

CALLISTO PHARMACEUTICALS INC  
Form 10-Q  
May 21, 2007

**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, 2007**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE**

**SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-32325

**CALLISTO PHARMACEUTICALS, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**13-3894575**

(I.R.S. Employer Identification No.)

**420 Lexington Avenue, Suite 1609, New York, New York 10170**

(Address of principal executive offices) (Zip Code)

**(212) 297-0010**

(Registrant's telephone number)

(Former Name, Former Address and Former Fiscal Year,

if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject

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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 39,694,995 as of May 18, 2007.

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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 March 31, 2007 (unaudited) and December 31, 2006</u> <u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2007 and 2006 (unaudited) and the period June 5, 1996 (Inception) to March 31, 2007 (unaudited)</u> <u>Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period June 5, 1996 (Inception) to March 31, 2007 (unaudited)</u> <u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2007 and 2006 (unaudited) and for the period June 5, 1996 (Inception) to March 31, 2007 (unaudited)</u> <u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>

**PART II OTHER INFORMATION**

<u>Item 1A.</u>	<u>Risk Factors</u>
<u>Item 6.</u>	<u>Exhibits</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 for the year ended December 31, 2006 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

	(unaudited) March 31, 2007	December 31, 2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,158,676	\$ 3,904,232
Prepaid expenses and other	46,256	66,741
	2,204,932	3,970,973
Property and equipment - net	6,451	6,451
Security deposits	73,716	73,716
	\$ 2,285,099	\$ 4,051,140
<b>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 1,741,705	\$ 1,843,422
Accrued expenses	1,183,449	1,357,600
	2,925,154	3,201,022
Stockholders' equity (deficit):		
Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized, 614,125 shares outstanding at March 31, 2007 with a liquidation preference of \$6,141,250 and 586,125 shares outstanding at December 31, 2006 with a liquidation preference of \$5,861,250.	61	58
Common stock, par value \$.0001, 150,000,000 and 100,000,000 shares authorized, respectively, 39,194,996 shares outstanding at both March 31, 2007 and December 31, 2006, respectively.	3,919	3,919
Additional paid-in capital	61,749,956	61,290,509
Deficit accumulated during development stage	(62,393,991)	(60,444,368)
	(640,055)	) 850,118
	\$ 2,285,099	\$ 4,051,140

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, 2007	March 31, 2006	For the period from June 5, 1996 (Inception) to March 31, 2007
Revenues	\$	\$	\$
Costs and expenses:			
Research and development	958,683	2,193,840	22,996,497
Government grant	(43,956 )	(54,267 )	(888,421 )
Purchased in process research and development			6,944,553
General and administrative	959,660	1,754,090	21,713,401
Stock-based compensation non-employees	(19,478 )	504,047	9,679,083
Loss from operations	(1,854,909 )	(4,397,710 )	(60,445,113 )
Interest and investment income	24,971	23,082	728,587
Other expense			(173,295 )
Net loss	(1,829,938 )	(4,374,628 )	(59,889,821 )
Series A Preferred stock beneficial conversion feature accreted as a dividend	(119,685 )		(2,504,170 )
Net loss available to common stockholders	\$ (1,949,623 )	\$ (4,374,628 )	\$ (62,393,991 )
Weighted average shares outstanding:			
basic and diluted	39,194,996	35,798,019	
Net loss per common share:			
basic and diluted	\$ (0.05 )	\$ (0.12 )	

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

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	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



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	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

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	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

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	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

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	Series A Convertible Preferred Shares	Convertible Preferred Stock	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, 2005			33,233,096	\$ 3,323	\$ 46,387,875	\$ (1,583,463 )	\$ (45,140,654 )	\$ (332,919 )
Net loss for the period							(12,919,229 )	(12,919,229 )
Reclassification of deferred unamortized stock-based compensation upon adoption of FAS 123R					(1,583,463 )	1,583,463		
Stock based compensation expense					2,579,431			2,579,431
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 )
April 2006			666,667	67	799,933			800,000
Finders fees and expenses					(41,000 )			(41,000 )
Waiver and Lock-up Agreement			740,065	74	579,622			579,696
Common stock issued for services			87,000	9	121,101			121,110
Exercise of common stock warrants			184,500	18	190,017			190,035
Series A convertible preferred stock issued via private placement:	574,350	57			5,743,443			5,743,500
Finders fees and expenses	11,775	1			(448,909 )			(448,908 )
Detachable warrants					2,384,485			
Beneficial conversion feature accreted as a dividend							(2,384,485 )	

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Balance, December 31, 2006	586,125	\$ 58	39,194,996	\$ 3,919	\$ 61,290,509	\$	\$ (60,444,368 )	\$ 850,118
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The accompanying notes are an integral part of these condensed consolidated financial statements

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## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

## CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)

	Series A Convertible Preferred Shares	Convertible Preferred Stock	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, 2006	586,125	\$ 58	39,194,996	\$ 3,919	\$ 61,290,509	\$	\$ (60,444,368 )	\$ 850,118
Net loss for the period							(1,829,938 )	(1,829,938 )
Stock based compensation expense					96,165			96,165
Series A convertible preferred stock issued via private placement:	28,000	3			279,997			280,000
Finders fees and expenses					(36,400 )			(36,400 )
Detachable warrants					119,685			
Beneficial conversion feature accreted as a dividend							(119,685 )	
Balance, March 31, 2007	614,125	\$ 61	39,194,996	\$ 3,919	\$ 61,749,956	\$	\$ (62,393,991 )	\$ (640,055 )

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
	2007	2006	June 5, 1996 (inception) to March 31, 2007
<b>Cash flows from operating activities:</b>			
Net loss	\$ (1,829,938 )	\$ (4,374,628 )	\$ (59,889,821 )
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation			86,788
Stock-based compensation expense	96,165	994,050	16,613,610
Stock-based liquidated damages			579,696
Purchased in-process research and development (non-cash portion)			6,841,053
<b>Changes in operating assets and liabilities:</b>			
Prepaid expenses	20,486	81,415	(46,255 )
Rent deposits		17,480	(73,716 )
Accounts payable and accrued expenses	(275,869 )	(108,160 )	2,632,725
Total adjustments	(159,218 )	984,785	26,633,901
Net cash used in operating activities	(1,989,156 )	(3,389,843 )	(33,255,920 )
<b>Cash flows from investing activities:</b>			
Acquisition of equipment		(8,602 )	(93,239 )
Net cash used in investing activities		(8,602 )	(93,239 )
<b>Cash flows from financing activities:</b>			
Issuance of common and preferred stock, net of repurchases	280,000	5,140,210	37,249,173
Finders fees and expenses	(36,400 )	(561,808 )	(2,060,123 )
Exercise of common stock warrants		190,035	318,785
Net cash provided by financing activities	243,600	4,768,437	35,507,835
Net (decrease) increase in cash and cash equivalents	(1,745,556 )	1,369,992	2,158,676
Cash and cash equivalents at beginning of period	3,904,232	1,420,510	
Cash and cash equivalents at end of period	\$ 2,158,676	\$ 2,790,502	\$ 2,158,676
<b>Supplementary disclosure of cash flow information:</b>			
Cash paid for taxes	\$ 1,441	\$ 12,146	\$ 124,928
Cash paid for interest	\$	\$	\$
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Accretion of fair value of beneficial conversion feature as a dividend to Series A Preferred stockholders	\$ 119,685		2,504,170
Stock options, warrants and common stock issued for services	\$ 96,165	\$ 994,050	\$ 16,613,610
Stock-based liquidated damages	\$	\$	\$ 579,676

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

CALLISTO PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

**1. Business overview:**

Callisto Pharmaceuticals, Inc. ( Callisto ) is a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. Since inception in June of 1996 Callisto's efforts have been principally devoted to research and development, securing and protecting patents and raising capital. From inception through March 31, 2007, Callisto has sustained cumulative net losses of \$59,889,821. Callisto's losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, stock based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees. From inception through March 31, 2007, Callisto has not generated any revenue from operations, expects to incur additional losses to perform further research and development activities and does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all.

Callisto's product development efforts are thus in their early stages and Callisto cannot make estimates of the costs or the time they will take to complete. The risk of completion of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, the nature and timing of costs and competing technologies being developed by organizations with significantly greater resources.

**2. Basis of presentation and going concern:**

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, 2006, included in Form 10-K filed with the SEC on April 17, 2007. 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, 2007 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2007.

Callisto's consolidated financial statements as of March 31, 2007 and December 31, 2006 have been prepared under the assumption that Callisto will continue as a going concern for the twelve months ending December 31, 2007. Callisto's independent registered public accounting firm has issued a report dated April 13, 2007 that included an explanatory paragraph referring to Callisto's 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. Callisto's ability to continue as a going concern is dependent upon its 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. 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 the current cash expenditure levels.

To date, Callisto's sources of cash have been primarily limited to the sale of equity securities. Net cash provided by financing activities for the three months ended March 31, 2007 and 2006 and for the period from June 5, 1995 (inception) to March 31, 2007 was approximately \$244,000, \$4.8 million and \$35.5 million respectively. Callisto cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Callisto can raise additional funds by issuing equity securities, Callisto's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Callisto's ability to conduct its business. If Callisto is unable to raise additional capital when required or on acceptable terms, it may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of Callisto's product candidates. Callisto also may be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and relinquish licenses or otherwise dispose of rights to technologies, product candidates or



products.

11

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### 3. Accounting for share-based payments

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 was effective as of the beginning of the first interim or annual reporting period that began after December 15, 2005 and accordingly Callisto adopted SFAS 123R 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* method in adopting this standard.

Prior to January 1, 2006, Callisto had adopted SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ). As provided for by SFAS 123, Callisto had elected to continue to account for stock-based compensation 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. Callisto accounts for common stock, stock options, and warrants granted to non-employees based on the fair 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.

For all awards granted prior to January 1, 2006, stock based compensation expense is being recognized on a straight line basis over the remaining requisite service period, which ranged from nine months to three years at the date of adoption. The adoption of SFAS 123R increased net loss for the three months ended March 31, 2007 and 2006 by \$115,643 and \$490,003, or \$0.003 and \$0.01 per share, 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 March 31, 2007 and 2006 was \$593,578 and \$621,853, respectively, to be recognized over a weighted average vesting period of 1.24 and 1.37 years, respectively.

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 ). Total stock based compensation expense related to employee and non-employee stock options recognized in operating results was as follow:

	Three Months Ended March 31 ,		June 5, 1996
Stock based compensation expense	2007	2006	(Inception) to March 31 2007
Employees included in research and development	\$ 17,846	\$ 148,596	\$ 2,570,390
Employees included in general and administrative	97,797	341,407	4,364,137
Subtotal employee stock option grants	115,643	490,003	6,934,527
Non-employee research and development			102,750
Non-employee general and administrative	(19,478 )	504,047	9,576,333
Subtotal non-employee stock option grants	(19,478 )	504,047	9,679,083
Total stock based compensation expense	\$ 96,165	\$ 994,050	\$ 16,613,610

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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 employee options granted during the three months ended March 31, 2007 and 2006:

	Three months ended March 31,			
	2007		2006	
Risk free interest rate	4.68	%	4.25	%
Dividend yield	0.0	%	0.0	%
Expected volatility	60	%	79	%
Expected term	7 years		7 years	

*Risk-free interest rate:* assumption is based upon observed interest rates appropriate for the expected term of Callisto's employee stock options.

*Dividend yield:* Callisto 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.

*Expected volatility:* Is based on the historical volatility of Callisto's stock.

*Expected term:* 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. Callisto estimated future unvested option forfeitures based on historical Company experience and has incorporated this rate in determining the fair value of employee option grants.

A summary of stock option activity and of changes in options outstanding under Callisto's plans is presented below:

	Number of options	Exercise Price Per Share	Weighted Average Exercise Price Per Share
Balance, December 31, 2006	8,053,375	\$ 0.75 - 6.75	\$ 1.75
Granted	450,000	\$ 0.81 - 0.96	\$ 0.89
Forfeitures	(115,000)	\$ 0.75 - 1.60	\$ 0.86
Balance, March 31, 2007	8,388,375	\$ 0.75 - 6.75	\$ 1.72
Exercisable as of March 31, 2007	5,364,046	\$ 0.75 - 6.75	\$ 1.64

The weighted average remaining term of all options outstanding at March 31, 2007 was 6.6 years as compared to 7.3 years at December 31, 2006.

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.

### RECENT ACCOUNTING PRONOUNCEMENTS:

In February 2007, the FASB issued Statement of Financial Accounting Standards No.159, "The Fair Value Option for Financial Assets and Financial Liabilities, including an Amendment to SFAS 115 (SFAS 159)". The fair value option established by SFAS 159 permits all entities to measure all eligible items at fair value at specified election dates. A business entity shall report all unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. The provisions of SFAS 159 are effective for fiscal years beginning after November 15, 2007. Callisto is currently evaluating the impact, if any, of the provisions of SFAS 159.

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In December 2006, the Financial Accounting Standards Board ( FASB ) issued a FASB Staff Position ( FSP ) Emerging Issues Task Force ( EITF ) Issue No. 00-19-2 Accounting for Registration Payment Arrangements ( FSP 00-19-2 ) which addresses an issuer's accounting for registration payment arrangements. FSP 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No.5 Accounting for Contingencies . The guidance in FSP 00-19-2 amends FASB Statements No. 133, Accounting for Derivative Instruments and Hedging Activities , and No.150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity , and FASB Interpretation No.45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others to include scope exceptions for registration payment arrangements. FSP 00-19-2 is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of FSP 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of FSP 00-19-2, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. Callisto has analyzed the provisions of FSP 00-19-2 and adoption of this standard did not have a material effect on Callisto's consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No.157, Fair Value Measurements ( SFAS 157 ). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective for fiscal years beginning after November 15, 2007. Callisto is currently evaluating the impact, if any, of the provisions of SFAS 157.

In July 2006, the FASB issued FASB Interpretation No. 48 ( FIN 48 ) Accounting for Uncertainty in Income Taxes (an interpretation of FASB Statement No. 109 ) which is effective for fiscal years beginning after December 15, 2006. This interpretation was issued to clarify the accounting for uncertainty in the amount of income taxes recognized in the financial statements by prescribing a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The provisions of FIN 48 are effective January 1, 2007, with the cumulative effect of the change in accounting principle recorded as an adjustment to retained earnings. The adoption of FIN 48 did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

#### **4. 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, 2007 and 2006 there were 16,296,620 and 3,844,018 warrants outstanding, respectively and 8,388,375 and 8,508,210 total options outstanding, respectively. In addition Callisto had 8,031,033 common shares issuable upon conversion of its Series A convertible preferred stock as of March 31, 2007 (See Note 5 below) and no preferred stock was outstanding as of March 31, 2006.

## 5. Stockholders equity (deficit):

From October 23, 2006 until January 10, 2007, Callisto placed 602,350 shares of Series A Convertible Preferred Stock and 8,031,333 warrants to certain investors for aggregate gross proceeds of \$6,023,500. As of December 31, 2006 Callisto had closed on 574,350 shares of such Series A Convertible Preferred Stock for aggregate gross proceeds of \$5,743,500. The final tranche of this financing closed January 10, 2007 when Callisto placed 28,000 shares of such Series A Convertible Preferred Stock for aggregate gross proceeds of \$280,000. The shares of Series A Convertible Preferred Stock are convertible into shares of common stock at a conversion price of \$0.75 per share. The investors also are parties to a Registration Rights Agreement, dated as of October 23, 2006 pursuant to which Callisto agreed to file, within 60 days of closing, a registration statement with the Securities and Exchange Commission (the SEC) covering the resale of the shares of common stock underlying the Series A Convertible Preferred Stock and the warrants issued to the investors. The warrants are immediately exercisable at \$0.75 per share, will expire five years from the date of issuance, and have certain antidilution rights for the twelve month period beginning on the effective date of the registration statement registering the shares of common stock underlying the warrants. Callisto (i) paid aggregate fees and expenses of \$485,308 (\$448,908 prior to December 31, 2006) in cash and (ii) issued an aggregate 11,775 shares of Series A Convertible Preferred Stock and 1,228,761 warrants to purchase common stock, to certain selling agents. The warrants are immediately exercisable at \$0.75 per share, will expire five years after issuance and have the same anti-dilutive rights as the investor warrants. On January 12, 2007 Callisto filed a registration statement on Form S-3 registering the common stock issuable upon (i) the conversion of the all Series A Convertible Preferred Stock, (ii) the exercise of all related investor warrants and (iii) the exercise of all selling agent warrants. On February 15, 2007 Amendment No.1 to this registration statement was declared effective by the SEC.

The material terms of the Series A Preferred Stock consist of:

*Dividends* . Holders of the Series A Convertible Preferred Stock shall not be entitled to receive dividends except as and if declared at Callisto's sole election.

*Voting Rights* .. Shares of the Series A Convertible Preferred Stock shall have no voting rights. However, so long as any shares of Series A Convertible Preferred Stock are outstanding, Callisto shall not, without the affirmative vote of a majority in interest of the shares of Series A Convertible Preferred Stock then outstanding, (a) alter or change adversely the powers, preferences or rights given to the Series A Convertible Preferred Stock, (b) authorize or create any class of stock senior or equal to the Series A Convertible Preferred Stock, (c) amend its articles of incorporation or other charter documents, so as to affect adversely any rights of the holders of Series A Convertible Preferred Stock or (d) increase the authorized number of shares of Series A Convertible Preferred Stock.

*Liquidation*. Upon any liquidation, dissolution or winding-up of Callisto, the holders of the Series A Convertible Preferred Stock shall be entitled to receive an amount equal to the Stated Value per share, which is \$10 per share plus any accrued and unpaid dividends.

*Conversion Rights* .. Each share of Series A Convertible Preferred Stock shall be convertible into that number of shares of common stock determined by dividing the Stated Value, currently \$10 per share, by the conversion price, currently \$0.75 per share. The conversion price is subject to adjustment for dilutive issuances.

*Automatic conversion* .. Beginning October 24, 2007, if the price of the common stock equals \$1.50 per share for 20 consecutive trading days, and an average of 50,000 shares of common stock per day shall have been traded during the 20 trading days, Callisto shall have the right to deliver a notice to the holders of the Series A Convertible Preferred Stock, to convert any portion of the shares of Series A Convertible Preferred Stock into shares of Common Stock at the conversion price.

As per Emerging Issues Task Force (EITF) Issue 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, Company Stock*, Callisto has determined that the warrants should be treated as permanent equity.

As per FASB Staff Position (FSP) Emerging Issues Task Force (EITF) Issue No. 00-19-2 *Accounting for Registration Payment Arrangements* (FSP 00-19-2), issued in December 2006, which specifies that contingent obligations under a registration payment arrangement should be separately recognized and measured in accordance with FASB Statement No.5 *Accounting for Contingencies*, Callisto has determined that it is not likely have a material effect on Callisto's consolidated financial statements. On January 12, 2007 Callisto filed a registration statement on

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Form S-3 registering the common stock issuable upon (i) the conversion of the all Series A Convertible Preferred Stock, (ii) the exercise of all related investor warrants and (iii) the exercise of all selling agent warrants. On February 15, 2007 Amendment No.1 to this registration statement was declared effective by the SEC.

As per EITF 00-27, *Application of Issue 98-5 to Certain Convertible Instruments* Callisto evaluated the preferred stock transaction and accordingly found that there was an embedded beneficial conversion feature. The fair value of the detachable warrants on the date of grant was \$3,557,872 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.57% to 4.84%, no dividend, an expected life of 5 years and a stock price on that dates of grant ranging from \$0.88 to \$ 0.75 per share. The conversion rights of the preferred stock contained a beneficial conversion feature totaling \$2,504,170, using the effective conversion price method based on relative fair value of the preferred stock and the warrants. This beneficial conversion feature was immediately accreted to the preferred stock as a dividend because the preferred stock could be converted immediately upon issuance. The beneficial conversion feature associated with final tranche of 28,000 shares of Series A Convertible Preferred Stock placed in January 2007 amounted to \$119,685 and was recorded as a beneficial conversion feature accreted as a dividend in the quarter ended March 31, 2007.

14

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**6. Commitments and contingencies:**

Employment and consulting agreements:

On January 25, 2007, Callisto entered into an Extension and Amendment Agreement with Mr. Cerrone. The agreement extends the term of the consulting agreement between us and Mr. Cerrone, dated as of December 27, 2004, to December 31, 2009. Among other things, the agreement increases Mr. Cerrone's compensation from \$205,000 to \$275,000 per year. Additionally, pursuant to the agreement, in recognition of the services beyond that required of Mr. Cerrone during the period from July 1, 2006 to January 25, 2007, Callisto had accrued a bonus to Mr. Cerrone of \$75,000, as of March 31, 2007, which was paid on April 5, 2007. Mr. Cerrone shall be eligible to earn a cash bonus of up to 22.5% of his base compensation for each twelve month period during the term of the agreement based on meeting performance objectives and bonus criteria to be mutually identified by Mr. Cerrone and Callisto's Board.

On January 25, 2007, in conjunction with the Extension and Amendment Agreement, Mr. Cerrone was granted 225,000 ten year non-qualified stock options at an exercise price of \$0.96 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. The stock-based compensation expense associated with this option grant during the three months ended March 31, 2007 was \$14,695. This expense was based on an initial Black-Scholes fair value of \$165,040 or \$0.44 per share on the date of grant. In accordance with EITF - Emerging Issues Task Force Issue 96-18: *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* ( EITF 96-18 ), the measurement date will be the earliest of the third anniversary of the agreement (when performance commitment is completed ) or the accelerated vesting date if Mr. Cerrone is terminated without cause or good reason. Accordingly the fair value of these options will be marked to market quarterly.

On February 16, 2007, Dr. Jacob entered into an Extension and Amendment Agreement with Callisto as approved by the Compensation Committee which extended the term under his employment agreement to June 30, 2009. In addition, pursuant to the agreement, Dr. Jacob was granted 225,000 ten year incentive stock options exercisable at \$0.81 per share of which 75,000 vest on each of December 31, 2007, 2008 and 2009. His salary and other compensation was unchanged.

**7. Subsequent events:**

On April 24, 2007, we entered into a services agreement with Barretto Pacific Corporation pursuant to which Barretto will provide beginning May 1, 2007 investor relations services to us. We will pay Barretto a fee of \$120,000 over a seven month period and 80,000 shares of restricted common stock.

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and 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, 2007, we have sustained cumulative net losses of \$59,889,821. 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, 2007 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.

Our research and development expenses consist primarily of costs associated with clinical development team salaries and staff costs, application and filing for regulatory approval of our proposed products, regulatory and scientific consulting fees, clinical and patient costs for product candidates in on-going trials, sponsored pre-clinical research, royalty payments as well as legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products. We expense all research and development costs as they are incurred. We expect our research and development expenses to increase significantly in the future as we develop our product candidates.

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

### HISTORY

In March 2002, Callisto Pharmaceuticals, Inc. ( Old Callisto ), 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 clinical development of our two drugs, Atiprimod and L-Annamycin, to treat neuroendocrine carcinomas (including advanced carcinoid cancer), adult and pediatric acute leukemia (a disease of the white blood cells) and multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow).

Our lead drug candidate, Atiprimod, is an orally administered drug with antiproliferative and antiangiogenic activity. We are presently enrolling patients in two clinical trials in low to intermediate grade neuroendocrine cancer and relapsed or refractory multiple myeloma at a number of clinical sites in the U.S. On November 7, 2006, we announced the initiation of a multi-center open-label Phase II clinical trial of Atiprimod in low- to intermediate-grade neuroendocrine cancers, including advanced carcinoid cancer patients. This trial is based on earlier encouraging clinical results from an ongoing trial of Atiprimod in advanced cancer patients that showed stable disease and disease-related symptom relief in patients with advanced carcinoid cancer. Atiprimod is also in a multi-center, dose-escalation Phase I/IIa clinical trial in relapsed or refractory multiple myeloma patients. In December 2005, we announced interim results from this trial on 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. In 2006, we amended the protocol to continue the trial at higher dose levels and currently have this trial underway at clinical sites in the U.S.

16

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Our second lead drug candidate, L-Annamycin, earlier completed an initial Phase I/IIa clinical trial in relapsed or refractory leukemia patients with a prior sponsor. L-Annamycin is a novel compound from the anthracycline family of proven anti-cancer drugs, which has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart. L-Annamycin was in-licensed by Callisto in October 2004 and is presently in two clinical trials: 1) a Phase I/IIa clinical trial in adult relapsed or refractory acute lymphocytic leukemia (ALL) patients at three clinical sites in the U.S.; and 2) a Phase I clinical trial in children and young adults with relapsed or refractory ALL or AML.

#### **ATIPRIMOD TO TREAT ADVANCED CARCINOID CANCER PATIENTS AND MULTIPLE MYELOMA**

On August 28, 2002, our wholly-owned subsidiary, Synergy, entered into a worldwide license agreement with AnorMED Inc. ( AnorMED ), a Canadian corporation, to research, develop, sell and commercially exploit the Atiprimod (SKF 106615) patent rights.

Atiprimod is one of a class of compounds known as azaspiranes and was originally developed as a potential treatment for rheumatoid arthritis based on encouraging data from a number of animal models of arthritis and autoimmune indications. The development of this drug originated with a partnership between AnorMED and SmithKline Beecham ( SKB ) that led to the successful filing of an investigational new drug application, or IND, and completion of three Phase I clinical trials involving a total of 63 patients. The drug successfully completed both single and multiple dose Phase I clinical trials in patients with rheumatoid arthritis. Both trials evaluated the safety and pharmacokinetics (how the body takes up and eliminates drugs) of Atiprimod and showed that the drug is well tolerated. In the third Phase I clinical trial, the drug was found to be well tolerated in an open label extension study performed with 43 patients from the first two studies, with patients on the drug for as long as one year.

#### **PRECLINICAL STUDIES**

Atiprimod's specific ability to lower the level of key growth factors, known to play an important role in the development of multiple myeloma, is the basis for its potential use as a drug to treat this disease. Atiprimod was previously shown to inhibit the production of the pro-inflammatory mediators IL-6 and TNF (alpha) in a number of animal models of inflammation and autoimmune disease. Atiprimod was also demonstrated using in vitro models of tumor cell growth to inhibit proliferation of a number of human multiple myeloma cell lines. Characterization of the mechanism of Atiprimod's antiproliferative activity in a series of experiments showed that the drug works by inducing apoptosis (programmed cell death) in myeloma cells. In a second series of experiments performed with Atiprimod on co-cultures composed of multiple myeloma cells plus bone marrow stromal cells (used to simulate the human disease), the drug was found to have a profound effect on secretion of the angiogenic (blood vessel related) growth factor VEGF. A separate set of experiments also suggest an additional explanation for the disease-modifying activity of Atiprimod originally observed in chemically-induced arthritic-rat animal studies, and provide a further rationale for the application of this drug to treat multiple myeloma. Using a bone resorption assay (bone degradation experiment) to measure the effect of drug on osteoclast-mediated bone resorption, Atiprimod demonstrated a profound effect on osteoclast, or white blood cell, function. The drug appears to be selectively toxic for activated osteoclasts, displaying a negligible effect on bone marrow stromal cells.

#### **COMPLETED CLINICAL STUDIES**

Atiprimod successfully completed single and multiple dose Phase I clinical trials in patients with rheumatoid arthritis (RA). In the initial Phase I study, 28 patients were given single escalating doses of drug (0.002 - 1.0 mg/kg), with a 4-month follow-up. Atiprimod was well tolerated, displaying no clinically relevant changes in any laboratory parameters. In particular, liver function tests remained in the normal range. The second Phase I study involved a 28-day multiple-dose-rising study in 35 RA patients. The study evaluated the effect of food on bioavailability, or the concentration of drug in the body, as well as the safety and pharmacokinetics of repeat dosing. Dosages included 0.1, 1.0, 5.0, and 10 mg/day plus a 14-day cohort at 30 mg/day, with 4-month follow-up. All doses were well tolerated and clinical tests were unremarkable. Significantly, reductions in tender and swollen joint counts were noted in a number of subjects during the course of the dosing period. Individuals from the two Phase I safety studies were also involved in a Phase I open-label extension trial at 5 mg/day dosage. Forty-three patients entered the study and remained on the drug as long as 12 months. Clinical laboratory results for all patients were unremarkable, in particular liver enzyme levels remained within the normal range in all patients throughout the study period.

#### **DEVELOPMENT STRATEGY**

Atiprimod commenced a Phase I/IIa clinical trial in relapsed or refractory 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 an open label study, with the primary objective of assessing safety of 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 the drug to better determine the mechanism of drug action. 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. In 2006, we amended the protocol to continue the trial at higher dose levels and currently have this trial open at 4 clinical sites in the U.S.

17

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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 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 hematological malignancies. This study was conducted at the University of Texas M.D. Anderson Cancer Center, and was closed to enrollment in November 2006.

On November 7, 2006, we announced the initiation of a multi-center, open-label Phase II clinical trial of Atiprimod in low to intermediate grade neuroendocrine carcinomas, including advanced carcinoid cancer patients. This trial is based on encouraging clinical results from the Phase I clinical trial in advanced cancer patients that showed stable disease and a reduction in disease-related symptoms in patients with advanced carcinoid cancer. The first study site to enter the trial was the Hematology Oncology Services of Arkansas in Little Rock, Arkansas. On January 31, 2007 we announced the opening of a second site for this trial the Dana-Farber Cancer Institute in Boston, MA. Subjects will also be seen at the following facilities: Brigham and Women s Hospital, Massachusetts General Hospital and Beth Israel Deaconess Medical Center. On March 12, 2007 we announced the opening of the third site for this trial The Physician Offices at Mount Sinai Medical Center, NY

The primary objective of the Phase II clinical trial is to evaluate efficacy of Atiprimod in patients with low to intermediate grade neuroendocrine carcinoma who have metastatic or unresectable cancer and who have either symptoms, despite standard therapy (octreotide), or progression of neuroendocrine tumors. Patients, after signing an informed consent, are required to complete two weeks of a symptoms diary to establish their symptoms baseline before commencing Atiprimod dosing. A maximum of 40 evaluable patients will be enrolled in this trial. Efficacy evaluations will include the measure of target lesions (per RECIST), and the quantization of symptom relief.

#### **MANUFACTURING OF ATIPRIMOD**

A practical, efficient and cost effective method for producing Atiprimod on a commercial scale was originally developed by SKB. In the course of this work, a new dimaleate salt form was developed. A portion of the 7 kilos of Atiprimod drug substance, available from SKB, was used as the source for generating the Atiprimod dimaleate drug product presently being used in the Phase I/IIa clinical study. Several lots of drug substance were re-qualified to meet current FDA approved release specifications. The full package of fully validated analytical methods developed by SKB was transferred to a contract research organization used by us to perform all analytical tests. 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.

#### **L-ANNAMYCIN TO TREAT RELAPSED ACUTE LEUKEMIA**

On August 12, 2004 we entered into a worldwide exclusive license agreement with The University of Texas M.D. Anderson Cancer Center to develop and commercially exploit the L-Annamycin patent rights. L-Annamycin, an anthracycline drug for leukemia therapy, has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced toxicity.

#### **PRECLINICAL STUDIES**

Nonclinical studies have shown that Annamycin delivered as a liposomal preparation (L-Annamycin) is effective against several different in vivo tumor models (animal experiments), including human tumors which are resistant to other chemotherapy drugs, grafted into animals. Additionally, results from in vitro studies (cell culture experiments) indicate that L-Annamycin and free Annamycin were able to partially overcome tumor resistance to chemotherapy drugs in several tumor cell lines that were resistant to other drugs such as doxorubicin. In nonclinical toxicity studies, myelosuppression (suppression of the body s immune response) was noted in mice at a single intravenous dose of 15.7 mg/kg L-Annamycin. With weekly intravenous doses of 5.2 mg/kg L-Annamycin for 6 weeks, or 3.1 and 4.2 mg/kg L-Annamycin for 10 weeks in mice, the cardiotoxicity (toxicity to heart tissue) of L-Annamycin was substantially less than an equivalent dose of doxorubicin. In dogs, a single 15-minute intravenous infusion of up to 1.42 mg/kg L-Annamycin was well tolerated, with no clinically significant adverse effects, hematological or chemical changes, or pathological changes.

## COMPLETED CLINICAL STUDIES

L-Annamycin was evaluated previously by Aronex Pharmaceuticals, Inc. in 3 clinical trials: 1) a Phase I clinical trial in 36 patients with relapsed solid tumors, 2) a Phase II clinical trial in 13 patients with doxorubicin-resistant breast cancer, and 3) a Phase I/IIa trial in 20 patients with relapsed/refractory AML and ALL. In the initial Phase I study, L-Annamycin was administered by a single 1- to 2-h intravenous infusion at 3-week intervals. Thirty-six patients with relapsed solid tumors were treated and 109 treatment courses were administered at doses ranging from 3 to 240 mg/m<sup>2</sup>. No cardiotoxicity was seen on biopsy of heart tissue of four patients studied. The maximum tolerated dose (MTD) for L-Annamycin in solid tumor patients was found to be 190 mg/m<sup>2</sup>. A second Phase II study of L-Annamycin was performed in 13 women with doxorubicin-resistant breast cancer. The median number of prior chemotherapy regimens was two, and six patients had two or more organ sites of involvement. L-Annamycin was administered at 190-250 mg/m<sup>2</sup> as a single i.v. infusion over 1-2 h every 3 weeks. Of the 13 patients, 12 had clear deterioration and new tumor growth after one or two courses.

The potential of a less cardiotoxic drug that was active against multi-drug resistant tumors led to a third trial in relapsed leukemia patients (both AML and ALL). The trial involved 20 patients with relapsed/refractory AML (n=17) or ALL (n=3). The conclusions drawn from the trial were that L-Annamycin was safe, well tolerated and showed potential clinical activity in patients with acute leukemias, and that further evaluation of this novel anthracycline in patients with hematopoietic, or blood borne, malignancies was clearly warranted.

## DEVELOPMENT STRATEGY

We began a Phase I 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. Additional sites enrolled in this study include the Roswell Park Cancer Institute (Buffalo, NY) and the Montefiore Medical Center (New York, NY). The single-arm, open-label L-Annamycin trial is designed to enroll patients in a dose escalation Phase I portion followed by 10 patients at a final fixed dose in the Phase II portion once the maximum tolerated dose (MTD) is determined. Up to 34 adult patients can be treated in this single-arm trial. On February 22, 2007, we announced the opening of a Phase I clinical trial of L-Annamycin in pediatric relapsed or refractory ALL or AML patients. The trial is presently open at two sites in the U.S., Phoenix Children's Hospital, Phoenix, AZ, and the University of Arizona, Tucson, AZ.

## MANUFACTURING OF ANNAMYCIN

An improved manufacturing method for Annamycin has been developed at Antibioticos S.p.A., our commercial supplier of GMP ( Good Manufacturing Practice ) drug substance. GMP material is currently being produced in sufficient quantity for all three anticipated trials outlined in the development strategy section. The analytical methods developed previously have been successfully transferred, and are in the process of being validated by Quantitative Technologies, Inc., our analytical contract research organization, or CRO, for Annamycin development work. The final lyophilized GMP formulated drug product is being manufactured by Pharmaceutical Services, Inc., who previously produced final product for the earlier clinical trials. Currently, Antibioticos S.p.A. is our sole supplier of Annamycin for our clinical trials. Our agreement with Antibioticos provides that Antibioticos will provide 400 grams of GMP drug substance (Annamycin) for our L-Annamycin clinical trials. Upon the conclusion of our Phase IIb clinical trials, the agreement provides that the parties will negotiate in good faith towards a commercial supply agreement for Annamycin.

## ORPHAN DRUG STATUS OF ATIPRIMOD AND L-ANNAMYCIN

On January 6, 2004, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of multiple myeloma. On September 26, 2006, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of carcinoid tumors. On June 24, 2005, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to L-Annamycin for the treatment of acute lymphoblastic leukemia. On June 28, 2005, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to L-Annamycin for the treatment of acute myeloid leukemia. The FDA grants orphan drug status for drug candidates that are intended to treat rare life-threatening diseases that, at the time of application, affect no more than 200,000 patients in the United States. The drug must have the ability to provide significant patient benefit over currently available treatment or fill an unmet medical need. Orphan drug designation entitles us to seven years of market exclusivity in the United States of America, and ten years of market exclusivity in Europe, upon FDA marketing approval, provided that we continue to meet certain conditions established by the FDA. Once the FDA grants marketing approval of a new drug, the FDA will not accept or approve other applications to market the same medicinal product for the same therapeutic indication. Other incentives provided by orphan status include certain tax benefits, eligibility for research grants and protocol assistance. Protocol assistance includes regulatory assistance and possible exemptions or reductions of certain regulatory fees.



### **GUANYLATE CYCLASE RECEPTOR AGONIST TECHNOLOGY (Guanilib)**

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 North Carolina, Chapel Hill, NC. Recent results from his laboratory showed that Guanilib was efficacious in treatment of ulcerative colitis in mice. A patent allowance covering therapeutic applications of Guanilib in colon cancer and GI inflammatory diseases has recently been granted 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 2007 to bring forward a pre-clinical candidate for development in the clinic.

### **SUPERANTIGEN-BASED BIOTERRORISM DEFENSE**

On August 20, 1996, we entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University ( Rockefeller ) licensed patents covering peptides and antibodies useful in treating toxic shock syndrome and septic shock. In addition, on July 25, 2001, we entered into a license agreement for two additional patents related to the regulation of exoproteins in staphylococcus aureus.

On April 1, 2005 we were awarded a two-year \$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. The goal was to design a monoclonal antibody and vaccine that prevent the unregulated activation of T-cells (human white blood cells) by bacteria from the class of staphylococcus aureus and streptococcus pyogenes. Funding for this program will end in the spring of 2007. Because the bioterrorism program is not a core activity of Callisto, we expect to terminate further development work upon the expiration of the research grant.

### **EMPLOYEES**

Our plan is to use contract research organizations ( CRO ) for most of our development efforts, including monitoring of clinical trial results, thus minimizing the need to hire full time employees. As of May 14, 2007, we had 9 full-time and 4 part-time employees.

### **OFF-BALANCE SHEET ARRANGEMENTS**

We had no off-balance sheet arrangements as of March 31, 2007.

## RESULTS OF OPERATIONS

### THREE MONTHS ENDED MARCH 31, 2007 AND MARCH 31, 2006

We had no revenues during the three months ended March 31, 2007 and 2006 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 \$1,235,157 or 56%, to \$958,683 for the three months ended March 31, 2007 from \$2,193,840 for the three months ended March 31, 2006. While we have recently closed on a private placement (see Liquidity and Capital Resources below) we refocused our development activities onto the clinical development of our most promising drug candidate, Atiprimod, during our first quarter of 2007. Atiprimod development expenses were approximately \$500,000 in the three months ended March 31, 2007 which was unchanged from the level of spending during the three months ended March 31, 2006. All other development programs were significantly curtailed during the three months ended March 31, 2007 resulting in the following: (i) costs related to the development of L-Annamycin were reduced by approximately \$360,000, or 65%, (ii) Degrasyns development spending was curtailed 100% from approximately \$300,000 in the quarter ended March 31, 2006 and (iii) Guanilib development expenditures were reduced by 80% or approximately \$100,000, as compared to the three months ended March 31, 2006. In addition our research and development overhead not allocated to specific programs, principally in-house staff related expenses, was reduced approximately \$500,000 or 67% during the three months ended March 31, 2007. Included in research and development overhead was stock based compensation expense, associated with options granted to employees, which decreased approximately \$130,000 from approximately \$149,000 in the quarter March 31, 2006 to approximately \$19,000 in the quarter ended March 31, 2007.

General and administrative expenses for the three months ended March 31, 2007 were also curtailed to \$959,660, a decrease of \$794,430 or 45%, from \$1,754,090 for the three months ended March 31, 2006. This decrease was accomplished primarily by reducing (i) spending on investor relations by approximately \$347,000, (ii) bonuses by approximately \$70,000, (iii) accounting, audit and legal expenses by approximately \$60,000 and (iv) stock based compensation expense associated with options granted to employees by approximately \$243,000 or 72% from approximately \$341,000 in the quarter ended March 31, 2006 to approximately \$98,000 in the quarter ended March 31, 2007. This reduced stock-based compensation is primarily attributable to the forfeiture of options held by Dr. Donald Picker who resigned on December 19, 2006.

Net loss for the three months ended March 31, 2007 was \$1,829,928 compared to a net loss of \$4,374,628 incurred for the three months ended March 31, 2006. The decreased net loss is the result of lower research and development, and general and administrative expenses both of which are discussed above. In addition we recorded a net gain of \$19,478 in non-employee stock based compensation expense during the three months ended March 31, 2007 due to a lower stock price which resulted in a reversal of expense previously recorded on certain options we account for as variable as required by FIN No. 44. This compared to an expense of \$504,047 recorded during the three months ended March 31, 2006.

The beneficial conversion dividend accreted to the Series A preferred stockholders, upon issuance in the quarter ended March 31, 2007, was \$119,685, resulting in a net loss available to common stockholders of \$1,949,623 for the three months ended March 31, 2007. This compared to a net loss available to common stockholders of \$4,374,628 reported for the three months ended March 31, 2006, during which period we had no preferred share transactions and no related beneficial conversion feature that needed to be accreted as a dividend.



## LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2007 we had \$2,158,676 in cash and cash equivalents, compared to \$3,904,232 as of December 31, 2006. This decrease in cash of \$1,745,556 during the three months ended March 31, 2007 was principally the result of cash used in operating activities of \$1,989,156; partially offset by the completion of a private placement of Series A Convertible preferred stock yielding net proceeds of \$243,600.

From October 2006 until January 2007, we placed 602,350 shares of Series A Convertible Preferred Stock and 8,031,333 warrants to certain investors for aggregate gross proceeds of \$6,023,500. As of December 31, 2006 we had closed on 574,350 shares of such Series A Convertible Preferred Stock for aggregate gross proceeds of \$5,743,500. The final tranche of this financing closed January 10, 2007 when we placed 28,000 shares of such Series A Convertible Preferred Stock for aggregate gross proceeds of \$280,000. The shares of Series A Convertible Preferred Stock are convertible into shares of common stock at a conversion price of \$0.75 per share. The investors also are parties to a Registration Rights Agreement, dated as of October 23, 2006 pursuant to which we agreed to file, within 60 days of closing, a registration statement with the Securities and Exchange Commission (the "SEC") covering the resale of the shares of common stock underlying the Series A Convertible Preferred Stock and the warrants issued to the investors. The warrants are immediately exercisable at \$0.75 per share, will expire five years from the date of issuance, and have certain antidilution rights for the twelve month period beginning on the effective date of the registration statement registering the shares of common stock underlying the warrants. We paid aggregate fees and expenses of \$485,308 (\$448,908 prior to December 31, 2006) in cash, issued an aggregate 11,775 shares of Series A Convertible Preferred Stock and 1,228,761 warrants to purchase common stock to certain selling agents. The warrants are immediately exercisable at \$0.75 per share, will expire five years after issuance and have the same anti-dilutive rights as the investor warrants. On January 12, 2007 we filed a registration statement on Form S-3 registering the common stock issuable upon (i) the conversion of the all Series A Convertible Preferred Stock, (ii) the exercise of all related investor warrants and (iii) the exercise of all selling agent warrants. On February 15, 2007 Amendment No.1 to this registration statement was declared effective by the SEC.

On April 24, 2007, we entered into a services agreement with Barretto Pacific Corporation pursuant to which Barretto will provide beginning May 1, 2007, investor relations services to us. We will pay Barretto a fee of \$120,000 over a seven month period and 80,000 shares of restricted common stock.

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, 2006 have been prepared under the assumption that we will continue as a going concern for the twelve months ending December 31, 2007. Our independent registered public accounting firm has issued a report dated April 13, 2007 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.

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 this Annual Report on Form 10-K for the fiscal year ended December 31, 2006. 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.

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, 2007 stock based compensation expense has totaled \$16,613,610 or 27% of our total accumulated deficit of \$62,393,991.

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 was effective as of the beginning of the first interim or annual reporting period that began after December 15, 2005 and accordingly we adopted SFAS 123R 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. We have elected to use the modified *prospective* method in adopting this standard.

Prior to January 1, 2006, we had adopted SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ). As provided for by SFAS 123, we had elected to continue to account for stock-based compensation 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 services rendered based on the intrinsic value of stock options granted under the plan.

SFAS 123R did not change the way we account for non-employee stock-based compensation. We continue to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant.

For all fair value computations required for employee and non-employee stock-based compensation we use the Black-Scholes option-pricing model which requires assumptions for expected stock price volatility, expected term of the option, risk-free interest rate and expected dividend yield at the grant date. Our stock price has fluctuated from \$3.95 per share as of December 31, 2003 to \$0.75 per share as of March 31, 2007.

Research and Development: We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all and therefore our research and development costs are expensed as incurred. These include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of our proposed products, purchase of in-process research and development, regulatory and scientific consulting fees, contract research and royalty payments to outside suppliers, facilities and universities as well as legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products. While certain of our research and development costs may have future benefits, our policy of expensing all research and development expenditures is predicated on the fact that we have no history of successful commercialization of biopharmaceutical products to base any estimate of the number of future periods that would be benefited.



**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk 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, 2007 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, 2007, our Chief Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were not effective due to the fact that we lack sufficient internal accounting personnel and segregation of duties necessary to ensure that an adequate review of the financial statements and notes thereto is performed 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, 2007, our disclosure controls and procedures were not 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 order to ensure the effectiveness of our disclosure controls in the future we plan to add financial staff resources to our accounting and finance department. 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.

The consolidated financial statements include all adjustments identified as a result of the evaluation performed.

There were no changes in our internal controls over financial reporting that could significantly affect internal controls over financial reporting during the quarter ended March 31, 2007.

**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 for the year ended December 31, 2006, which could materially affect our business, financial condition or future results. There have been no material changes to the risk factors disclosed in the Annual Report.

**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: May 21, 2007*

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

*Date: May 21, 2007*

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