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CALLISTO PHARMACEUTICALS INC  
Form 10QSB  
July 27, 2004

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-QSB

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the quarterly period ended: June 30, 2004

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: 33-63474

CALLISTO PHARMACEUTICALS, INC.  
(Exact name of Registrant as specified in its charter)

Delaware 13-3894575

-----  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) 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)

Check whether the issuer: (1) filed all reports required to be filed by Section  
13 or 15(d) of the Exchange Act during the preceding 12 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 past 90 days.

Yes  No

APPLICABLE ONLY TO CORPORATE ISSUERS:

State the number of shares outstanding of each of the issuer's classes of common  
equity, as of the latest practicable date:

Class	Outstanding at July 26, 2004
-----	-----
Common Stock, par value \$0.0001	29,175,102 shares

Transitional Small Business Disclosure Format (check one): Yes No

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#### INTRODUCTORY NOTE

This Report on Form 10-QSB for Callisto Pharmaceuticals, Inc. (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

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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, 2003 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.

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### PART I - FINANCIAL INFORMATION

#### Item 1. Condensed Consolidated Financial Statements

CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEET as of June 30, 2004  
(Unaudited)

#### ASSETS

Current assets:		
Cash and cash equivalents	\$	7,269,421
Prepaid expenses		101,766
		-----
		7,371,187
		-----
Property and equipment, net of accumulated depreciation of \$ 51,965		32,672
Rent deposits		62,980
		-----
	\$	7,466,839
		=====

#### LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$	387,053
Accrued expenses		91,827
		-----
		478,880
Stockholders' equity:		
Preferred stock, \$.0001 par value, authorized 20,000,000 shares, none outstanding		--
Common stock, \$.0001 par value, authorized 75,000,000 shares, 29,175,102 outstanding		2,915

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Additional paid-in-capital	40,702,564
Unamortized deferred stock-based compensation	(4,162,080)
Deficit accumulated during the development stage	(29,555,440)
	-----
	6,987,959
	-----
	\$ 7,466,839
	=====

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

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CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)

	Six Months Ended June 30,		Three Months Ended June 30,	
	2004	2003	2004	2003
	-----	-----	-----	-----
Revenues	\$ --	\$ --	\$ --	\$ --
Costs and expenses:				
Research and development	925,652	308,986	324,363	231,532
Government grant	(100,220)	--	(47,962)	--
General and administrative	1,074,233	497,619	555,893	405,979
Purchased in process R&D	209,735	6,833,454	--	6,833,454
Stock based compensation	1,665,594	2,463,007	1,102,218	2,106,636
	-----	-----	-----	-----
Loss from operations	(3,774,994)	(10,103,066)	(1,934,512)	(9,577,601)
Interest income	37,284	7,056	24,715	2,813
Other income	--	--	--	--
	-----	-----	-----	-----
Net loss	\$ (3,737,710)	\$ (10,096,010)	\$ (1,909,797)	\$ (9,574,788)
	=====	=====	=====	=====
Weighted average shares outstanding:				
basic and diluted	27,767,221	19,306,915	28,749,608	21,272,990
Net loss per common share:				
basic and diluted	\$ (0.13)	\$ (0.52)	\$ (0.07)	\$ (0.45)

The accompanying notes are an integral part of these 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	Co Sto V
	-----	-----	-----	-----
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 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	--	--	--	

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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.

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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	Total Stockholders' Equity
	-----	-----	-----
Balance at inception, June 5, 1996	\$ --	\$ --	\$ --
Net loss for the year	--	(404,005)	(404,005)
Issuance of founder shares	--	--	792
Common stock issued	--	--	408
Common stock issued via private placement	--	--	1,025,000
	-----	-----	-----
Balance, December 31, 1996	--	(404,005)	622,195
Net loss for the year	--	(894,505)	(894,505)
Common stock issued via private placement	--	--	1,081,999
	-----	-----	-----
Balance, December 31, 1997	--	(1,298,510)	809,689
Net loss for the year	--	(1,484,438)	(1,484,438)
Amortization of stock based compensation	--	--	52,778
Common stock issued	--	--	1,062,500
Common stock issued for services	--	--	591,667
Common stock repurchased and cancelled	--	--	(97,000)
	-----	-----	-----
Balance, December 31, 1998	--	(2,782,948)	935,196

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Net loss for the year	--	(4,195,263)	(4,195,263)
Deferred compensation - stock options	(9,946)	--	--
Amortization of stock based compensation	3,262	--	3,262
Common stock issued for services	--	--	3,168,832
Common stock issued via private placement	--	--	260,000
	-----	-----	-----
Balance, December 31, 1999	(6,684)	(6,978,211)	172,027
Net loss for the year	--	(2,616,261)	(2,616,261)
Amortization of stock based compensation	4,197	--	4,197
Common stock issued	--	--	251,344
Other	--	--	432
Preferred stock issued	--	--	5,986,650
Preferred stock issued for services	--	--	1,125,000
	-----	-----	-----
Balance, December 31, 2000	(2,487)	(9,594,472)	4,923,389
Net loss for the year	--	(1,432,046)	(1,432,046)
Deferred compensation - stock options	(20,000)	--	--
Amortization of stock based compensation	22,155	--	22,155
	-----	-----	-----
Balance, December 31, 2001	(332)	(11,026,518)	3,513,498
Net loss for the year	--	(1,684,965)	(1,684,965)
Amortization of stock based compensation	332	--	332
	-----	-----	-----
Balance, December 31, 2002	\$ --	\$ (12,711,483)	\$ 1,828,865

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

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CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (CONTINUED)

	Preferred Stock	Preferred Par Value	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamo Defer Stock Compe
	-----	-----	-----	-----	-----	-----
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	--	

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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 stock based compensation	--	--	--	--	3,833,946	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	(5,481,715)
Net loss for the period (unaudited)	--	--	--	--	--	--
Amortization of stock based compensation (unaudited)	--	--	--	--	--	1,313,953
Stock-based compensation expense (unaudited)	--	--	--	--	286,918	
Common stock issued via private placements (unaudited)	--	--	3,311,342	331	6,098,681	
Warrant and stock-based compensation for services in connection with the Merger (unaudited)	--	--	--	--	269,826	
Common stock issued for patent rights (unaudited)	--	--	25,000	3	56,247	
Common stock returned from former Synergy stockholders (unaudited)	--	--	(90,000)	(9)	(159,083)	
	-----	-----	-----	-----	-----	-----
Balance June 30, 2004 (Unaudited)	--	\$ --	29,175,102	\$ 2,915	\$40,702,564	(\$4,161,715)
	=====	=====	=====	=====	=====	=====

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

CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)



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	Six months ended June 30,		
	2004	2003	
Cash flows from operating activities:			
Net loss	\$ (3,737,710)	\$ (10,096,010)	\$ (
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	13,816	7,850	
Stock-based compensation expense	1,665,594	2,463,007	
Purchased in-process research and development-non cash	106,235	6,833,454	
Changes in operating assets and liabilities:			
Prepaid expenses	(49,122)	(188,694)	
Rent deposit	--	(47,246)	
Accounts payable and accrued expenses	(784,890)	127,896	
Total adjustments	(951,633)	9,196,267	
Net cash used in operating activities	(2,786,077)	(899,743)	(
Cash flows from investing activities:			
Acquisition of property and equipment	--	(54,462)	
Net cash used in investing activities	--	(54,462)	
Cash flows from financing activities:			
Net proceeds from issuance of common and preferred stock, net of repurchases	6,099,012	--	
Net cash provided by financing activities	6,099,012	--	
Net increase (decrease) in cash and cash equivalents	3,312,935	(954,205)	
Cash and cash equivalents at beginning of the period	3,956,486	2,223,462	
Cash and cash equivalents at end of the period	\$ 7,269,421	\$ 1,269,257	\$
Supplementary disclosure of cash flows information:			
Cash paid for taxes	\$ 2,921	\$ 24,558	\$

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

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CALLISTO PHAMACEUTICALS, INC.  
(A Development Stage Company)

## NOTES TO JUNE 30, 2004 CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

### 1. Basis of presentation:

The accompanying unaudited condensed 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 (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") for quarterly reports on Form 10-QSB. The results of operations of Synergy are included in the condensed consolidated statement of operations for the six months ended June 30, 2004 and since May 1, 2003 in the period from June 5, 1996 (inception) to June 30, 2004 and for the six months ended June 30, 2003. (see note 3.) 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, 2003, included in Form 10-KSB filed with the SEC on April 14, 2004.

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.

### 2. Accounting for stock based compensation:

Callisto has adopted Statement of Financial Accounting Standard No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). 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 options or shares granted under the plans. Callisto has also adopted the disclosure provisions required by SFAS 123, as amended by SFAS 148, "Accounting for Stock-Based Compensation - Transition and Disclosure, an amendment to FASB Statement No. 123."

Had compensation cost for stock options granted 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 and net loss per share would have been as follows:

	Six Months Ended June 30,	
	2004	2003
	----	----
Net loss, as reported	\$ (3,737,710)	\$ (10,096,010)
Add: Stock-based employee compensation		

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expense recorded under APB No. 25	1,334,442	1,245,876
Deduct: stock-based employee compensation		
expense determined under fair value method	(2,041,916)	( 1,504,199)
	-----	-----
Pro forma net loss	\$ (4,445,184)	\$ (10,354,333)
	=====	=====
Net loss per share:		
Basic and diluted -as reported	\$ (0.13)	\$ (0.52)
	=====	=====
Basic and diluted -pro forma	\$ (0.16)	\$ (0.54)
	=====	=====

The fair value of the options granted to employees during 2004 and 2003 ranged from \$0.26 to \$5.53 on the date of the respective grant using the Black-Scholes option-pricing model. The following weighted average assumptions were used for 2004 and 2003: 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 rate ranged from 4.50% to 2.87% and an expected term of 7 to 10 years.

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### 3. 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 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. 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.

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 consummated in January 2004. 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.

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### 4. Net loss per share:

The assumed exercise of all of Callisto's outstanding stock options was excluded from the computation of net loss per share due to their anti-dilutive effect because of the net losses reported for the three and six months ended June 30, 2004 and 2003. 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 June 30, 2003.

### 5. Government Research Grant:

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 three and six months ended June 30, 2004, Callisto received \$47,962 and \$100,220 of grant funding, respectively, as reimbursement of expense and recorded the receipt as an offset to research and development expense. As of June 30, 2004 Callisto had unused grant funding available of \$165,477.

### 6. Stockholders' equity:

In January 2004, Callisto completed a private placement begun in late 2003 and issued 1,128,766 shares of common stock at an issue price of \$1.50 for aggregate proceeds of \$1,693,149, less \$139,891 in fees to various selling agents. In addition, Callisto incurred and 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.

During the three months ended March 31, 2004:

- a.) Callisto issued to Houston Pharmaceuticals, Inc. ("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.

During the three months ended June 30, 2004:

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.

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 grants, based on a Black-Scholes fair value

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of \$2.87 per share.

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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.

### 8. Commitments and contingencies:

#### License agreements:

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 six months ended June 30, 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.

On February 24, 2004, Callisto entered into an agreement with 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 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 6)

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

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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.

### Employment Agreements:

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.

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 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, based on the original intrinsic value, associated with the remaining 100,000 options of \$314,139, will be expensed over the vesting period of the new grant (e.g. April 7, 2004 through December 31, 2004).

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### Lease agreements:

On June 7, 2004 Callisto extended its lease for its corporate headquarters in New York City 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 quarter ended June 30, 2004.

### 7. Subsequent Event:

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 cash bonuses of up to \$92,500 over a 12 month period may be paid.

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and notes to those statements. 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 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 biopharmaceutical products, and do not expect to have such for several years, if at all.

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.

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2004 AND JUNE 30, 2003.

The results of operations of Synergy are included in the consolidated statement of operations for the full quarter ended June 30, 2004 but are only included from May 1, 2003 in the quarter ended June 30, 2003.

We had no revenues during the three 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 \$92,831, or 40%, to \$324,363 for the three months ended June 30, 2004 from \$231,532 for the same period in 2003. Of this increase in research and development expense, approximately \$37,000 was incurred in patient cost associated with the clinical trials of Atiprimod which began during the three months ended June 30, 2004,

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where none was incurred during the same period of 2003. Also contributing to higher research and development expense in the quarter ended June 30, 2004 was an increase of \$63,875 in payroll cost as we retained two Synergy executive staff scientists, Drs. Picker and Shailubhai, subsequent to the Merger.

Government grant funding for the three months ended June 30, 2004 was \$47,962 as compared to \$0 for the three 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 three months ended June 30, 2004 increased \$149,914, or 37%, to \$555,893, from \$405,979 for the three months ended June 30, 2003. The increase was due in part to approximately \$69,000 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. In addition we incurred approximately \$43,000 in higher outside board of directors fees associated with the cost of attracting outside directors to serve on our Board. Our common stock began to trade publicly on June 16, 2003. Also contributing to this increase in general and administrative expense were approximately \$34,000 in higher public relations costs during the quarter ended June 30, 2004 associated with news of Atiprimod clinical trial developments and our fund raising efforts.

We had no purchased in-process research and development for the three months ended June 30, 2004 whereas during the same period of 2003 we incurred \$6,833,454 in connection with the Merger.

Net loss for the three months ended June 30, 2004 was \$1,909,797 compared to a net loss of \$9,574,788 incurred for the three months ended June 30, 2003. This decrease in our net loss is primarily the result of \$6,833,454 in lower purchased in-process research and development and lower stock-based compensation expense of \$1,102,218 recorded during the three months ended June 30, 2004, as compared to \$2,106,636 of stock-based compensation expense recorded during the three months ended June 30, 2003, partially offset by higher operating expenses discussed above.

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SIX MONTHS ENDED JUNE 30, 2004 AND JUNE 30, 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 the Merger.



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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 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 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 Houston Pharmaceuticals, Inc ("HPI") a privately held company. 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 months ended June 30, 2003 we recorded \$6,833,454 of purchased in-process research and development expense in connection with the Merger.

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 cost, 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.

### 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.

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.

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 for aggregate proceeds of \$1,693,149, less \$139,891 in fees to various selling agents. In

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addition, we incurred and 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.

### CONTRACTUAL OBLIGATIONS:

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%. 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, 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 cash bonuses of up to \$92,500 may be paid over a 12 month period.

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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, 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.

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### ITEM 3. 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 June 30, 2004, 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.

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## PART II. OTHER INFORMATION

### Item 2. Changes in Securities and Use of Proceeds

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. The issuance of shares was done in accordance with Regulation D under the Securities Act of 1933, as amended. In connection therewith, a filing on Form D with the Securities and Exchange Commission was made on April 27, 2004. We intend to use the net proceeds from the sale of these shares for working capital and to further the clinical development of our lead drug candidate, Atiprimod and other drug candidates. 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.

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### Item 6. Exhibits and Reports on Form 8-K

#### (a) Exhibits

- 10.1 Amendment No. 2 to Employment Agreement dated July 22, 2004 by and between Callisto Pharmaceuticals, Inc. and Donald H. Picker.
- 10.2 Amendment No. 1 to License Agreement dated as of May 23, 2003, by and between Synergy Pharmaceuticals Inc, and AnorMED Inc.
- 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

#### (b) Reports on Form 8-K.

On April 19, 2004, we filed a Form 8-K announcing the completion of a private placement of 2,151,109 shares of common stock at an issue price of \$2.25 per share for aggregate gross proceeds of \$4,839,995.

On May 13, 2004 we filed a Form 8-K/A amending our Form 8-K filed on May 15, 2003 in order to amend our financial statements for the years ended December 31 2002 and 2001, filed under Items 7(a) and (b) in their entirety.

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SIGNATURES

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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.  
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(Registrant)

Date: July 27, 2004

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

Date: July 27, 2004

By: /s/ Bernard F. Denoyer  
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Bernard F. Denoyer  
Vice President, Finance