

CALLISTO PHARMACEUTICALS INC  
Form 10-Q  
August 14, 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: JUNE 30, 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.)

**420 Lexington Avenue, Suite 1609, New York, New York**  
(Address of principal executive offices)

**10170**  
(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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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 38,454,931 as of August 11, 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 as of June 30, 2006 (unaudited) and December 31, 2005</u>	1
	<u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2006 and 2005 (unaudited) and the period June 5, 1996 (Inception) to June 30, 2006 (unaudited)</u>	2
	<u>Condensed Consolidated Statements of Changes in Stockholders' Equity for the period June 5, 1996 (Inception) to June 30, 2006 (unaudited)</u>	3
	<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2006 and 2005 (unaudited) and for the period June 5, 1996 (Inception) to June 30, 2006 (unaudited)</u>	9
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	10
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	23
<u>Item 4.</u>	<u>Controls and Procedures</u>	23
<b><u>PART II OTHER INFORMATION</u></b>		
<u>Item 1A.</u>	<u>Risk Factors</u>	24
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	24
<u>Item 6.</u>	<u>Exhibits</u>	24

Signatures

**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 cont 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

	June 30, 2006 (Unaudited)	December 31, 2005
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 728,539	\$ 1,420,510
Prepaid expenses	189,545	181,284
	918,084	1,601,794
Property and equipment net		
Rent deposits	7,885	82,196
	73,716	82,196
	\$ 999,685	\$ 1,683,990
<b>Liabilities and Stockholders Deficit</b>		
Current liabilities:		
Accounts payable	\$ 978,090	1,424,612
Accrued expenses	733,106	592,297
	1,711,196	2,016,909
Stockholders deficit:		
Common stock, par value \$.0001, 100,000,000 shares authorized, 38,454,931 and 33,233,096 outstanding at June 30, 2006 and December 31, 2005, respectively	3,845	3,323
Additional paid-in capital	52,216,098	46,387,875
Unamortized deferred stock-based compensation		(1,583,463 )
Deficit accumulated during development stage	(52,931,454 )	(45,140,654 )
	(711,511 )	(332,919 )
	\$ 999,685	\$ 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 June 30,		Six Months Ended June 30,		June 5, 1996
	2006	2005	2006	2005	(Inception) to June 30, 2006
Revenues	\$	\$	\$	\$	\$
Costs and expenses:					
Research and development	1,565,591	1,582,800	3,759,430	3,158,568	19,765,292
Government grants	(201,155 )		(255,422 )		(747,238 )
Purchased in process research and development					6,944,553
General and administrative	1,457,120	1,092,562	3,211,210	2,100,378	18,852,075
Stock based compensation non employees	456,201	(26,405 )	960,248	3,733	9,284,818
Loss from operations	(3,277,757 )	(2,648,957 )	(7,675,466 )	(5,262,679 )	(54,099,500 )
Interest and investment income	19,021	38,280	42,101	57,871	697,086
Other income (expense)	(157,435 )		(157,435 )		470,960
Net loss	\$ (3,416,171 )	\$ (2,610,677 )	\$ (7,790,800 )	\$ (5,204,808 )	\$ (52,931,454 )
Weighted average shares outstanding:					
basic and diluted	38,216,561	31,228,893	37,103,474	30,490,517	
Net loss per common share:					
basic and diluted	\$ (\$0.09 )	\$ (0.08 )	\$ (\$0.21 )	\$ (0.17 )	

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 (DEFICIT)

(Unaudited)

	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 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 six months ended June 30, 2006					(7,790,800 )	(7,790,800 )
Reclassification of deferred unamortized stock-based compensation upon adoption of FAS 123R			(1,583,463 )	1,583,463		
Stock based compensation expense			1,763,661			1,763,661
Common stock issued via private placement:						
February 2006	4,283,668	428	5,139,782			5,140,210
Finders fees and expenses - February 2006			(561,808 )			(561,808 )
April 2006	666,667	67	799,933			800,000
Finders fees and legal exp - April 2006			(41,000 )			(41,000 )
Exercise of common stock warrants	184,500	18	190,017			190,035
Common stock issued for services	87,000	9	121,109			121,110
Balance, June 30, 2006	38,454,931	\$ 3,845	\$ 52,216,098		\$ (52,931,454 )	\$ (711,511 )

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

(Unaudited)

	Six months Ended June 30, 2006	2005	Period from June 5, 1996 (inception) to June 30, 2006
<b>Cash flows from operating activities:</b>			
Net loss	(7,790,800 )	\$ (5,204,808 )	\$ (52,931,454 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	717	10,144	85,354
Stock based compensation expense	1,911,021	768,940	15,681,988
Purchased in-process research and development (non-cash portion)			6,841,053
Amortization of purchase discount on marketable securities		(1,373 )	
Changes in operating assets and liabilities:			
Prepaid expenses	(8,261 )	(91,086 )	(189,545 )
Rent deposits	8,480		(73,716 )
Accounts payable and accrued expenses	(331,963 )	470,579	1,438,455
Total adjustments	1,579,994	1,157,202	23,783,589
Net cash used in operating activities	(6,210,806 )	(4,047,604 )	(29,147,865 )
<b>Cash flows from investing activities:</b>			
Acquisition of equipment	(8,602 )		(93,239 )
Purchase of marketable investments		(990,417 )	
Net cash used in investing activities	(8,602 )	(990,417 )	(93,239 )
<b>Cash flows from financing activities:</b>			
Issuance of common and preferred stock, net of repurchases	5,940,210	3,018,402	31,225,673
Finders fees and expenses	(602,808 )	(25,000 )	(1,574,815 )
Exercise of common stock warrants	190,035	0	318,785
Net cash provided by financing activities	5,527,437	2,993,402	29,969,643
Net (decrease)increase in cash and cash equivalents	(691,971 )	(2,044,619 )	728,539
Cash and cash equivalents at beginning of period	1,420,510	5,323,384	
Cash and cash equivalents at end of period	\$ 728,539	\$ 3,278,765	\$ 728,539
Supplementary disclosure of cash flow information:			
Cash paid for taxes	\$ 7,984	\$ 36,443	\$ 117,590
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 and six months ended June 30, 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 ongoing uncertainty. Callisto will be required to raise additional capital to complete the development and commercialization of current product candidates and to continue to fund operations at our 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. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. As of August 14, 2006 Callisto's cash balance was approximately \$487,000. 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.

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.

SFAS 123R provides for two transition methods. The *modified prospective* method requires that share-based compensation expense be recorded for any employee options granted after the adoption date and for the unvested portion of any employee options outstanding as of the adoption date. The *modified retrospective* method requires that, beginning in the first quarter of 2006, all prior periods presented be restated to reflect the impact of share-based compensation expense consistent with the proforma disclosures previously required under SFAS 123. Callisto has elected to use the *modified prospective* in adopting this standard.

Prior to January 1, 2006, Callisto had adopted 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.

10

---



Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

For all awards granted prior to January 1, 2006, the unearned deferred fair value of stock based compensation was 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 and six months ended June 30, 2006 by approximately \$78,000 and \$186,000, respectively 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 June 30, 2006, as measured at the date of grant, was approximately \$1,100,000.

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 expense related to employee and non-employee stock options recognized in the operating results for the three and six months ended June 30, 2006, June 30, 2005 and for the period from June 6, 1996 (inception), through June 30, 2006 were as follow:

	Three Months Ended June 30,		Six Months Ended June 30,		June 5, 1996
Stock based compensation expense	2006	2005	2006	2005	(Inception) to June 30, 2006
Employees included in research and development	\$ 141,008	\$ 69,063	\$ 289,604	\$ 138,126	\$ 2,421,464
Employees included in general and administrative	319,762	313,541	661,169	627,081	3,975,706
Subtotal employee stock option grants	460,770	382,604	950,773	765,207	6,397,170
Non-employee research and development	102,750		102,750		102,750
Non-employee general and administrative	353,451	(26,405)	857,498	3,733	9,182,068
Subtotal non-employee stock option grants	456,201	(26,405)	960,248	3,733	9,284,818
Total stock based compensation expense	\$ 916,971	\$ 356,199	\$ 1,911,021	\$ 768,940	\$ 15,681,988

The estimated fair value of employee options 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 options granted during the six months and three months ended June 30, 2006: As no options were granted during the three months ended June 30, 2006 the following assumptions remain the same: Risk free interest rate 4.25%; Dividend yield 0%; Volatility 79% and expected life of 3 to 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 six months ended June 30, 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 June 30, 2006 and of changes in options outstanding under Callisto's plans during the six months ended June 30, 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		

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Terminated	(508,335	)	1.04
Outstanding at June 30, 2006	8,349,875	\$	1.81
Options exercisable at June 30, 2006	4,845,712	\$	1.63

11

---

## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

The weighted average remaining term of all options outstanding decreased from 7.4 years at December 31, 2005 to 7.2 years at June 30, 2006. At June 30, 2006 Callisto had 775,000 stock options outstanding under the 2005 Equity Plan, 52,500 stock options outstanding under the 2005 Director s Plan and 7,522,375 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.

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 and six months ended June 30, 2005 would have been as follows:

	<b>Three Months Ended June 30, 2005</b>	<b>Six Months Ended June 30, 2005</b>
Net loss, as reported	\$ (2,610,676 )	\$ (5,204,808 )
Add: Stock-based employee compensation expense recorded under APB No. 25 intrinsic value method	330,404	652,268
Deduct: Stock-based employee compensation expense determined under fair value method	(600,125 )	(1,185,403 )
Pro forma net loss	\$ (2,880,397 )	\$ (5,737,943 )
Net loss per share:		
Basic and diluted -as reported	\$ (0.08 )	\$ (0.17 )
Basic and diluted -pro forma	\$ (0.09 )	\$ (0.19 )
Black-Scholes Methodology Assumptions:		
Dividend yield	0	% 0 %
Risk free interest rate	4.25	% 4.25 %
Expected lives of options	7 to 10 years	7 to 10 years

Volatility of 0% was used until Callisto s common stock began to trade publicly on June 16, 2003. From June 13, 2003 through June 30, 2005 Callisto used 100% volatility to determine the fair value of options granted to employees. Since July 1, 2005 Callisto has used a volatility factor of 79%.

### 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, 2006 there were 4,077,352 warrants and 8,349,875 stock options outstanding, and at June 30, 2005 there were 758,995 warrants and 7,875,710 stock 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 \$201,155 and \$255,422, during the three and six months ended June 30, 2006, respectively 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 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 \$5.34 million. Placement agent fees of \$41,000 were paid on this second closing and 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 approximately \$51,400 for every 30-day period that a registration statement has not been filed for the shares sold on February 3, 2006 and \$8,000 for every 30-day period that a registration statement has not been filed for the shares sold on April 7, 2006. As of June 30, 2006 Callisto has incurred \$157,435 in liquidated damages related to the registration rights agreement, which has been classified as other expense in the condensed consolidated statements of operations.

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 (See Note 6).

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 tyrphostins (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 which occurred on May 18, 2006. 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 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 with the first payment due within 30 days, and the second payment due within six months of execution.

## 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 June 30, 2006, we have sustained cumulative net losses of \$52,931,454. 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, 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 \$5.34 million. Placement agent fees of \$41,000 were paid on this second closing and 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 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), 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 and AML 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 University of Michigan Medical Center (Ann Arbor, MI), Fred Hutchinson Cancer Research Center (Seattle, WA), 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 have amended the protocol to enable us to continue this trial at higher dose levels until the maximum tolerated dose is reached and we then plan to treat 10 additional patients at that level.

On June 2, 2006 at the American Society of Clinical Oncology (ASCO) annual meeting abstract number 13050, titled Phase I study of the safety and efficacy of atiprimod, a novel azaspirane, for patients with advanced cancer described data from our clinical trial in advanced cancer patients. The abstract stated that 14 patients had been treated at that date with 60 mg tablets (n=3), 60 mg capsules (n=3), 90 mg capsules (n=3) and 120 mg capsules (n=5). Of the 14 patients, 4 had carcinoid tumors and 3 of these patients had shown responses with one patient being on drug for 7 cycles of therapy (7 months). Due to the encouraging results in the carcinoid patients from the Phase I trial in advanced cancer, on June 27, 2006 we announced plans to begin a Phase II trial in advanced carcinoid patients that will include approximately 30 patients.

#### **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 of L-Annamycin in 2006, a single agent trial in pediatric relapsed or refractory ALL and AML patients and a combination therapy trial with Ara-C (cytosine arabinoside) in relapsed or refractory acute myeloid leukemia (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**

### **Multiple Myeloma:**

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. On April 12, 2006 we announced that we received Institutional Review Board approval from 3 clinical trial sites to continue our Phase I/IIa trial in multiple myeloma at higher doses of Atiprimod. We plan to announce more specifics on this trial shortly.

### **Advanced Cancer and Carcinoid:**

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 June 2, 2006 at the American Society of Clinical Oncology (ASCO) annual meeting abstract number 13050, titled Phase I study of the safety and efficacy of atiprimod, a novel azaspirane, for patients with advanced cancer described data from our clinical trial in advanced cancer patients. The abstract stated that 14 patients had been treated at that date with 60 mg tablets (n=3), 60 mg capsules (n=3), 90 mg capsules (n=3) and 120 mg capsules (n=5). Of the 14 patients, 4 had carcinoid tumors and 3 of these patients had shown responses with one patient being on drug for 7 cycles of therapy (7 months). Due to encouraging results in the carcinoid patients from the Phase I trial in advanced cancer, on June 27, 2006 we announced plans to begin a Phase II trial in advanced carcinoid patients to include approximately 30 patients.

## **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. On May 9, 2006 the U.S. Patent and Trademark Office (USPTO) notified Callisto that its patent issued covering a novel drug candidate, Guanilib, developed by Callisto scientists to treat and prevent a variety of inflammatory diseases of the bowel. The drug candidate is first-in-class of a new category of compounds with the potential to treat gastro-intestinal diseases such as ulcerative colitis.

## **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, 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, 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/II 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 August 3, 2006, we had 8 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 June 30, 2006.

## RESULTS OF OPERATIONS

### THREE MONTHS ENDED JUNE 30, 2006 AND JUNE 30, 2005

We had no revenues during the three months ended June 30, 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 decreased by \$17,209, or 1%, to \$1,565,591 for the three months ended June 30, 2006 from \$1,582,800 for the three months ended June 30, 2005. During the three months ended June 30, 2006, cash research and development expenses were \$1,424,583 as compared to \$1,513,737 for the three months ended June 30, 2005, a decrease of \$89,154 or 6%. Stock based compensation expense increased by \$71,945 from \$69,063 to \$141,008 due to an increase in research and development staff and the adoption of SFAS 123R on January 1, 2006. See Note 2 to our condensed consolidated financial statements for more detailed discussion of stock based compensation. The factors contributing to the decreased cash research and development expense during the quarter ended June 30, 2006 were a decrease in spending for L-Annamycin drug manufacturing costs and testing of \$685,280 or 68% from the quarter ended June 30, 2005 offset by an increase in spending for non-allocated R&D expense. Non-allocated R&D expense increased during the period to \$726,032 for the three months ended June 30, 2006 from \$250,966 in the three months ended June 30, 2005, an increase of 189% due to the increase in our ongoing clinical trials. During the quarter there was \$120,939 in new spending on the Degrasyns program.

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. Government grant funding for the three months ended June 30, 2006 was \$201,155 as compared to \$0 for the three months ended June 30, 2005. We request grant funding to reimburse research and development expenses as incurred.

General and administrative expenses for the three months ended June 30, 2006 were \$1,457,120, an increase of \$364,558 or 33%, from \$1,092,562 for the three months ended June 30, 2005. The increase was due primarily to approximately (i) \$306,690 of increased spending on investor relations to increase public investors awareness of our stock to \$342,944 in the three months ended June 30, 2006 versus \$36,254 for the three months ended June 30, 2005, an increase of 846%. This expense increase was in addition to a \$77,000 increase in salaries and wages and a \$37,668 increase in accounting audit and tax service, and was offset by (i) a \$39,385 decrease in recruiting and relocation costs due to the expense of hiring our former CMO in the prior year period and a decrease in rent expense of \$20,103 due to the relocation of our lab and office space in New Jersey to Doylestown PA.

Stock-based compensation for non employees increased \$482,606 from (\$26,405) for the three months ended June 30, 2005 to \$456,201 for the three months ended June 30, 2006 primarily attributable to the warrants granted to Trilogy Capital Partners in July 2005.

Interest income of \$19,021 for the three months ended June 30, 2006 decreased \$19,259 or 50% from \$38,280 in the three months ended June 30, 2005 due to decreased average cash balances.

Other Expense for the three months ended June 30, 2006 was \$157,435 due to liquidated damage payments to investors for failure to register shares of the Company s common stock sold in a private placement in February and April 2006. We had no such payments during the three months ended June 30, 2005.

Net loss for the three months ended June 30, 2006 was \$3,416,171 compared to a net loss of \$2,610,677 incurred for the three months ended June 30, 2005. The biggest components of the increased net loss were increased stock-based compensation expense and increased public relations expense related to Trilogy Capital Partners.

**SIX MONTHS ENDED JUNE 30, 2006 AND JUNE 30, 2005**

We had no revenues during the six months ended June 30, 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 by \$600,862 or 19%, to \$3,759,430 for the six months ended June 30, 2006 from the \$3,158,568 we incurred for the six months ended June 30, 2005. During the six months ended June 30, 2006 cash research and development expenses were \$3,469,826, versus \$3,020,442 for the six months ended June 30, 2005, an increase of \$449,384 or 15%. Non-cash stock based compensation expense was \$289,604 for the six months ended June 30, 2006 versus \$138,126 for the six months ended June 30, 2005, an increase of \$151,478 or 110% due to an increase in research and development staff and the adoption of SFAS 123R on January 1, 2006. See Note 2 to our condensed consolidated financial statements for more detailed discussion of stock based compensation. The factors contributing to the increase in cash research and development expenses were (i) an increase in pre-clinical programs of \$550,980, (ii) general research and development of \$210,937, (iii) an increase in product license and related legal fees of \$200,000, and (iv) an increase in legal patents and regulatory expenses of \$130,607, offset by the absence of large purchases of L-Annamycin drug substance and testing which decreased by \$625,146.

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. Government grant funding for the six months ended June 30, 2006 was \$255,422 from our NIAID grant versus \$0 for the six months ended June 30, 2005.

General and administrative expenses increased by \$1,110,832 or 53%, to \$3,211,210 for the six months ended June 30, 2006 from \$2,100,378 for the six months ended June 30, 2005. During the six months ended June 30, 2006 cash general and administrative expenses were \$2,550,041 versus \$1,473,297 for the six months ended June 30, 2005, an increase of \$1,076,743 or 73%. Non-cash stock based compensation expense was \$661,169 for the six months ended June 30, 2006 versus \$627,081 for the six months ended June 30, 2005, an increase of \$34,088 or 5%. See Note 2 to our condensed consolidated financial statements for more detailed discussion of stock based compensation. The increase in cash general and administrative expenses was due primarily to approximately (i) \$730,000 of increased investor relations costs including the fees paid to Trilogy Capital Partners and affiliates, (ii) \$140,000 of increased expenses related to salaries due an increase in headcount, and (iii) \$134,000 in increased management bonuses.

Stock-based compensation related to non-employee options recorded during the six months ended June 30, 2006 totaled \$960,248 as compared to \$3,733 recorded during the six months ended June 30, 2005 attributable to the warrants granted to Trilogy Capital Partners in July 2005.

Interest income of \$42,101 for the six months ended June 30, 2006 decreased \$15,770 or 27%, from \$57,871 for the six months ended June 30, 2005 due to lower cash balances.

Other expense for the six months ended June 30, 2006 was \$157,435 due to liquidated damage payments to investors for failure to register shares of the Company's common stock sold in a private placement in February and April 2006. We had no such payments during the six months ended June 30, 2005.

Net loss for the six months ended June 30, 2006 was \$7,790,800 compared to a net loss of \$5,204,808 incurred for the six months ended June 30, 2005. The increased net loss is primarily the result of higher research and development, general and administrative expenses, and higher stock based compensation expense, as discussed above.

## LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2006 we had \$728,539 in cash and cash equivalents, compared to \$1,420,510 as of December 31, 2005. This decrease in cash of \$691,971 for the six months ended June 30, 2006 was principally the result of cash used in operating activities of \$6,210,806, partially offset by a private placement of common stock yielding net proceeds of \$5,337,402 and warrant exercise proceeds of \$190,035.

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

On April 7, 2006 we had a second closing of the financing described below, 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 \$5.34 million. Placement agent fees of \$41,000 were incurred on this second closing and 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 liquidated damages 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 and we are incurring liquidated damages at the rate of approximately \$51,400 for every 30-day period that a registration statement has not been filed for the shares sold on February 3, 2006 and \$8,000 for every 30-day period that a registration statement has not been filed for the shares sold on April 7, 2006. As of June 30, 2006 we have incurred \$157,435 in liquidated damages related to the registration rights agreement, which have been classified as other expense on our condensed consolidated statement of operations.

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. The first payment was made in April 2006 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. The first payment was made in April 2006 and the second payment is due within six months of execution.

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.

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. Our existing capital resources will not be sufficient to fund our operations and 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.



## Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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. As of August 14, 2006 our cash balance was approximately \$487,000. 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.

21

---

## 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. See Note 2 to our condensed consolidated financial statements for more detailed discussion of stock based compensation.

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 June 30, 2006 stock based compensation expense totaled \$15,681,988 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.

**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 June 30, 2006 our money market balances totaled approximately \$848,000.

**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 June 30, 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 June 30, 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.

During the three months ended June 30, 2006, 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 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

At a Special Meeting of Stockholders held on May 18, 2006, two matters were voted upon. A description of each matter and a tabulation of the votes for each of the matters follow:

1. Proposal to approve the potential issuance 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

Votes		
For	Against	Abstain
19,670,050	350,388	40,112

2. Proposal to approve 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:

Votes		
For	Against	Abstain
19,850,710	189,112	20,727

**ITEM 6. 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: August 14, 2006

By: */s/ Gary S. Jacob*

Gary S. Jacob  
Chief Executive Officer

Date: August 14, 2006

By: */s/ Bernard F. Denoyer*

Bernard F. Denoyer  
Vice President, Finance