

CALLISTO PHARMACEUTICALS INC  
Form 10-Q  
August 08, 2005

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-Q**

(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, 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  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

420 Lexington Avenue, Suite 1609, New York, New York 10170  
(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.

Yes

No

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

Yes

No

As of August 8, 2005 the issuer had 31,238,893 shares of common stock outstanding.

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**CALLISTO PHARMACEUTICALS, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**

**FORM 10-Q**

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## 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-K/A 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**

ASSETS	June 30, 2005 (UNAUDITED)	December 31, 2004
Current assets:		
Cash and cash equivalents	\$ 3,278,765	\$ 5,323,384
Marketable investments	991,790	—
Prepaid expenses	136,317	45,231
	4,406,872	5,368,615
Property and equipment - net	8,712	18,856
Rent deposits	82,196	82,196
	\$ 4,497,780	\$ 5,469,667
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,475,069	\$ 984,486
Accrued expenses	215,799	235,803
	1,690,868	1,220,289
Stockholders' equity:		
Common stock, par value \$.0001, 75,000,000 shares authorized, 31,228,893 and 29,219,102 outstanding at June 30, 2005 and December 31, 2004, respectively	3,123	2,922
Additional paid-in capital	42,907,120	39,910,187
Unamortized deferred stock based compensation	(1,537,326)	(2,302,534)
Deficit accumulated during development stage	(38,566,005)	(33,361,197)
	2,806,912	4,249,378
	\$ 4,497,780	\$ 5,469,667

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)

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>		<b>June 5, 1996</b>
	<b>2005</b>	<b>2004</b>	<b>2005</b>	<b>2004</b>	<b>(Inception) to</b>
					<b>June 30, 2005</b>
Revenues	\$ —	\$ —	\$ —	\$ —	\$ —
Costs and expenses:					
Research and development	1,513,737	324,363	3,020,442	925,652	10,740,190
Government grant	—	(47,962)	—	(100,220)	(265,697)
Purchased in process research and development	—	—	—	209,735	6,944,553
Stock based compensation - research and development	69,063	881,371	138,126	1,066,892	2,080,901
General and administrative	779,021	555,893	1,473,297	1,074,233	10,085,543
Stock based compensation - general and administrative	287,136	220,847	630,814	598,702	10,039,311
Loss from operations	(2,648,957)	(1,934,512)	(5,262,679)	(3,774,994)	(39,624,801)
Interest and investment income	38,280	24,715	57,871	37,284	607,552
Other income	—	—	—	—	451,244
Net loss	\$ (2,610,677)	\$ (1,909,797)	\$ (5,204,808)	\$ (3,737,710)	\$ (38,566,005)
Weighted average shares outstanding:					
basic and diluted	31,228,893	28,749,608	30,490,517	27,767,221	—
Net loss per common share:					
basic and diluted	\$ (0.08)	\$ (0.07)	\$ (0.17)	\$ (0.13)	—

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	Common Stock, Par Value	Additional Paid in Capital
Balance at inception, June 5, 1996	—	—	—	—	—
Net loss for the period					
Issuance of founder shares	—	—	2,642,500	264	528
Common stock issued	—	—	1,356,194	136	272
Common stock issued via private placement	—	—	1,366,667	137	1,024,863
Balance, December 31, 1996	—	—	5,365,361	537	1,025,663
Net loss for the year	—	—	—	—	—
Common stock issued via private placement	—	—	1,442,666	144	1,081,855
Balance, December 31, 1997	—	—	6,808,027	681	2,107,518
Net loss for the year	—	—	—	—	—
Amortization of Stock based Compensation	—	—	—	—	52,778
Common stock issued via private placement	—	—	1,416,667	142	1,062,358
Common stock issued for services	—	—	788,889	79	591,588
Common stock repurchased and cancelled	—	—	(836,792)	(84)	(96,916)
Balance, December 31, 1998	—	—	8,176,791	818	3,717,326
Net loss for the year	—	—	—	—	—
Deferred Compensation - stock options	—	—	—	—	9,946
Amortization of Stock based Compensation	—	—	—	—	—
Common stock issued for services	—	—	—	—	3,168,832
Common stock issued via private placement	—	—	346,667	34	259,966
Balance, December 31, 1999	—	—	8,523,458	852	7,156,070
Net loss for the year	—	—	—	—	—
Amortization of Stock based Compensation	—	—	—	—	—
Common stock issued	—	—	4,560,237	455	250,889
Other	—	—	—	—	432
Preferred shares issued	3,485,299	348	—	—	5,986,302
Preferred stock issued for services	750,000	75	—	—	1,124,925



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Balance, December 31, 2000	4,235,299	423	13,083,695	1,307	14,518,618
Net loss for the year	—	—	—	—	—
Deferred Compensation - stock Options	—	—	—	—	20,000
Amortization of Stock based Compensation	—	—	—	—	—
Balance, December 31, 2001	4,235,299	423	13,083,695	1,307	14,538,618
Net loss for the year	—	—	—	—	—
Amortization of Stock based Compensation	—	—	—	—	—
Balance, December 31, 2002	4,235,299 \$	423	13,083,695 \$	1,307 \$	14,538,618

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**  
(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
<b>Balance, December 31, 1996</b>	—	(404,005)	622,195
Net loss for the year	—	(894,505)	(894,505)
Common stock issued via private placement	—	—	1,081,999
<b>Balance, December 31, 1997</b>	—	(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)
<b>Balance, December 31, 1998</b>	—	(2,782,948)	935,196
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
<b>Balance, December 31, 1999</b>	(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 issue	—	—	251,344
Other	—	—	432
Preferred shares issued	—	—	5,986,650
Preferred stock issued for services	—	—	1,125,000
<b>Balance, December 31, 2000</b>	(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 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 Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
	Preferred Stock	Par Value	Common Stock	Par Value				
Balance December 31, 2002	4,235,299	\$ 423	13,083,695	\$ 1,307	\$ 14,538,618		—(\$12,711,483)	\$ 1,828,865
Net loss for the year	—	—	—	—	—	—	(13,106,247)	(13,106,247)
Conversion of preferred stock in connection with the Merger	(4,235,299)	(423)	4,235,299	423	—	—	—	—
Common stock issued to former Synergy stockholders	—	—	4,329,927	432	6,494,458	—	—	6,494,890
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	—	3,833,946
Private placement of common stock, net	—	—	2,776,666	278	3,803,096	—	—	3,803,374
	—	—	25,928,760	2,590	34,149,975	(5,480,007)	(25,817,730)	2,854,828

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Balance, December 31, 2003								
Net loss for the period	—	—	—	—	—	—	(7,543,467)	(7,543,467)
Amortization of deferred Stock-based compensation expense	—	—	—	—	—	3,084,473	—	3,084,473
Variable accounting for stock options	—	—	—	—	(816,865)	—	—	(816,865)
Stock-based compensation net of forfeitures	—	—	—	—	240,572	93,000	—	333,572
Common stock issued via private placements, net	—	—	3,311,342	331	6,098,681	—	—	6,099,012
Warrant and stock-based compensation for services in connection with the Merger	—	—	—	—	269,826	—	—	269,826
Common stock returned from former Synergy stockholders	—	—	(90,000)	(9)	(159,083)	—	—	(159,092)
Stock issued for patent rights	—	—	25,000	3	56,247	—	—	56,250
Common stock issued for services	—	—	44,000	7	70,833	—	—	70,840
Balance, December 31, 2004	—	—	29,219,102	2,922	39,910,187	(2,302,534)	(33,361,197)	4,249,378
	—	—	—	—	—	—	(5,204,808)	(5,204,808)

Net loss for the period									
Amortization of deferred Stock-based compensation expense	—	—	—	—	—	765,208	—	—	765,208
Variable accounting for stock options	—	—	—	—	(112,941)	—	—	—	(112,941)
Stock-based compensation net of forfeitures	—	—	—	—	80,193	—	—	—	80,193
Common stock issued via private placement, net	—	—	1,985,791	199	2,993,203	—	—	—	2,993,402
Common stock issued for services	—	—	24,000	2	36,478	—	—	—	36,480
Balance, June 30, 2005	-\$	—	31,228,893	\$ 3,123	\$ 42,907,120	(\$1,537,326)	(\$38,566,005)	\$	2,806,812

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)

	Six months ended June 30,		Period from
	2005	2004	June 5, 1996 (inception) to June 30, 2005
Cash flows from operating activities:			
Net loss	\$ (5,204,808)	\$ (3,737,710)	\$ (38,566,005)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	10,144	13,816	75,925
Stock based compensation expense	768,940	1,665,594	12,120,212
Purchased in-process research and development (non-cash portion)	—	106,235	6,841,053
Amortization of purchase discount on marketable investments	(1,373)	—	(1,373)
Changes in operating assets and liabilities:			
Prepaid expenses	(91,086)	(49,122)	(136,317)
Security deposit	—	—	(82,196)
Accounts payable and accrued expenses	470,579	(784,890)	1,450,940
Total adjustments	1,157,202	951,633	20,268,244
Net cash used in operating activities	(4,047,604)	(2,786,077)	(18,297,761)
Cash flows from investing activities:			
Acquisition of equipment	—	—	(84,637)
Purchase of marketable investments	(990,417)	—	(990,417)
Net cash used in investing activities	(990,417)	—	(1,075,054)
Cash flows from financing activities:			
Net proceeds from issuance of common and preferred stock, net of repurchases			2,993,402
			6,099,012
			22,651,580
Net cash provided by financing activities			2,993,402
			6,099,012
			22,651,580
Net (decrease)increase in cash and cash equivalents			

)	(2,044,619
	3,312,935
	3,278,765
Cash and cash equivalents at beginning of period	
	5,323,384
	3,956,486
	—
Cash and cash equivalents at end of period	
\$	3,278,765
\$	7,269,421
\$	3,278,765
Supplementary disclosure of cash flow information:	
Cash paid for taxes	
\$	36,443
\$	2921
\$	99,405

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 June 30, 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-K/A filed with the SEC on June 6, 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 six months ended June 30, 2005 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2005.

**CASH, CASH EQUIVALENTS AND MARKETABLE INVESTMENTS**

Callisto considers all highly liquid debt instruments, including treasury bills, purchased with original maturities of three months or less to be cash equivalents

Marketable investments consisted of available-for-sale debt investments that are reported at fair market value. As of June 30, 2005 approximately \$991,790 was held in a US Treasury bill that had a maturity date of October 9, 2005. All treasury bills are purchased at a discount to face value, which discount is amortized until maturity, in accordance with Statement of Financial Accounting Standard ("SFAS") No. 115 "Accounting for Debt and Equity Securities". The amortization of purchase discount of \$1,373 on this investment was recorded as interest income in Callisto's results of operations for the six months ended June 30, 2005.

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.

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Had compensation cost for stock options granted to employees 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 June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net loss, as reported	\$ (2,610,676)	\$ (1,909,797)	\$ (5,204,808)	\$ (3,737,710)
Add: Stock-based employee compensation expense recorded under APB No. 25 intrinsic value method	330,404	1,020,679	652,268	1,334,442
Deduct: Stock-based employee compensation expense determined under fair value method	(600,125)	(1,557,530)	(1,185,403)	(2,041,916)
Pro forma net loss	\$ (2,880,397)	\$ (2,446,648)	\$ (5,737,943)	\$ (4,445,184)
Net loss per share:				
Basic and diluted -as reported	\$ (0.08)	\$ (0.07)	\$ (0.17)	(\$0.13)
Basic and diluted -pro forma	\$ (0.09)	\$ (0.09)	\$ (0.19)	(\$0.16)
Black-Scholes Methodology Assumptions:				
Dividend yield	0%	0%	0%	0% to 2.87%
Risk free interest rate	4.25%	4.0%	4.25%	4.0%
Expected lives of options	7 to 10 years	7 to 10 years	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 June 30, 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 June 30, 2005 and December 31, 2004 there were 7,875,710 and 7,322,060 total options outstanding, respectively. As of June 30, 2005 and December 31, 2004 there were 758,995 warrants outstanding.

### 4. Government Grants

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. Work on the NIAID superantigen grant started in early July 2005.

During 2004 Callisto had a research grant from the National Institutes of Health (NIH) for studies on Atiprimod. This amount totaled \$100,220 during the six months ended June 30, 2004 and has been reported on our Condensed Consolidated Statements of Operations as a separate line item entitled "Government Grant". The work under the NIH grant was completed in the fourth quarter of 2004 and Callisto received no further funding during the six months ended June 30, 2005. Callisto requests cash funding under approved grants only as expenses are incurred.

5. Stockholders' equity:

On March 9, 2005 Callisto 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 management Callisto paid no selling agent fees and legal fees were \$25,000.

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 which is scheduled for October 20, 2005.

## 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.

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

On June 9, 2005, Callisto entered into Extension and Severance Compensation Agreements (the "Agreements") with each of Gary S. Jacob, Callisto's Chief Executive Officer and Donald H. Picker, Callisto's Executive Vice President, R&D (collectively, the "Executives"). The Agreements extend the term of the employment agreement for each of the Executives to June 13, 2007.

Each of the Agreements provide that in the event there is a change of control of Callisto and the Executive's employment by Callisto shall have been terminated within two years after a change in control by him for good reason or by Callisto and such termination did not occur as a result of (i) the Executive's death, (ii) the Executive's disability, (iii) the Executive's retirement or (iv) the Executive's termination for cause, the Executive shall be entitled to an amount equal to the compensation due to the Executive for the Employment Term under the Executive's Employment Agreement for the time remaining of such Employment Term. In addition, all of the Executive's unvested stock options shall immediately and irrevocably 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.

7. Subsequent events:

On July 18, 2005, Callisto entered into a letter of engagement (the "Agreement") with Trilogy Capital Partners, Inc. ("Trilogy"). The term of the Agreement is for twelve months beginning on July 18, 2005 and terminable thereafter by either party upon 30 days' prior written notice. Pursuant to the Agreement, Trilogy will provide marketing and financial public relations services to the Company and will assume the responsibilities of an investor relations officer for Callisto. Callisto will pay Trilogy \$12,500 per month under the Agreement.

Pursuant to the Agreement, Callisto issued warrants to Trilogy to purchase 1,793,322 shares of Common Stock of Callisto at an exercise price of \$1.03 per share (the "Warrants"). The exercise price of \$1.03 was determined by calculating the average of the closing sales price of Callisto's Common Stock on the American Stock Exchange over the 15 trading days preceding the date of the Agreement. The Warrants issued to Trilogy are exercisable upon issuance and expire on July 18, 2008. Callisto has agreed to file by August 30, 2005 a registration statement with the Securities and Exchange Commission registering for resale the shares of Common Stock underlying the Warrants. The Fair Value of the Warrants using the Black-Scholes methodology is approximately \$1,679,000 which will be recorded as stock-based compensation expense over the term of the Agreement starting in the quarter ended September 30, 2005.

## **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 June 30, 2005, we have sustained cumulative net losses of \$38,566,005. 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 June 30, 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 the third quarter of 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 the third quarter of 2005 will include an initial evaluation of a small number of 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 the second half of 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 six months ended June 30, 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 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 to make a decision on moving this drug forward into the clinic.

### **SUPERANTIGEN-BASED BIOTERRORISM 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 sub licensees. 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 they 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 July 22, 2005, we had 7 full-time and 2 part-time employees.

## **OFF-BALANCE SHEET ARRANGEMENTS**

We had no off-balance sheet arrangements as of June 30, 2005.

## **RESULTS OF OPERATIONS**

### **THREE MONTHS ENDED JUNE 30, 2005 AND JUNE 30, 2004**

We had no revenues during the three months ended June 30, 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 \$1,189,374, or 367%, to \$1,513,737 for the three months ended June 30, 2005 from \$324,363 for the three months ended June 30, 2004. The most significant factor contributing to this increase in research and development expense were direct out of pocket expenditures of approximately \$1,014,000 related to the preparation of our Annamycin drug candidate to re-enter human clinical trials during the third quarter of 2005. We acquired the rights to Annamycin in August of 2004 and therefore had no expenditures during the three months ended June 30, 2004 related to this drug candidate. During the three months ended June 30, 2005 our out of pocket expenditures related to Atiprimod totaled approximately \$369,000 as compared to the period ended June 30, 2004 when we incurred approximately \$132,000 for the start-up of the clinical trials of our Atiprimod drug candidate.

Government grant funding for the three months ended June 30, 2005 was \$0 as compared to \$47,962 from the National Institute of Health (“NIH”) grant during the three months ended June 30, 2004. On April 1, 2005 we 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. Work on the NIAID grant was started in July 2005. We request grant funding to reimburse research and development expenses only as incurred.

Stock-based compensation – research and development recorded during the three months ended June 30, 2005 totaled \$69,063 as compared to \$881,371 recorded during the three months ended June 30, 2004. The higher stock-based compensation in 2004 is attributable to the restructuring of Dr. Kunwar M. Shailubhai’s employment with us. On April 6, 2004, Dr. Shailubhai's previous employment agreement was terminated and he entered into a new employment agreement with Synergy in which he agreed to serve as Senior Vice President, Drug Discovery. Dr. Shailubhai's unvested options totaling 325,000 shares, granted June 13, 2003 in connection with his previous employment agreement, were cancelled and Dr. Shailubhai received a new grant of 100,000 stock options. 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.

General and administrative expenses for the three months ended June 30, 2005 were \$779,021, an increase of \$223,128 or 40%, from \$555,893 for the three months ended June 30, 2004. The increase was due primarily to approximately (i) \$75,000 of increased consulting fees related to our Chairman becoming a consultant and the addition of a financial advisory consultant, (ii) \$50,000 in higher outside services of which \$43,000 was for our American Stock Exchange Listing fee, (iii) \$30,000 of increased recruiting and relocation expenses related to the hiring of clinical and regulatory personnel and management, and (iv) \$22,000 in higher SEC legal fees associated with filing our registration statements and responding to SEC comments.

Stock-based compensation – general and administrative recorded during the three months ended June 30, 2005 totaled \$287,136 as compared to \$220,847 recorded during the three months ended June 30, 2004. This increase was primarily attributable to a decline in our stock price during the three months ended June 30, 2004 from \$3.40 as of April 1, 2004 to \$2.00 per share as of June 30, 2004. This share price decrease resulted in the recapture during 2004 of

stock based compensation expense recorded on certain variable options granted to non-employees during 2003. This recapture of variable stock based compensation expense occurred to a much lesser extent during the three months ended June 30, 2005 as our stock price declined less severely from \$1.50 per share as of April 1, 2005 to \$1.03 per share as of June 30, 2005.

Net loss for the three months ended June 30, 2005 was \$2,610,677 compared to a net loss of \$1,909,797 incurred for the three months ended June 30, 2004. The increased net loss is primarily the result of higher research and development, and general and administrative expenses, offset by lower stock based compensation expense - research and development as discussed above.

## **SIX MONTHS ENDED JUNE 30, 2005 AND JUNE 30, 2004**

We had no revenues during the six months ended June 30, 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 of \$3,020,442 for the six months ended June 30, 2005 were \$2,094,790, or 226%, higher than the \$925,652 we incurred for the six months ended June 30, 2004. During the six months ended June 30, 2005 we accelerated out of pocket expenditures to contract research organizations (“CROs”) for clinical protocol development consultants, drug substance formulation and tabletizing, data monitoring, blood testing, and drug dosing at our clinical trial sites, for our two major drug candidates, Annamycin and Atiprimod. The most significant portion contributing to this increase in research and development expense were CRO expenditures of approximately \$1,493,000 related to the preparation of our Annamycin drug candidate to re-enter human clinical trials during the third quarter of 2005. We acquired the rights to Annamycin in August of 2004 and therefore had no expenditures during the six months ended June 30, 2004 related to this drug candidate. During the six month period ended June 30, 2004 we incurred approximately \$204,000 in out of pocket CRO costs associated with our Atiprimod clinical trials, which began in May of 2004. During the six months ended June 30, 2005 we incurred approximately \$617,000 in CRO costs for our Atiprimod Phase I/IIa clinical trials.

Government grant funding for the six months ended June 30, 2005 was \$0 as compared to \$100,220 for the six months ended June 30, 2004.

Stock based compensation expense - research and development was \$138,126 during the six months ended June 30, 2005, as compared to \$1,066,892 recorded during the six months ended June 30, 2004. The higher stock-based compensation in 2004 is attributable to the restructuring of Dr. Kunwar Shailubhai’s compensation arrangement with us. On April 6, 2004, Dr. Shailubhai's previous employment agreement with us was terminated and he entered into a new 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. His unvested options for 325,000 shares, granted June 13, 2003 in connection with his previous employment agreement, were cancelled and Dr. Shailubhai received a new grant of 100,000 stock options. 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.

General and administrative expenses for the six months ended June 30, 2005 were \$1,473,297, an increase of \$399,064 or 37%, from \$1,074,233 for the six months ended June 30, 2004. The increase was due primarily to approximately (i) \$153,000 of increased consulting fees related to our Chairman becoming a consultant and the addition of a financial advisory consultant, (ii) \$67,000 in higher outside services of which \$43,000 was for our American Stock Exchange Listing fee and the balance associated with higher financial printing cost, (iii) \$85,000 of increased recruiting and relocation expenses related to the hiring of clinical and regulatory personnel and management, and (iv) \$27,000 in higher SEC legal fees associated with filing our registration statements and responding to SEC comments.

Stock-based compensation – general and administrative recorded during the six months ended June 30, 2005 totaled \$630,814 as compared to \$598,702 recorded during the six months ended June 30, 2004. This increase was primarily attributable to a decline in our stock price during the six months ended June 30, 2004 from \$3.95 as of January 1, 2004 to \$2.00 per share as of June 30, 2004. This share price decrease resulted in the recapture during 2004 of stock based compensation expense recorded on certain variable options granted to non-employees during 2003. This recapture of variable stock based compensation expense occurred to a lesser extent during the six month ended June 30, 2005 as our stock price decline from \$1.98 per share as of January 1, 2005 to \$1.03 per share as of June 30, 2005.

Purchased in-process research and development was \$0 for the six months ended June 30, 2005, as compared to \$209,735 for the six months ended June 30, 2004 which was primarily 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 six months ended June 30, 2005 was \$5,204,808 compared to a net loss of \$3,737,710 incurred for the six months ended June 30, 2004. The increased net loss is primarily the result of higher research and development, and general and administrative expenses, partially offset by lower stock based compensation expense - research and development as discussed above.



## LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2005 we had \$4,270,555 in cash, cash equivalents and marketable investments, compared to cash and cash equivalents of \$5,323,384 as of December 31, 2004. This decrease of \$1,052,829 during the six months ended June 30, 2005 was principally the result of cash used in operating activities of \$4,047,604 during the six months ended June 30, 2005. This was partially offset by completing a private placement of common stock yielding net proceeds of \$2,993,402.

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 during the quarter ended June 30, 2005.

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. Funding of this new grant will begin in July 2005 when work was started.

On July 18, 2005, Callisto entered into a letter of engagement (the "Agreement") with Trilogy Capital Partners, Inc. ("Trilogy"). The term of the Agreement is for twelve months beginning on July 18, 2005 and terminable thereafter by either party upon 30 days' prior written notice. Pursuant to the Agreement, Trilogy will provide marketing and financial public relations services to the Company and will assume the responsibilities of an investor relations officer for Callisto. Callisto will pay Trilogy \$12,500 per month under the Agreement.

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

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 will be required to raise additional capital within the next twelve months in order to complete the development and commercialization of our current product candidates and to continue to fund operations at the current cash expenditure levels.

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 June 30, 2005 stock based compensation expense totaled \$12,120,212 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.

**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.

## **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 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.

In December 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 153 ("SFAS No. 153"), "Exchanges of Non-monetary Assets an amendment of APB Opinion No. 29". SFAS No. 153 amends Opinion 29 to eliminate the exception for non-monetary exchanges of similar productive assets and replaces it with a general exception for exchanges of non-monetary assets that do not have commercial substance. A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for fiscal periods after June 15, 2005. We do not expect the adoption of SFAS No. 153 to have a material impact on our consolidated financial statements.

In June 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections," which changes the requirements for accounting for and reporting of a change in accounting principle. SFAS No. 154 requires retrospective application to prior periods' financial statements of a voluntary change in accounting principle unless it is impracticable. SFAS No. 154 also requires that a change in method of depreciation, amortization, or depletion for long-lived, nonfinancial assets be accounted for as a change in accounting estimate that is effected by a change in accounting principle. SFAS No. 154 is effective for accounting changes and a correction of errors made in fiscal years beginning after December 15, 2005, but does not change the transition provisions of any existing accounting pronouncements, including those that are in a transition phase as of the effective date of SFAS No. 154. The adoption of SFAS No. 154 will not have a material effect on our results of operations or our financial position.

#### **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 June 30, 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.
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**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: August 8, 2005

By: /s/ Gary S. Jacob

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Gary S. Jacob  
Chief Executive Officer

Date: August 8, 2005

By: /s/ Bernard F. Denoyer

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Bernard F. Denoyer  
Vice President, Finance

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