

CALLISTO PHARMACEUTICALS INC
Form 10-Q
May 22, 2006

UNITED STATES OF AMERICA

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: MARCH 31, 2006

**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.)

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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 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 the past 90 days.

Yes No

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

Large accelerated Filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

The number of the registrant's shares of common stock outstanding was 37,808,316 as of May 15, 2006.

CALLISTO PHARMACEUTICALS, INC.

FORM 10-Q

CONTENTS

PART I FINANCIAL INFORMATION

<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements</u>	
	<u>Condensed Consolidated Balance Sheets</u> <u>as of March 31, 2006 (unaudited) and December 31, 2005</u>	<u>1</u>
	<u>Condensed Consolidated Statements of Operations</u> <u>for the Three Months Ended March 31, 2006 and 2005 (unaudited)</u> <u>and the period June 5, 1996 (Inception) to March 31, 2006 (unaudited)</u>	<u>2</u>
	<u>Condensed Consolidated Statements of Changes in Stockholders' Equity</u> <u>for the period June 5, 1996 (Inception) to March 31, 2006 (unaudited)</u>	<u>3</u>
	<u>Condensed Consolidated Statements of Cash Flows</u> <u>for the Three Months Ended March 31, 2006 and 2005 (unaudited)</u> <u>and for the period June 5, 1996 (Inception) to March 31, 2006 (unaudited)</u>	<u>9</u>
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>10</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>14</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>21</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>	<u>21</u>

PART II OTHER INFORMATION

<u>Item 1A.</u>	<u>Risk Factors</u>	<u>22</u>
<u>Item 2.</u>	<u>Unregistered sales of Equity Securities and Use of Proceeds</u>	<u>22</u>
<u>Item 5.</u>	<u>Exhibits</u>	<u>22</u>
<u>Signatures</u>		

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 control and 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, 2005 and other periodic reports filed with the SEC. Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of the Company, please be advised that Callisto's actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements.

PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

CALLISTO PHARMACEUTICALS, INC.

(A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2006 (Unaudited)	December 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,790,502	\$ 1,420,510
Prepaid expenses	86,745	181,284
	2,877,247	1,601,794
Property and equipment net	8,602	
Rent deposits	64,716	82,196
	\$ 2,950,565	\$ 1,683,990
Liabilities and Stockholders Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 1,192,196	1,424,612
Accrued expenses	716,554	592,297
	1,908,750	2,016,909
Stockholders equity:		
Common stock, par value \$.0001, 100,000,000 shares authorized, 37,713,264 and 33,233,096 outstanding at March 31, 2006 and December 31, 2005, respectively	3,770	3,323
Additional paid-in capital	50,553,327	46,387,875
Unamortized deferred stock-based compensation		(1,583,463)
Deficit accumulated during development stage	(49,515,282)	(45,140,654)
	1,041,815	(332,919)
	\$ 2,950,565	\$ 1,683,990

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

CALLISTO PHARMACEUTICALS, INC.

(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended March 31,		For the Period
	2006	2005	From June 5, 1996 (inception) to March 31, 2006
Revenues	\$	\$	\$
Costs and Expenses:			
Research and development	2,193,840	1,575,769	18,199,702
Government grant	(54,267)		(546,083)
Purchased in-process research and development			6,944,553
General and administrative	1,754,090	1,007,816	17,394,954
Stock based compensation non employees general and administrative	504,047	30,137	8,828,617
Loss from operations	(4,397,710)	(2,613,722)	(50,821,743)
Interest income	23,082	19,591	678,066
Other income			628,395
Net loss	\$ (4,374,628)	\$ (2,594,131)	\$ (49,515,282)
Weighted average number of common shares outstanding:			
Basic and diluted	35,978,019	29,743,937	
Net loss per common share: basic and diluted	\$ (0.12)	\$ (0.09)	

See accompanying notes to condensed consolidated financial statements.

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)

	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
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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

	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
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 issue			251,344
Other			432
Preferred shares 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 condensed consolidated financial statements

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

	Preferred Stock	Preferred Stock Par Value	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders Equity
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
Balance, December 31, 2003	\$	\$	25,928,760	\$ 2,590	\$ 34,149,975	\$ (5,480,007)	\$ (25,817,730)	\$ 2,854,828

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

	Preferred Stock	Preferred Stock Par Value	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders Equity
Balance, December 31, 2003		\$	25,928,760	\$ 2,590	\$ 34,149,975	\$ (5,480,007)	\$ (25,817,730)	\$ 2,854,828
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

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders Equity (Deficit)
Balance, December 31, 2004	29,219,102	\$ 2,922	\$ 39,910,187	\$ (2,302,534)	\$ (33,361,197)	\$ 4,249,378
Net loss for the year					(11,779,457)	(11,779,457)
Deferred stock-based compensation - new grants			1,571,772	(1,571,772)		
Amortization of deferred stock-based compensation				2,290,843		2,290,843
Variable accounting for stock options			75,109			75,109
Common stock issued via private placement:						
March 2005	1,985,791	198	3,018,203			3,018,401
August 2005	1,869,203	187	1,812,940			1,813,127
Finders fees and expenses			(176,250)			(176,250)
Exercise of common stock warrant	125,000	13	128,737			128,750
Common stock issued for services	34,000	3	47,177			47,180
Balance, December 31, 2005	33,233,096	\$ 3,323	\$ 46,387,875	\$ (1,583,463)	\$ (45,140,654)	\$ (332,919)

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders Equity (Deficit)
Balance, December 31, 2005	33,233,096	\$ 3,323	\$ 46,387,875	\$ (1,583,463)	\$ (45,140,654)	\$ (332,919)
Net loss for the quarter ended March 31, 2006					(4,374,628)	(4,374,628)
Amortization and reclassification of deferred stock-based compensation			(675,057)	1,583,463		908,406
Variable accounting for stock options			54,159			54,159
Common stock issued via private placement:						
February 2006	4,283,668	428	5,139,782			5,140,210
Finders fees and expenses			(561,808)			(561,808)
Exercise of common stock warrant	184,500	18	190,017			190,035
Common stock issued for services	12,000	1	18,359			18,360
Balance, March 31, 2006	37,713,264	\$ 3,770	\$ 50,553,327		\$ (49,515,282)	\$ 1,041,815

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

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three months Ended March 31,		Period from
	2006	2005	June 5, 1996 (inception) to March 31, 2006
Cash flows from operating activities:			
Net loss	\$ (4,374,628)	\$ (2,594,131)	\$ (49,515,282)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation		5,072	84,637
Stock based compensation expense	994,050	412,741	14,765,017
Purchased in-process research and development (non-cash portion)			6,841,053
Changes in operating assets and liabilities:			
Prepaid expenses	81,415	1,090	(106,433)
Rent deposits	17,480		(64,716)
Accounts payable and accrued expenses	(108,160)	611,026	1,668,822
Total adjustments	984,785	1,029,929	23,188,380
Net cash used in operating activities	(3,389,843)	(1,564,202)	(26,326,902)
Cash flows from investing activities:			
Acquisition of equipment	(8,602)		(93,239)
Net cash used in investing activities	(8,602)		(93,239)
Cash flows from financing activities:			
Issuance of common and preferred stock, net of repurchases	5,140,210	3,018,401	30,425,673
Finders fees and expenses	(561,808)	(25,000)	(1,533,815)
Exercise of common stock warrants	190,035		318,785
Net cash provided by financing activities	4,768,437	2,993,401	29,210,643
Net increase in cash and cash equivalents	1,369,992	1,429,199	2,790,502
Cash and cash equivalents at beginning of period			
	1,420,510	5,323,384	
Cash and cash equivalents at end of period	\$ 2,790,502	\$ 6,752,583	\$ 2,790,502
Supplementary disclosure of cash flow information:			
Cash paid for taxes	\$ 12,146	\$ 27,800	\$ 121,753
Cash paid for interest	\$	\$	\$

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

CALLISTO PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. 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 condensed consolidated financial statements since May 1, 2003. All intercompany balances and transactions have been eliminated and certain expense items in prior periods have been reclassified to conform to current financial statement presentation. 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, 2005, included in Form 10-K/A filed with the SEC on April 18, 2006. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, primarily consisting of normal adjustments, necessary for the fair presentation of the balance sheet and results of operations for the interim periods. The results of operations for the three months ended March 31, 2006 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2006.

The audited financial statements and notes thereto for the year ended December 31, 2005, included in Form 10-K/A filed with the SEC on April 18, 2006, have been prepared under the assumption that Callisto will continue as a going concern for the twelve months ending December 31, 2006. Callisto's independent registered public accounting firm has issued a report dated March 29, 2006 that included an explanatory paragraph referring to recurring losses from operations and expressing substantial doubt in Callisto's ability to continue as a going concern without additional capital becoming available. The financial statements do not include any adjustments that might result from the unfavorable outcome of this uncertainty. Callisto will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at our current cash expenditure levels.

2. Accounting for stock based compensation

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard (SFAS) No. 123 (Revised 2004), *Share-Based Payments* (SFAS 123R). SFAS 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 expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005 and accordingly Callisto adopted this standard on January 1, 2006.

For all awards granted prior to January 1, 2006, the unearned deferred fair value of stock based compensation will be recognized as an expense on a straight line basis over the remaining requisite service period, ranging from six months to three years. Our financial results for prior periods have not been restated. The adoption of SFAS 123R increased net loss for the three months ended March 31, 2006 by approximately \$107,000

for stock based compensation cost related to employee stock options. The unrecognized compensation cost related to non-vested share-based compensation arrangements for all employee stock options outstanding at March 31, 2006, as measured at the date of grant, was approximately \$1,652,000.

Effective with the adoption of SFAS 123R stock-based compensation expense related to Callisto's share-based compensation arrangements attributable to employees is being recorded as a component of general and administrative expense and research and development expense in accordance with the guidance of Staff Accounting Bulletin 107, Topic 14, paragraph F. *Classification of Compensation Expense Associated with Share-Based Payment Arrangements* (SAB 107). Prior period financial statement accounts have been reclassified to conform to this presentation. Stock based compensation cost related to employee stock options recognized in the operating results for the three months ended March 31, 2006, March 31, 2005 and for the period from June 6, 1996 (inception, through March 31, 2006 included approximately \$341,000, \$314,000 and \$3,656,000 in general and administrative expenses and approximately \$149,000, \$69,000 and \$2,280,000 included in the research and development expenses, respectively. For the three months ended March 31, 2006, March 31, 2005 and for the period from June 6, 1996 (inception) through March 31, 2006, Callisto recognized approximately \$504,000, \$30,000 and \$8,800,000 respectively of non-employee share-based compensation expense.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

The estimated fair value of each employee option award granted was determined in accordance with SFAS 123R on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for option granted during the three months ended March 31, 2006 and 2005:

	Employee options granted during the three months ended March 31,	
	2006	2005
Risk free interest rate	4.25%	4.25%
Dividend yield	0.0%	0.0%
Volatility	79%	79%
Expected Life	3 to 7 years	7 years

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of Callisto's employee stock options. The expected volatility is based on the historical volatility of Callisto's stock. The Company has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future. The computation of the expected option term is based on expectations regarding future exercises of options which generally vest over 3 years and have a 10 year life.

SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Based on historical Company experience Callisto estimated future unvested option forfeitures at 20% as of January 1, 2006 and incorporated this rate in estimated fair value of employee option grants.

Callisto's determination of fair value is affected by Callisto's stock price as well as the assumptions discussed above that require judgment. The weighted-average fair value of all options granted during the three months ended March 31, 2006, estimated as of the grant date using the Black-Scholes option valuation model, was \$1.19 per share. A summary of the status of Callisto's stock option plans as of March 31, 2006 and of changes in options outstanding under Callisto's plans during the three months ended March 31, 2006 is as follows:

	Number of Shares	Weighted Average Price Per Share
Outstanding at January 1, 2006	8,008,210	\$ 1.79
Granted	850,000	1.57
Exercised		
Terminated	(350,000)	1.32
Outstanding at March 31, 2006	8,508,210	\$ 1.79
Options exercisable at March 31, 2006	4,370,052	\$ 1.62

The weighted average remaining term of all options outstanding decreased from 7.4 years at December 31, 2005 to 7.3 years at March 31, 2006. At March 31, 2006 Callisto had 850,000 stock options outstanding under the 2005 Equity Plan, 52,500 stock options outstanding under the 2005 Director's Plan and 7,605,710 stock options outstanding under the 1996 Plan.

SFAS 123R requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to Callisto's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Prior to January 1, 2006, Callisto had adopted Statement of Financial Accounting Standard (SFAS) No. 123, Accounting for Stock-Based Compensation. As provided for by SFAS 123, Callisto had 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 had been recognized to the extent of employee or director services rendered based on the intrinsic value of stock options granted under the plan. Callisto accounts for common stock, stock options, and warrants granted to non-employees based on the fair market value of the instrument, using the Black-Scholes option pricing model based on assumptions for expected stock price volatility, term of the option, risk-free interest rate and expected dividend yield at the grant date.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Had compensation cost for stock options granted to employees and directors prior to January 1, 2006 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 for the three months ended March 31, 2005 would have been as follows:

	Three months ended March 31, 2005
Net loss, as reported	\$ (2,594,131)
Add: Stock-based employee compensation expense recorded under APB No. 25 intrinsic value method	382,604
Deduct: Stock-based employee compensation expense determined under fair value based method	(584,440)
Pro forma net loss	\$ (2,795,967)
Net loss per share:	
Basic and diluted -as reported	\$ (0.09)
Basic and diluted -pro forma	\$ (0.09)

3. Net Loss per Share

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, Earnings per Share, for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares since the inclusion of issuable shares pursuant to the exercise of stock options and warrants, would have been antidilutive. As of March 31, 2006 there were 3,844,018 warrants outstanding and 8,508,210 total vested and unvested options outstanding.

4. Government Grants

Callisto requests cash funding under approved grants as expenses are incurred (not in advance) and records the receipt as an offset to research and development expense. On April 1, 2005 Callisto received a research grant for work on a biodefense program from the National Institute of Allergy and Infectious Diseases to develop a monoclonal antibody and vaccine against bacterial superantigen toxins under our August 20, 1996 license with Rockefeller University. This amount totaled \$54,267 during the three months ended March 31, 2006 and has been reported on our Condensed Consolidated Statements of Operations as a separate line item entitled Government Grant.

5. Stockholders' equity:

On February 3, 2006, Callisto closed on a private placement of 4,283,668 shares of common stock and 1,070,917 common stock purchase warrants to certain accredited investors. The warrants are exercisable for 18 months from closing at an exercise price of \$1.60 per share. The securities were sold at a price of \$1.20 per share for aggregate gross proceeds of approximately \$5.14 million. Net proceeds, after fees and

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

expenses, were \$4.58 million. As provided for by Emerging Issues Task Force Issue 00-19: *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* (EITF 00-19) the warrants will be classified as permanent equity. The fair value of the investor warrants on February 3, 2006, the date of grant was \$662,680 using Black Scholes assumptions of 79% volatility, a risk free interest rate of 4.25%, no dividend, an expected life of 18 months and a stock price on that date of \$1.59 per share. This fair value allocated to the investor warrants was recorded as additional paid in capital during the quarter ended March 31, 2006.

On April 7, 2006 Callisto had a second closing of the financing described above, in which we sold an additional 666,667 shares of common stock and issued 166,667 common stock purchase warrants at the same terms, for gross proceeds of \$800,000, bringing the total gross proceeds of the financing to \$5.94 million and net proceeds to \$5.38 million. No placement agent fees or legal fees were incurred on this second closing however three year warrants to purchase a total of 66,667 common shares at a per share price of \$1.25 were issued to several selling agents.

Callisto agreed to file, within 60 days after the first closing, a registration statement covering the resale of the shares of common stock and the shares underlying the warrants, and to use its commercially reasonable efforts to cause such registration statement to be declared effective within 120 days after closing or pay financial penalties to the investors in the event a registration statement is not filed or declared effective within such time period. Callisto has not yet filed a registration statement within the 60-day time period and is incurring financial penalties of \$51,404 for every 30-day period that a registration statement has not been filed. As of May 22, 2006 Callisto has incurred \$83,960 for financial penalties related to the registration rights agreement.

6. Commitments and contingencies:

Licensing agreements:

On January 10, 2006, Callisto entered into a Patent and Technology License Agreement with The University of Texas M.D. Anderson Cancer Center. Pursuant to the license agreement, Callisto was granted the exclusive right to manufacture, have manufactured, use, import, offer to sell and/or sell anti-cancer compounds called tyrophostins (renamed Degrasyns). Callisto paid a nonrefundable fee upon execution of this agreement and is obligated to pay annual license maintenance fees to The University of Texas M.D. Anderson Cancer Center. Callisto is also obligated under this agreement to pay for the legal fees and expenses associated with establishing and protecting the patent rights worldwide.

Callisto 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 \$1,750,000 based upon achieving certain regulatory submissions and approvals. The term of the agreement is from January 10, 2006 until the end of the term for which the patent rights associated with the licensed technology have expired. If the first pending patent is issued, the agreement is projected to expire in 2025. In addition, at any time after two years from January 10, 2006, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if Callisto fails to provide evidence within 90 days of written notice that it has commercialized or is actively and effectively attempting to commercialize the licensed technology.

Employment and consulting agreements:

On January 31, 2006, Callisto entered into a consulting agreement with Dr. Moshe Talpaz, whereby Dr. Talpaz will provide consulting services for Callisto's Degrasyns program. Under the agreement Dr. Talpaz will be paid \$10,000 per year and was granted 575,000 10-year options to purchase Callisto common stock at \$1.60 per share. Such options vest based on milestones related to the Degrasyns compounds being developed towards FDA approval. Callisto also agreed to issue to Dr. Talpaz 75,000 shares of restricted common stock, subject to shareholder approval. The term of the agreement is for the length of time Callisto is developing the Degrasyns platform of compounds in all indications.

On February 17, 2006, Pamela Harris, the Chief Medical Officer of Callisto, resigned from the Company. As a result the employment agreement between Dr. Harris and Callisto dated as of March 28, 2005, as amended, was terminated.

On March 23, 2006, Callisto entered into a 2-year sponsored laboratory study agreement with the University of Texas M. D. Anderson Cancer Center whereby Dr. Nicholas Donato, as principal investigator, will analyze the anti-tumor activity and mechanism of action of Callisto's WP1130 Degrasyn compound and analogs. The agreement calls for payment of \$145,900 to M.D. Anderson in two installments of \$72,950.00 with the first payment due within 30 days, and the second payment due within six months of execution.

On March 27, 2006, Callisto entered into a 2-year sponsored laboratory study agreement with the University of Texas M. D. Anderson Cancer Center whereby Dr. William Bornmann, as principal investigator, will perform molecular modeling and synthesize a library of compounds based on Callisto's Degrasyn platform technology. The agreement calls for payment of \$127,145 to M.D. Anderson in two installments of \$63,572.50 with the first payment due within 30 days, and the second payment due within six months of execution.

7. Subsequent events:

On April 18, 2006 Callisto filed a Definitive Proxy Statement with the SEC to call a special shareholder meeting for shareholders to vote to approve the potential issuance of up to 20,000,000 shares (or up to \$30,000,000) of our common stock, \$.0001 par value (or securities convertible into or exercisable for common stock) at a price below fair market value and to consider the approval of the issuance of 75,000 shares of our restricted common stock to Dr. Moshe Talpaz pursuant to a consulting agreement between us and Dr. Talpaz.

On May 18, 2006 Callisto held a special shareholder meeting and approved (i) the potential issuance and sale of up to 20,000,000 shares of Callisto common stock (or securities convertible into or exercisable for common stock) at a price below fair market value for aggregate gross proceeds of up to \$30,000,000 and (ii) the issuance of 75,000 shares of Callisto's restricted common stock to Dr. Moshe Talpaz pursuant to a consulting agreement between Callisto and Dr. Talpaz.

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

The following discussion should be read in conjunction with our condensed consolidated 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

Since inception in June 1996 our efforts have been principally devoted to research and development, securing patent protection, obtaining corporate relationships and raising capital. Since inception through March 31, 2006, we have sustained cumulative net losses of \$49,515,282. Our losses have resulted primarily from expenditures incurred in connection with clinical development of licensed products, the purchase of in-process research and development, stock based compensation expense, patent filing and maintenance, outside accounting and legal services and regulatory consulting fees.

From inception through March 31, 2006 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.

On February 3, 2006, we closed on a private placement of 4,283,668 shares of common stock and 1,070,917 common stock purchase warrants to certain accredited investors. The warrants are exercisable for 18 months from closing at an exercise price of \$1.60 per share. The securities were sold at a price of \$1.20 per share for aggregate gross proceeds of approximately \$5.14 million. The net proceeds, after fees and expenses, were \$4.58 million.

On April 7, 2006 we had a second closing of the financing described above, in which we sold an additional 666,667 shares of common stock and issued 166,667 common stock purchase warrants at the same terms, for gross proceeds of \$800,000, bringing the total gross proceeds of the financing to \$5.94 million and net proceeds to \$5.38 million. No placement agent fees or legal fees were incurred on this second closing however three year warrants to purchase a total of 66,667 common shares at a per share price of \$1.25 were issued to several selling agents.

HISTORY

In March 2002, Callisto Pharmaceuticals, Inc. (Old Callisto), a non-public company, 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 at December 31, 2002.

On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Synergy Pharmaceuticals Inc. (Synergy) and Callisto Acquisition Corp., a wholly-owned

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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 the Merger Webtronics issued 17,318,994 shares of its common stock in exchange for outstanding Old Callisto common stock and an additional 4,395,684 shares in exchange for outstanding Synergy common stock. Old Callisto changed its name to Callisto Research Labs, LLC (Callisto Research) and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware. Subsequently, 171,818 shares of common stock issued to former Synergy shareholders were returned to us under the terms of certain indemnification agreements.

PLAN OF OPERATIONS

Our plan of operations for the next twelve months is to focus primarily on the development of drugs to treat relapsed (re-occurrence of active disease) or refractory acute leukemia (a disease of the white blood cells), multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow), and advanced carcinoid cancer patients. Our lead drug candidate, L-Annamycin, a drug from the anthracycline family (chemotherapy drugs which are derived from antibiotics), earlier completed an initial Phase I/IIa clinical trial in relapsed or refractory leukemia patients with a prior sponsor. L-Annamycin, originally developed by scientists at The University of Texas M.D. Anderson Cancer Center to address the clinical limitations associated with anthracycline drugs such as

Adriamycin (doxorubicin) to treat cancer, began a clinical trial at The University of Texas M.D. Anderson Cancer Center in adult relapsed or refractory acute lymphocytic leukemia (ALL) patients on December 1, 2005. This single-arm, open label trial will enroll 12 patients in a dose escalation Phase I portion, followed by 10 patients in a final fixed dose in the Phase II portion. We plan to treat up to 34 patients. We also expect to commence two additional trials of L-Annamycin in 2006, a single agent trial in pediatric relapsed or refractory ALL patients and a combination therapy trial with Ara-C (cytosine arabinoside) in relapsed or refractory acute myeloid leukemia (AML) patients.

Our second drug candidate, Atiprimod, is an orally administered drug with antiproliferative and antiangiogenic activity. Atiprimod commenced a Phase I/IIa clinical trial in relapsed multiple myeloma patients on May 26, 2004. These are patients that have a re-occurrence of active disease, and no longer respond to approved therapies. The Phase I/IIa clinical trial is being performed at four sites, The University of Texas M.D. Anderson Cancer Center (Houston, TX), the Dana-Farber Cancer Institute (Boston, MA), the St. Vincent's Comprehensive Cancer Center (New York, NY) and the Roswell Park Cancer Institute (Buffalo, NY). In December 2005, we announced interim results from this trial performed in relapsed or refractory multiple myeloma patients which consisted of 15 patients treated with Atiprimod, including 3 patients at the highest dose level of 180 mg/day. Two patients exhibited stable disease, with one patient having a 34% decrease in M protein (measure of tumor burden) over 3 months of treatment. It was also noted that two patients reported a subjective decrease in bone pain. We plan to continue this trial at higher dose levels until the maximum tolerated dose is reached and then treat 10 additional patients at that level.

On March 15, 2005 we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The trial is entitled: An Open Label Study of the Safety and Efficacy of Atiprimod Treatment for Patients with Advanced Cancer, and is currently being conducted at the University of Texas M.D. Anderson Cancer Center. On February 28, 2006, we announced plans to launch an additional indication for clinical development of Atiprimod based on encouraging clinical results from the advanced cancer clinical trial that showed a clear response in a patient with advanced carcinoid cancer plus additional encouraging clinical data on other carcinoid patients. Based on these new clinical data, we plan to initiate a new Phase I/IIa clinical trial of Atiprimod in carcinoid cancer patients with advanced metastatic tumors at several clinical sites in the next few months.

L-ANNAMYCIN TO TREAT RELAPSED ACUTE LEUKEMIA

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 L-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 L-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 one year period after March 2006. 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 L-Annamycin.

L-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.

DEVELOPMENT STRATEGY FOR L-ANNAMYCIN

We began a clinical trial at The University of Texas M.D. Anderson Cancer Center in adult relapsed or refractory acute lymphocytic leukemia (ALL) patients on December 1, 2005. This single-arm, open label trial will enroll 12 patients in a dose escalation Phase I portion, followed by 10 patients in a final fixed dose in the Phase II portion. We plan to treat up to 34 patients. We also expect to commence two additional trials with L-Annamycin in 2006, a single agent trial of L-Annamycin in pediatric relapsed ALL patients, and a combination trial of L-Annamycin in combination with Ara-C in adult relapsed or refractory AML patients.

ATIPRIMOD TO TREAT MULTIPLE MYELOMA AND ADVANCED CARCINOID CANCER PATIENTS

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.

DEVELOPMENT STRATEGY FOR ATIPRIMOD

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. If Atiprimod produces positive responses, we intend to initiate a Phase IIb trial in relapsed multiple myeloma patients in 2006. We have received Institutional Review Board approval to continue our Phase II trial in multiple myeloma at higher doses of Atiprimod. We plan to announce more specifics on this trial shortly.

On March 15, 2005 we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The 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 IRB approval on February 22, 2005 at The University of Texas M. D. Anderson Cancer Center with Dr. Razelle Kurzrock acting 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.

On February 28, 2006, we announced plans to launch an additional indication for clinical development of Atiprimod based on encouraging clinical results from the advanced cancer patient clinical trial that showed a clear response in a patient with advanced carcinoid cancer plus additional encouraging clinical data on other carcinoid patients. Based on these new clinical data, we plan to initiate a new Phase I/IIa clinical trial of Atiprimod in carcinoid cancer patients with advanced metastatic tumors at several clinical sites in the next few months.

GUANYLATE CYCLASE RECEPTOR AGONIST TECHNOLOGY

Our guanylate cyclase receptor agonist (GCRA) program is based on control of cyclic guanosine monophosphate (cyclic GMP), an important second messenger involved in key cellular processes, which are essential for maintenance of the balance between proliferation and cellular death (apoptosis). Uroguanylin, a hormone produced by and secreted by specialized cells in the human GI tract, helps to maintain this balance by activating synthesis of cyclic GMP through activation of guanylate cyclase receptor. Recent findings suggest a role of cyclic GMP in gastrointestinal (GI) inflammatory diseases.

We have successfully developed a potent analog (synthetic molecule) of uroguanylin called Guanilib (formerly called SP304). Guanilib has been demonstrated to be superior to uroguanylin in its biological activity, protease stability and pH characteristics. Guanilib is currently undergoing pre-clinical animal studies as a treatment for gastrointestinal or GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of Pittsburgh. Recent results from his laboratory showed that Guanilib was efficacious in treatment of ulcerative colitis in mice. A patent covering compositions of matter and formulations of Guanilib, alone or in combination with a phosphodiesterase inhibitor, an anti-inflammatory agent, an antiviral agent, or an anticancer agent, has recently been issued to us by the U.S. Patent and Trademark Office.

DEGRASYNS

On January 10, 2006, we entered into a license agreement with the University of Texas M.D. Anderson Cancer Center whereby we were granted the exclusive right to manufacture, have manufactured, use, import, offer to sell and/or sell anti-cancer compounds called tyrphostins (renamed Degrasyns). Degrasyns are a second-generation class of tyrphostins developed by scientists at the University of Texas M.D. Anderson Cancer Center that have a novel anti-cancer mechanism-of-action that centers on their ability to selectively degrade key proteins that are involved in tumor cell proliferation and survival. We plan to work closely with scientists at the University of Texas M.D. Anderson Cancer Center during 2006 to bring forward a pre-clinical candidate for development in the clinic.

On March 23, 2006, we entered into a 2-year sponsored laboratory study agreement with the University of Texas M. D. Anderson Cancer Center whereby Dr. Nicholas Donato, as principal investigator, will analyze the anti-tumor activity and mechanism of action of our WP1130 Degrasyn compound and analogs. The agreement calls for payment of \$145,900 to M.D. Anderson in two installments of \$72,950.00, with the first payment due within 30 days and the second payment due within six months.

On March 27, 2006, we entered into a 2-year sponsored laboratory study agreement with the University of Texas M. D. Anderson Cancer Center whereby Dr. William Bornmann, as principal investigator, will perform molecular modeling and synthesize a library of compounds based on our Degrasyn platform technology. The agreement calls for payment of \$127,145 to M.D. Anderson in two installments of \$63,572.50, with the first payment due within 30 days and the second payment due within six months.

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 I/II trials. Currently, Antibioticos S.p.A. is our sole supplier of Annamycin for our clinical trials. Our agreement with Antibioticos provides that Antibioticos S.p.A. will provide 400 grams of GMP drug substance (Annamycin) for our L-Annamycin clinical trials. Upon the conclusion of our Phase I/b 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 L-Annamycin, entail higher costs, and could result in our being unable to commercialize L-Annamycin successfully.

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. We plan to enter into a supply contract for Atiprimod with a commercial supplier by the end of 2007 or after confirming activity of the drug candidate in our current human clinical trials.

EMPLOYEES

Our plan is to use contract research organizations for most of our development efforts, including monitoring of clinical trial results, thus minimizing the need to hire full time employees. As of May 15, 2006, we had 9 full-time and 3 part-time employees. We believe our employee relations are satisfactory.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of March 31, 2006.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2006 AND MARCH 31, 2005

We had no revenues during the three months ended March 31, 2006 and 2005 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 \$618,071 or 39%, to \$2,193,840 for the three months ended March 31, 2006 from \$1,575,769 for the three months ended March 31, 2005. The most significant factors contributing to this increase in research and development expense were an increase in both drug and patient costs as we significantly increased the number of patients in our L-Annamycin clinical trial during the three months ended March 31, 2006, higher in-license and fees due to our newly in-licensed Degrasyn platform from M. D. Anderson, and higher legal and patent expense. We had a \$139,189 increase in expenses related to our L-Annamycin drug candidate, an \$86,075 increase in clinical trials hospital expense and \$111,884 increase in patent and legal expense related to our Degrasyn platform development for the quarter ended March 31, 2006. During the three month period ended March 31, 2005 the research and development expenses of \$1,575,769 were primarily related to costs associated with preparing our L-Annamycin drug candidate to enter a Phase I/IIa clinical trial, and the ongoing expense of our Atiprimod clinical trial in multiple myeloma. Stock based compensation expense associated with options granted to employees increased approximately \$80,000 from approximately \$69,000 in the quarter March 31, 2005 to approximately \$149,000 in the quarter ended March 31, 2006, as a result of adopting SFAS 123R on January 1, 2006.

Government grant funding for the three months ended March 31, 2006 was \$54,267 as compared to \$0 for the three months ended March 31, 2005. We request grant funding to reimburse research and development expenses as incurred.

General and administrative expenses for the three months ended March 31, 2006 were \$1,754,090, an increase of \$746,274 or 74%, from \$1,007,816 for the three months ended March 31, 2005. The increase was due primarily to approximately (i) \$422,979 of increased spending on investor relations to increase public investors awareness of our stock, (ii) \$168,222 of increased bonuses and wages to management due to performance-based compensation and the addition of a senior medical position, and (iii) \$53,279 in higher audit, legal and tax expenses related to the filing of registration statements for our financings and (iv) stock based compensation expense associated with options granted to employees increased \$27,000 or 9% from approximately \$314,000 in the quarter ended March 31, 2005 to approximately \$341,000 in the quarter ended March 31, 2006 as a result of adopting SFAS 123R on January 1, 2006.

Net loss for the three months ended March 31, 2006 was \$4,374,628 compared to a net loss of \$2,594,131 incurred for the three months ended March 31, 2005. The increased net loss is the result of higher research and development, and general and administrative expenses both of which are discussed above. In addition we recorded higher non-employee stock based compensation expense of \$504,047 during the three months ended March 31, 2006, as compared to \$30,137 recorded during the same period ended March 31, 2005.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2006 we had \$2,790,502 in cash and cash equivalents, compared to \$1,420,510 as of December 31, 2005. This increase in cash of \$1,369,992 at March 31, 2006 was principally the result of completing a private placement of common stock yielding net proceeds of \$4,578,402. This was partially offset by cash used in operating activities of \$3,389,843, warrant exercise proceeds of \$190,035 and \$8,602 of equipment purchases during the three months ended March 31, 2006. Cash used in operating activities was mainly for research and development and general and administrative expenses discussed above totaling \$3,947,930 plus \$108,160 in decreased payables and accrued expenses, less stock based compensation expense of \$994,050 during the quarter.

On February 3, 2006, we closed on a private placement of 4,283,668 shares of common stock and 1,070,917 common stock purchase warrants to certain accredited investors. The warrants are exercisable for 18 months from closing at an exercise price of \$1.60 per share. The securities were sold at a price of \$1.20 per share for aggregate gross proceeds of approximately \$5.14 million. Net proceeds after fees and expenses were \$4.58 million.

On March 23, 2006, we entered into a 2-year sponsored laboratory study agreement with the University of Texas M.D. Anderson Cancer Center whereby Dr. Nicholas Donato, as principal investigator, will analyze the anti-tumor activity and mechanism of action of our WP 1130 Degrasyn compound and analogs. The agreement calls for payment of \$145,900 to M.D. Anderson in two installments of \$72,950.00 with the first payment due within 30 days, and the second payment due within six months of execution.

On March 27, 2006, we entered into a 2-year sponsored laboratory study agreement with the University of Texas M.D. Anderson Cancer Center whereby Dr. William Bornmann, as principal investigator, will perform molecular modeling and synthesize a library of compounds based on our Degrasyn platform technology. The agreement calls for payment of \$127,145 to M.D. Anderson in two installments of \$63,572.50 with the first payment due within 30 days, and the second payment due within six months of execution.

On April 7, 2006 we had a second closing of the financing described above, in which we sold an additional 666,667 shares of common stock and issued 166,667 common stock purchase warrants at the same terms, for gross proceeds of \$800,000, bringing the total gross proceeds of the financing to \$5.94 million and net proceeds to \$5.38 million. No placement agent fees or legal fees were incurred on this second closing however three year warrants to purchase a total of 66,667 common shares at a per share price of \$1.25 were issued to several selling agents. We agreed to file, within 60 days after the first closing, a registration statement covering the resale of the shares of common stock and the shares underlying the warrants, and to use our commercially reasonable efforts to cause such registration statement to be declared effective within 120 days after closing or pay financial penalties to the investors in the event a registration statement is not filed or declared effective within such time period. We have not yet filed a registration statement within the 60-day time period and are incurring financial penalties of \$51,404 for every 30-day period (or \$1,713 per day) that a registration statement has not been filed. As of May 22, 2006 we have incurred approximately \$83,960 for financial penalties related to the registration rights agreement.

On May 3, 2006 we were awarded the second installment of \$366,211 from an April 1, 2005 grant totaling \$885,641 for biodefense partnerships from the National Institute of Allergy and Infectious Diseases (NIAID) to develop a monoclonal antibody and vaccine against bacterial superantigen toxins. Bacterial Superantigens are among the most lethal of toxins that can potentially be used as bioweapons. Our lead monoclonal antibody (Mab) and antagonist peptide are being developed to provide broad-spectrum protection against a variety of superantigen toxins from staphylococcal and streptococcal bacterial strains

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of: pharmaceutical research and development programs; pre-clinical and clinical testing; obtaining regulatory approvals; technological advances and our ability to establish collaborative arrangements with research organizations and individuals needed to commercialize our products. Our capital resources will be focused primarily on the clinical development and regulatory approval of our current product candidates, and the acquisition of licenses and rights to certain other cancer related drug technologies. We expect that our existing capital resources will not be sufficient to fund our operations for at least the next 12 months. We will be required to raise additional capital to complete the development and commercialization of our current product candidates.

Our consolidated financial statements as of December 31, 2005 have been prepared under the assumption that we will continue as a going concern for the twelve months ending December 31, 2006. Our independent registered public accounting firm has issued a report dated March 29, 2006 that included an explanatory paragraph referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at our current cash expenditure levels.

On May 18, 2006 we held a special shareholder meeting and approved (i) the potential issuance and sale of up to 20,000,000 shares of our common stock (or securities convertible into or exercisable for common stock) at a price below fair market value for aggregate gross proceeds of up to \$30,000,000 and (ii) the issuance of 75,000 shares of our restricted common stock to Dr. Moshe Talpaz pursuant to a consulting agreement between us and Dr. Talpaz.

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, revenue and expense, 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.

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in Note 3 of the notes to our consolidated financial statements included in our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2005. The financial statements are prepared in accordance with accounting principles generally accepted in the United States of America, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard (SFAS) No. 123 (Revised 2004), *Share-Based Payments* (SFAS 123R). SFAS 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 expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005 and accordingly Callisto adopted this standard on January 1, 2006. For all awards granted prior to January 1, 2006, the unearned deferred fair value of stock based compensation, on the date of adoption, will be recognized as an expense on a straight line basis over the remaining requisite service period. Our financial results for prior periods have not been restated. The adoption of SFAS 123R increased net loss by approximately \$107,000 for the three months ended March 31, 2006. The remaining requisite service period for employee options thus accounted for ranged from six months to three years. Based on historical information the Company estimated future unvested option forfeitures at 20% as of January 1, 2006.

Prior to January 1, 2006 we accounted for stock-based compensation expense in accordance with Statement of Financial Accounting Standard No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). As provided for by SFAS 123, we had 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 had been recognized based on the intrinsic value of stock issued or options granted to employees and directors for services rendered. We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options is designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage. Since inception through March 31, 2006 stock based compensation expense totaled \$14,765,016 or approximately 30% 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.

The single most significant factor impacting our operating results is the price of our stock which is used in the computation of stock-based compensation expense, particularly for variable options. Our stock price fluctuated from \$3.95 per share as of December 31, 2003 to \$1.46 per share as of March 31, 2006. As of March 31, 2006, 803,500 of our non-employee options required variable accounting treatment in accordance with FASB Interpretation No. 44 *Accounting for Certain Transactions Involving Stock Compensation*, an Interpretation of APB Opinion No. 25 (FIN 44). Our stock-based compensation expense associated with these non-employee variable options during the three months ended March 31, 2006 was \$54,159.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk on the fair values of certain assets is related to credit risk associated with short term investment grade commercial paper included in short term money market accounts and the FDIC insurance limit on our balances. At March 31, 2006 our money market balances totaled approximately \$2.0 million.

ITEM 4. CONTROLS AND PROCEDURES

Based on an 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 March 31, 2006, our Chief Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms. Our Chief Executive Officer and Principal Financial Officer also concluded that, as of March 31, 2006, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the relationship between the benefit of desired controls and procedures and the cost of implementing new controls and procedures.

During the quarter ended March 31, 2006 we took the following actions which we believe materially affected or are reasonable likely to materially affect our internal controls over financial reporting:

- (i) formed a Disclosure Committee, comprising members of our senior management and corporate counsel, charged with the task of discussing and reviewing all transactions occurring during each quarter prior to filing our periodic reports with the SEC;
- (ii) tightened our policy regarding review and approval of all contractual obligations;
- (iii) created a policy of including our Chief Business Officer and our Principal Financial and Accounting Officer in all Board of Directors meetings;
- (iv) segregated financial reporting and accounting duties more effectively between our Chief Business Officer and our Principal Financial and Accounting Officer in preparing all periodic reports filed with the SEC; and
- (v) retained a third party GAAP advisor to assist the Principal Financial and Accounting Officer, as well as advise the Audit Committee from time to time.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K/A for the year ended December 31, 2005, which could materially affect our business, financial condition or future results.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On April 7, 2006, we had a second closing of a previously announced private placement in which we sold an additional 666,667 shares of common stock and 166,667 common stock purchase warrants to certain accredited investors. The warrants are exercisable for 18 months from closing at an exercise price of \$1.60 per share. The securities were sold pursuant to a securities purchase agreement dated April 7, 2006. The securities were sold at a price of \$1.20 per share for aggregate proceeds of \$800,000. We issued an aggregate 66,667 warrants to certain selling agents. The selling agent warrants are exercisable at \$1.25 per share and will expire three years after closing.

In connection with the offer and sale of securities to the investors, we relied on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, (the Securities Act) and Rule 506 promulgated thereunder. We believe that the investors are accredited investors, as such term is defined in Rule 501(a) promulgated under the Securities Act.

ITEM 5. EXHIBITS

(a) Exhibits

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

SIGNATURES

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

CALLISTO PHARMACEUTICALS, INC.
(Registrant)

Date: May 22, 2006

By: /s/ Gary S. Jacob

Gary S. Jacob
Chief Executive Officer

Date: May 22, 2006

By: /s/ Bernard F. Denoyer

Bernard F. Denoyer
Vice President, Finance