to the warrant agent.

Until the warrant is properly exercised, no holder of any warrant will be entitled to any rights of a holder of the securities purchasable upon exercise of the warrant.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

### **Enforceability of Rights By Holders of Warrants**

Any warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants in accordance with their terms.

### **Warrant Agreement Will Not Be Qualified Under Trust Indenture Act**

No warrant agreement will be qualified as an indenture, and no warrant agent will be required to qualify as a trustee, under the Trust Indenture Act. Therefore, holders of warrants issued under a warrant agreement will not have the protection of the Trust Indenture Act with respect to their warrants.

**Governing Law**

Each warrant agreement and any warrants issued under the warrant agreements will be governed by New York law.

### **Calculation Agent**

Calculations relating to warrants may be made by a calculation agent, an institution that we appoint as our agent for this purpose. The prospectus supplement for a particular warrant will name the institution that we have appointed to act as the calculation agent for that warrant as of the original issue date for that warrant. We may appoint a different institution to serve as calculation agent from time to time after the original issue date without the consent or notification of the holders.

The calculation agent's determination of any amount of money payable or securities deliverable with respect to a warrant will be final and binding in the absence of manifest error.

### **DESCRIPTION OF UNITS**

We may issue units comprised of one or more of the other securities described in this prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

The applicable prospectus supplement will describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any unit agreement under which the units will be issued;
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
- whether the units will be issued in fully registered or global form.

The applicable prospectus supplement will describe the terms of any units. The preceding description and any description of units in the applicable prospectus supplement does not purport to be complete and is subject to and is qualified in its entirety by reference to the unit agreement and, if applicable, collateral arrangements and depositary arrangements relating to such units.

### **PLAN OF DISTRIBUTION**

We may sell the securities being offered pursuant to this prospectus through underwriters or dealers, through agents, or directly to one or more purchasers or through a combination of these methods. The applicable prospectus supplement will describe the terms of the offering of the securities, including:

- the name or names of any underwriters, if any, and if required, any dealers or agents;
- the purchase price of the securities and the proceeds we will receive from the sale;
- any underwriting discounts and other items constituting underwriters' compensation;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

We may distribute the securities from time to time in one or more transactions at:

- a fixed price or prices, which may be changed;

- market prices prevailing at the time of sale;
- prices related to such prevailing market prices; or
- negotiated prices.

Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement.

If underwriters are used in an offering, we will execute an underwriting agreement with such underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement. The securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by one or more investment banking firms or others, as designated. If an underwriting syndicate is used, the managing underwriter(s) will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent and the underwriters will be obligated to purchase all of the offered securities if any are purchased.

We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price, with additional underwriting commissions or discounts, as may be set forth in a related prospectus supplement. The terms of any over-allotment option will be set forth in the prospectus supplement for those securities.

If we use a dealer in the sale of the securities being offered pursuant to this prospectus or any prospectus supplement, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. The names of the dealers and the terms of the transaction will be specified in a prospectus supplement.

We may sell the securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, any agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

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In connection with the sale of the securities, underwriters, dealers or agents may receive compensation from us or from purchasers of the common stock for whom they act as agents in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of the securities, and any institutional investors or others that purchase common stock directly and then resell the securities, may be deemed to be underwriters, and any discounts or commissions received by them from us and any profit on the resale of the common stock by them may be deemed to be underwriting discounts and commissions under the Securities Act.



We may provide agents and underwriters with indemnification against particular civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to such liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

In addition, we may enter into derivative transactions with third parties (including the writing of options), or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with such a transaction, the third parties may, pursuant to this prospectus and the applicable prospectus supplement, sell securities covered by this prospectus and the applicable prospectus supplement. If so, the third party may use securities borrowed from us or others to settle such sales and may use securities received from us to close out any related short positions. We may also loan or pledge securities covered by this prospectus and the applicable prospectus supplement to third parties, who may sell the loaned securities or, in an event of default in the case of a pledge, sell the pledged securities pursuant to this prospectus and the applicable prospectus supplement. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement or in a post-effective amendment.

To facilitate an offering of a series of securities, persons participating in the offering may engage in transactions that stabilize, maintain, or otherwise affect the market price of the securities. This may include over-allotments or short sales of the securities, which involves the sale by persons participating in the offering of more securities than have been sold to them by us. In those circumstances, such persons would cover such over-allotments or short positions by purchasing in the open market or by exercising the over-allotment option granted to those persons. In addition, those persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to underwriters or dealers participating in any such offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. We make no representation or prediction as to the direction or magnitude of any effect that the transactions described above, if implemented, may have on the price of our securities.

Any common stock sold pursuant to a prospectus supplement will be eligible for quotation and trading on the American Stock Exchange, subject to official notice of issuance. Any underwriters to whom securities are sold by us for public offering and sale may make a market in the securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice.

In order to comply with the securities laws of some states, if applicable, the securities offered pursuant to this prospectus will be sold in those states only through registered or licensed brokers or dealers. In addition, in some states securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and complied with

## **LEGAL MATTERS**

The validity of the issuance of the securities offered hereby will be passed upon for us by Sichenzia Ross Friedman FERENCE LLP, New York, New York.

## **EXPERTS**

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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 which contains an explanatory paragraph regarding our ability to continue as a going concern, is 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.

### WHERE YOU CAN FIND MORE INFORMATION

This prospectus constitutes a part of a registration statement on Form S-3 filed under the Securities Act. As permitted by the SEC's rules, this prospectus and any prospectus supplement, which form a part of the registration statement, do not contain all the information that is included in the registration statement. You will find additional information about us in the registration statement. Any statements made in this prospectus or any prospectus supplement concerning legal documents are not necessarily complete and you should read the documents that are filed as exhibits to the registration statement or otherwise filed with the SEC for a more complete understanding of the document or matter.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read, without charge, and copy the documents we file at the SEC's public reference rooms in Washington, D.C. at 100 F Street, NE, Room 1580, Washington, DC 20549, or in New York, New York and Chicago, Illinois. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our SEC filings are also available to the public at no cost from the SEC's website at <http://www.sec.gov>.

### INCORPORATION OF DOCUMENTS BY REFERENCE

We incorporate by reference the filed documents listed below, except as superseded, supplemented or modified by this prospectus, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"):

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2007;
- our Current Report on Form 8-K filed on April 11, 2008;
- our Current Report on Form 8-K filed on April 7, 2008; and
- the description of our common stock contained in Item 1 of our Registration Statement on Form 8-A, filed with the SEC on October 22, 2004.

The reports and other documents that we file after the date of this prospectus pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act will update, supplement and supersede the information in this prospectus. You may request and obtain a copy of any of the filings incorporated herein by reference, at no cost, by writing or telephoning us at the following address or phone number:

Callisto Pharmaceuticals, Inc.  
420 Lexington Avenue

Suite 1609

New York, New York 10170

Attn.: Corporate Secretary  
Tel: (212) 297-0010  
[www.callistopharma.com](http://www.callistopharma.com)



**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth an estimate of the fees and expenses relating to the issuance and distribution of the securities being registered hereby, other than underwriting discounts and commissions, all of which shall be borne by Callisto Pharmaceuticals, Inc. (the Registrant or the Company). All of such fees and expenses, except for the SEC Registration Fee, are estimated:

SEC registration fee	\$	983
Transfer agent's fees and expenses	\$	3,000*
Legal fees and expenses	\$	25,000*
Printing fees and expenses	\$	10,000*
Accounting fees and expenses	\$	8,500*
Miscellaneous fees and expenses	\$	2,517*
Total	\$	50,000*

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\* Estimated

**Item 15. Indemnification of Officers and Directors.**

Our certificate of incorporation, as amended, 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, as amended, 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 non-monetary 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, as amended, 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 its directors and officers, within the limits and subject to the limitations of the policy, against certain expenses in connection with the defense of actions, suits or proceedings, and certain liabilities that might be imposed as a result of such actions, suits or proceedings, to which they are parties by reason of being or having been directors or officers.

**Item 16. Exhibits.**

a) Exhibits.

<b>Exhibit Number</b>	<b>Description of Document</b>
1.1*	Form of underwriting agreement with respect to debt securities, common stock, preferred stock and warrants.

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- 3.1 Certificate of Incorporation of Registrant, as amended (Previously filed as Exhibit 3.1 to the Registrant's Form 10-K filed March 27, 2008, and incorporated herein by reference).
- 3.2 Amended and Restated By-laws of Registrant (Previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 4, 2007, and incorporated herein by reference).
- 4.1 Specimen Common Stock Certificate of the Registrant (Previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on May 28, 2003, and incorporated herein by reference).
- 4.2 Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Previously filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 27, 2006, and incorporated herein by reference)
- 4.3 Certificate of Amendment to Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Previously filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on December 27, 2006, and incorporated herein by reference)
- 4.4 Certificate of Amendment to Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Previously filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on August 7, 2007, and incorporated herein by reference)
- 4.5 Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series B Convertible Preferred Stock of Callisto Pharmaceuticals, Inc. (Previously filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on August 7, 2007, and incorporated herein by reference)
- 4.6\* Form of specimen certificate for preferred stock of registrant, if any.
- 4.7\* Certificate of designation for preferred stock, if any.
- 4.8\* Form of warrant agreement and warrant certificate, if any.
- 4.9\* Form of unit agreement and unit certificate, if any.
- 5.1\*\* Opinion of Sichenzia Ross Friedman FERENCE LLP as to the legality of the securities being registered.
- 23.1\*\* Consent of Sichenzia Ross Friedman FERENCE LLP (included in Exhibit 5.1).
- 23.2\*\* Consent of BDO Seidman, LLP
- 24.1\*\* Power of Attorney (included on signature pages to the registration statement).

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\* To the extent applicable, to be filed by an amendment or as an exhibit to a document filed under the Securities Exchange Act of 1934, as amended, and incorporated by reference herein.

\*\* Filed herewith.

**Item 17. 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, as amended;

(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; and

(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 subparagraphs (i) and (ii) above do not apply if the information required to be included in a post-effective amendment by these subparagraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in this registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

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

(3) 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 the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the Registrant is relying on Rule 430B:

(A) Each prospectus filed by the 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 that 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; or

(ii) If the Registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. 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 first use, 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 date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of such 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, such 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 the 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 the undersigned registrant or used or referred to by the undersigned registrant;

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

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

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, as amended, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.



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

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in New York, New York, on the 16th day of April 2008.

CALLISTO PHARMACEUTICAL, INC.

By: /s/ Gary S. Jacob  
 Gary S. Jacob  
 Chief Executive Officer

**POWER OF ATTORNEY**

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

Pursuant to the requirements of the Securities Act of 1933, the following persons in the capacities and on the dates indicated have signed this Registration Statement below.

Signature	Title	Date
/s/ Gary S. Jacob Gary S. Jacob	Chief Executive Officer and Director (Principal Executive Officer)	April 16, 2008
/s/ Gabriele M. Cerrone Gabriele M. Cerrone	Chairman of the Board	April 16, 2008
/s/ Riccardo Dalla-Favera Riccardo Dalla-Favera	Director	April 16, 2008
/s/ John P. Brancaccio John P. Brancaccio	Director	April 16, 2008
/s/ Stephen K. Carter Stephen K. Carter	Director	April 16, 2008
/s/ Bernard F. Denoyer Bernard F. Denoyer	Senior Vice President, Finance	April 16, 2008

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(Principal Accounting Officer and Principal Financial Officer)

/s/ Christoph Bruening  
Christoph Bruening

Director

April 16, 2008

/s/ Randall K. Johnson  
Randall K. Johnson

Director

April 16, 2008