CALLISTO PHARMACEUTICALS INC
Form 10-Q
May 16, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)
[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED: MARCH 31, 2005

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

COMMISSION FILE NUMBER: 001-32325

CALLISTO PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	13-3894575
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

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

(212) 297-0010
(Registrant's telephone number)

(Former Name, Former Address and Former Fiscal Year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding twelve months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

|X| Yes |_| No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

|_| Yes |X| No

As of May 13, 2005 the issuer had 31,228,893 shares of common stock outstanding.

CALLISTO PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)

FORM 10-Q

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PART I -- FINANCIAL INFORMATION

INTRODUCTORY NOTE

This Report on Form 10-Q for Callisto Pharmaceuticals, Inc. ("Callisto" or the "Company") may contain forward-looking statements. You can identify these statements by forward-looking words such as "may," "will," "expect," "intend," "anticipate," believe," "estimate" and "continue" or similar words. Forward-looking statements include information concerning possible or assumed

future business success or financial results. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Accordingly, we do not undertake any obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under "Risk Factors" in our Annual Report on Form 10-KSB for the year ended December 31, 2004 and other periodic reports filed with the SEC. Accordingly, to the extent that this Report contains forward-looking statements regarding the acquisitions, financial condition, operating results, business prospects or any other aspect of the Company, please be advised that the Company's actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements.

PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

CALLISTO PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED BALANCE SHEETS

	MARCH 31, 2005
ASSETS	(UNAUDITED)
Current assets:	
Cash and cash equivalents	$ 6,752,583
Prepaid expenses	44,141
	6,796,724
Property and equipment - net	13,784
Rent deposits	82,196
	$ 6,892,704
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	$ 1,575,823
Accrued expenses	255,491
	1,831,314
Stockholders' equity:	
Common stock, par value $.0001, 75,000,000 shares authorized, 31,228,893	

and 29,219,102 outstanding at March 31, 2005 and December 31, 2004, respectively	3,123
Additional paid-in capital	42,933,525
Unamortized deferred stock based compensation	(1,919,930)
Deficit accumulated during development stage	(35,955,328)
	5,061,390
	$ 6,892,704

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

CALLISTO PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	THREE MONTHS ENDED MARCH	
	2005	
Revenues	$ --	$
Costs and Expenses:		
Research and development	1,506,706	6
Government grant	--	(
Purchased in-process research and development	--	2
Stock based compensation - research and development	69,063	1
General and administrative	694,275	5
Stock based compensation - general and administrative	343,678	3
Loss from operations	(2,613,722)	(1,8
Interest income	19,591	
Other income	--	
Net loss	$(2,594,131)	$(1,8
Weighted average number of common shares outstanding:		
Basic and diluted	29,743,937	26,7
Net loss per common share: basic and diluted	($0.09)	

See accompanying notes to condensed consolidated financial statements.

CALLISTO PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)

CONDENSED 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
	--	--	---
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 shares 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

CALLISTO PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS 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 issue	--	--
Other	--	--
Preferred shares issued	--	--
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 condensed consolidated financial statements.

CALLISTO PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (CONTINUED)

	Preferred Stock	Common Stock	Additional	Unamortized Deferred

	Preferred Stock	Par Value	Common Stock	Par Value	Paid in Capital	Stock Based Compensation
Balance December 31, 2002	4,235,299	$423	13,083,695	$1,307	$14,538,618	--
Net loss for the year	--	--	--	--	--	--
Conversion of preferred stock in connection with the Merger	(4,235,299)	(423)	4,235,299	423	--	--
Common stock issued to former Synergy stockholders	--		4,329,927	432	6,494,458	--
Common stock issued in exchange for Webtronics common stock	--		1,503,173	150	(150)	--
Deferred Compensation - stock options	--		--	--	9,313,953	(9,313,953
Amortization of deferred Stock based Compensation	--		--	--	--	3,833,946
Private placement of common stock, net	--	--	2,776,666	278	3,803,096	--
	--	--	---------	---	---------	----------
Balance, December 31, 2003	--	--	25,928,760	2,590	34,149,975	(5,480,007
Net loss for the period	--	--	--	--	--	--
Amortization of deferred Stock-based compensation expense	--	--	--	--	--	3,084,473
Variable accounting for stock options	--	--	--	--	(816,865)	--
Stock-based compensation net of forfeitures	--	--	--	--	240,572	93,000
Common stock issued via private placements, net	--	--	3,311,342	331	6,098,681	--
Warrant and stock-based compensation for services in connection with the Merger	--	--	--	--	269,826	--
Common stock returned from former Synergy stockholders	--	--	(90,000)	(9)	(159,083)	--
Stock issued for patent rights	--	--	25,000	3	56,247	--
Common stock issued for services	--	--	44,000	7	70,833	--
	---	---	----------	------	----------	----------
Balance, December 31, 2004	--	--	29,219,102	2,922	39,910,187	(2,302,534
Net loss for the period	--	--	--	--	-	--
Amortization of deferred Stock-based compensation expense	--	--	--	--	-	382,604

Variable accounting for stock options	--	--	--	--	(60,741)	--
Stock-based compensation net of forfeitures	--	--	--	--	54,398	--
Common stock issued via private placement, net	--	--	1,985,791	199	2,993,204	--
Common stock issued for services	--	--	24,000	2	36,478	--
Balance, March 31, 2005	--	$--	31,228,893	$3,123	$42,933,525	($1,919,930

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

CALLISTO PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Three months ended March 31,	
	2005	2004
Cash flows from operating activities:		
Net loss	$(2,594,131)	$(1,827,913)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,072	3,179
Stock based compensation expense	412,741	563,376
Purchased in-process research and development (non-cash portion)	--	106,235
Changes in operating assets and liabilities:		
Prepaid expenses	1,090	35,763
Security deposit	--	--
Accounts payable and accrued expenses	611,025	(578,174)
Total adjustments	1,029,928	130,379
Net cash used in operating activities	(1,564,203)	(1,697,534)
Cash flows from investing activities:		
Acquisition of equipment	--	--
Net cash used in investing activities	--	--

Cash flows from financing activities:		
Net proceeds from issuance of common and preferred stock, net of repurchases	2,993,402	1,553,258
Net cash provided by financing activities	2,993,402	1,553,258
Net increase in cash and cash equivalents	1,429,199	(144,276)
Cash and cash equivalents at beginning of period	5,323,384	3,956,486
Cash and cash equivalents at end of period	$ 6,752,583	$ 3,812,210
Supplementary disclosure of cash flow information:		
Cash paid for taxes	$27,800	$2,921

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

CALLISTO PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Summary of significant accounting policies

BASIS OF PRESENTATION:

The accompanying unaudited condensed consolidated financial statements of Callisto Pharmaceuticals, Inc. ("Callisto"), which include its wholly owned subsidiaries: (1) Callisto Research Labs, LLC (including its wholly owned but inactive subsidiary, Callisto Pharma, GmbH (Germany)) and (2) Synergy Pharmaceuticals Inc. ("Synergy" , including its wholly owned but inactive subsidiary IgX, Ltd (Ireland)), have been prepared in accordance with (i) accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and (ii) the rules of the Securities and Exchange Commission (the "SEC") for quarterly reports on Form 10-Q. The results of operations of Synergy are included in the consolidated statement of operations since May 1, 2003 in the period from June 5, 1996 (inception) to March 31, 2005. All intercompany balances and transactions have been eliminated. These condensed consolidated financial statements do not include all of the information and footnote disclosures required by GAAP for complete financial statements. These statements should be read in conjunction with Callisto's audited financial statements and notes thereto for the year ended December 31, 2004, included in Form 10-KSB filed with the SEC on March 30, 2005. 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 three months ended March 31, 2005 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2005.

CASH AND CASH EQUIVALENTS

Callisto considers all highly liquid debt instruments, including treasury bills,

purchased with original maturities of three months or less to be cash equivalents. Callisto's cash balances are held in a mixture of investment grade commercial paper, Treasury bills and a money market account.

2. 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 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 plan.

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 and interim financial statements (see below) about the method of accounting for stock-based employee compensation and the effect of the method used on reported results.

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:

	Three months ended March 31,	
	2005	2004
Net loss, as reported	$(2,594,131)	$(1,827,913)
Add: Stock-based employee compensation expense recorded under APB No. 25 intrinsic value method	321,864	313,762
Deduct: Stock-based employee compensation expense determined under fair value based method	(584,440)	(484,385)
Pro forma net loss	$(2,856,707)	$(1,998,536)
Net loss per share:		
Basic and diluted -as reported	$ (0.09)	$ (0.07)
Basic and diluted -pro forma	$ (0.10)	$ (0.07)
Black-Scholes Methodology Assumptions:		
Dividend yield	0%	0%
Risk free interest rate	2.87% to 4.0%	4.5% to 2.87%
Expected lives of options	7 to 10 years	7 to 10 years

Volatility of 0% was used until Callisto's common stock began to trade publicly on June 16, 2003. Since June 13, 2003 through March 31, 2005 Callisto has used 100% volatility to determine Fair Value of options granted to employees.

3. 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 and warrants, would have been antidilutive. As of March 31, 2005 and December 31, 2004 there were 7,957,060 and 7,322,060 total options outstanding, respectively. As of March 31, 2005 and December 31, 2004 there were 758,995 warrants outstanding.

4. Government Grants

Callisto requests cash funding under approved grants as expenses are incurred (not in advance) and records the receipt as an offset to research and development expense. During 2004 Callisto had a research grant from the National Institutes of Health for studies on Atiprimod. This amount totaled $52,259 during the three months ended March 31, 2004 and has been reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grant". The work under this grant was completed in the fourth quarter of 2004 and Callisto received no further funding during the three months ended March 31, 2005. Read footnote 10 "Subsequent events" for a description of the Superantigen grant which Callisto received on April 1, 2005.

5. Stockholders' equity:

On March 9, 2005 Callisto completed a private placement of an aggregate 1,985,791 shares of its common stock at a per share price of $1.52, for aggregate gross proceeds of $3,018,402 and net proceeds of $2,993,402. The financing was led by certain current institutional shareholders and included certain members of the Callisto's management, therefore no selling agent fees were incurred, and legal fees were $25,000. Callisto has filed a registration statement covering resale of the shares.

6. Commitments and contingencies:

Employment and consulting agreements:

On January 10, 2005 Gabriele M. Cerrone, Callisto's Chairman of the Board (the "Consultant") began his duties under a consulting agreement (the "Agreement") with Callisto, which had been entered into on December 27, 2004. The duties of the Consultant and the obligations of Callisto to pay compensation commenced on January 10, 2005 (the "Start Date"), and continue until December 31, 2006 with automatic renewal for successive one year periods unless either party gives notice to the other not to renew the Agreement.

Callisto will pay Consultant the annual sum of $205,000 (the "Base Compensation") at the rate of $17,083.33 per month commencing on the Start Date. In addition, Consultant was granted 375,000 ten year non-qualified stock options at an exercise price of $1.70 per share. One half of such options vest on each of the first two anniversaries of the date of the Agreement. Stock-based compensation expense associated with these option grants was recorded based on an initial Black-Scholes Fair Value of $1.52 per share for the portion earned for services rendered to date and will be marked to market quarterly with an adjustment to compensation expense from January 10, 2005 until the measurement

date is known. The measurement date in this case will be the earlier of the second anniversary of the agreement or the accelerated vesting date if Mr. Cerrone is terminated without cause or good reason.

In the event the Agreement is terminated without cause or for good reason, the Consultant will receive a cash payment equal to the aggregate amount of Base Compensation for the then remaining term of the Agreement and all unvested stock options will immediately vest and the exercise period of such options will be extended to the later of the longest period permitted by Callisto's stock option plans or ten years following termination. In the event a change of control of Callisto occurs, Consultant shall be entitled to such compensation upon the subsequent termination of the Agreement within two years of the change in control unless such termination is the result of the Consultant's death, disability or retirement or the Consultant's termination for cause.

On December 22, 2004 the Board of Directors of Callisto, acting upon advice of its Compensation Committee, awarded Mr. Cerrone a cash bonus of $200,000 in recognition of his contributions to the Company including negotiation and acquisition of certain intellectual property licenses during 2004. Accordingly this bonus was charged to research and development expense during 2004 and paid on January 10, 2005.

On March 28, 2005 Callisto entered into an employment agreement with Dr. Pamela Harris to serve as Callisto's Chief Medical Officer. Pursuant to the Employment Agreement, Callisto will employ Dr. Harris for a period of one year commencing March 28, 2005 which will be automatically renewed for successive one year periods until written notice not to renew is delivered by either

Callisto or Dr. Harris. Dr. Harris will be paid an annual base salary of $220,000 ("Base Salary"). In addition, Dr. Harris will be eligible to earn an annual cash bonus of up to $20,000 based on meeting performance objectives and bonus criteria.

Dr. Harris was granted an aggregate 200,000 incentive stock options pursuant to Callisto's stock option plan with an exercise price of $1.54 per share. 100,000 of such options will vest pursuant to the following schedule: 30,000 options will vest on March 28, 2006; 30,000 options will vest on March 28, 2007; and 40,000 options will vest on March 28, 2008. The remaining 100,000 options will vest pursuant to the following schedule: 30,000 options will vest upon the successful completion of a Phase IIb clinical trial for Atiprimod or a comparable clinical trial involving another Callisto drug candidate, other than Atiprimod or Annamycin; 30,000 options will vest upon the successful completion of a Phase IIb clinical trial for Annamycin; and 40,000 options will vest upon the successful completion of a Phase III clinical trial for Annamycin

7. Subsequent events:

On April 1, 2005 Callisto received an $885,641 biodefense partnership grant from the National Institute of Allergy and Infectious Diseases (NIAID) to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over the next two years.

On April 25, 2005 Callisto filed a Preliminary Proxy Statement with the SEC and announced a proposal to amend Callisto's certificate of incorporation to increase the authorized number of shares of common stock from 75,000,000 shares to 100,000,000 shares at Callisto's 2005 Annual Meeting of Shareholders.

8. Recent accounting pronouncements:

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") No. 123 (Revised 2004), "Share-Based Payment." SFAS No. 123R is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation" and supersedes Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees" and its related implementation guidance. SFAS No. 123R focuses primarily on accounting for transactions in which an entity obtains employee services through share-based payment transactions. SFAS No. 123R requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The cost will be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS No. 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. While Callisto cannot precisely determine the impact on net loss as a result of the adoption of SFAS No. 123R, estimated compensation expense related to prior periods can be found in footnote 2.

In December 2004, the FASB issued SFAS 153, "Exchanges of Nonmonetary Assets", which is effective for fiscal years beginning after June 15, 2005. SFAS 153 amends APB 29, "Accounting for Nonmonetary Transactions"' which is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB 29 included certain exceptions to that principle. SFAS 153 amends APB 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The adoption of this statement is not expected to have a material effect on our financial position or results of operations.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our financial statements and other financial information appearing elsewhere in this Quarterly Report. In addition to historical information, the following discussion and other parts of this quarterly report 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 March 31, 2005, we have sustained cumulative net losses of $35,955,328. Our losses have resulted primarily from expenditures incurred in connection with clinical development of licensed products, 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 March 31, 2005 we have not generated any revenue from operations. We expect to incur substantial and increasing losses for the next several years as we develop our product candidates, expand our clinical development team and prepare for the commercial launch of our product candidates. We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all.

To date, our sources of cash have been primarily limited to the sale of our

equity securities. On March 9, 2005, we completed a private placement of an aggregate 1,985,791 shares of our common stock at a per share price of $1.52, for net proceeds of $2,993,402. The financing was led by certain current institutional shareholders and included certain members of our management. We have devoted substantially all of our capital resources to the in-licensing and development of our product candidates.

Our research and development expenses consist primarily of costs associated with an in-house research and development laboratory, salaries and staff, 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. We expense all research and development costs as they are incurred. We expect our research and development expenses to increase significantly in the future as we develop our product candidates.

Our general and administrative expenses primarily include personnel and related costs, rent and professional service fees. We expect our general and administrative expenses to increase significantly over the next few years as we continue to build our operations to support our product candidates and as we incur costs associated with being a publicly traded company.

HISTORY

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

PLAN OF OPERATIONS

Our plan of operations for the next twelve months is to focus primarily on the development of two drugs to treat leukemia and multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow). Our lead drug in development for leukemia, Annamycin, earlier completed a Phase I/IIa trial in refractory leukemia patients. We plan to initiate clinical trials in relapsed (failure of prior therapy) leukemia patients in 2005. Our second drug candidate, Atiprimod, is presently in a Phase I/IIa clinical trial in multiple myeloma patients, and is an orally available drug with antiproliferative and antiangiogenic activity. We also have three drugs in preclinical development, WP760, for melanoma, SP304 for gastrointestinal inflammation, and a monoclonal antibody that is being explored as a biodefensive agent against staphylococcal and streptococcal bioweapons.

ANNAMYCIN

On August 12, 2004, we entered into a world-wide license agreement with The University of Texas M.D. Anderson Cancer Center to research, develop, sell and

commercially exploit the patent rights for Annamycin, an anthracycline cancer drug for leukemia therapy. Consideration paid for this license amounted to $31,497 for reimbursement of out-of-pocket costs for filing, enforcing and maintaining the Annamycin patent rights and a $100,000 initial license fee. We also agreed to pay The University of Texas M.D. Anderson Cancer Center royalties based on net sales from any licensed products, plus aggregate milestone payments of up to $750,000 based upon achieving certain regulatory submissions and approvals. The term of the agreement is from August 12, 2004 until November 2, 2019. Under the terms of the license agreement, we are required to make certain good faith expenditures towards the clinical development of at least one licensed product within the two year period after March 2005. In addition, at any time after five years from August 12, 2004, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or we are actively and effectively attempting to commercialize Annamycin.

Annamycin was discovered by scientists at The University of Texas M.D. Anderson Cancer Center and initially evaluated in a Phase I clinical trial in 36 patients with relapsed solid tumors, a Phase II clinical trial in 13 patients with doxorubicin-resistant breast cancer, and a Phase I/IIa trial in 20 patients with relapsed/refractory acute myeloid leukemia, or AML and acute lymphocytic leukemia, or ALL. The Phase I trial of Annamycin performed in relapsed/refractory acute leukemia patients by a prior sponsor has recently been subjected to a careful audit by us of efficacy and safety data. Based on this review, we have decided that the next trial with Annamycin in adult ALL patients planned to begin in mid-2005 will include an initial evaluation of a small number of patients (2 cohorts totaling approximately 6 patients) in a Phase I/IIa trial that will be rolled into a larger Phase IIb trial. We also expect to commence two additional trials with Annamycin in 2005, a single agent trial of liposomal Annamycin in pediatric relapsed ALL patients, and a combination trial of Annamycin in combination with Ara-C in adult relapsed AML patients.

ATIPRIMOD

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 of up to $14 million based upon achieving certain regulatory submissions and approvals for an initial indication, and additional payments of up to $16 million for each additional indication based on achieving certain regulatory submissions and approvals. In addition the agreement requires Synergy to pay AnorMED royalties on net sales. 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. Pursuant to the license agreement, failure to pay the maintenance fee is a material breach of the license agreement. The license agreement will terminate in 2018.

On May 26, 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). On January 31, 2005, we announced the opening of two additional sites for the Phase I/IIa clinical trial of Atiprimod, the Roswell Park Cancer Institute in Buffalo, New York, and the St. Vincent's Comprehensive Cancer Center in New York, NY. The clinical trial is an open label study, with the primary objective of assessing the safety of the 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 depends on the enrollment rate, how well the drug is tolerated, and on drug response, with final results not anticipated until the end of 2005. If Atiprimod produces

positive responses, we intend to initiate a Phase IIb trial in relapsed multiple myeloma patients in 2006.

On March 15, 2005 we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The new trial is entitled: "An Open Label Study of the Safety and Efficacy of Atiprimod Treatment for Patients with Advanced Cancer". The primary objective is to assess the safety and determine the maximum tolerated dose (MTD) of Atiprimod in advanced cancer patients. The secondary objectives are to measure the pharmacokinetics of Atiprimod and evaluate the response in a variety of relapsed solid tumors and hematologic malignancies. The trial protocol received institutional review board (IRB) approval on February 22, 2005 at The University of Texas M.D. Anderson Cancer Center with Dr. Razelle Kurzrock as the Principal Investigator. Site initiation was completed on March 3, 2005, and patient screening and dosing began in April, 2005. The duration of this study will depend on the enrollment rate, how well the drug is tolerated and on drug response.

SITE DIRECTED INTERCALATION TECHNOLOGY

On February 24, 2004, we entered into an agreement with Houston Pharmaceuticals, Inc., or HPI, to sublicense the rights to a key patent covering a technology platform for site-directed DNA intercalation, or a compound's ability to insert between the base pairs in DNA, and we acquired the rights to a patent covering new anthracycline analogs. 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 accounted for as purchased in-process research and development expense 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.

In addition, we 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, we will record additional purchased in-process research and development expense based upon the fair value of the options at that time. We also agreed to pay HPI royalties of 2% on net sales from any products resulting from commercializing the site-directed DNA intercalation. Pursuant to the sublicense agreement, in the event our Board of Directors determines to abandon its development and commercialization of the site-directed DNA intercalation, HPI shall have the right to terminate the sublicense agreement. The technology platform for site-directed DNA intercalation is exemplified by the identification of a lead drug candidate, WP760, for melanoma that shows remarkable selectivity for human melanoma cancer cell lines. We are presently evaluating this drug pre-clinically in animal models of human melanoma, and based on these results plan to make a decision in 2005 on further development of WP760.

GUANYLYL CYCLASE RECEPTOR AGONIST TECHNOLOGY

Our GCRA program has resulted in the development of SP304, a biologically functional analog that has demonstrated superior biological activity, enhanced temperature and protease stability and superior pH characteristics relative to human uroguanylin. SP304 is currently undergoing pre-clinical evaluation as a treatment for GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of Pittsburgh. Based on these animal studies, we plan in 2005 to make a decision on moving this drug forward into the clinic.

SUPERANTIGEN-BASED BIOTERORRISM DEFENSE

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, plus royalties of 2% and 0.75% of net sales of product depending on whether the product is covered by a claim under the licensed patents or derived from a claim under the licensed patents and will pay Rockefeller 15% of any sublicense fee paid by sublicensees. The agreement will terminate on July 25, 2021. Rockefeller may terminate the license agreement if we are more than 30 days late in paying Rockefeller any amounts due under the license agreement or if we breach the license agreement.

We are exploring the development of a 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 an animal model in which toxic shock is induced by an aerosolized superantigen toxin. The research work involves a collaboration with Dr. Sina Bavari, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD. We are also exploring strategic alternatives regarding further development of the superantigen program, including spin-off or strategic partnership.

MANUFACTURING

An improved manufacturing method for Annamycin has been developed at Antibioticos S.p.A., our commercial supplier of Good Manufacturing Practice, or GMP, drug substance. GMP material is currently being produced in sufficient quantity for all three anticipated Phase II trials. Currently, Antibioticos S.p.A. is our sole supplier of liposomal Annamycin for our clinical trials. Our agreement with Antibioticos provides that Antibioticos S.p.A. will provide 400 grams of GMP drug substance for our Annamycin clinical trials. Upon the conclusion of our Phase IIb clinical trials, the agreement provides that the parties will negotiate in good faith towards a commercial supply agreement for Annamycin. If our relationship with this contract manufacturer, or any other contract manufacturer we might use, terminates or if any of their facilities are damaged for any reason, including fire, flood, earthquake or other similar event, we may be unable to obtain supply of Annamycin. If any of these events were to occur, we may need to find alternative manufacturers or manufacturing facilities. The number of contract manufacturers with the expertise, required regulatory approvals and facilities to manufacture Annamycin on a commercial scale is extremely limited, and it would take a significant amount of time to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must approve these manufacturers' facilities and processes prior to our use, which would require new testing and compliance inspections. In addition, we may not have the intellectual property rights, or may have to share intellectual property rights, to any improvements in the current manufacturing processes or any new manufacturing processes for Annamycin. Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of Annamycin, entail higher costs, and could result in our being unable to commercialize Annamycin successfully.

We have entered into a contract with Delmar Chemicals, Inc. to be the commercial supplier of future Atiprimod GMP drug substance. One large-scale GMP production run of Atiprimod dimaleate led to the successful release of 10 Kg of material available for future Phase II clinical studies.

EMPLOYEES

Our plan is to use contract research organizations (CROs) for most of our development efforts, including monitoring of clinical trial results, thus

minimizing the need to hire full time employees. As of May 13, 2005, we had 5 full-time and 2 part-time employees.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of March 31, 2005.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2005 AND MARCH 31, 2004

We had no revenues during the three months ended March 31, 2005 and 2004 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 $905,416, or 151%, to $1,506,706 for the three months ended March 31, 2005 from $601,290 for the three months ended March 31, 2004. The most significant factors contributing to this increase in research and development expense were increasing expenditures on our two major drug candidates, Annamycin and Atiprimod. We had a $479,207 increase in expenses related to preparation of our Annamycin drug candidate to re-enter human clinical trials in mid-2005 and an increase of $369,829 for the management of our ongoing Atiprimod clinical trials which began in May of 2004. During the three month period ended March 31, 2004 the research and development expenses of $601,290 were primarily related to costs associated with preparing our Atiprimod drug candidate to enter a Phase I/IIa clinical trial.

Government grant funding for the three months ended March 31, 2005 was $0 as compared to $52,259 for the three months ended March 31, 2004. We request grant funding to reimburse research and development expenses as incurred.

General and administrative expenses for the three months ended March 31, 2005 were $694,275, an increase of $175,904 or 34%, from $518,371 for the three months ended March 31, 2004. The increase was due primarily to approximately (i) $100,000 of increased consulting and directors fees related to our Chairman becoming a consultant, the addition of a financial advisory consultant and outside directors fees, (ii) $55,000 of increased recruiting and relocation expenses related to the hiring of clinical and regulatory personnel and management, and (ii) $19,000 in higher facilities and office overhead related to our move into our larger corporate headquarters in New York City subsequent to March 31, 2004.

Purchased in-process research and development was $0 for the three months ended March 31, 2005, as compared to $209,735 for the three months ended March 31, 2004 which was related to the acquisition of rights to two key patents covering a novel cancer platform technology and anthracycline analogs from Houston Pharmaceuticals, Inc.

Net loss for the three months ended March 31, 2005 was $2,594,131 compared to a net loss of $1,827,913 incurred for the three months ended March 31, 2004. The increased net loss is the result of higher research and development, and general and administrative expenses, offset by the decrease in purchased in-process research and development, all of which is discussed above. In addition we recorded lower stock based compensation expense of $412,741 during the three months ended March 31, 2005, as compared to $563,376 recorded during the same period ended March 31, 2004.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2005 we had $6,752,583 in cash and cash equivalents, compared to $5,323,384 as of December 31, 2004. This increase in cash of $1,429,199 during the three months ended March 31, 2005 was principally the result of completing a private placement of common stock yielding net proceeds of $2,993,402. This was partially offset by cash used in operating activities of $1,564,203 during the three months ended March 31, 2005. Cash used in operating activities was primarily for research and development and general and administrative expenses discussed above totaling $2,200,982, less $611,025 in increased accounts payable due to the commencement of commercial relationships with clinical research and drug formulation and manufacturing companies.

On March 9, 2005 we sold and issued in a private placement an aggregate 1,985,791 shares of common stock at a per share price of $1.52, for aggregate gross proceeds of $3,018,402 and net proceeds of $2,993,402. Because this transaction was completed with certain existing institutional shareholders and certain members of our management we paid no selling agent fees and legal fees were $25,000. We filed a registration statement covering resale of the shares.

On April 1, 2005 we received an $885,641 biodefense partnerships grant from the National Institute of Allergy and Infectious Diseases (NIAID) to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over the next two years.

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 our current product candidates, and the acquisition of licenses and rights to certain other cancer related drug technologies. 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.

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. 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.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of financial condition and results of operations are based upon our condensed consolidated financial statements, which have been prepared by us without audit in accordance with the rules and regulations of the Securities and Exchange Commission. The preparation of our financial statements requires us to make estimates that affect the reported amounts of assets, liabilities, expenses, and related disclosure of contingent assets and liabilities. We base our accounting estimates on historical experience and other factors that are believed to be reasonable under the circumstances. However,

actual results may vary from these estimates under different assumptions or conditions. The following is a summary of our critical significant accounting policies and 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. Other stock based compensation associated with grants to non-employees, as well as directors who perform services outside of their Board duties, is measured using the fair value method. We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options is designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage. Since inception through March 31, 2005 stock based compensation expense totaled $11,764,013, or approximately one third of our accumulated deficit.

We account for stock options and warrants granted to non-employees based on the fair value of the stock option or warrant using the Black-Scholes option-pricing model based on assumptions for expected stock price volatility, expected term of the option, risk-free interest rate and expected dividend yield at the grant date.

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard ("SFAS") No. 123 (Revised 2004), "Share-Based Payment." SFAS No 123R is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation" and supersedes Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees" and its related implementation guidance. SFAS No. 123R focuses primarily on accounting for transactions in which an entity obtains employee services through share-based payment transactions. SFAS No 123R requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The cost will be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS No. 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. While we cannot precisely determine the impact on net loss as a result of the adoption of SFAS No 123R, estimated compensation expense related to prior periods can be found in footnote 2 to our condensed consolidated financial statements included herein.

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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is primarily related to credit risk associated with short term investment grade commercial paper which at March 31, 2005 totaled $2,000,000.

ITEM 4. CONTROLS AND PROCEDURES

Our Chief Executive Officer and Principal Financial Officer, based on the evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of the end of the period covered by this report, have concluded that our disclosure controls and procedures were effective to ensure the timely collection, evaluation and disclosure of information relating to our company that would potentially be subject to disclosure under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated there under.

During the three months ended March 31, 2005, there were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 5. EXHIBITS

(a) Exhibits

31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CALLISTO PHARMACEUTICALS, INC.
(Registrant)

DATE: MAY 16, 2005 BY: /s/ GARY S. JACOB

GARY S. JACOB
CHIEF EXECUTIVE OFFICER

DATE: MAY 16, 2005 BY: /s/ BERNARD F. DENOYER

BERNARD F. DENOYER
VICE PRESIDENT, FINANCE