

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

CALLISTO PHARMACEUTICALS INC  
Form 424B3  
August 12, 2004

Filed pursuant to Rule 424(b)(3)  
File No. 333-115471

PROSPECTUS

CALLISTO PHARMACEUTICALS, INC.

6,056,541 Shares of Common Stock

The selling stockholders named in this prospectus are offering to sell up to 6,056,541 shares of common stock of Callisto Pharmaceuticals, Inc. which are currently issued and outstanding and were previously issued by us to the selling stockholders in private transactions. We will not receive any proceeds from the resale of shares of our common stock.

Our common stock currently trades on the Over the Counter Bulletin Board ("OTC Bulletin Board") under the symbol "CLSP.OB."

On August 3, 2004, the last reported sale price for our common stock on the OTC Bulletin Board was \$1.72 per share.

The securities offered in this prospectus involve a high degree of risk. See "Risk Factors" beginning on page 5 of this prospectus to read about factors you should consider before buying shares of our common stock.

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

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

The date of this Prospectus is August 12, 2004

TABLE OF CONTENTS

	Page
Prospectus Summary .....	3
Risk Factors .....	5
Forward Looking Statements .....	14
Use of Proceeds .....	14
Management's Discussion and Analysis of	

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Financial Condition or Plan of Operation .....	14
Description of Business .....	19
Description of Property .....	23
Legal Proceedings .....	23
Directors and Executive Officers .....	23
Executive Compensation .....	26
Changes In and Disagreements With Accountants on Accounting and Financial Disclosure .....	29
Market for Common Equity and Related Stockholder Disclosure .....	29
Security Ownership of Certain Beneficial Owners and Management .....	30
Selling Shareholders .....	32
Certain Transactions .....	34
Description of Securities .....	34
Plan of Distribution .....	35
Legal Matters .....	36
Experts .....	36
Where You Can Find More Information .....	37
Disclosure of Commission Position on Indemnification for Securities Act Liabilities .....	37
Index to Consolidated Financial Statements .....	F-1

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

### PROSPECTUS SUMMARY

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

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

Atiprimod successfully completed Phase I clinical trials in rheumatoid arthritis patients and in May 2004 we commenced a Phase I/IIa open-label clinical trial of Atiprimod in relapsed multiple myeloma patients. These are patients that no longer respond to chemotherapy, and are in advanced stages of the disease. The Phase I/IIa clinical trial will be performed at two sites, the Dana-Farber Cancer Institute (Boston) and The University of Texas M.D. Anderson Cancer Center (Houston). On January 6, 2004, we announced that the Office of

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Orphan Products Development of the United States Food and Drug Administration, or FDA, granted orphan drug designation to Atiprimod for the treatment of multiple myeloma.

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

### THIS OFFERING

Shares offered by Selling Stockholders	6,056,541
Use of Proceeds	We will not receive any of the proceeds from the sale of common stock by the selling stockholders. The proceeds from this offering are solely for the account of the selling stockholders.
Risk Factors	The purchase of our common stock involves a high degree of risk. You should carefully review and consider "Risk Factors" beginning on page 5.
OTC Bulletin Board Trading Symbol	CLSP.OB

3

### SUMMARY FINANCIAL INFORMATION

The following table summarizes our financial data. The statement of operations data for the two years ended December 31, 2003 and 2002 are derived from our audited financial statements included elsewhere in this prospectus. The balance sheet data as of June 30, 2004 and the statement of operations data for the six months ended June 30, 2004 and 2003 and for the period June 5, 1996 (inception) to June 30, 2004 are derived from our unaudited financial statements, which are included elsewhere in this prospectus. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under "Management's Discussion and Analysis of Financial Condition or Plan of Operation."

Statement of Operations Data:

	For the Years Ended December 31,		Six Months Ended J
	2003	2002	2004
	----	----	----
Revenues	\$--	\$--	\$--
Costs and expenses:			
Research and development	1,369,985	491,430	925,652
Government grant	--	--	(100,220)
Purchased in-process research and development	6,734,818	--	209,735
General and administrative	1,398,090	1,227,699	1,074,233

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Stock-based compensation	3,833,946	332	1,665,594	2,
	-----	-----	-----	-----
Loss from operations	(13,336,839)	(1,719,461)	(3,774,994)	(10,
	-----	-----	-----	-----
Interest income	8,767	34,496	37,284	
Other income	221,824	--	--	
	-----	-----	-----	-----
Net loss	\$(13,106,247)	\$ (1,684,965)	\$ (3,737,710)	\$(10,
	=====	=====	=====	=====
Net loss per common share:				
Basic and diluted	\$ (0.61)	\$ (0.10)	\$ (0.13)	\$
Weighted average shares outstanding:				
Basic and diluted	21,357,659	17,318,994	27,767,221	19,

### Balance Sheet Data:

As of June 30, 2004

Cash and cash equivalents	\$ 7,269,421
Current assets	7,371,187
Total liabilities	478,880
Total stockholders' equity	6,987,959

4

### RISK FACTORS

An investment in our shares involves a high degree of risk. Before making an investment decision, you should carefully consider all of the risks described in this prospectus. If any of the risks discussed in this prospectus actually occur, our business, financial condition and results of operations could be materially and adversely affected. If this were to happen, the price of our shares could decline significantly and you may lose all or a part of your investment. The risk factors described below are not the only ones that may affect us. Additional risks and uncertainties that we do not currently know about or that we currently deem immaterial may also adversely affect our business, financial condition and results of operations. Our forward-looking statements in this prospectus are subject to the following risks and uncertainties. Our actual results could differ materially from those anticipated by our forward-looking statements as a result of the risk factors below. See "Forward-Looking Statements."

#### RISKS RELATED TO OUR BUSINESS

We are at an early stage of development as a company, currently have no source of revenue and may never become profitable.

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

- o demonstration in Phase I/IIa clinical trials that our lead product

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

candidate, Atiprimod for the treatment of multiple myeloma, is safe and effective;

- o the successful development of our other product candidates;
- o our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;
- o the successful commercialization of our product candidates; and
- o market acceptance of our products.

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

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future.

As of June 30, 2004, we had an accumulated deficit of \$29,555,440. We have incurred losses in each year since our inception in 1996. We incurred a net loss of \$13,106,247 and \$3,737,710 for the year ended December 31, 2003 and the six months ended June 30, 2004, respectively. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development, initiate our clinical trials of Atiprimod for the treatment of multiple myeloma, acquire or license technologies, advance our other product candidates into clinical development, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock will likely decline.

We will need to raise substantial additional capital to fund our operations, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- o complete the clinical development of our lead product candidate, Atiprimod for the treatment of multiple myeloma;
- o continue the development of our other product candidates;
- o finance our general and administrative expenses;

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

- o prepare regulatory approval applications and seek approvals for Atiprimod for the treatment of multiple myeloma and our other product candidates;
- o license or acquire additional technologies;
- o launch and commercialize our product candidates, if any such product candidates receive regulatory approval; and
- o develop and implement sales, marketing and distribution capabilities.

In 2003, our cash used in operations increased significantly over 2002 and we expect that our cash used in operations will continue to increase for the next several years. We expect that our existing capital resources will be sufficient to fund our operations for at least the next 12 months. We will be required to raise additional capital to complete the development and commercialization of our current product candidates. Our future funding requirements will depend on many factors, including, but not limited to:

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

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

- o 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
- o relinquish, license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

If our agreement with AnorMED Inc. terminates, we may be unable to continue

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

our business.

Our business is dependent on rights we have licensed from AnorMED Inc. Under the terms of the license agreement, we are obligated to make specified payments. If we fail to fulfill those obligations or other material obligations, the license agreement may be terminated. If AnorMED terminates its agreement with us, we will have no further rights to utilize the intellectual property covered by the terminated agreement, we would not be able to commercialize Atiprimod and we may be forced to cease our operations, particularly if we do not have rights to other product candidates.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

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

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

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable clinical trial terms with prospective sites, in obtaining

6

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

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

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

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

If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidates.

We need FDA approval prior to marketing our product candidates in the United States. We commenced in May 2004 a Phase I/IIa trial of Atiprimod for the treatment of multiple myeloma. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States and we will not generate any revenue.

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

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

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing the product in those countries. The approval process



## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

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.

7

The commercial success of our product candidates will depend upon the degree of market acceptance of these products among physicians, patients, health care payors and the medical community.

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

- o acceptance by physicians and patients of each such product as a safe and effective treatment;
- o cost effectiveness;
- o adequate reimbursement by third parties;
- o potential advantages over alternative treatments;
- o relative convenience and ease of administration; and
- o prevalence and severity of side effects.

If our product candidates are unable to compete effectively with marketed cancer drugs, our commercial opportunity will be reduced or eliminated.

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

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

- o successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- o maintain a proprietary position for our products and manufacturing processes and other related product technology;

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

- o attract and retain key personnel;
- o develop relationships with physicians prescribing these products; and
- o build an adequate sales and marketing infrastructure for our product candidates.

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

We currently have no sales and marketing organization. If we are unable to establish a direct sales force in the United States to promote our products, the commercial opportunity for our products may be diminished.

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

We may need others to market and commercialize our product candidates in international markets.

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

international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

If the FDA does not approve our contract manufacturers' facilities, we may be unable to develop or commercialize our product candidates.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

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:

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

We have "clinical trial" liability insurance with a \$2,000,000 annual aggregate limit for up to 40 patients participating in our Atiprimod clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

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.

9

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

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

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

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

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

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

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

If we fail to acquire and develop other products or product candidates, we may be unable to grow our business.

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

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

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

We may undertake acquisitions in the future, and any difficulties from integrating these acquisitions could damage our ability to attain or maintain profitability.

We may acquire additional businesses, products or product candidates that complement or augment our existing business. Integrating any newly acquired

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

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 6 employees as of August 3, 2004, most of whom have joined us in the preceding 12 months. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

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

10

- o integrate additional management, administrative, manufacturing and sales and marketing personnel;
- o maintain sufficient administrative, accounting and management information systems and controls; and
- o 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

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

generate revenue, attain profitability or commercialize our products.

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

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

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

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

### RISKS RELATED TO OUR INTELLECTUAL PROPERTY

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

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

As of August 3, 2004, we own 4 issued United States patents and have licensed rights to 8 issued United States patents and 78 issued foreign patents, and to 3 pending United States patent applications and 39 pending foreign patent applications. We do not and have not had any control over the filing or prosecution of these patents or patent applications. We may file additional patent applications and extensions.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The biotechnology patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

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:

- o 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;

11

- o 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;
- o we or our licensors might not have been the first to file patent applications for these inventions;
- o others may independently develop similar or alternative technologies or duplicate any of our technologies;
- o 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;
- o 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;
- o we may not develop additional proprietary technologies that are patentable; or
- o 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



## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

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

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

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

### RISKS RELATED TO OUR COMMON STOCK

Market volatility may affect our stock price and the value of your investment.

The market prices for securities of biopharmaceutical companies in

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

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:

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

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

We are at risk of securities class action litigation.

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

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

As of August 3, 2004, our officers, directors and holders of 5% or more

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

of our outstanding common stock beneficially own approximately 27.9% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

13

news events because major wire services, such as the Dow Jones News Service, generally do not publish press releases about such companies, and (iii) to obtain needed capital.

We have not paid cash dividends in the past and do not expect to pay cash dividends in the future. Any return on investment may be limited to the value of our stock.

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

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

If our stockholders sell substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants, the market price of our common stock could fall. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Approximately 21.6 million shares of our restricted common stock is eligible for sale pursuant to Rule 144. In addition, the 6,056,541 shares of common stock to be registered under this registration statement will be freely tradable upon effectiveness of this registration statement.

### FORWARD-LOOKING STATEMENTS

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

### USE OF PROCEEDS

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

### MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion should be read in conjunction with our financial statements and other financial information appearing elsewhere in this prospectus. In addition to historical information, the following discussion and other parts of this prospectus contain forward-looking information that involves risks and uncertainties.

### OVERVIEW

We are a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. Since inception in June 1996 our efforts have been principally devoted to research and development, securing patent protection, obtaining corporate relationships and raising capital. Since inception through June 30, 2004, we have sustained cumulative net losses of \$29,555,440. Our losses have resulted primarily from expenditures incurred in connection with the purchase of in-process research and development, stock based compensation expense, patent filing and maintenance, outside accounting and legal services and regulatory consulting fees.

From inception through June 30, 2004 we have not generated any revenue from operations. We expect to incur additional losses to perform further research and development activities. We do not currently have any commercial

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

biopharmaceutical products, and do not expect to have such for several years, if at all. Our lead drug candidate, Atiprimod, is a small molecule, orally available drug, with antiproliferative and antiangiogenic activity. Atiprimod successfully completed Phase I clinical trials in rheumatoid arthritis patients.

### HISTORY

In March 2002, Callisto Pharmaceuticals, Inc., or Old Callisto, purchased 99.7% of the outstanding common shares of Webtronics, Inc., or Webtronics, a public company for \$400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations at December 31, 2002.

On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Synergy Pharmaceuticals Inc., or Synergy, and Callisto Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Old Callisto. As a result of the merger, Old Callisto and Synergy became wholly-owned subsidiaries of

14

Webtronics. In the merger, Webtronics issued 17,318,994 shares of its common stock in exchange for outstanding Old Callisto common stock and an additional 4,395,684 shares in exchange for outstanding Synergy common stock. Old Callisto changed its name to Callisto Research Labs, LLC and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware. Callisto Pharmaceuticals, Inc. remains the continuing legal entity for Securities and Exchange Commission reporting purposes.

### PLAN OF OPERATION

Our plan of operations for the next twelve months is to focus primarily on the clinical development of Atiprimod for multiple myeloma and bone resorption disease. Additionally we are seeking to acquire or in-license additional clinical drug candidates.

On August 28, 2002, Synergy entered into a worldwide license agreement with AnorMED Inc., or AnorMED, to research, develop, sell and commercially exploit the Atiprimod patent rights. The license agreement provides for aggregate milestone payments by Synergy of up to \$14 million based on achieving regulatory submissions and approvals for an initial indication and additional payments of \$16 million for each additional indication based on achieving regulatory submissions and approvals. In addition, the license agreement requires Synergy to pay royalties based on net sales to AnorMED. Commencing on January 1, 2004 and on January 1 of each subsequent year Synergy is obligated to pay AnorMED a maintenance fee of \$200,000 until the first commercial sale of the product. The first of these annual maintenance fee payments under this agreement was made on January 22, 2004 and was reported as research and development expense in the quarter ended March 31, 2004.

On September 23, 2003, we submitted to the FDA an IND for Atiprimod to treat multiple myeloma patients. In May 2004 we commenced a Phase I/IIa clinical trial of Atiprimod in relapsed multiple myeloma patients at two sites, the Dana-Farber Cancer Institute (Boston) and The University of Texas M.D. Anderson Cancer Center (Houston). This Phase I/IIa clinical trial is an open label study, with the primary objective of assessing safety of our drug and identifying the maximum tolerated dose. The duration of this Phase I/IIa clinical trial will depend on how well the drug is tolerated, and on drug response, with final results not available until the fourth quarter of 2004 or the first quarter of 2005. If Atiprimod produces positive responses, we intend to initiate a Phase

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

IIB trial in relapsed multiple myeloma patients in 2005.

From November 2003 through January 21, 2004, we sold and issued 3,905,432 shares of common stock at an issue price of \$1.50 per share for aggregate gross proceeds of \$5,858,148. We incurred fees aggregating \$508,615 to various selling agents. In addition, we issued 31,467 shares of common stock and an aggregate 370,543 warrants to purchase common stock to such selling agents. The warrants are immediately exercisable at \$1.90 per share and will expire five years after issuance. As of December 31, 2003, we had closed on a portion of this transaction, specifically 2,776,666 shares of common stock at a price of \$1.50 per share, for aggregate gross proceeds of \$4,164,721, less \$361,625 in fees to various selling agents.

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

### ATIPRIMOD FOR OTHER CANCER INDICATIONS

The National Cancer Institute (NCI) is presently evaluating Atiprimod in a number of xenograft mouse tumor model studies, including breast, colon, lung and prostate solid tumors at no cost to us. Successful completion of these models could provide an additional therapeutic use for Atiprimod that would require only a small amendment to the existing IND to begin further clinical trials of Atiprimod. This study is being funded entirely by NCI. We have filed new patents for broad use of Atiprimod to treat cancer.

### DNA INTERCALATION TECHNOLOGY

On February 24, 2004, we entered into an agreement with Houston Pharmaceuticals, Inc., or HPI, to acquire the rights to a novel site-directed DNA intercalation cancer platform technology. We issued to HPI 25,000 shares of common stock and reimbursed HPI approximately \$100,000 for various costs and expenses. In addition we granted HPI 1,170,000 performance based stock options exercisable at \$3.60 per share which vest upon the achievement of certain milestones. We also agreed to pay HPI a royalty of 2% of the net sales of any products resulting from commercializing the patents. The technology platform for site-directed DNA intercalation is exemplified by the identification of a lead drug candidate for melanoma that shows remarkable selectivity for human melanoma cancer cell lines. We intend to pre-clinically evaluate this compound as a potential drug to treat melanoma, and plan to pursue further development of site-directed intercalation studies to identify additional clinical candidates from this technology.

### SUPERANTIGEN-BASED BIOTERRORISM DEFENSE

We intend to evaluate our superantigen-based monoclonal antibody in an animal model for toxic shock syndrome in 2004. Successful demonstration of this antibody's ability to protect animals against aerosolized forms of superantigen toxins is key to the development of this antibody as a biodefense against bioweapons that utilize streptococcal and staphylococcal bacteria.

### MANUFACTURING

We currently do not manufacture our drug compounds in-house and we do not intend to do so in the future. We currently use a non-commercial supplier to manufacture Atiprimod for use in our clinical trials. We intend to identify and contract with a commercial supplier of Atiprimod in the fourth quarter of 2004.

#### EMPLOYEES

Our plan is to use contract research organizations for most of our development efforts, including monitoring of clinical trial results, thus minimizing the need to hire full time employees. As of August 3, 2004, we had 6 full-time employees.

Our product development activities are in their early stages and we cannot make estimates of the costs or the time it will take to complete. Net cash inflows from any products developed may take several years to achieve. We may need additional funding to complete these activities. We expect that our existing capital resources will be sufficient to fund our operations for at least the next 12 months.

#### OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of June 30, 2004.

#### CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in Note 3 of the notes to our consolidated financial statements included in this prospectus. The financial statements are prepared in accordance with accounting principles generally accepted in the United States of America, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Accounting for Stock Based Compensation:** We have adopted Statement of Financial Accounting Standard No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). As provided for by SFAS 123, we have also elected to account for our stock-based compensation programs according to the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"). Accordingly, compensation expense has been recognized based on the intrinsic value of stock issued or options granted to employees and directors for services rendered.

**Research and Development:** We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all and therefore our research and development costs are expensed as incurred. These include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of our proposed products, purchase of in-process research and development, regulatory and scientific consulting fees, contract research and royalty payments to outside suppliers, facilities and universities as well as legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products. While certain of our research and development costs may have future benefits, our policy of expensing all research and development expenditures is predicated on the fact that we have no history of successful commercialization of biopharmaceutical products to base any estimate of the number of future periods that would be benefited.

**Research Grants:** We currently have a research grant from the National Institute of Health for studies on Atiprimod. The studies began in early 2004 and no funding was received during 2003. We request grant funding to reimburse

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

expenses as incurred and record the receipt as an offset to research and development expense.

### RESULTS OF OPERATIONS

Six Months Ended June 30, 2004 and 2003

We had no revenues during the six months ended June 30, 2004 and 2003 because we do not have any commercial biopharmaceutical products, and we do not expect to have such products for several years, if at all.

Research and development expenses increased approximately \$616,666, or 200%, to \$925,652 for the six months ended June 30, 2004 from \$308,986 for the same period in 2003. Of this increase in research and development expense, \$200,000 was attributable to our payment of the first annual maintenance fee to AnorMED, Inc. for the Atiprimod license. In addition, approximately \$280,000 was incurred in preparing for and administering the clinical trials of Atiprimod which began during the six months ended June 30, 2004, whereas none of these costs were incurred during the same period of 2003. These clinical trial costs included management consulting fees paid to contract research organizations to develop and advise on clinical trial protocols, site selection and principal investigator contracting, patient site cost plus formulation of drugs and clinical trial liability insurance. Also contributing to this increase in research and development expense was an increase of approximately \$118,000 in personnel costs as we retained two Synergy executive staff scientists, Drs. Picker and Shailubhai, subsequent to our merger with Synergy.

Government grant funding for the six months ended June 30, 2004 was \$100,220 as compared to \$0 for the six months ended June 30, 2003. We request grant funding to reimburse research and development expenses as incurred and record the receipt as an offset to research and development expenses.

General and administrative expenses for the six months ended June 30, 2004 were \$1,074,233 an increase of \$576,614, or 116%, from \$497,619 for the six months ended June 30, 2003. The increase was due primarily to approximately (i) \$139,000 of increased personnel costs as a result of the merger with Synergy and the hiring of a senior financial officer in January 2004, (ii) \$113,000 in higher facilities and office overhead related to the move into our new corporate headquarters in New York City during the quarter ended September 30, 2003, (iii) \$100,000 in higher legal and accounting fees related to certain regulatory filings and corporate business development activities, (iv) \$70,000 in higher business travel, (v) \$63,000 in higher public relations costs associated with news of Atiprimod clinical trial start-up and our fund raising efforts and (vi) \$44,000 in

16

outside director fees associated with the cost of attracting outside directors to serve on our Board.

Purchased in-process research and development was \$209,735 for the six months ended June 30, 2004, primarily the result of \$159,750 consideration paid in connection with the acquisition of rights to two key patents covering a novel cancer platform technology from HPI. We issued to HPI 25,000 shares of common stock at a fair value of \$56,250 and reimbursed HPI approximately \$103,500 for various costs and expenses. The total consideration of \$159,750 was allocated in full to the HPI patent rights, which have not yet reached technological feasibility, and having no alternative use, was expensed as purchased in-process research and development during the quarter ended March 31, 2004. During the six



## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

months ended June 30, 2003 we recorded \$6,833,454 of purchased in-process research and development expense in connection with the merger with Synergy.

Net loss for the six months ended June 30, 2004 was \$3,737,710 compared to a net loss of \$10,096,010 incurred for the six months ended June 30, 2003. The decreased net loss is primarily the result of the lower purchased in-process research and development costs, partially offset by higher research, development, general and administrative expenses discussed above. In addition we recorded lower stock based compensation expense of \$1,665,594 during the six months ended June 30, 2004, as compared to \$2,463,007 recorded during the same period ended June 30, 2003.

Twelve Months Ended December 31, 2003 and December 31, 2002

We had no revenues during the twelve months ended December 31, 2003 and December 31, 2002 because we do not have any commercial biopharmaceutical products, and we do not expect to have such products for several years, if at all.

Research and development expenses increased \$878,555 or 179% to \$1,369,985 for the twelve months ended December 31, 2003 from \$491,430 for the same period in 2002. The results of operations of Synergy for the period May 1, 2003 through December 31, 2003 are included in the consolidated statement of operations for the year ended December 31, 2003, and are not included in the results of 2002. Of this increase in research and development expense, approximately 63% or \$556,000 was attributable to costs associated with preparing and filing our IND for Atiprimod in September of 2003. These IND related costs included quantitative analysis and synthesis, as well as pre-clinical management consulting fees paid to contract research organizations to develop and advise on IND requirements, proposed clinical trial protocols, site selection and principal investigator contracting. Also contributing to this increase in research and development expense were higher salaries and wages, which increased approximately \$200,000 as we retained two key executive staff scientists from Synergy. The remainder of this increase in research and development was primarily due to the acquisition of the Synergy research laboratory facility in conjunction with the Synergy merger. No such expenses were incurred in 2002. We expect our research and development expenses to increase in 2004 as our products move into more expensive later stages of development.

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

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

Stock-based compensation expense recorded during the twelve months ended December 31, 2003, totaled \$3,833,946 as compared to \$332 recorded during the twelve months ended December 31, 2002. This increase was primarily attributable to options issued in connection with the Synergy merger, to retain several key Synergy scientists, at approximately the same time our shares of common stock commenced trading on the OTC Bulletin Board on June 17, 2003. The

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

remaining balance of unamortized deferred stock based compensation expense, presented in the stockholder's equity section of our December 31, 2003 Balance Sheet, totaled \$5,480,007.

During December 2003 Synergy sold certain New Jersey State tax loss carry forwards under a state economic development program for cash of approximately \$221,000, the proceeds of which have been and will be used to support research and development activities in New Jersey. This state tax benefit was recorded as Other Income during the fourth quarter ended December 31, 2003 and there was no such benefit in 2002.

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

### LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2004 we had \$7,269,421 in cash and cash equivalents, compared to \$3,956,486 as of December 31, 2003. This increase in cash of \$3,312,935 during the six months ended June 30, 2004 was principally the result of completing two private placements of common stock yielding net proceeds of \$6,099,012. This was partially offset by cash used in operating activities of \$2,786,077 during the six months ended June 30, 2004.

In January 2004, we completed a private placement begun in late 2003 and issued 1,128,766 shares of common stock at an issue price of \$1.50 per share for aggregate proceeds of \$1,693,149, less \$139,891 in fees to various selling agents. As of December 31, 2003, we had issued 2,776,666 shares of common stock at a price of \$1.50 per share for aggregate gross proceeds of \$4,164,999, less \$361,625 in fees to various selling agents. In addition, we issued 31,467 shares of common stock and 370,543 warrants to purchase common stock to such selling agents. The warrants are exercisable at \$1.90 per share and will expire five years after issuance.

17

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

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of: pharmaceutical research and development programs; pre-clinical and clinical testing; obtaining regulatory approvals; technological advances and our ability to establish collaborative arrangements with research organizations and individuals needed to commercialize our products.

Our capital resources will be focused primarily on the clinical development and regulatory approval of Atiprimod for multiple myeloma and bone resorption disease and the acquisition of licenses and rights to certain other cancer related drug technologies. In May 2004, we commenced a Phase I/IIa trial of Atiprimod for the treatment of multiple myeloma.

On October 7, 2003, we were awarded a \$265,267 Small Business Technology Transfer Research grant from the National Institutes of Health for studies on Atiprimod. The studies began in early 2004 and no funding was received during 2003. We request grant funding to reimburse expenses as incurred

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

and record the receipt as an offset to research and development expenses.

Our product development efforts are thus in their early stages and we cannot make estimates of the costs or the time it will take to complete. The risk of completion of any program is high because of the long duration of clinical testing, extended regulatory approval and review cycles and uncertainty of the costs. Net cash inflows from any products developed make take several years to achieve. We could however receive grants, contracts or technology licenses in the short-term. The amount and timing of these inflows, if any, is not known.

We expect that our existing capital resources will be sufficient to fund our operations for at least the next 12 months. We will be required to raise additional capital to complete the development and commercialization of our current product candidates.

### CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following is a summary of our significant contractual cash obligations for the periods indicated that existed as of December 31, 2003, and is based on information appearing in the Notes to Consolidated Financial Statements.

	Total -----	Less than 1 year -----	1 - 3 years -----	3 - 5 years -----	More than 5 years -----
Operating Leases	\$ 582,710	\$ 150,895	\$ 253,983	\$177,832	
Minimum patent royalty /license fees	1,037,500 -----	207,500 -----	415,000 -----	415,000 -----	
Total obligations	\$1,620,210 =====	\$ 358,395 =====	\$ 668,983 =====	\$592,832 =====	

(1) For purposes of this schedule we have assumed that all patents not commercialized within 5 years will be abandoned, license agreements will be terminated and associated minimum royalty payments will cease.

On June 7, 2004, we extended our lease for our corporate headquarters in New York City for two additional years through August 2010 and increased our space by approximately 60%. These changes have increased average annual rent by approximately \$50,000 to \$150,000.

On July 22, 2004, the employment agreement of Donald H. Picker, our Executive Vice President, R&D was amended. Dr. Picker's salary was increased from \$175,000 to \$200,000 per year and certain milestones were added upon which achievement cash bonuses of up to \$92,500 may be paid over a 12 month period.

### DESCRIPTION OF BUSINESS

We are a biopharmaceutical company focused on the development of drugs to treat multiple myeloma (an incurable blood cancer that invades and

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

proliferates in bone marrow), other cancers and osteolytic bone disease. Our lead drug candidate, Atiprimod, is a small-molecule, orally available drug with antiproliferative and antiangiogenic activity.

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

In March 2002, Callisto Pharmaceuticals, Inc., or Old Callisto, purchased 99.7% of the outstanding common shares of Webtronics, Inc., or Webtronics, a public company for \$400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations at December 31, 2002.

On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Synergy Pharmaceuticals Inc., or Synergy, and Callisto Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Old Callisto. As a result of the merger, Old Callisto and Synergy became wholly-owned subsidiaries of Webtronics. In the merger, Webtronics issued 17,318,994 shares of its common stock in exchange for outstanding Old Callisto common stock and an additional 4,395,684 shares in exchange for outstanding Synergy common stock. Old Callisto changed its name to Callisto Research Labs, LLC and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware. Subsequently, 171,818 shares of common stock issued to former Synergy shareholders were returned to us under the terms of certain indemnification agreements.

On February 24, 2004, we entered into an agreement with HPI to acquire rights to a novel cancer platform technology that deals with the design of novel intercalator drug candidates that specifically target sites on DNA using a technique referred to as site-directed intercalation. The site-directed intercalation technology has resulted in the identification of a lead drug candidate for melanoma that shows remarkable selectivity for human melanoma cancer cell lines. We intend to pre-clinically evaluate this compound as a drug candidate to treat melanoma. We intend to further explore the site-directed intercalation technology as a platform to provide new anti-cancer drug candidates for development.

### ATIPRIMOD TO TREAT MULTIPLE MYELOMA

On August 28, 2002, our wholly-owned subsidiary, Synergy, entered into a license agreement with AnorMED Inc., or AnorMED, a Canadian corporation, to license Atiprimod from AnorMED. Atiprimod is one of a class of compounds known as azaspiranes and was originally developed as a potential treatment for rheumatoid arthritis based on encouraging data from a number of animal models of arthritis and autoimmune indications. The development of this drug originated with a partnership between AnorMED and SmithKline Beecham that led to the successful filing of an investigational new drug application, or IND, and completion of three Phase I clinical trials involving a total of 63 patients. The drug successfully completed both single and multiple dose Phase I clinical trials in patients with rheumatoid arthritis. Both trials evaluated the safety and pharmacokinetics (how the body takes up and eliminates drugs) of Atiprimod and showed that the drug is well tolerated. In the third Phase I clinical trial, the drug was found to be well tolerated in an open label extension study

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

performed with 43 patients from the first two studies, with patients on the drug for as long as one year.

### PRECLINICAL STUDIES

Atiprimod's specific lowering effect on the level of key growth factors known to play an important role in the pathogenesis of multiple myeloma is the basis for its potential use as a drug to treat this disease. Atiprimod has been shown to inhibit the production of the pro-inflammatory mediators IL-6 and TNF $\alpha$  in a number of animal models of inflammation and autoimmune disease. Atiprimod has also been demonstrated using in vitro models of autocrine and paracrine growth to inhibit proliferation of a number of human multiple myeloma cell lines. Characterization of the mechanism of Atiprimod's antiproliferative activity in a series of experiments showed that the drug works by inducing apoptosis (programmed cell death) in myeloma cells. In a second series of experiments performed with Atiprimod on co-cultures composed of multiple myeloma cells plus bone marrow stromal cells (used to simulate the human disease), the drug was found to have a profound effect on secretion of the angiogenic growth factor VEGF. A separate set of experiments also suggest an additional explanation for the disease modifying activity of Atiprimod originally observed in adjuvant-induced arthritic-rat animal studies, and provide a further rationale for the application of this drug to treat multiple myeloma. Using a bone resorption assay to measure the effect of drug on osteoclast-mediated bone resorption, Atiprimod demonstrated a profound effect on osteoclast function. The drug appears to be selectively toxic for activated osteoclasts, displaying a negligible effect on bone marrow stromal cells. Atiprimod has also recently been demonstrated to show anti-cancer activity in the low micromolar range in human colorectal cancer cell lines and in a number of other human tumor cell lines. The drug was found to induce apoptosis and display anti-angiogenic activity. Additional anticancer uses for Atiprimod are presently being evaluated preclinically.

### COMPLETED CLINICAL STUDIES

Atiprimod successfully completed single and multiple dose Phase I clinical trials in patients with rheumatoid arthritis, or RA. In the initial Phase I study, 28 patients were given single escalating doses of drug (0.002 - 1.0 mg/kg), with a 4-month follow-up. Atiprimod was well tolerated, displaying no clinically relevant changes in any laboratory parameters. In particular, liver function tests remained in the normal range. The second Phase I study involved a 28-day multiple-dose-rising study in 35 RA patients. The study evaluated the effect of food on bioavailability, as well as the safety and pharmacokinetics of repeat dosing. Dosages included 0.1, 1.0, 5.0, and 10 mg/day plus a 14-day cohort at 30 mg/day, with 4-month follow-up. All doses were well tolerated and clinical tests were unremarkable. Significantly, reductions in tender and swollen joint counts were noted in a number of subjects during the course of the dosing period. Individuals from the two Phase I safety studies were also involved in a Phase I open-

19

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

### DEVELOPMENT STRATEGY

On September 23, 2003, we submitted to the FDA an IND for Atiprimod to treat multiple myeloma patients. In May 2004 we commenced a Phase I/IIa clinical

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

trial of Atiprimod in relapsed multiple myeloma patients at two sites, the Dana-Farber Cancer Institute (Boston) and The University of Texas M.D. Anderson Cancer Center (Houston). The clinical trial is an open label study, with the primary objective assessing safety of drug and identifying the maximum tolerated dose. The secondary objectives are to measure the pharmacokinetics, evaluate the response in patients with refractory disease and to identify possible surrogate responses to drug to better determine the mechanism of drug action. The duration of this clinical study will depend on how well the drug is tolerated, and on drug response, with final results not available until the fourth quarter of 2004 or the first quarter of 2005. If Atiprimod produces positive responses, we intend to initiate a Phase IIB trial in relapsed multiple myeloma patients in 2005.

Although the primary indication of this Phase I/IIa clinical trial will focus on multiple myeloma, the clinical trial will also look at bone resorption, a considerable problem in multiple myeloma patients. We have preclinical data showing a potent ability of Atiprimod to suppress bone resorption. Successful demonstration of this indication in a clinical setting could have broad applicability to other medical conditions exhibiting bone resorption, such as metastatic breast and prostate cancer.

### MANUFACTURING

A practical, efficient and cost effective synthetic route for producing Atiprimod on a commercial scale was originally developed by SmithKline Beecham, or SKB. In the course of this work, a new dimaleate salt form was developed. Over 7 kilos of Atiprimod drug substance, available from SKB, were used as a source for generating the Atiprimod dimaleate drug product needed for the planned Phase I/IIa clinical study. Several lots of drug substance were re-qualified to meet current FDA approved release specifications. The full package of fully validated analytical methods developed by SKB was transferred to a contract research organization used by us to perform all analytical tests. We intend to identify and contract with a future commercial supplier of both drug substance and drug product in the fourth quarter of 2004.

### ORPHAN DRUG STATUS

On January 6, 2004, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of multiple myeloma. The FDA grants orphan drug status for drug candidates that are intended to treat rare life-threatening diseases that, at the time of application, affect no more than 200,000 patients in the United States. The drug must have the ability to provide significant patient benefit over currently available treatment or fill an unmet medical need. Orphan drug designation entitles us to seven years of market exclusivity in the United States, and ten years of market exclusivity in Europe, upon FDA marketing approval, provided that we continue to meet certain conditions established by the FDA. Once the FDA grants marketing approval of a new drug, the FDA will not accept or approve other applications to market the same medicinal product for the same therapeutic indication. Other incentives provided by orphan status include certain tax benefits, eligibility for research grants and protocol assistance. Protocol assistance includes regulatory assistance and possible exemptions or reductions of certain regulatory fees.

### STUDIES ON ATIPRIMOD FOR OTHER CANCER INDICATIONS

We have also tested Atiprimod in the National Cancer Institute, or NCI, cancer screen and found the drug to be highly active in vitro screens of human cell lines from a number of solid tumors. The NCI is presently evaluating Atiprimod in a number of xenograft mouse tumor model studies, including breast, colon, lung and prostate solid tumors. Successful completion of these models could provide an additional therapeutic use for Atiprimod that would require

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

only a small amendment to the existing IND to begin further clinical trials of Atiprimod. New patents have been filed for broad use of Atiprimod to treat cancer.

### SITE DIRECTED INTERCALATION TECHNOLOGY

On February 24, 2004, we entered into an agreement with HPI to acquire the rights to two key patents covering a novel cancer platform technology. The lead inventor on both patents, Dr. Waldemar Priebe, a Professor of Medicinal Chemistry at The University of Texas M.D. Anderson Cancer Center, is an expert in the synthesis of novel anti-cancer compounds. The first patent covers a technology platform for site-directed DNA intercalation. This approach to target intercalator drug candidates to new sites on DNA can potentially provide a new way to attack cancer targets not achievable with older technologies. The second patent covers new anthacycline analogs with increased potency and reduced toxicity.

The site-directed intercalation technology is exemplified by the identification of a lead drug candidate for melanoma that shows remarkable selectivity for human melanoma cancer cell lines. We intend to pre-clinically evaluate this compound as a potential drug to treat melanoma.

We also plan to pursue further development of site-directed intercalation studies to identify additional clinical candidates from this technology.

20

### GUANYLYL CYCLASE RECEPTOR AGONIST TECHNOLOGY

Our guanylyl cyclase receptor agonist, or GCRA, program is focused on the control of cyclic GMP, an important second messenger involved in key cellular functions that are tied to inflammation, anti-tumorigenic responses and/or cellular death (apoptosis). Uroguanylin, a hormone produced and secreted by specialized cells in the human gastrointestinal tract, activates synthesis of cyclic GMP, leading to apoptosis, an important event in the turnover of cells lining the GI tract mucosa. Production of uroguanylin is dramatically suppressed in colon cancer patients, and there is increasing evidence that the deficiency of uroguanylin is one of the major reasons for development of polyps and colon cancer. The discovery that uroguanylin is dramatically reduced in gastrointestinal polyps and colon cancer and that the deficiency of this hormone peptide is linked to the onset of colon carcinogenesis forms the basis for the development of GCRA peptides as drugs to treat colon cancer and gastrointestinal inflammation.

Our GCRA program led to the development of CP304, a biologically functional analog that has demonstrated superior biological activity, enhanced temperature and protease stability and superior pH characteristics relative to human uroguanylin. We are presently looking to out-license the GCRA technology, or seek a partner, for further development as a potential treatment for colon cancer and gastrointestinal inflammation.

### SUPERANTIGEN-BASED BIOTERRORISM DEFENSE

We have designed both a monoclonal antibody and a peptide that prevents unregulated activation of T-cells (human white blood cells) by a wide range of bacterial toxins (superantigens). This form of T-cell activation leads to a lethal condition called toxic shock syndrome, and is typically generated by

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

bacteria from the class of *Staphylococcus aureus* and *Streptococcus pyogenes*. These bacteria offer attractive opportunities for bioterrorists, and, in particular, the toxin from *S. aureus* is listed as a priority list B bioagent by the national bioterrorism defense program. Both the antibody and the antagonist peptide developed by us effectively block actions of the toxins in in vitro assays as well as in mice and in rabbits. These experiments indicate that both the peptide and the antibody have potential as biodefensive agents against a bioweapon that utilizes toxins from *Staphylococcus* and *Streptococcus* strains. In addition, the peptide may also be used directly or indirectly as an antigen in a vaccine for the prevention and control of toxic shock and septic shock due to *Staphylococcal* and *Streptococcal* infections.

### DRUG DEVELOPMENT STRATEGY

We are exploring the development of the monoclonal antibody as a therapeutic agent to prevent, treat and control superantigen-mediated bioweapons. Our goal is to demonstrate therapeutic utility of this agent in animal models in which toxic shock and septic shock are induced by aerosolized forms of superantigen toxins. The research work will be accomplished jointly in collaboration with Dr. John Zabriskie, Professor Emeritus at the Rockefeller University, NY, and with Dr. Sina Bavari, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD. This program has been funded in part by a \$1.1 million grant from the U.S. Army.

### DIAGNOSTIC TEST FOR OBSESSIVE-COMPULSIVE DISORDER

During 2003 our Management and Board of Directors decided to terminate our program to develop a diagnostic test for obsessive-compulsive disorder.

### LICENSE AGREEMENTS

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

On July 25, 2001, we entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University licensed patents covering peptides and antibodies useful in treating toxic shock syndrome and septic shock. We will pay Rockefeller a \$7,500 annual maintenance fee until the first commercial sale of the product. We will also pay royalties of 2% and 0.75% of net sales of product as defined in the agreement and will pay Rockefeller 15% of any sublicense fee paid by sublicensees.

### GOVERNMENT REGULATION

Regulation by governmental authorities in the United States and other countries will be a significant factor in the production and marketing of any products that may be developed by us. The nature and the extent to which such regulation may apply will vary depending on the nature of any such products. Virtually all of our potential products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous pre-clinical and clinical testing and other approval procedures by the FDA and similar health authorities in



## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

foreign countries. Various federal statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of such products. The process of obtaining these approvals and the subsequent compliance with appropriate federal and foreign statutes and regulations requires the expenditure of substantial resources. In order to test clinically, produce and market products for diagnostic or therapeutic use, a company must comply with mandatory procedures and safety standards established by the FDA and comparable agencies in foreign countries. Before beginning human clinical testing of a potential new drug, a company must file an IND and receive clearance from the FDA. This application is a summary of the pre-clinical studies that were conducted to characterize the drug, including toxicity and safety studies, as well as an in-depth discussion of the human clinical studies that are being proposed.

21

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

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

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

### COMPETITION

The biopharmaceutical industry is characterized by rapidly evolving technology and intense competition. Our competitors include major pharmaceutical and biotechnology companies, most of which have financial, technical and marketing resources significantly greater than our resources. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint venture. We are aware of certain development projects for products to prevent or treat certain diseases targeted by us. The existence of these potential products or other products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of products developed.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

### RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses consist primarily of salaries and other personnel-related expenses, facilities costs, laboratory supplies, license fees and patent legal costs. Research and development expenses were \$1,369,985 and \$925,652 for the year ended December 31, 2003 and the six months ended June 30, 2004, respectively, compared to \$491,430 and \$308,986 for the year ended December 31, 2002 and the six months ended June 30, 2003, respectively. We expect our research and development expenses to increase in 2004 as our products move into more expensive later stages of development, including the Phase I/IIa clinical study on Atiprimod and related activities.

In addition, during the twelve months ended December 31, 2003 and the six months ended June 30, 2004, we incurred \$6,734,818 and \$209,735, respectively, of net purchased in-process research and development expense related to the Synergy merger. During the twelve months ended December 31, 2002 there was no such expense and during the six months ended June 30, 2003, we incurred \$6,833,454 of such expense.

On October 7, 2003 we were awarded a \$265,267 Small Business Technology Transfer Research grant from the National Institutes of Health for studies on Atiprimod. The Principal and Co-Principal Investigators of the grant entitled "Atiprimod to Treat Multiple Myeloma and Bone Resorption" are Dr. Gary S. Jacob, our Chief Executive Officer, and Dr. Kenneth C. Anderson, Director of the Jerome Lipper Multiple Myeloma Center of the Dana-Farber Cancer Institute, respectively. The studies, which began in early 2004, utilize unique in vitro and in-vivo methods and animal models at the Dana-Farber Cancer Institute and at our in house laboratory facilities to explore Atiprimod's pharmacological activity and mechanism of action. No funding was received during 2003 and we will request grant funding as expenses are incurred during the first half of 2004. Approximately \$25,000 of this grant will defray certain salary and wages of our in-house scientists, the balance of which will reimburse incremental supplies and sub-contractors.

### PROPRIETARY RIGHTS

We are able to protect our technology from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents or is effectively maintained as a trade secret. Accordingly, patents or other proprietary rights are an essential element of our business. We are the assignee or exclusive licensee of 3 pending patent applications and 12 issued patents in the United States, and in most cases corresponding patents/applications in foreign countries that we have deemed desirable. We seek patent protection of inventions originating from our ongoing research and development activities that are commercially important to our business.

We have obtained licenses from various parties that give us rights to technologies that we deem to be necessary or desirable for our research and development. These licenses (both exclusive and non-exclusive) may require us to pay royalties to the parties in addition to upfront or milestone payments.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

While trade secret protection is an essential element of our business and we have taken security measures to protect our proprietary information and trade secrets, we cannot give assurance that our unpatented proprietary technology will afford us significant commercial protection. We seek to protect

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and

22

consultants also sign agreements requiring that they assign to us their interests in intellectual property arising from their work for us. All employees sign an agreement not to engage in any conflicting employment or activity during their employment with us and not to disclose or misuse our confidential information. However, it is possible that these agreements may be breached or invalidated, and if so, there may not be an adequate corrective remedy available. Accordingly, we cannot ensure that employees, consultants or third parties will not breach the confidentiality provisions in our contracts, infringe or misappropriate our trade secrets and other proprietary rights or that measures we are taking to protect our proprietary rights will be adequate.

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or us, we may face costly litigation and the diversion of management's attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, or at all.

### EMPLOYEES

As of August 3, 2004, we had 6 full-time employees. We believe our employee relations are satisfactory.

### DESCRIPTION OF PROPERTY

We currently lease 3,886 square feet of office space located at 420 Lexington Avenue, Suite 1609, New York, New York through June 30, 2010. This facility contains our executive and administrative headquarters. Additionally, we currently lease 2,120 square feet of laboratory space located at 7 Deer Park Drive, Suite N, Monmouth Junction, New Jersey through November 2005 and approximately 300 square feet in Frankfurt, Germany. We believe our existing facilities are well maintained, in good operating condition, and that our existing and planned facilities will be adequate to support our operations for the foreseeable future.

### LEGAL PROCEEDINGS

We are not a party to any pending legal proceedings.

### DIRECTORS AND EXECUTIVE OFFICERS

The following table sets forth certain information regarding the directors and executive officers of Callisto Pharmaceuticals, Inc. as of August 3, 2004:

Name	Age	Positions
----	---	-----

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Gabriele M. Cerrone	32	Chairman of the Board
Gary S. Jacob	57	Chief Executive Officer, Chief Scientific Officer; Chairman of Synergy Pharmaceuticals Inc.
Donald H. Picker	58	Executive Vice President, R&D
Bernard F. Denoyer	57	Vice President, Finance
Kunwar Shailubhai	46	Senior Vice President, Drug Discovery of Synergy Pharmaceuticals Inc.
Christoph Bruening	36	Director
Albert J. Henry	66	Director
Iain G. Ross	50	Director
Edwin Snape	63	Director
Michael J. Zelefsky	43	Director
John P. Brancaccio	56	Director

Gabriele M. Cerrone has served as our Chairman of the Board of Directors since May 2003. Mr. Cerrone has served as a Senior Vice President of Investments of Oppenheimer & Co. Inc., a financial services firm since March 1999. Prior to such affiliation, Mr. Cerrone held the position of Managing Director of Investments at Barrington Capital, L.P., a merchant bank, between March 1998 and March 1999. Between May 2001 and May 2003, Mr. Cerrone served on the board of directors of SIGA Technologies, Inc.

Gary S. Jacob, Ph.D. has served as our Chief Executive Officer as well as Chief Scientific Officer since May 2003 and Chairman of Synergy Pharmaceuticals Inc. since October 2003. Dr. Jacob served as Chief Scientific Officer of Synergy Pharmaceuticals Inc. from 1999 to 2003. From 1990 to 1998, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of Glycobiology. From 1997 to 1998, Dr. Jacob was Director of Functional Genomics, Corporate Science & Technology, Monsanto, where he played a pivotal role in the rapid development of Monsanto's plant genomics strategy and the buildup of the in-house advanced genomics program. From 1990 to 1997, Dr. Jacob was Director of Glycobiology, G.D. Searle Pharmaceuticals Inc. From 1986 to 1990, Dr. Jacob was Manager of the G.D. Searle Glycobiology Group located at Oxford University, England.

Donald H. Picker, Ph.D. has served as our Executive Vice President, R&D since April 2004. From May 2003 until March 2004, Dr. Picker served as Senior Vice President, Drug Development. Dr. Picker was Chief Executive Officer and President of Synergy Pharmaceuticals Inc. and a member of its board of directors from 1998 to April 2003. From 1996 to 1998, Dr. Picker was President and Chief Operating Officer of LXR Biotechnology Inc., an apoptosis drug development company. From 1991 to 1996, he was Senior Vice President of Research and Development at Genta Inc., an antisense drug development company.

23

Bernard F. Denoyer, CPA has served as our Vice President, Finance since January 2004. From July 2003 to December 2003, Mr. Denoyer served as an independent consultant to our company providing interim CFO services. In addition to our company, Mr. Denoyer provided interim CFO and other services to emerging technology companies, principally portfolio companies of Marsh & McLennan Capital, LLC, from October 2000 to December 2003. From October 1994 until September 2000, Mr. Denoyer served as Chief Financial Officer and Senior Vice President. at META Group, Inc., a public information technology research company. From 1990 to 1993 he was Vice President Finance of Environetics, Inc., a pharmaceutical water diagnostic business.

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

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

April 2003, Dr. Shailubhai held the position of Vice President, Drug Discovery at Synergy Pharmaceuticals Inc. Between 1993 and 2000, he was affiliated with Monsanto Company as Group Leader of the cancer chemoprevention group during which time he was involved in several cancer research projects.

Christoph Bruening has served as a Director of our company since May 2003. Mr. Bruening organized Value Relations GmbH, a full service investor relations firm operating in Frankfurt, Germany in 1999 and currently serves as its Managing Partner. From 1998 to 1999, Mr. Bruening served as a funds manager and Director of Asset Management for Value Management and Research AG, a private investment fund and funds manager in Germany. From 1997 to 1998, Mr. Bruening was a financial analyst and Head of Research for Value Research GmbH. On February 26, 2004, Mr. Bruening became President and the sole director of Used Kar Parts, Inc., a company which planned to develop an on-line marketplace for used car parts. Mr. Bruening is currently evaluating the company's current business plan and evaluating potential acquisitions. In addition, Mr. Bruening is currently a member of the advisory board of Clarity AG.

Albert J. Henry has served as a Director of our company since May 2003. From 1992 to 1996 Mr. Henry was Chief Executive Officer of Synergy Pharmaceuticals Inc. and from 1992 to April 2003, Mr. Henry served as Chairman of Synergy Pharmaceuticals Inc. Mr. Henry is founder of the Wall Street venture capital firm Henry & Associates. Most recently, Mr. Henry was Vice Chairman of IVAC Medical Systems, Inc. and Chairman of Ivonyx, Inc. Mr. Henry is currently Chairman and Chief Executive Officer of Infusion Reimbursement Specialists, Inc. and MSO Medical. Mr. Henry is currently a director of Motion Analysis Corp and Intercept Corp.

Iain G. Ross has served as a Director of our company since June 2003. Mr. Ross has been Chairman of Biomer Technology Ltd. since January 2003 and serves as a director of a number of healthcare technology companies including Angle Technology plc, Eden Biopharm Group and Pegasus Therapeutics Ltd. Mr. Ross is an advisor to Apax Partners and PPM Ventures in London. From 2001 to 2002, Mr. Ross was Chairman and Chief Executive Officer of Allergy Therapeutics Ltd. and from 1995 to 2000, Mr. Ross was Chief Executive Officer of Quadrant Healthcare plc, which was sold to Elan Corporation in 2000.

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

Michael J. Zelefsky, M.D. has served as a Director of our company since September 2003. Since 1997, Dr. Zelefsky has been the Chief of Brachytherapy Service, Department of Radiation Oncology, Memorial Sloan-Kettering Cancer Center, where he is board certified in radiation oncology. He is Editor-In-Chief of the Journal of Brachytherapy, and Past President of the American Brachytherapy Society. Dr. Zelefsky has received a number of awards including the Memorial Sloan-Kettering Cancer Center Boyer Award for Excellence in Clinical Research. He is an active clinical researcher, as well, who has been the Principal Investigator on prospective trials using novel therapeutic agents with radiotherapy for patients with advanced stage genitourinary and head and neck cancers.

John P. Brancaccio has served as a Director of our company since April 2004. Since April 2004, Mr. Brancaccio has been the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Group, an entertainment and media company. Mr. Brancaccio is currently a director of Alfacell Corporation.

### COMPENSATION OF DIRECTORS

Each of our directors is entitled to receive a cash payment of \$5,750 per calendar quarter. Messrs. Cerrone, Snape and Henry have waived their right to such payments. Messrs. Cerrone, Bruening, Ross, Snape and Henry each received a grant of 75,000 stock options to purchase common stock at an exercise price equal to \$1.50 per share. Such options vest over a period of three years. Dr. Zelefsky received a grant of 60,000 stock options to purchase common stock at an exercise price equal to \$2.50 per share and Mr. Brancaccio received a grant of 75,000 stock options to purchase common stock at an exercise price equal to \$3.20 per share. These options also vest over a period of three years.

### AUDIT COMMITTEE

The audit committee's responsibilities include: (i) reviewing the independence, qualifications, services, fees, and performance of the independent auditors, (ii) appointing, replacing and discharging the independent auditors, (iii) pre-approving the professional services provided by the independent auditors, (iv) reviewing the scope of the annual audit and reports and recommendations submitted by the independent auditors, and (v) reviewing our financial reporting and accounting policies, including any significant changes, with management and the independent auditors. The audit committee currently consists of John Brancaccio, chairman of the audit committee, and Christoph Bruening. Our Board has determined that each of Mr. Bruening and Mr. Brancaccio is "independent" as that term is defined under applicable SEC rules. Mr. Brancaccio is our audit committee financial expert.

24

### COMPENSATION COMMITTEE

We have a compensation committee consisting of Iain Ross and Christoph Bruening. The compensation committee reviews, and makes recommendations to the board of directors regarding, the compensation and benefits of our chief executive officer and other executive officers. The compensation committee also administers the issuance of stock options and other awards under our stock plan and establishes and reviews policies relating to the compensation and benefits of our employees.

### SCIENTIFIC ADVISORY BOARD

Our scientific advisory board assists us in identifying research and development opportunities, in reviewing with management the progress of our projects and in recruiting and evaluating scientific staff. Although we expect to receive guidance from the members of our scientific advisory board, all of its members are employed on a full-time basis by others and, accordingly, are able to devote only a small portion of their time to us. Management expects to meet with its scientific advisory board members individually from time to time on an informal basis. We have entered into a consulting agreement with each member of the scientific advisory board. The scientific advisory board consists of the following scientists:

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

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

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

Kenneth C. Anderson, M.D. Dr. Anderson is the Kraft Family Professor of Medicine at Harvard Medical School; and serves as Chief of the Division of Hematologic Neoplasia, Director of the Jerome Lipper Multiple Myeloma Center and Vice Chair of the Joint Program in Transfusion Medicine at Dana-Farber Cancer Institute. His translational research focuses on development of novel therapeutics targeting the myeloma cell in its microenvironment. He hosted the VI International Myeloma Workshop on Multiple Myeloma, serves on the Board of Directors and as Chairman of the Scientific Advisors of the Multiple Myeloma Research Foundation, and is a Doris Duke Distinguished Clinical Research Scientist.

Moshe Talpaz, M.D. Dr. Talpaz currently holds the titles of Professor of Medicine, David Burton, Jr. Endowed Chair at the M.D. Anderson Cancer Center, Houston, Texas. Dr. Talpaz was formerly Chairman of the Department of Bioimmunotherapy of the M.D. Anderson Cancer Center. Dr. Talpaz has been and continues to be involved in the clinical development of numerous cancer drugs and has been a pioneer in developing currently accepted treatment protocols especially in the leukemia area. Dr. Talpaz is a member of many committees such as the National Comprehensive Cancer Network Guidelines Panel and sits on several editorial and advisory boards, such as Hematology Digest, Bone Marrow Transplantation and Clinical Cancer Research. In 2003, Dr. Talpaz received the prestigious "Leukemia and Lymphoma Society Service to Mankind Award" for his pioneering work in this cancer field. Dr. Talpaz discovered the use of interferon -a for treating chronic myeloid leukemia (CML) and he was the principal investigator until FDA approval. In addition, Dr. Talpaz has acted as a consultant to Hoffman LaRoche with regards to the FDA approval process for interferon.

Randall K. Johnson, Ph.D. Dr. Johnson has over 30 years of experience in government and industry working in cancer drug discovery and development. His career began as section head at the laboratories of experimental chemotherapy at The National Cancer Institute and was followed by over 20 years at SmithKline Beecham and later GlaxoSmithKline. At SmithKline Beecham and GlaxoSmithKline, Dr. Johnson held numerous positions including Director of the Department of Biomolecular Discovery, Development Project Leader, Research Program Leader and culminating in the Group Director of the Department of Oncology Research. Dr. Johnson has been involved in numerous cancer working group committees such as The Southern Cancer Study Group and The Southwest Oncology Group and on editorial boards of cancer journals such as "Cancer Treatment Reports" and "The Journal of the National Cancer Institute."

### EXECUTIVE COMPENSATION

The following summary compensation table sets forth certain information concerning compensation paid to our Chief Executive Officer and our two most highly paid executive officers (the "Named Executive Officers") for services rendered in all capacities for the year ended December 31, 2003. Our predecessor

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

company, Webtronics, never paid any executive compensation to its officers. No other executive officer of our company was paid a salary and bonus aggregating greater than \$100,000 during such time period.

Name and Principal Position -----	Year ----	Annual Compensation -----		Long T ----- Securi Option -----
		Salary (\$) ---	Bonus (\$) ---	
Gary S. Jacob Chief Executive Officer and Chief Scientific Officer	2003	\$144,792	\$ 0	
Donald H. Picker Executive Vice President, R&D	2003	\$126,661	\$ 10,000	
Kunwar Shailubhai Executive Vice President, Drug Discovery of Synergy Pharmaceuticals Inc.	2003	\$110,833	\$ 0	

(1) All of such stock options were granted on June 13, 2003 pursuant to an employment agreement entered into with us at that time. On April 6, 2004, the employment agreement was terminated and the 325,000 unvested stock options were canceled. At the same time, Dr. Shailubhai entered into an employment agreement with Synergy Pharmaceuticals Inc. and was granted 100,000 stock options exercisable at \$1.50 per share, 50,000 of such stock options vest in June 2004 and the remainder vest in December 2004.

26

### OPTION GRANTS IN FISCAL YEAR 2003

The following table sets forth certain information concerning grants of stock options to the Named Executive Officers during the fiscal year ended December 31, 2003.

Name ----	Number of Shares Underlying Options Granted -----	Percent of Total Options Granted to Employees in 2003 ----	Exercis Sha ---
Gary S. Jacob Chief Executive Officer and Chief Scientific Officer	500,000 (1)	42.5%	\$1.
Donald H. Picker Executive Vice President, R&D	325,000 (2)	27.7%	\$1.



Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Kunwar Shailubhai Senior Vice President, Drug Discovery of Synergy Pharmaceuticals Inc.	350,000 (3)	29.8%	\$1.
--	-------------	-------	------

- (1) 150,000 options vest on 6/13/2004; 150,000 options vest on 6/13/2005 and 200,000 options vest on 6/13/2006.
- (2) 83,333 options vest on 7/19/2004; 108,333 options vest on 7/19/2005 and 133,333 options vest on 7/19/2006.
- (3) All of such stock options were granted on June 13, 2003 pursuant to an employment agreement entered into with us at that time. On April 6, 2004, the employment agreement was terminated and the 325,000 unvested stock options were canceled. At the same time, Dr. Shailubhai entered into an employment agreement with Synergy Pharmaceuticals Inc. and was granted 100,000 stock options exercisable at \$1.50 per share, 50,000 of such stock options vest in June 2004 and the remainder vest in December 2004.

27

AGGREGATED OPTION EXERCISES IN 2003 AND YEAR END OPTION VALUES

The following table provides certain information with respect to the Named Executive Officers concerning the exercise of stock options during the fiscal year ended December 31, 2003 and the value of unexercised stock options held as of such date.

Name -----	Number of Shares Underlying Options at December 31, 2003		Value of Un Money Option 200 ---
	Exercisable -----	Unexercisable -----	Exercisable -----
Gary S. Jacob Chief Executive Officer and Chief Scientific Officer	0	500,000	\$0
Donald H. Picker Executive Vice President, R&D	0	325,000	\$0
Kunwar Shailubhai Senior Vice President, Drug Discovery of Synergy Pharmaceuticals Inc.	25,000	325,000 (2)	\$61,250

During the fiscal year ended December 31, 2003, no options were exercised.

- (1) Amounts calculated by subtracting the exercise price of the options from the market value of the underlying common stock using the closing bid

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

price on the OTCBB of \$3.95 per share on December 31, 2003.

- (2) All of such stock options were granted on June 13, 2003 pursuant to an employment agreement entered into with us at that time. On April 6, 2004, the employment agreement was terminated and the 325,000 unvested stock options were canceled. At the same time, Dr. Shailubhai entered into an employment agreement with Synergy Pharmaceuticals Inc. and was granted 100,000 stock options exercisable at \$1.50 per share, 50,000 of such stock options vest in June 2004 and the remainder vest in December 2004.

### EMPLOYMENT AGREEMENTS

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

On June 13, 2003, we entered into an employment agreement with Kunwar Shailubhai, Ph.D., pursuant to which Dr. Shailubhai serves as Executive Vice President, and Head of Research and Development for a term of 18 months beginning June 13, 2003, which is automatically renewable for successive one year periods at the end of the term. Dr. Shailubhai's salary is \$170,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. In connection with the employment agreement, Dr. Shailubhai received a grant of 25,000 stock options which are fully vested and have an exercise price of \$1.50 per share. Dr. Shailubhai also received a grant of 325,000 stock options which vest over a three year period and are exercisable at \$1.50 per share.

On April 6, 2004, Dr. Shailubhai's employment agreement was terminated and Dr. Shailubhai entered into an employment agreement with Synergy pursuant to which he agreed to serve as Senior Vice President, Drug Discovery of Synergy. The agreement is for a term of 12 months beginning April 6, 2004 and is automatically renewable for successive one year periods at the end of term. Dr. Shailubhai's salary is \$150,000 and he is eligible to receive a cash bonus of up to 15% of his salary. Dr. Shailubhai's 325,000 unvested stock options, granted pursuant to his previous employment agreement, were cancelled and he received a new grant of 100,000 stock options exercisable at \$1.50 per share, 50,000 of such stock options vest in June 2004 and the remainder vest in December 2004.

On September 23, 2003, we entered into an employment agreement with Donald H. Picker, Ph.D., pursuant to which Dr. Picker agreed to serve as our Vice President, Drug Development. Dr. Picker's employment agreement is for a term of 18 months beginning September 23, 2003 and is automatically renewable for successive one year periods at the end of the term. Dr. Picker's salary is \$175,000 per year and he is eligible to receive cash bonuses upon the achievement of certain milestones. Dr. Picker received a grant of 325,000 stock options which vest over a three year period and are exercisable at \$1.50 per share. On April 6, 2004 Dr. Picker's employment agreement was amended and his title changed to Executive Vice President, R&D. On July 22, 2004, Dr. Picker's employment agreement was further amended and his salary was increased to \$200,000 per year certain performance milestones upon which cash bonuses are based were added.

On January 15, 2004, we entered into an employment agreement with Bernard Denoyer, our Vice President, Finance. Mr. Denoyer's employment agreement is for a term of 12 months beginning January 15, 2004 and is automatically

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

renewable for successive one year periods at the end of the term. Mr. Denoyer's salary is \$90,000 per year and he is eligible to receive a cash bonus of up to 10% of his salary per year. Mr. Denoyer received a grant of 100,000 stock options which vest over a three year period and are exercisable at \$3.60 per share.

28

### STOCK OPTION PLAN

We rely on incentive compensation in the form of stock options to retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options is designed to provide long-term incentives to directors, executive officers employees and consultants, to encourage them to remain with us and to enable them to develop and maintain an ownership position in our common stock.

The stock option plan authorizes the grant of stock options to directors, eligible employees, including executive officers and consultants. The value realizable from exercisable options is dependent upon the extent to which our performance is reflected in the value of our common stock at any particular point in time. Equity compensation in the form of stock options is designed to provide long-term incentives to directors, executive officers and other employees. We approve the granting of options in order to motivate these employees to maximize stockholder value. Generally, vesting for options granted under the stock option plan is determined at the time of grant, and options expire after a 10-year period. Options are generally granted at an exercise price not less than the fair market value at the date of grant. As a result of this policy, directors, executives, employees and consultants are rewarded economically only to the extent that the stockholders also benefit through appreciation in the market. Options granted to employees are based on such factors as individual initiative, achievement and performance. In administering grants to executives, the compensation committee of the Board of Directors evaluates each executive's total equity compensation package. The compensation committee generally reviews the option holdings of each of the executive officers, including vesting and exercise price and the then current value of such unvested options. We consider equity compensation to be an integral part of a competitive executive compensation package and an important mechanism to align the interests of management with those of our stockholders.

As of August 3, 2004, options for 3,032,222 shares were outstanding under our stock option plan, and options for 6,967,778 shares remain available for future grants. The options we grant under the Plan may be either "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), or non-statutory stock options at the discretion of the Board of Directors and as reflected in the terms of the written option agreement. The stock option plan is not a qualified deferred compensation plan under Section 401(a) of the Code, and is not subject to the provisions of the Employee Retirement Income Security Act of 1974, as amended. In addition, as of August 3, 2004, we have granted 3,716,338 stock options not subject to the stock option plan.

### CHANGES AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On August 6, 2003, we filed a Form 8-K disclosing that Baum & Company, PA had resigned as our independent accountants with no disagreements and that BDO Seidman, LLP had been retained as our independent accountants.

# Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

## MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

### MARKET INFORMATION

Our common stock has been quoted on the OTC Bulletin Board under the symbol "CLSP.OB" since May 21, 2003. Prior to May 21, 2003, our common stock was quoted on the OTC Bulletin Board under the symbol "WEBR.OB" but never traded. The following table shows the reported high and low closing bid quotations per share for our common stock based on information provided by the OTC Bulletin Board. Particularly since our common stock is traded infrequently, such over-the-counter market quotations reflect inter-dealer prices, without markup, markdown or commissions and may not necessarily represent actual transactions or a liquid trading market.

	High ----	Low ---
2004		
First Quarter	\$ 4.25	\$ 3.25
Second Quarter	\$ 3.70	\$ 1.95
2003		
Fourth Quarter	\$ 4.05	\$ 3.95
Third Quarter	\$ 5.30	\$ 3.00
Second Quarter	\$ 5.80	\$ 4.50

### NUMBER OF STOCKHOLDERS

As of August 3, 2004, there were 227 holders of record of our common stock.

29

### DIVIDEND POLICY

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

### SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of August 3, 2004 by (i) each person known to beneficially own more than 5% of the outstanding common stock, (ii) each of our directors, (iii) the Named Executive Officers and (iv) all directors and executive officers as a group. Except as otherwise indicated, the persons named in the table have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable. Unless otherwise indicated, the address of each beneficial owner listed below is c/o Callisto Pharmaceuticals, Inc., 420 Lexington Avenue, Suite 1609, New York, N.Y. 10170.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Name and Address of Beneficial Owner -----	Shares of Common Stock -----
	Number of Shares -----
Gabriele M. Cerrone Chairman of the Board	2,924,237 (2)
Gary S. Jacob Chief Executive Officer and Chief Scientific Officer	258,297 (3)
Donald H. Picker Executive Vice President, R&D	180,741 (4)
Kunwar Shailubhai Senior Vice President, Drug Discovery of Synergy Pharmaceuticals Inc.	75,000 (5)
Iain G. Ross Director	25,000 (6)
Edwin Snape Director	939,402 (7)
Michael J. Zelefsky Director	20,000 (8)
Christoph Bruening Director	368,199 (9)
Albert J. Henry Director	1,407,164 (10)
John P. Brancaccio Director	0
All Directors and Executive Officers as a group (11 persons)	6,228,040 (11)
Donald G. Drapkin	2,350,000 (12)
Panetta Partners Ltd.	2,049,237

\* less than 1%

(1) Applicable percentage ownership as of August 3, 2004 is based upon 29,175,102 shares of common stock outstanding. Beneficial ownership is determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended. Under Rule 13d-3, shares issuable within 60 days upon exercise of outstanding options, warrants, rights or conversion privileges ("Purchase

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

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

(2) Consists of 875,000 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone and 2,049,237 shares held by Panetta Partners, Ltd., of which Mr. Cerrone is the sole general partner and in such capacity only exercises voting and dispositive control.

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

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

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

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

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

(8) Includes 20,000 shares of common stock issuable upon exercise of stock options.

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

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

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

(12) Includes 250,000 shares of common stock issuable upon exercise of stock options held by Mr. Drapkin and 1,500,000 shares of common stock held by the Drapkin Family Charitable Foundation.

### SELLING STOCKHOLDERS

From November 2003 through January 2004, we sold and issued 3,905,432 shares of common stock in a private placement. In addition, on April 19, 2004, we sold and issued 2,151,109 shares of common stock in a private placement. This prospectus only covers the 6,056,541 shares of common stock issued in the private placements. The following table lists certain information with respect to the selling stockholders as follows: (i) each selling stockholder's name, (ii) the number of outstanding shares of common stock beneficially owned by the selling stockholders prior to this offering; (iii) the number of shares of common stock to be beneficially owned by each selling stockholder after the

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

completion of this offering assuming the sale of all of the shares of the common stock offered by each selling stockholder; and (iv) if one percent or more, the percentage of outstanding shares of common stock to be beneficially owned by each selling stockholder after the completion of this offering assuming the sale of all of the shares of common stock offered by each selling stockholder. Except as noted, none of the selling stockholders have had any position, office, or other material relationship with us or any of our predecessors or affiliates within the past three years. The selling stockholders may sell all, or none of their shares in this offering. See "Plan of Distribution."

Selling Stockholder -----	Shares Beneficially Owned Prior to the Offering -----	Shares Being Offered -----	Share A ----- Numbe Share -----
Wanda H. Harrington	100,000	100,000	-0-
R. Merrill & Marilyn Hunter Childrens' Trust f/b/o/ Kathryn Leigh Hunter	50,000	50,000	-0-
R. Merrill & Marilyn Hunter Childrens' Trust f/b/o Christopher Tyler Hunter	50,000	50,000	-0-
R. Merrill & Marilyn Hunter Childrens' Trust f/b/o Matthew Reaves Hunter	50,000	50,000	-0-
R. Merrill & Marilyn Hunter Childrens' Trust f/b/o/ Julianna Marie Hunter	50,000	50,000	-0-
R. Merrill Hunter	1,000,000	1,000,000	-0-
William J. Ritger	181,666	166,666	15,
Robert Shapiro Revocable Trust u/t/a/ dtd 4/6/94	70,000	70,000	-0-
Jonah Jay Lobell	70,000	70,000	-0-
Alfonse Melohn	210,000	210,000	-0-
WMSBG - Kolel Damesek Eliezer, Inc.	70,000	70,000	-0-
Howard Zuckerman	34,667	34,667	-0-
John E.M. McConnaughy, Jr.	70,000	70,000	-0-
MLC Management Co.	140,000	140,000	-0-
Blenton Management S.A.	1,004,099	1,004,099	-0-
Howard Gittis	806,000 (3)	400,000	406

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

New England Partners Capital, L.P.	914,402 (2)	200,000	714
Black Flower Ltd.	35,000	35,000	-0-
Stanley Neal Tennant	100,000	100,000	-0-
Keith C. Alliotts	35,000	35,000	-0-
Shekhar Basu	44,444	44,444	-0-
Greenberg Health Care Partners LLC	444,444	444,444	-0-

32

Alexandra Global Master Fund, Ltd.	250,000	250,000	-0-
Punk Ziegel & Company (4)	100,000	100,000	-0-
Atlas Equity I, Ltd.	200,000	200,000	-0-
BioMed Venture Partners, L.P.	150,000	150,000	-0-
InvestBio Partners, L.P.	150,000	150,000	-0-
Pamela Kaweske	22,222	22,222	-0-
Baffles S.A.	22,222	22,222	-0-
SEGOES Trust	20,000	20,000	-0-
Hytec International, Ltd.	8,889	8,889	-0-
Nicholas DiFalco	22,222	22,222	-0-
Mark J. Sklar and Andrea D. Sklar	10,000	10,000	-0-
W. Harrison Wellford	40,000	40,000	-0-
Orion Biomedical Offshore Fund, LP	79,333	79,333	-0-
Orion Biomedical Fund, LP	365,111	365,111	-0-
Seneca Capital International Ltd.	141,222	141,222	-0-



## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Seneca Capital L.P.

81,000

81,000

-0-

\* less than 1%.

(1) Mr. Ritger is the President of The Research Works, Inc. which has a contract with Callisto to provide equity research services. The Research Works, Inc. received 15,000 shares of common stock for its services.

(2) NEGF II, L.P. owns 714,402 of such shares. NEGF II, L.P. is an affiliate of New England Partners Capital, L.P.

(3) Includes 406,000 shares held by the Gittis Family Foundation.

(4) Punk Ziegel & Company LLP acted as placement agent to Callisto in the April 19, 2004 private placement pursuant to an Engagement Letter dated January 22, 2004 and was issued warrants to purchase 101,111 shares of common stock exercisable at \$2.48 per share in addition to a cash placement fee.

33

### CERTAIN TRANSACTIONS

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

On June 29, 2004, our Compensation Committee recommended and our Board of Directors approved the grant of 275,000 stock options to Gary Jacob, Chief Executive Officer, as additional compensation. The stock options are exercisable at \$3.00 per share. 25,000 options vest on each of June 1, 2005 and June 1, 2006 and 50,000 options vest on June 1, 2007. The remaining 175,000 options vest upon the achievement of certain performance milestones.

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

### DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 75,000,000 shares of common stock, \$.0001 par value, and 20,000,000 shares of preferred stock, \$.0001 par value. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our certificate of incorporation and bylaws, which are exhibits to the registration statement of which this prospectus forms a part.

### COMMON STOCK

As of August 3, 2004, 29,175,102 shares of our common stock were outstanding and held of record by 227 stockholders. Each share of our common

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

stock entitles its holder to one vote on all matters to be voted by our stockholders. Subject to preferences that may apply to any of our outstanding preferred stock, holders of our common stock will receive ratably any dividends our board of directors declares out of funds legally available for that purpose. If we liquidate, dissolve or wind up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and any liquidation preference of any of our outstanding preferred stock. Our common stock has no preemptive rights, conversion rights, or other subscription rights or redemption or sinking fund provisions. The shares of our common stock to be sold in this offering are fully paid and non-assessable.

### PREFERRED STOCK

Our board of directors has the authority, without further action by our stockholders, to issue up to 20,000,000 shares of our preferred stock in one or more series. Our board of directors may designate the rights, preferences, privileges, and restrictions of our preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference, sinking fund terms, and number of shares constituting any series or the designation of any series. The issuance of our preferred stock could have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying or preventing a change in control. Even the ability to issue preferred stock could delay or impede a change in control. As of August 3, 2004, no shares of our preferred stock are outstanding, and we currently have no plans to issue any shares of our preferred stock.

### WARRANTS

As of August 3, 2004, 758,995 warrants to purchase common stock were outstanding. 370,543 of such warrants are exercisable at \$1.90 per share and expire on January 21, 2009, 263,741 of such warrants are exercisable at \$1.50 per share and expire on January 21, 2014 and 124,711 of such warrants are exercisable at \$2.48 per share and expire on April 19, 2009.

### ANTI-TAKEOVER PROVISIONS

Delaware Law. We are subject to Section 203 of the General Corporation Law of the State of Delaware, which regulates acquisitions of some Delaware corporations. In general, Section 203 prohibits, with some exceptions, a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date the person becomes an interested stockholder, unless:

- o Our board of directors approved the business combination or the transaction in which the person became an interested stockholder prior to the date the person attained this status;
- o Upon consummation of the transaction that resulted in the person becoming an interested stockholder, the person owned at least 85% of our voting stock outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers and issued under employee stock plans under which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- o On or subsequent to the date the person became an interested stockholder, our board of directors approved the business combination and the stockholders other than the interested stockholder authorized the transaction at an annual or special meeting of stockholders by the affirmative vote of at least 66 2/3% of the outstanding stock not owned by the interested stockholder.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Section 203 defines a "business combination" to include:

34

- o Any merger or consolidation involving us and the interested stockholder;
- o Any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of our assets;
- o In general, any transaction that results in the issuance or transfer by us of any of our stock to the interested stockholder;
- o Any transaction involving us that has the effect of increasing the proportionate share of our stock owned by the interested stockholder;
- o the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided through us.

In general, Section 203 defines an "interested stockholder" as any person who, together with the person's affiliates and associates, owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of a corporation's voting stock.

### TRANSFER AGENT

StockTrans, Inc. is the transfer agent for our common stock.

### PLAN OF DISTRIBUTION

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

- o Block trades in which the broker or dealer so engaged will attempt to sell the common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o An exchange distribution in accordance with the rules of any stock exchange on which the common stock is listed;
- o Ordinary brokerage transactions and transactions in which the broker solicits purchases;
- o Privately negotiated transactions;
- o In connection with short sales of company shares;

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

- o Through the distribution of common stock by any selling stockholder to its partners, members or stockholders;
- o By pledge to secure debts of other obligations;
- o In connection with the writing of non-traded and exchange-traded call options, in hedge transactions and in settlement of other transactions in standardized or over-the-counter options;
- o Purchases by a broker-dealer as principal and resale by the broker-dealer for its account; or
- o In a combination of any of the above.

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

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

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

time to time, sell the shares short, and, in those instances, this prospectus may be delivered in connection with the short sales and the shares offered under this prospectus may be used to cover short sales.

To the extent required under the Securities Act, the aggregate amount of selling stockholders' shares being offered and the terms of the offering, the names of any agents, brokers, dealers or underwriters, any applicable commission and other material facts with respect to a particular offer will be set forth in

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

an accompanying prospectus supplement or a post-effective amendment to the registration statement of which this prospectus is a part, as appropriate. Any underwriters, dealers, brokers or agents participating in the distribution of the common stock may receive compensation in the form of underwriting discounts, concessions, commissions or fees from a selling stockholder and/or purchasers of selling stockholders' shares, for whom they may act (which compensation as to a particular broker-dealer might be less than or in excess of customary commissions). Neither we nor any selling stockholder can presently estimate the amount of any such compensation.

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

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

The selling stockholders and other persons participating in the sale or distribution of the common stock will be subject to applicable provisions of the Exchange Act, and the rules and regulations under the Exchange Act, including Regulation M. This regulation may limit the timing of purchases and sales of any of the common stock by the selling stockholders and any other person. The anti-manipulation rules under the Exchange Act may apply to sales of common stock in the market and to the activities of the selling stockholders and their affiliates. Regulation M may restrict the ability of any person engaged in the distribution of the common stock to engage in market-making activities with respect to the particular common stock being distributed for a period of up to five business days before the distribution. These restrictions may affect the marketability of the common stock and the ability of any person or entity to engage in market-making activities with respect to the common stock.

We have agreed to indemnify the selling stockholders who participated in our January 21, 2004 private placement and our April 19, 2004 private placement (the "Private Placement Stockholders") and any brokers, dealers and agents who may be deemed to be underwriters, if any, of the common stock offered by this prospectus, against specified liabilities, including liabilities under the Securities Act. The Private Placement Stockholders have agreed to indemnify us against specified liabilities.

The common stock offered by this prospectus was originally issued to the Private Placement Stockholders pursuant to an exemption from the

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

registration requirements of the Securities Act, as amended. We agreed to register the common stock issued to the Private Placement Stockholders under the Securities Act, and to keep the registration statement of which this prospectus is a part effective until three years after the effective date of the registration statement. We have agreed to pay all expenses incident to the registration of the common stock held by the Private Placement Stockholders in connection with this offering, but all selling expenses related to the securities registered shall be borne by the individual holders of such securities pro rata on the basis of the number of shares of securities so registered on their behalf.

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

### LEGAL MATTERS

The validity of the common stock has been passed upon by Sills Cummis Epstein & Gross, P.C., Newark, New Jersey.

### EXPERTS

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

36

### WHERE YOU CAN FIND MORE INFORMATION

We filed with the SEC a registration statement on Form SB-2 under the Securities Act for the common stock to be sold in this offering. This prospectus does not contain all of the information in the registration statement and the exhibits and schedules that were filed with the registration statement. For further information with respect to the common stock and us, we refer you to the registration statement and the exhibits and schedules that were filed with the registration statement. Statements made in this prospectus regarding the contents of any contract, agreement or other document that is filed as an exhibit to the registration statement are not necessarily complete, and we refer you to the full text of the contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules that were filed with the registration statement may be inspected without charge at the public reference facilities maintained by the SEC in Room 1024, 450 Fifth Street, NW, Washington, DC 20549, and at the SEC's regional offices at 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, Woolworth Building, 233 Broadway New York, New York. Copies of all or any part of the registration statement may be obtained from the SEC upon payment of the prescribed fee. Information regarding the operation of the public reference rooms may be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the site is <http://www.sec.gov>.

### DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR

# Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

## SECURITIES ACT LIABILITIES

Section 145 of the Delaware General Corporation Law, the DGCL, empowers a corporation to indemnify its directors and officers and to purchase insurance with respect to liability arising out of the performance of their duties as directors and officers. The DGCL provides further that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's by-laws, any agreement, vote of stockholders or otherwise.

Article Ninth of our Certificate of Incorporation eliminates the personal liability of our directors to the fullest extent permitted by the DGCL. Article Ninth also provides for indemnification of all persons whom we have the power to indemnify pursuant to Section 145 of the DGCL.

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

37

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

Index to Consolidated Financial Statements

	Page
	----
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheet as of December 31, 2003 and June 30, 2004 (unaudited)	F-3
Consolidated Statements of Operations for the two years in the period ended December 31, 2003, for the six months ended June 30, 2004 and 2003 (unaudited) and for the period from June 5, 1996 (inception) to June 30, 2004 (unaudited)	F-4
Consolidated Statements of Changes in Stockholders' Equity for the period from June 5, 1996 (inception) to December 31, 2003 and for the six months ended June 30, 2004 (unaudited)	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2003 and 2002, for the six months ended June 30, 2004 and 2003 (unaudited) and for the period from June 5, 1996 (inception) to June 30, 2004 (unaudited)	F-8
Notes to consolidated financial statements	F-9

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

F-1

Report of Independent Registered Public Accounting Firm

Board of Directors  
Callisto Pharmaceuticals, Inc.  
New York, NY

We have audited the accompanying consolidated balance sheet of Callisto Pharmaceuticals, Inc. (a development stage company) (the "Company") as of December 31, 2003, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Callisto Pharmaceuticals, Inc. as of December 31, 2003, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2003 in conformity with U.S. generally accepted accounting principles.

/s/ BDO Seidman, LLP

April 8, 2004  
New York, New York

F-2

CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

December 31, 2003

-----

June 30, 2003

-----

(unaudited)

ASSETS

Current assets:



Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Cash and cash equivalents	\$ 3,956,486	\$ 7,269,4
Prepaid expenses	52,644	101,7
	-----	-----
	4,009,130	7,371,1
Property and equipment, net	46,488	32,6
Security deposits	62,980	62,9
	-----	-----
	\$ 4,118,598	\$ 7,466,8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 842,520	\$ 387,0
Accrued expenses	79,625	91,8
Selling agent fees payable related to private placement	341,625	
	-----	-----
	1,263,770	478,8
Stockholders' equity:		
Preferred stock, \$.0001 par value, authorized 20,000,000 shares, none outstanding	--	
Common stock, \$.0001 par value, authorized 75,000,000 shares, 25,928,760 and 29,175,102 outstanding, respectively	2,590	2,9
Additional paid-in-capital	34,149,975	40,702,5
Unamortized deferred stock based compensation	(5,480,007)	(4,162,0
Deficit accumulated during the development stage	(25,817,730)	(29,555,4
	-----	-----
	2,854,828	6,987,9
	\$ 4,118,598	\$ 7,466,8
	=====	=====

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

F-3

CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	Six Months Ended
	2003	(unaudited)
	2002	2004

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Revenues	\$--	\$--	\$--
Costs and expenses:			
Research and development	1,369,985	491,430	925,652
Government grant	-	-	(100,220)
Purchased in-process research and development	6,734,818	--	209,735
General and administrative	1,398,090	1,227,699	1,074,233
Stock-based compensation	3,833,946	332	1,665,594
Loss from operations	(13,336,839)	(1,719,461)	(3,774,994)
Interest income	8,767	34,496	37,284
Other income	221,824	--	--
Net loss	\$ (13,106,247)	\$ (1,684,965)	\$ (3,737,710)
Weighted average shares outstanding:			
Basic and diluted	21,357,659	17,318,994	27,767,221
Net loss per common share:			
Basic and diluted	\$ (0.61)	\$ (0.10)	\$ (0.13)

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

F-4

CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Preferred Shares	Preferred Stock Par Value	Common Shares
Balance at inception, June 5, 1996	--	\$ --	--
Net loss for the period	--	--	--
Issuance of founder shares	--	--	2,642,500
Common stock issued	--	--	1,356,194
Common stock issued via private placement	--	--	1,366,667
Balance, December 31, 1996	--	--	5,365,361
Net loss for the year	--	--	--
Common stock issued via private placement	--	--	1,442,666

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Balance, December 31, 1997	--	--	6,808,027
Net loss for the year	--	--	--
Amortization of stock based compensation	--	--	--
Common stock issued via private placement	--	--	1,416,667
Common stock issued for services	--	--	788,889
Common stock repurchased and cancelled	--	--	(836,792)
Balance, December 31, 1998	--	--	8,176,791
Net loss for the year	--	--	--
Deferred compensation - stock options	--	--	--
Amortization of stock based compensation	--	--	--
Common stock issued for services	--	--	--
Common stock issued via private placement	--	--	346,667
Balance, December 31, 1999	--	--	8,523,458
Net loss for the year	--	--	--
Amortization of stock based compensation	--	--	--
Common stock issued	--	--	4,560,237
Other	--	--	--
Preferred stock issued	3,485,299	348	--
Preferred stock issued for services	750,000	75	--
Balance, December 31, 2000	4,235,299	423	13,083,695
Net loss for the year	--	--	--
Deferred compensation - stock options	--	--	--
Amortization of stock based compensation	--	--	--
Balance, December 31, 2001	4,235,299	423	13,083,695
Net loss for the year	--	--	--
Amortization of stock based compensation	--	--	--
Balance, December 31, 2002	4,235,299	\$ 423	13,083,695

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

F-5

CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (Continued)

	Unamortized Deferred Stock Based Compensation -----	Deficit Accumulated during the Development Stage -----
Balance at inception, June 5, 1996	\$--	\$--
Net loss for the year	--	(404,005)
Issuance of founder shares	--	--
Common stock issued	--	--
Common stock issued via private placement	--	--
	-----	-----
Balance, December 31, 1996	--	(404,005)
Net loss for the year	--	(894,505)
Common stock issued via private placement	--	--
	-----	-----
Balance, December 31, 1997	--	(1,298,510)
Net loss for the year	--	(1,484,438)
Amortization of stock based compensation	--	--
Common stock issued	--	--
Common stock issued for services	--	--
Common stock repurchased and cancelled	--	--
	-----	-----
Balance, December 31, 1998	--	(2,782,948)
Net loss for the year	--	(4,195,263)
Deferred compensation - stock options	(9,946)	--
Amortization of stock based compensation	3,262	--
Common stock issued for services	--	--
Common stock issued via private placement	--	--
	-----	-----
Balance, December 31, 1999	(6,684)	(6,978,211)
Net loss for the year	--	(2,616,261)
Amortization of stock based compensation	4,197	--
Common stock issued	--	--
Other	--	--
Preferred stock issued	--	--

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Preferred stock issued for services	--	--
	-----	-----
Balance, December 31, 2000	(2,487)	(9,594,472)
Net loss for the year	--	(1,432,046)
Deferred compensation - stock options	(20,000)	--
Amortization of stock based compensation	22,155	--
	-----	-----
Balance, December 31, 2001	(332)	(11,026,518)
Net loss for the year	--	(1,684,965)
Amortization of stock based compensation	332	--
	-----	-----
Balance, December 31, 2002	--	(\$12,711,483)

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

F-6

CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (CONTINUED)

	Preferred Stock	Preferred Stock Par Value	Common Stock
	-----	-----	-----
Balance, December 31, 2002	4,235,299	\$ 423	13,083,695
Net loss for the year	--	--	--
Conversion of preferred stock in connection with the Merger	(4,235,299)	(423)	4,235,299
Common stock issued to former Synergy stockholders	--		4,329,927
Common stock issued in exchange for Webtronics common stock	--		1,503,173

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Deferred compensation - stock options	--	--	--
Amortization of stock based compensation	--	--	--
Private placement of common stock, net	--	--	2,776,666
	-----	-----	-----
Balance, December 31, 2003	--	--	25,928,760
Net loss for the period (unaudited)	--	--	--
Amortization of stock based compensation (unaudited)	--	--	--
Stock-based compensation expense (unaudited)	--	--	--
Common stock issued via private placements (unaudited)	--	--	3,311,342
Warrant and stock-based compensation for services in connection with the Merger (unaudited)	--	--	--
Common stock issued for patent rights (unaudited)	--	--	25,000
Common stock returned from former Synergy stockholders (unaudited)	--	--	(90,000)
	-----	-----	-----
Balance June 30, 2004 (Unaudited)	--	\$--	29,175,102
	=====	=====	=====

	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
	-----	-----	-----
Balance, December 31, 2002	--	(\$12,711,483)	\$ 1,828,865
Net loss for the year	--	(13,106,247)	(13,106,247)
Conversion of preferred stock in connection with the Merger	--	--	--
Common stock issued to			

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

former Synergy stockholders	--	--	6,494,890
Common stock issued in exchange for Webtronics common stock	--	--	--
Deferred compensation - stock options	(9,313,953)	--	--
Amortization of stock based compensation	3,833,946	--	3,833,946
Private placement of common stock, net	--	--	3,803,374
	-----	-----	-----
Balance, December 31, 2003	(5,480,007)	(25,817,730)	2,854,828
Net loss for the period (unaudited)	--	(3,737,710)	(3,737,710)
Amortization of stock based compensation (unaudited)	1,317,927	--	1,317,927
Stock-based compensation expense (unaudited)	--	--	286,918
Common stock issued via private placements (unaudited)	--	--	6,099,012
Warrant and stock-based compensation for services in connection with the Merger (unaudited)	--	--	269,826
Common stock issued for patent rights (unaudited)	--	--	56,250
Common stock returned from former Synergy stockholders (unaudited)	--	--	(159,092)
	-----	-----	-----
Balance June 30, 2004 (Unaudited)	(\$ 4,162,080)	(\$29,555,440)	\$ 6,987,959
	=====	=====	=====

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

F-7

CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		Six months e
	2003	2002	(una
	----	----	----
Cash flows from operating activities:			
Net loss	\$ (13,106,247)	\$ (1,684,965)	\$ (3,737,710)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	27,755	6,778	13,816
Stock-based compensation expense	3,833,946	332	1,665,594
Purchased in-process research and development - non-cash	6,734,818	--	106,235
Changes in operating assets and liabilities:			
Prepaid expenses	(24,188)	(8,796)	(49,122)
Security deposit	(62,980)	--	--
Accounts payable and accrued expenses	581,008	304,663	(784,890)
	-----	-----	-----
Total adjustments	11,090,359	302,977	(951,633)
	-----	-----	-----
Net cash used in operating activities	(2,015,888)	(1,381,988)	(2,786,077)
	-----	-----	-----
Cash flows from investing activities:			
Acquisition of equipment	(54,462)	(22,029)	--
	-----	-----	-----
Net cash used in investing activities	(54,462)	(22,029)	--
	-----	-----	-----
Cash flows from financing activities:			
Net proceeds from issuance of common and preferred stock, net of repurchases	3,803,374	--	6,099,012
	-----	-----	-----
Net cash provided by financing activities	3,803,374	--	6,099,012
	-----	-----	-----
Net increase (decrease) in cash and cash equivalents	1,733,024	(1,404,017)	3,312,935
Cash and cash equivalents at beginning of year	2,223,462	3,627,479	3,956,486
	-----	-----	-----
Cash and cash equivalents at end of year	\$ 3,956,486	\$ 2,223,462	\$ 7,269,421
	=====	=====	=====
Supplementary disclosure of cash flows information:			
Cash paid for taxes	\$ 23,834	\$ 13,487	\$ 2,921
	=====	=====	=====



## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

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

F-8

CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Information as of June 30, 2004 and for the period ended June 30, 2004 and 2003 are unaudited)

#### 1. Business overview:

Callisto Pharmaceuticals, Inc. ("Callisto") is a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. See footnote 4 for a complete description of recent business combination and basis of presentation. Since inception in June of 1996 our efforts have been principally devoted to research and development, securing and protecting our patents and raising capital. From inception through June 30, 2004, Callisto has sustained cumulative net losses of \$29,555,440. Callisto's losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of our proposed products, stock based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees. From inception through June 30, 2004, Callisto has not generated any revenue from operations, expects to incur additional losses to perform further research and development activities and does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all.

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

#### 2. Basis of presentation:

The accompanying consolidated financial statements of Callisto Pharmaceuticals, Inc., and its wholly owned subsidiaries Synergy Pharmaceuticals Inc. ("Synergy") and Callisto Pharmaceuticals, GmbH ("GmbH"), (collectively, "Callisto," a development stage company), have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). All significant intercompany balances and transactions have been eliminated. The results of operations of Synergy are included in the consolidated statements of operations since May 1, 2003 (see note 4).

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

The accompanying unaudited consolidated financial statements of Callisto have been prepared in accordance with (i) accounting principles generally accepted in the United States ("GAAP") for interim financial information and (ii) the rules of the Securities and Exchange Commission (the "SEC").

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, primarily consisting of normal adjustments, necessary for the fair presentation of the balance sheet and results of operations for the interim periods. The results of operations for the six months ended June 30, 2004 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2004.

F-9

### 3. Summary of significant accounting policies

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

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

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

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

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

**Recent accounting pronouncement** - In December 2002, the Financial Accounting Standards Board issued SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of FASB Statement No. 123", to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this statement amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual (see below) and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results.

F-10

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

	Years ended December 31,	
	2003	2002
Net loss, as reported	\$ (13,106,247)	\$ (1,684,965)
Add: Stock-based employee compensation expense recorded under APB No. 25	1,996,890	--
Deduct: stock-based employee compensation expense determined under fair value method	(2,510,721)	--
Pro forma net loss	\$ (13,620,078)	\$ (1,684,965)
Net loss per share:		
Basic and diluted -as reported	\$ (0.61)	\$ (0.10)
Basic and diluted -pro forma	\$ (0.64)	\$ (0.10)

The fair value of the options granted to employees during 2003 and 2002 ranged from \$0.00 to \$5.53 on the date of grant using the Black-Scholes methodology. The following weighted average assumptions were used for determining fair value in 2003 and 2002: no dividend yield, expected volatility of 0% to April 30, 2003 and 100% since Callisto's common stock began to trade publicly on June 16, 2003, risk free interest rates of 2.87% to 4.50% and expected lives of 7 to 10 years.

Net Loss per Share - Basic and diluted net loss per share is presented in conformity with SFAS No. 128, "Earnings per Share", for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares since the inclusion of issuable shares pursuant to the exercise of stock options, would have been antidilutive. As of December 31, 2003 and 2002, Callisto had 4,853,560 and 2,991,505 stock options outstanding, respectively. As of June 30, 2004 and 2003, Callisto had 6,748,560 and 5,030,227 stock options outstanding, respectively. In addition Callisto had 758,995 common stock warrants outstanding as of June 30, 2004. No warrants were outstanding as of December 31, 2003, June 30, 2003 and December 31, 2002.

Research and development - Callisto does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years,

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

if at all and therefore research and development costs are expensed as incurred. These include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of our proposed products, patent filing and maintenance expenses, purchase of in-process research and development, regulatory and scientific consulting fees as well as contract research and royalty payments to outside research suppliers, facilities and universities. In addition 100% of the salary of Callisto's Chief Executive Officer was also included in research and development expense during the twelve months ended December 31, 2002 due to his extensive involvement with Callisto's product development efforts. During the twelve months ended December 31, 2003 Callisto's Chief Executive Officer devoted nearly 100% of his time to the Merger, staff recruitment, office relocation, public relations and presentations, and the private placement, thus we charged his salary to general and administrative expense.

Research Grants - Callisto currently has a research grant from the National Institutes of Health for studies on Atiprimod. The studies began in early 2004 and no funding was received during 2003. We request grant funding to reimburse expenses as incurred and record the receipt as an offset to research and development expense.

F-11

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

#### 4. Merger and consolidation:

In March 2002, Callisto Pharmaceuticals, Inc. ("Old Callisto") purchased 99.7% of the outstanding common shares of Webtronics, Inc., ("Webtronics") a public company for \$400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations during the year ended December 31, 2002. The purchase price of Webtronics was treated as a cost of becoming a public company, however because there was no capital raised at the time, the amount was charged to general and administrative expense during the year ended December 31, 2002.

On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Synergy Pharmaceuticals Inc. ("Synergy") and Callisto Acquisition Corp., a wholly-owned subsidiary of Webtronics, merged into Old Callisto (collectively, the "Merger"). As a result of the Merger, Old Callisto and Synergy became wholly-owned subsidiaries of Webtronics. In connection with the Merger, Webtronics issued 17,318,994 shares of its common stock in exchange for outstanding Old Callisto common stock and an additional 4,395,684 shares in exchange for outstanding Synergy common stock. The Merger was accounted for as a recapitalization of Old Callisto by an exchange of Webtronics common stock for the net assets of Old Callisto consisting primarily of cash and fixed assets. Old Callisto then changed its name to Callisto Research Labs, LLC and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware. Callisto

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

remains the continuing legal entity and registrant for Securities and Exchange Commission reporting purposes. Subsequently, 171,818 shares of common stock issued to former Synergy shareholders were returned to Callisto under the terms of certain indemnification agreements through June 30, 2004.

F-12

The merged companies are considered to be in the development stage. No revenues have been realized since inception and all activities have been concentrated in research and development of biopharmaceutical products not yet approved by the Food and Drug Administration. The fair value of the net shares issued to former Synergy shareholders in the Merger totaled \$6,335,799 through June 30, 2004. The fair value per share of \$1.50, used to determine this amount, was the value per share Callisto sold common stock in a private placement. The total consideration was allocated in full to the Synergy research and development projects which had not yet reached technological feasibility and having no alternative use was charged to purchased in-process research and development expense.

The results of operations of Synergy for the period May 1, 2003 through December 31, 2003 are included in the Consolidated Statement of Operations for the year ended December 31, 2003 and for the period from June 5, 1996 (inception) to December 31, 2003. The Statement of Operations for the year ended December 31, 2002 includes only the results of Old Callisto.

The following combined pro forma results of operations for the years ended December 31, 2003 and 2002 have been prepared as if the merger with Synergy had occurred at January 1, 2002.

	2003	2002
	----	----
Revenues	\$ -	\$ -
Net loss	(13,513,820)	(2,559,554)
Net loss per common share - basic and diluted (23,296,920 and 23,217,578 common shares in 2003 and 2002, respectively)	\$ (0.58)	\$ (0.11)

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

Cash		\$9,501
Accounts receivable		258,928
Rent deposit		44,746
Fixed assets		38,343
		-----
Total assets acquired		351,518
Accounts payable and other liabilities assumed		(591,446)
		-----
Net liabilities assumed in excess of assets acquired		(239,928)
Fair value of shares issued to Synergy shareholders		(6,494,890)
		-----
Total consideration paid by Callisto to acquire Synergy		\$ (6,734,818)
		=====

F-13

## 5. Property and equipment:

Equipment consists of laboratory, testing and computer equipment, stated at cost, with useful lives ranging from 2-4 years, depreciated on a straight line basis. Furniture and fixtures are stated at cost, with a useful life of 3 years, depreciated on a straight line basis. Depreciation expense for the years ended December 31, 2003 and 2002 and from June 5, 1996 (inception) to December 31, 2003 was \$27,755, \$6,778 and \$38,149, respectively.

	December 31,	
	2003	2002
	-----	-----
Equipment	\$46,294	\$30,175
Furniture and fixtures	38,343	-
Less - Accumulated depreciation	(38,149)	(10,394)
	-----	-----
Property and equipment, net	\$46,488	\$19,781
	=====	=====

## 6. Stock option plan:

In 1996, Callisto adopted an incentive and non-qualified stock option plan (the "Plan") for employees, consultants and outside directors to purchase up to 2,000,000 shares of common stock. The Plan was amended in December 2002 to increase the number of shares authorized under the Plan to 10,000,000. The option term for options granted under the Plan is ten years from date of grant and there were 7,916,944 option shares available for future grants as of December 31, 2003.

Callisto recognizes deferred compensation expense for the intrinsic value of stock options granted to employees. Deferred stock-based compensation is amortized to stock-based compensation expense over the vesting period of the stock option. During the twelve months ended December 31, 2003, 2002 and for the period from June 5, 1996 (inception) to June 30, 2004 Callisto recognized \$3,833,946, \$332 and \$10,284,096, respectively, as stock-based compensation expense related to issuance of stock and stock options. At December 31, 2003 and June 30, 2004 there was \$5,480,007 and \$4,162,080, respectively, remaining in unamortized deferred compensation.

F-14

The following represent options outstanding for the years since June 5, 1996 (inception) through December 31, 2003.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Price	Number of Shares -----	Exercise Price Per Share -----	Weight Ex ---
Balance, June 5, 1996 (inception)	0	\$0.00	\$
1996: Granted	66,668 -----	\$0.75	\$
Balance, December 31, 1996	66,668	\$0.75	\$
1997: Granted	166,668 -----	\$0.75	\$
Balance, December 31, 1997	233,336	\$0.75	\$
1998: Granted	264,169 -----	\$0.75	\$
Balance, December 31, 1998	497,505	\$0.75	\$
1999: Granted	633,334 -----	\$0.75 - \$4.90	\$
Balance, December 31, 1999	1,130,839	\$0.75 - \$4.90	\$
2000: Granted	815,666	\$2.85 - \$6.75	\$
Forfeitures	(15,000) -----	\$0.75	\$
Balance, December 31, 2000	1,931,505	\$0.75 - \$6.75	\$
2001: Granted	730,000 -----	\$1.25 - \$6.50	\$
Balance, December 31, 2001	2,661,505	\$0.75 - \$6.75	\$
2002: Granted	330,000 -----	\$4.50 - \$6.50	\$
Balance, December 31, 2002	2,991,505	\$0.75 - \$6.75	\$
2003: Granted	3,013,555	\$1.10 - \$2.50	\$
Forfeitures	(1,151,500) -----	\$2.85 - \$6.75	\$
Balance, December 31, 2003	4,853,560 =====	\$0.75 - \$6.75	\$

Included in the balance at December 31, 2003 were 2,770,504 non-Plan options, of which 2,092,504 were exercisable.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

Options are exercisable as follows at December 31, 2003:

Exercise Price	Number of Shares	Options Outstanding		Option Number of Shares
		Weighted Average Remaining Life	Weighted Average Exercise Price	
\$0.75 - \$1.10	1,115,839	6.3 years	\$0.91	1,115,839
\$1.25 - \$1.75	2,683,555	9.1 years	\$1.44	1,015,555
\$1.95 - \$2.85	892,500	6.9 years	\$2.33	807,500
\$4.90 - \$6.75	161,666	6.4 years	\$5.32	61,666
All options:				
\$0.75 - \$6.75	4,853,560	8.0 years	\$1.61	3,000,560

During the six months ended June 30, 2004 Callisto granted 1,895,000 options (net of cancellations) at exercise prices ranging from \$1.50 to \$3.60 per share and issued 758,995 immediately exercisable common stock warrants at exercise prices ranging from \$1.50 to \$2.48 per share.

As of June 30, 2004 and 2003, Callisto had 6,748,560 and 5,030,227 stock options outstanding, respectively. In addition Callisto had 758,995 common stock warrants outstanding as of June 30, 2004 and none as of December 31, 2003. (see notes 8 and 9)

### 7. Income taxes:

At December 31, 2003, Callisto had available Federal net operating tax loss carry forwards of approximately \$14,000,000 expiring through 2022 to offset future taxable income. The net deferred tax asset has been fully offset by a valuation allowance due to uncertainties regarding realization of benefits from these future tax deductions. As a result of the change in control provisions of Internal Revenue Code Section 382, a significant portion of these net operating loss carry forwards may be subject to limitation on future utilization.

On December 15, 2003 Synergy sold certain New Jersey State tax loss carry forwards under a state economic development program for cash of approximately \$222,000, the proceeds of which have been and will be used to support research and development activities in New Jersey. This state tax benefit was recorded as Other Income during the fourth quarter ended December 31, 2003.

### 8. Commitments and contingencies:

#### License agreements:

On February 24, 2004, Callisto entered into an agreement with Houston Pharmaceuticals, Inc. ("HPI"), a privately held company, to acquire the rights to two key patents covering a novel cancer platform technology. Callisto issued to HPI 25,000 shares of common stock at a fair value of \$56,250 and reimbursed HPI approximately \$103,500 for various costs and expenses. The total consideration of \$159,750 was allocated in full to the HPI patent rights, which have not yet reached technological feasibility, and having no alternative use, was accounted for as purchased in-process research and development expense



## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

during the quarter ended March 31, 2004. The fair value of the common stock issued to HPI was \$2.25, based on the price per share paid in the April 2004 private placement, which closed on April 19, 2004. (See note 9)

In addition, Callisto granted to HPI 1,170,000 performance based stock options, exercisable at \$3.50 per share, which vest upon the achievement of certain milestones. If the milestones are achieved, Callisto will record additional purchased in-process research and development expense based upon the fair value of the options at that time. Callisto also agreed to pay HPI a royalty of 2% of net sales from any products resulting from commercializing the patents.

On August 28, 2002, Synergy entered into a worldwide license agreement with AnorMED, Inc. ("AnorMED") to research, develop, sell and commercially exploit the Atiprimod patent rights. The license agreement provides for aggregate milestone payments by Synergy of up to \$14 million based on achieving regulatory submissions and approvals for an initial indication and additional payments of \$16 million for each additional indication based on achieving regulatory submissions and approvals. In addition, the license agreement requires Synergy to pay royalties based on net sales to AnorMED. Commencing on January 1, 2004 and on January 1 of each subsequent year Synergy is obligated to pay AnorMED a maintenance fee of \$200,000 until the first commercial sale of the product. The first of these annual maintenance fee payments made on January 22, 2004 was reported as research and development expense in the quarter ended March 31, 2004. The agreement will terminate upon expiration of the last to expire of any patents included in the licensed patents as defined in the agreement.

F-16

On July 25, 2001, Callisto entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University licensed patents covering peptides and antibodies useful in treating toxic shock syndrome and septic shock. Callisto will pay Rockefeller a \$7,500 annual maintenance fee until the first commercial sale of the product. Callisto will pay royalties of 2% and 0.75% of net sales of product as defined in the agreement and will pay Rockefeller 15% of any sublicense fee paid by sublicensees. The agreement will terminate upon the later of (a) expiration of the last to expire or become abandoned patent right or (b) 20 years after the effective date of the agreement. During the twelve months ended December 31, 2003 and 2002, Callisto paid Rockefeller University \$0 and \$7,500, respectively.

On April 11, 2001, Callisto entered into a license agreement with Dartmouth College to research, develop, manufacture and sell certain Dartmouth patent rights covering a method to enhance antibiotics against Staphylococcus and other bacteria. Callisto was obligated to pay to Dartmouth a minimum annual license fee of \$10,000 for 2002; \$15,000 for 2003 and \$25,000 per annum from 2004 and thereafter. During the twelve months ended December 31, 2003 and 2002 Callisto paid Dartmouth \$42,868 and \$265,261, respectively, under this agreement. Callisto and Dartmouth entered into a settlement and general release agreement which terminated this license in August 2003. Pursuant to the settlement and general release agreement, Callisto paid \$42,868 to Dartmouth.

On July 7, 1998 Callisto entered into a Patent License Agreement with the United States Public Health Service ("PHS"), under which Callisto had an exclusive license to make, use, sell, lease, import and export and to otherwise commercially exploit certain licensed patents covering a diagnostic method for detecting obsessive compulsive disorder. Callisto paid an initial license issue royalty fee in the amount of \$50,000 in 1998 and minimum annual royalty fees of

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

\$10,000 in each year through December 31, 2003. Callisto terminated this agreement by mutual consent in January 2004.

### Employment Agreements:

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

On June 13, 2003, Callisto entered into an employment agreement with Kunwar Shailubhai, Ph.D. to serve as Executive Vice President and Head of Research and Development for a term of 18 months beginning June 13, 2003 and is automatically renewable for successive one year periods at the end of the term. Dr. Shailubhai's salary is \$170,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. In connection with his employment agreement, Dr. Shailubhai received a grant of 25,000 stock options which are fully vested and have an exercise price of \$1.50 per share. Dr. Shailubhai also received a grant of 325,000 stock options which vest over a three year period and are exercisable at \$1.50 per share.

F-17

On April 6, 2004, Dr. Shailubhai's employment agreement was terminated and he entered into an employment agreement with Synergy in which he agreed to serve as Senior Vice President, Drug Discovery. Dr. Shailubhai's employment agreement is for a term of 12 months beginning April 6, 2004 and is automatically renewable for successive one year periods at the end of the term. Dr. Shailubhai's salary is \$150,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. His unvested options for 325,000 shares granted June 13, 2003 were cancelled and Dr. Shailubhai received a new grant of 100,000 stock options which are exercisable at \$1.50 per share. 50,000 of such stock options vest in June 2004 and the remainder vest in December 2004.

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

On September 23, 2003, Callisto entered into an employment agreement with Donald H. Picker, Ph.D., to serve as Vice President, Drug Development. The employment agreement is for a term of 18 months beginning September 23, 2003 and is automatically renewable for successive one year periods at the end of the term. Dr. Picker's salary is \$175,000 per year and he is eligible to receive a cash bonus of up to \$45,000 per year upon the achievement of certain performance milestones. During the twelve months ended December 31, 2004, Dr. Picker was paid \$10,000 of this bonus and earned an additional \$10,000 which was accrued as of December 31, 2003 and paid in early January 2004. In connection with his employment agreement, Dr. Picker received a grant of 325,000 stock options which vest over a three year period and are exercisable at \$1.50 per share. (see Note

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

10)

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

### Lease agreements:

On August 20, 2003 Callisto entered into a five year lease for its corporate headquarters in New York City with an approximate rent of \$100,000 annually through August 2008. On November 4, 2003, Synergy entered a two year lease for laboratory space in New Jersey, principally to support combined Callisto and Synergy research efforts, with an approximate rent of \$50,000 annually through November 2005. During the years ended December 31, 2003 and 2002 and for the period from June 5, 1996 (inception) to December 31, 2003, total rent expense was \$67,261, \$51,856 and \$187,083, respectively. Total annual commitments under these leases for each of the twelve months ended December 31, are as follows:

2004	\$150,895
2005	149,927
2006	104,055
2007	106,138
2008	71,695
	-----
Total	\$582,710
	=====

On June 7, 2004, Callisto extended its lease for its corporate headquarters in New York City for two additional years through August 2010, and increased its space by approximately 60%. This increases average annual rent by approximately \$50,000 to \$150,000. Laboratory space in New Jersey, principally to support combined Callisto and Synergy research efforts, with an approximate rent of \$50,000 annually through November 2005 was unchanged in the six months ended June 30, 2004.

F-18

### Other:

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

On October 7, 2003, Callisto was awarded a \$265,697 Small Business Technology Transfer Research Grant from the National Institutes of Health for studies on Atiprimod. No funding was received during 2003. During the six months ended June 30, 2004, Callisto received \$100,220 of grant funding, as reimbursement of expenses incurred and recorded the receipt as an offset to research and development expenses. As of June 30, 2004 Callisto had unused grant funding available of \$165,477. Approximately \$25,000 of this grant will defray certain salary and wages of in-house scientists, the balance of which will reimburse incremental supplies and sub-contractors.

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

### 9. Stockholders' equity:

During the three months ended June 30, 2004:

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

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

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

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

During the three months ended March 31, 2004:

a.) Callisto issued to HPI 25,000 shares of common stock at a fair value of \$56,250 in connection with the acquisition of certain patent rights, which cost was charged to purchased in-process research and development expense (see note 8);

b.) 90,000 shares of common stock issued to former Synergy shareholders were returned to Callisto and purchased in process research and development expense was decreased by \$159,092;

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

From November 2003 through January 2004, Callisto sold and issued 3,905,432 shares of common stock at an issue price of \$1.50 for aggregate gross proceeds of \$5,858,148. Callisto incurred an aggregate of \$508,615 in fees to various selling agents and issued 31,467 shares of common stock and an aggregate 370,543

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

warrants to purchase common stock to such selling agents. The warrants are immediately exercisable at \$1.90 per share and will expire five years after issuance. As of December 31, 2003, Callisto had closed on a portion of this transaction, specifically 2,776,666 shares of common stock at a price of \$1.50 per share for aggregate gross proceeds of \$4,164,999, less \$361,625 incurred in fees to various selling agents.

During 2000, the Board of Directors approved an increase in the authorized common shares from 35,000,000 shares to 60,000,000 shares and a one-for-three reverse split of the common stock. All share and per share information has been adjusted to reflect the stock split as if it had occurred at the beginning of the earliest period presented. In May 2003, as part of the Merger, the authorized common shares were increased to 75,000,000 shares and the authorized preferred shares were increased to 20,000,000 shares.

F-19

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

During 2000, Callisto also sold 4,526,903 shares of common stock at a purchase price of \$0.05 per share to certain officers and directors of the company for services performed in the year 1999. Based on the most recent private placement of common stock during the fourth quarter of 1999, the value of these shares was determined to be \$0.70 per share and Callisto recorded \$3,168,832 as stock based compensation expense for the twelve months ended December 31, 1999.

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

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

	Shares -----	Price per share -----	Gross proceeds -----
December 1996	1,366,667	\$0.75	\$1,025,000
December 1997	1,442,667	\$0.75	1,081,999
October 1998	1,416,667	\$0.75	1,062,500

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 424B3

January 1999	146,667	\$0.75	110,000
December 1999	200,000	\$0.75	150,000
	-----		-----
Total	4,572,668		\$3,429,499
	=====		=====

10. Subsequent events:

On July 22, 2004, the employment agreement of Donald H. Picker, Callisto's Executive Vice President, R&D was amended. Dr., Picker's salary was increased from \$175,000 to \$200,000 per year and certain milestones were added upon which achievement cash bonuses of up to \$92,500 over a 12 month period may be paid.