CALLISTO PHARMACEUTICALS INC
Form 10-Q
November 14, 2007

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UNITED STATES OF AMERICA
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: September 30, 2007

o **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	**13-3894575**
(State or Other Jurisdiction of Incorporation or Organization)	(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 to such filing requirements for the past 90 days. Yes ý No o

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 o Accelerated filer o Non-accelerated filer ý

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ý

The number of the registrant's shares of common stock outstanding was 46,863,161 as of November 12, 2007.

CALLISTO PHARMACEUTICALS, INC.

FORM 10-Q

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INTRODUCTORY NOTE

This Report on Form 10-Q for Callisto Pharmaceuticals, Inc. ("Callisto" or the "Company") may contain forward-looking statements. You can identify these statements by forward-looking words such as "may," "will," "expect," "intend," "anticipate," believe," "estimate" and "continue" or similar words. Forward-looking statements include information concerning possible or assumed future business success or financial results. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Accordingly, we do not undertake any obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under "Risk Factors" in our Annual Report on Form 10-K 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

	September 30, 2007	December 31, 2006
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 226,613	$ 3,904,232
Cash in escrow	8,480,000	
Prepaid expenses and other	94,122	66,741
	8,800,735	3,970,973
Property and equipment net	4,300	6,451
Security deposits	73,716	73,716
	$ 8,878,751	$ 4,051,140
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,718,623	$ 1,843,422
Accrued expenses	1,803,945	1,357,600
	3,522,568	3,201,022
Stockholders' equity:		
Series A convertible preferred stock, par value $0.0001, 700,000 shares authorized, 292,675 shares outstanding at September 30, 2007 with a liquidation preference of $2,926,750 and 586,125 shares outstanding at December 31, 2006 with a liquidation preference of $5,861,250	29	58
Series B convertible preferred stock, par value $0.0001, 2,500,000 shares authorized, 1,147,050 shares outstanding at September 30, 2007 with a liquidation preference of $11,470,500	115	
Common stock, par value $.0001, 225,000,000 and 100,000,000 shares authorized and 45,463,161 and 39,194,996 shares outstanding at September 30, 2007 and December 31, 2006, respectively	4,546	3,919
Additional paid-in capital	82,755,403	61,290,509
Deficit accumulated during development stage	(77,403,910)	(60,444,368)
	5,356,183	850,118
	$ 8,878,751	$ 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 September 30,		Nine Months Ended September 30,		June 5, 1996 (Inception) to September 30, 2007
	2007	2006	2007	2006	
Revenues	$	$	$	$	$
Costs and expenses:					
Research and development	1,420,886	1,139,094	3,498,604	4,898,524	25,536,419
Government grants	(93,000)	(43,956)	(196,069)	(299,378)	(1,040,534)
Purchased in process research and development					6,944,553
General and administrative	1,417,363	800,803	3,350,519	4,012,012	24,104,259
Stock based compensation non employees	(52,397)	(139,501)	(55,274)	820,747	9,643,287
Loss from operations	(2,692,852)	(1,756,440)	(6,597,780)	(9,431,905)	(65,187,984)
Interest and investment income	18,682	3,304	47,396	45,405	751,012
Other expense, net		(177,010)		(334,446)	(173,295)
Change in fair value of Series B warrants from date of issuance to expiration of put option	2,591,005		2,591,005		2,591,005
Net loss	(83,164)	(1,930,146)	(3,959,379)	(9,720,946)	(62,019,262)
Series A Preferred stock beneficial conversion feature accreted as a dividend	(2,384,790)		(2,504,475)		(4,888,960)
Series B Preferred stock beneficial conversion feature accreted as a dividend	(10,495,688)		(10,495,688)		(10,495,688)
Net loss available to common stockholders	$ (12,963,642)	$ (1,930,146)	$ (16,959,542)	$ (9,720,946)	$ (77,403,910)
Weighted average shares outstanding:					
basic and diluted	41,821,509	38,454,931	40,218,653	37,558,910	
Net loss per common share:					
basic and diluted	$ (0.31)	$ (0.05)	$ (0.42)	$ (0.26)	

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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

	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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

	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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

	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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

	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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

	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

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
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)	
Balance, December 31, 2006	586,125	$ 58	39,194,996	$ 3,919	$ 61,290,509	$	$ (60,444,368)	$ 850,118

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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Common Shares	Common Stock Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
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								(3,959,379)	(3,959,379)
Stock based compensation expense							226,509		226,509
Common stock issued for services					80,000	8	36,792		36,800
Series A convertible preferred stock, issued via private placement	28,000	3					279,997		280,000
Finders fees and expenses Series A private placement							(36,400)		(36,400)
Conversion of Series A preferred stock to common stock	(321,450)	(32)			6,188,165	619	(587)		
Beneficial conversion feature accreted as a dividend to Series A convertible preferred stock							2,504,475	(2,504,475)	
Series B convertible preferred stock, issued via private placement			1,147,050	115			11,470,385		11,470,500
Finders fees and expenses Series B private placement							(920,960)		(920,960)
Beneficial conversion feature accreted as a dividend to Series B convertible preferred stock							10,495,688	(10,495,688)	
Change in fair value of Series B warrants from date of issuance to expiration of put option							(2,591,005)		(2,591,005)
Balance September 30, 2007	292,675	$ 29	1,147,050	$ 115	45,463,161	$ 4,546	$ 82,755,403	$ (77,403,910)	$ 5,356,183

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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months Ended September 30,		Period from June 5, 1996 (inception) to September 30, 2007
	2007	2006	
Cash flows from operating activities:			
Net loss	$ (3,959,379)	$ (9,720,946)	$ (62,019,262)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,151	1,434	88,939
Stock based compensation expense	263,309	1,996,921	16,780,756
Purchased in-process research and development non-cash portion			6,841,053
Liquidated damages non-cash			579,696
Change in fair value of Series B warrants	(2,591,005)		(2,591,005)
Changes in operating assets and liabilities:			
Prepaid expenses	(27,381)	63,447	(94,122)
Rent deposits		8,480	(73,716)
Accounts payable and accrued expenses	321,546	835,335	3,230,139
Total adjustments	(2,031,380)	2,905,617	24,761,740
Net cash used in operating activities	(5,990,759)	(6,815,329)	(37,257,522)
Cash flows from investing activities:			
Acquisition of equipment		(8,602)	(93,239)
Net cash used in investing activities		(8,602)	(93,239)
Cash flows from financing activities:			
Issuance of common and preferred stock, net of repurchases	11,750,500	5,940,210	48,719,673
Finders' fees and expenses	(957,360)	(602,808)	(2,981,083)
Exercise of common stock warrants		190,035	318,785
Proceeds from private placement toescrow	(8,480,000)		(8,480,000)
Net cash provided by financing activities	2,313,140	5,527,437	37,577,375
Net (decrease) increase in cash and cash equivalents	(3,677,619)	(1,296,493)	226,613
Cash and cash equivalents at beginning of period	3,904,232	1,420,510	
Cash and cash equivalents at end of period	$ 226,613	$ 124,017	$ 226,613
Supplementary disclosure of cash flow information:			
Cash paid for taxes	$ 640	$ 6,409	$ 124,127
Cash paid for interest	$	$	$

	Nine months Ended September 30,		Period from June 5, 1996 (inception) to September 30, 2007
Supplemental disclosure of non-cash investing and financing activities:			
Beneficial conversion feature accreted as a dividend to Series A convertible preferred stock	$ 2,504,475	$	4,888,960
Beneficial conversion feature accreted as a dividend to Series B convertible preferred stock	$ 10,495,688	$	$ 10,495,688
Change in fair value of Series B warrants from date of issuance to expiration of put option	$ (2,591,005)	$	$ (2,591,005)
Stock options, warrants and common stock issued for services	$ 263,309	$ 1,996,921	$ 16,780,754
Common stock issued upon conversion of Series A convertible preferred stock	$ 619	$	$ 619
Stock-based liquidated damages	$	$	$ 579,696
Purchased in-process research and development	$	$	$ 6,841,053

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 September 30, 2007, Callisto has sustained cumulative net losses available to common stockholders of $77.4 million. Callisto's losses have resulted primarily from cash expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, patent filing and maintenance expenses, outside accounting and legal services and regulatory, scientific and financial consulting fees. Non-cash items included in the above cumulative net losses available to common stockholders totaled approximately $37 million, comprising stock-based compensation expense, purchase of in-process research and development, beneficial conversion features of preferred stock accreted as dividends, changes in fair value of investor warrants and stock-based liquidated damages. From inception through September 30, 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 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, 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 subsidiary Synergy Advanced Pharmaceuticals, Inc. and its 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 and nine months ended September 30, 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 September 30, 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 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 nine months ended September 30, 2007 and 2006 and for the period from June 5, 1995 (inception) to September 30, 2007 was approximately $2.3 million, $5.5 million and $37.6 million, respectively.

In August 2007, Callisto closed a private placement of 1,147,050 shares of Series B Convertible Preferred Stock (the "Series B Preferred Stock") and 22,941,000 warrants (the "Warrants") to certain investors (the "Investors") for aggregate gross proceeds of $11,470,500 pursuant to a Securities Purchase Agreement dated as of August 2, 2007 (the "SPA"). Each share of Series B Preferred Stock was immediately convertible into that number of shares of common stock determined by dividing the stated value of $10.00 of such share of Series B Preferred Stock by $0.50 (the "Conversion Price"), at the option of the holder, at any time and from time to time. The Warrants are immediately exercisable at $0.70 per share and are exercisable at any time within three years from the date of issuance.

In connection with this transaction Callisto paid aggregate fees and expenses of $920,960 and issued warrants to purchase 2,473,900 shares of common stock at $0.50 per share and 2,473,900 shares of common stock at $0.70 per share to certain selling agents, which are exercisable at any time within four years from the date of issuance. Subsequent to closing, $8,480,000 of the net proceeds was placed into escrow. (See note 5 below for a more detailed description of this transaction).

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.

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.

The unrecognized compensation cost related to non-vested share-based compensation arrangements for all employee stock options outstanding at September 30, 2007 and 2006 was $372,124 and $912,932, respectively, to be recognized over a weighted average remaining vesting period of 1.11 and 1.01 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:

Stock based compensation expense	Three Months Ended September 30, 2007	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2006	June 5, 1996 (Inception) to September 30, 2007
Employees included in research and development	$ 19,443	$ 74,059	$ 51,987	$ 363,662	$ 2,604,531
Employees included in general and administrative	64,636	151,342	266,596	812,512	4,532,937
Subtotal employee stock option grants	84,079	225,401	318,583	1,176,174	7,137,468
Non-employee research and development	1,004		1,004	102,750	103,754
Non-employee general and administrative	(53,401)	(139,501)	(56,278)	717,997	9,539,534
Subtotal non-employee stock option grants	(52,397)	(139,501)	(55,274)	820,747	9,643,288
Total stock based compensation expense	31,682	85,900	263,309	1,996,921	16,780,756

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 and nine months ended September 30, 2007 and 2006:

	Three months ended September 30, 2007	Three months ended September 30, 2006	Nine months ended September 30, 2007	Nine months ended September 30, 2006
Risk free interest rate	4.7%	4.3%	4.7%	4.3%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	60%	79%	60%	79%
Expected term	5 years	7 years	5-6 years	7 years

Risk-free interest rate: 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: 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. The expected term of the employee and non-employee director options is the estimated weighted-average period until exercise or cancellation of vested options (forfeited unvested options are not considered). SAB 107 guidance permits companies to use a "safe harbor" expected term assumption for grants up to December 31, 2007 based on the mid-point of the period between vesting date and contractual term, averaged on a tranche-by-tranche basis. Callisto used the SAB 107 safe harbor for its expected term assumption starting on January 1, 2006. Previously

Callisto had estimated expected term based on a sampling of industry comparables for publicly traded companies. The expected term for consultant awards is the remaining period to contractual expiration.

Forfeitures: 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	784,500	$ 0.47 - 0.96	$ 0.78
Forfeitures	(596,668)	$ 0.75 - 1.60	$ 1.24
Balance, September 30, 2007	8,241,207	$ 0.47 - 6.75	$ 1.69
Exercisable as of September 30, 2007	5,597,207	$ 0.75 - 6.75	$ 1.67

The weighted average remaining term of all options outstanding at September 30, 2007 was 6.04 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.

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, warrants and convertible preferred stock, would have been antidilutive.

The following table sets forth the potentially dilutive effect of all outstanding derivative instruments which were not included in weighted average shares outstanding:

	September 30, 2007	September 30, 2006
Common Shares outstanding	45,463,161	33,108,096
Potentially dilutive common shares issuable upon:		
Exercise of warrants	45,162,920	4,864,601
Exercise of stock options	8,241,207	8,424,875
Conversion of Series A Convertible Preferred Stock	5,853,500	
Conversion of Series B Convertible Preferred Stock	22,941,000	
Total fully diluted	127,661,788	46,397,572

5. Stockholders' equity (deficit):

On September 27, 2007, Callisto filed a Certificate of Amendment to its Certificate of Incorporation increasing its authorized number of shares of common stock from 150,000,000 to 225,000,000. The Certificate of Amendment was approved by Callisto's stockholders at its annual meeting on September 26, 2007.

On September 25, 2007, Callisto issued a warrant to purchase 1,150,000 shares of its common stock at an exercise price of $0.47 per share to a consultant for services to be rendered to the Company's newly formed subsidiary, Synergy Advanced Pharmaceuticals, Inc. ("Synergy"), in connection with the development of Guanilib, Callisto's proprietary compound to treat gastrointestinal disorders such as chronic constipation and irritable bowel syndrome. So long as the consultant continues to provide services in some capacity to the Company or any of its subsidiaries, the warrant will vest in installments of 225,000 warrant shares on each of the first four anniversaries of the initial exercise date. The remaining 250,000 warrant shares will vest immediately prior to the consummation of a sale or merger of Synergy provided that such transaction occurs on or prior to October 1, 2009 and Synergy is valued at no less than $250,000,000. In the event there is a change of control of the Company, all unvested warrant shares will immediately vest.

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 Service* s ("EITF 96-18"), the measurement date for purposes of recording stock based compensation on these warrants will be the earliest of the fourth anniversary of the agreement (when "performance commitment is completed") or the accelerated vesting date if a change of control occurs. Accordingly the fair value of the 900,000 warrants which vest over time is being "marked to market" quarterly until the measurement date is determined. The fair value of the 900,000 warrants vesting over time as of September 30, 2007 was $293,189 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.68%, no dividend, an expected life of 4 years and a stock price of $0.50 per share. Stock-based compensation expense associated with these 900,000 time vested options recorded during the

three and nine months ended September 30, 2007 was $1,004. The fair value of the 250,000 warrants which vest upon a change of control will not be measured until that milestone event occurs and thus no compensation expense has been recorded as of September 30, 2007.

In August 2007, Callisto closed a private placement of 1,147,050 shares of Series B Preferred Stock and 22,941,000 Warrants to certain Investors for aggregate gross proceeds of $11,470,500 pursuant to a Securities Purchase Agreement dated as of August 2, 2007. Each share of Series B Preferred Stock was immediately convertible into that number of shares of common stock determined by dividing the stated value of $10.00 of such share of Series B Preferred Stock by $0.50, at the option of the holder, at any time and from time to time. The Warrants are immediately exercisable at $0.70 per share at any time within three years from the date of issuance. In connection with this transaction, Callisto paid aggregate fees and expenses of $920,960 and issued warrants to purchase 2,473,900 shares of common stock at $0.50 per share at any time within three years from the date of issuance and 2,473,900 shares of common stock at $0.70 per share at any time within four years from the date of issuance to certain selling agents. The fair value of the selling agent warrants on the date of grant was $1,839,962 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.57% to 4.31%, no dividend, an expected life of 4 years and a stock price on the dates of grant ranging from $0.66 to $0.68 per share. This fair value was accounted for as a cost of capital.

Other than pursuant to certain issuances, for the twelve month period beginning on the effective date of the Registration Statement registering the resale of the shares of Common Stock underlying the Warrants by the Holder, if the Company at any time while the Warrants are outstanding, shall sell or grant any option to acquire shares of Common Stock, at an effective price lower than the then exercise price then, the exercise price shall be reduced to such lower price.

Subsequent to closing, $8,480,000 of the net proceeds were placed into escrow at the request of RAB Special Situations (Master) Fund Limited and Absolute Octane Master Fund Limited (collectively, the "Lead Investors"), each of which invested $5,000,000 in the private placement. Pursuant to a Put Option Agreement, the Lead Investors had the right until October 30, 2007 to require redemption by the Company of all of the Series B Convertible Preferred Stock and 85% of the Warrants purchased by them only upon the occurrence of any of the following events:

(i)

The Company shall have not received the approval of its common stockholders of the issuance of shares of Common Stock issuable upon the conversion of the Series B Convertible Preferred Stock or the exercise of the Warrants (the "Underlying Shares") by 5:00 pm New York time on September 30, 2007. Such approval was obtained at a meeting of stockholders held on September 26, 2007.

or

(ii)

The American Stock Exchange shall not have approved the Listing of Additional Securities application filed by the Company relating to the Underlying Shares by 5:00 pm New York time on September 30, 2007 (for a reason other than the Lead Investors failing to timely provide American Stock Exchange with information reasonably requested by Amex Listing Qualification as part of their review of the application); The American Stock Exchange approved the Company's Listing of Additional Securities on September 26, 2007.

or

(iii)

The American Stock Exchange or the Company delists the Common Stock on or before 5:00 pm New York time on September 30, 2007. As of September 30, 2007 Callisto stock continued to be listed on the American Stock Exchange.

Having satisfied these conditions of the Put Option as of September 30, 2007 the escrow was released on October 1, 2007.

The Investors also are parties to a Registration Rights Agreement, dated as of August 2, 2007 pursuant to which the Company agreed to file, within 45 days of closing, a registration statement covering the resale of the shares of common stock underlying the Series B Preferred Stock and Warrants issued to the Investors. Failure to file a registration statement and maintain its effectiveness as agreed will result in the Company being required to pay liquidated damages equal to 1% per month of the aggregate purchase price paid by the Investors, not to exceed an aggregate of 18%. The Company filed a Form S-3 Registration Statement covering the sale of the common shares underlying the conversion of the Series B Preferred Stock and the Warrants on September 11, 2007 and this Form S-3 was declared effective by the SEC on September 27, 2007.

Material terms of the Series B Preferred Stock are:

Use of Proceeds. At least 50% of the net proceeds from the sale of the Series B Preferred Stock to the Lead Investors shall be dedicated to the development and clinical trials of Guanilib and the remaining net proceeds shall be used for working capital purposes.

Voting Rights. The Series B Preferred Stock shall have no voting rights. However, so long as any shares of Series B Preferred Stock are outstanding, the Company shall not, without the affirmative vote of the holders of the shares of the Series B Preferred Stock then outstanding, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or

amend the Certificate of Designation (whether by merger, consolidation or otherwise), (b) authorize or create any class of stock ranking as to dividends, redemption or distribution of assets upon a Liquidation senior to or otherwise *pari passu* with the Series B Preferred Stock, (c) amend its certificate of incorporation or other charter documents so as to affect adversely any rights of the holders, (d) increase the authorized number of shares of Series B Preferred Stock, or (e) enter into any agreement with respect to the foregoing.

Liquidation. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders shall be entitled to receive out of the assets of the Company, whether such assets are capital or surplus, for each share of Series B Preferred Stock an amount equal to the stated value of $10.00 per share, plus any accrued and unpaid dividends thereon and any other fees or liquidated damages owing thereon before any distribution or payment shall be made to the holders of any junior securities, and if the assets of the Company shall be insufficient to pay in full such amounts, then the entire assets to be distributed to the Holders shall be distributed among the holders ratably in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Conversion.

Conversions at Option of Holder. Each share of Series B Preferred Stock shall be convertible into that number of shares of common stock determined by dividing the stated value of $10.00 of such share of Series B Preferred Stock by $0.50 (the "Conversion Price"), at the option of the holder, at any time and from time to time.

Conversion at the Option of the Company. Beginning August 2, 2008, provided certain conditions are satisfied, if the volume weighted average price of the Company's common stock equals $1.00 per share for the 20 consecutive trading days and the average daily volume of the common stock is at least 0.5% of the shares that are being converted, the Company shall have the right to convert any portion of the Series B Preferred Stock into shares of common stock at the then-effective Conversion Price.

Subsequent Equity Sales. For the twelve (12) month period beginning on the effective date of the registration statement registering the resale of the shares of common stock underlying the Series B Preferred Stock by the holder, if the Company at any time while Series B Preferred Stock is outstanding, shall sell or grant any option to purchase or otherwise dispose of or issue any common stock or common stock equivalents entitling any Person to acquire shares of Common Stock, at an effective price per share less than the then Conversion Price (the "*Base Conversion Price*"), then, the Conversion Price shall be reduced to an amount equal to the Base Conversion Price.

As per FASB Statement of Financial Accounting Standards No. 150: *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*, the Company determined the balance sheet classification of the Series B Preferred Stock to be equity given that the mandatory redemption option had expired as of September 30, 2007. The escrow was released on October 1, 2007 with no further claims or restrictions on the cash thus the Company classified these proceeds, totaling $8,480,000, as cash in escrow as of September 30, 2007.

As per Emerging Issues Task Force ("EITF") Issue 00-19, *"Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, Company Stock"*, ("EITF 00-19") Callisto has determined that the fair value of the Series B Warrants issued to the Lead Investors should be treated as a liability upon issuance and reclassified to permanent equity based on the fair value upon expiration of the Put Option. The change in fair value of the Series B Lead Investor warrant from the date of issuance through the expiration of the Put Option was recorded as other income totaling $2,591,005 during the three and nine months ended September 30, 2007. Callisto has determined that the warrants issued to other than Lead Investors should be treated as "permanent equity.

As per FSP 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 no liability needed to be recorded because the Company filed a timely registration statement covering the sale of the common shares underlying the conversion of the Series B Preferred Stock and the Warrants on September 11, 2007.

As per EITF 00-27, "Application *of Issue 98-5 to Certain Convertible Instruments*" ("EITF 00-27") Callisto evaluated the Series B 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 $6,677,513 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.57% to 4.31%, no dividend, an expected life of 3 years and a stock price on that dates of grant ranging from $0.66 to $0.68 per share. The conversion rights of the Series B Preferred Stock contained an embedded beneficial conversion feature totaling $10,495,688 that was immediately accreted to the Series B Convertible Preferred Stock as a dividend because the preferred stock could be converted immediately upon issuance.

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 traunche 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 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. The fair value of the selling agent warrants on the date of grant was $640,481 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.60%, no dividend, an expected life of 5 years and a stock price on the dates of grant of $0.88 per share. This fair value was accounted for as a cost of capital.

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. Subject to the rights of the holders of the Series B Convertible Preferred Stock, 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 EITF 00-19, Callisto has determined that the warrants should be treated as "permanent equity".

As per FSP No. 00-19-2 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 no liability needed to be recorded. 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.

As per EITF 00-27,Callisto evaluated the Series A Convertible 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 Series A Convertible 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 Series A Convertible Preferred Stock as a dividend because the preferred stock could be converted immediately upon issuance. The beneficial conversion feature associated with final traunche of 28,000 shares of Series A Convertible Preferred Stock placed on January 10, 2007 amounted to $119,685 and was recorded as a beneficial conversion feature accreted as a dividend in the quarter ended March 31, 2007.

The 292,675 shares of Series A Preferred Stock outstanding as of September 30, 2007 and 8,031,333 warrants issued from October 23, 2006 through January 10, 2007 in connection with the Series A Preferred Stock financing have certain antidilution rights. As a result of the August 2, 2007 Series B Preferred Stock financing the conversion price of the then remaining Series A Preferred Stock and the exercise price of the then remaining Series A Warrants was reset from $0.75 per share to $0.50 per share. This modification resulted in $2,384,790 of additional beneficial conversion accreted as a dividend during the quarter ended September 30, 2007.

During the nine months ended September 30, 2007 35,375 shares of Series A Convertible Preferred Stock were converted to 466,665 shares of common stock prior to August 2, 2007 at conversion price of $0.75 per share and 286,075 shares of Series A Convertible Preferred Stock were converted to 5,721,500 shares of common stock subsequent to August 2, 2007 at conversion price of $0.50 per share.

6. Commitments and contingencies:

Employment and consulting agreements:

On September 25, 2007, Synergy entered into a Service Agreement with Capebio, LLC ("Capebio") to provide research and development services for the commercialization of non-oncology related gastrointestinal pharmaceutical products under the Guanilib patent. The Service Agreement is for a minimum term of eleven months starting October 1, 2007 during which period Synergy paid an initial fee of $55,000 and is obligated to pay $26,000 per month through August 31, 2008. In addition Capebio will be eligible for a bonus of $58,000 if certain performance milestones are achieved by December 31, 2007 and Synergy is required to establish an escrow of $250,000 in favor of Capebio to guarantee specific performance under the Service Agreement.

In connection with this agreement Callisto issued a warrant to Capebio LLC to purchase 1,150,000 shares of common stock at a price of $0.47 per share. The warrant vests in installments of 225,000 shares each on September 25, 2008, 2009 and 2010. 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 Service*s ("EITF 96-18"), the measurement date for these 900,000 warrants will be each of the next three anniversaries of the agreement (when "performance commitment is completed"). The fair value of these 900,000 time vested warrants on the date of grant was $270,316 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.68%, no dividend, an expected life of 7 years and a stock price on the dates of grant of $0.47 per share. As per EITF 96-18 this fair value is being "marked to market" until each measurement date is determined. The fair value as of September 30, 2007 was $293,189 and Callisto recorded $1,004 of stock based compensation expense in the three and nine months ended September 30, 2007. The remaining installment of 250,000 shares vests if certain milestones are achieved prior to October 1,

2009 and stock based compensation, if any, will be measured and recorded at that date. All of the warrants expires on September 25, 2014.

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 by Mr. Cerrone during the period from July 1, 2006 to January 25, 2007, Callisto paid Mr. Cerrone a bonus of $75,000 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. In accordance with 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 of $165,040 on the date of grant is being "marked to market" quarterly until the measurement date is determined. The fair value of these options as of September 30, 2007 was $56,294. Stock-based compensation expense, associated with these options, recorded during the three and nine months ended September 30, 2007 was $132 and $12,750 respectively.

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 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 were unchanged.

On April 24, 2007, Callisto entered into a services agreement with Barretto Pacific Corporation ("Barretto") to provide, beginning May 1, 2007, investor relations services. Callisto agreed to pay Barretto a fee of $120,000 over a seven month period and issue 80,000 shares of restricted common stock. During the three months ended June 30, 2007 Callisto paid $20,000 of this fee and issued the 80,000 shares of common stock. The fair value of the common shares issued to Barretto was $55,200, of which $36,800 was accounted for as stock-based compensation expense during the three months ended June 30, 2007. On August 2, 2007 Callisto and Barretto entered into a Termination and Release Agreement cancelling any further obligations to pay fees beyond the $20,000 paid in June 2007 and Barretto returned the 80,000 shares of common stock. No stock based compensation was recorded on these shares during the quarter ended September 30, 2007.

On June 8, 2007 Callisto filed a complaint against Donald Picker, its former Executive Vice President, Research & Development in the Supreme Court of the State of New York alleging that (i) Dr. Picker breached his written employment agreement with Callisto by accepting employment with Tapestry Pharmaceuticals, Inc. a manner not in accordance with his agreement, (ii) Dr. Picker acted fraudulently by failing to reveal to Callisto that he was negotiating employment with Tapestry while purportedly representing Callisto in negotiations with Tapestry pursuant to a confidential disclosure

agreement between Tapestry and Callisto and (iii) Dr. Picker misappropriated confidential files and materials from Callisto's offices. Callisto is seeking $80 million in damages from Dr. Picker.

On June 18, 2007, Callisto received notice from the staff of the American Stock Exchange ("AMEX") indicating that it is not in compliance with certain continued listing standards, specifically, Section 1003(a) (ii) of the Company Guide with shareholders' equity of less than $4,000,000 and losses from continuing operations and/or net losses in three of its four most recent fiscal years.

On July 18, 2007 Callisto submitted a plan, advising AMEX of the actions it has taken, or will take, that would bring it into compliance with Section 1003(a)(ii) of the Company Guide by April 3, 2008. On August 29, 2007, the Company received a letter from the AMEX that it had reviewed the Company's plan of compliance to meet the AMEX's continued listing standards and will continue the Company's listing while the Company seeks to regain compliance with Sections 1003 (a)(i) and 1003 (a)(ii) of the Company Guide during the period ending April 3, 2008.

On July 31, 2007 Callisto entered in a Mutual Release and Settlement Agreement with Trilogy Capital Partners, Inc.("Trilogy") wherein the parties settled their dispute and pending litigation. Callisto paid Trilogy $47,000 which amount was accrued for during the year ended December 31, 2006.

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

We are a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. Since inception in June of 1996 our efforts have been principally devoted to research and development, securing and protecting patents and raising capital. From inception through September 30, 2007, we have sustained cumulative net losses available to common stock holders of $77.4 million. Our losses have resulted primarily from cash expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, patent filing and maintenance expenses, outside accounting and legal services and regulatory, scientific and financial consulting fees. Non-cash items included in the above cumulative net losses available to common stockholders totaled approximately $37 million, comprising stock-based compensation expense, purchase of in-process research and development, beneficial conversion features of preferred stock accreted as dividends and stock-based liquidated damages. From inception through September 30, 2007, we have not generated any revenue from operations, expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all.

Our product development efforts are in their early stages and we 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.

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 Atiprimod to treat advanced carcinoid cancer patients, and on the pre-clinical and clinical development of Guanilib to treat gastrointestinal disorders. We announced on October 3, 2007 a major strategic initiative to develop Guanilib, our guanylyl cyclase C (GC-C) receptor agonist, to treat gastrointestinal disorders, primarily chronic constipation and constipation-predominant irritable bowel syndrome (IBS-C). We plan to file an investigational new drug (IND) application with FDA in the first quarter of 2008, and to initiate a Phase I trial in volunteers shortly thereafter. We also plan to open a Phase Ib trial of Guanilib in chronic constipation patients in late 2008.

Our lead drug candidate in the clinic, Atiprimod, is an orally administered drug with antiproliferative and antiangiogenic activity. In September, 2007 we completed full enrollment of a 40-patient, multi-center, open-label Phase II clinical trial of Atiprimod in low- to intermediate-grade neuroendocrine cancers, primarily advanced carcinoid cancer patients. We plan to release interim data from the trial in the first quarter of 2008 and also plan to have a meeting with the FDA on design of a registration trial some time during the first quarter of 2008.

Our second cancer drug candidate in the clinic, L-Annamycin, is a member of the anthracycline family of proven anti-cancer drugs. 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. We recently reached the maximum tolerated dose (MTD) in the adult trial and are currently evaluating its potential at the fixed-dose portion of the trial. We have not yet established the MTD in children. We plan to review future development of this drug once data from the adult trial are available.

1. ATIPRIMOD TO TREAT ADVANCED CARCINOID CANCER

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 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. Further characterization of the drug's mechanism-of-action in a series of experiments showed that the drug works by inducing apoptosis (programmed cell death) in myeloma cells. In a separate series of experiments performed with Atiprimod in 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 significant 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. Using a bone resorption assay (bone degradation experiment) to measure the effect of drug on osteoclast-mediated bone resorption, Atiprimod demonstrated a specific effect on osteoclast, or white blood cell, function. The drug appeared 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 was an open label study, with the primary objective of assessing safety of drug and identifying the maximum tolerated dose. The secondary objectives were 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. Patients were given doses of Atiprimod as high as 180 mg/day. In 2006, we amended this protocol to continue the trial at higher dose levels. The amended trial included the combination of Atiprimod with a drug called ursodiol to enable patients to be dosed at levels of Atiprimod higher than 180 mg/day. In October, 2007 we met the primary objective and reached the MTD in the Atiprimod + ursodiol arm. However, we do not intend to pursue Atiprimod as a single agent in multiple myeloma.

On March 15, 2005, we announced a second Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The trial, entitled: "An Open Label Study of the Safety and Efficacy of Atiprimod Treatment for Patients with Advanced Cancer" had as its primary objective the assessment of safety and determination of the maximum tolerated dose of Atiprimod in advanced cancer patients. The secondary objectives were 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. This trial established the potential of Atiprimod to treat advanced carcinoid cancer patients based on encouraging clinical results in a cohort of 5 advanced carcinoid cancer patients within this study.

On November 7, 2006, we announced the initiation of a multi-center, open-label Phase II clinical trial of Atiprimod in neuroendocrine carcinoma, comprised primarily of advanced carcinoid cancer patients. The primary objective of this trial was 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, were required to complete two weeks of a symptoms diary to establish their symptoms baseline before commencing Atiprimod dosing. A maximum of 40 evaluable patients were planned for this trial. We presently have eight clinical sites participating in the study in the U.S., with patients currently enrolled in seven of these sites. On September 20, 2007 we announced that we had completed full enrollment of this study, and that patients had been on drug as long as 11 months. In October 2007, we announced the opening of a Phase II extension trial of carcinoid cancer patients to permit those patients who had successfully completed the full year on the earlier Phase II trial which was designed to only permit dosing for up to one year to continue to receive Atiprimod therapy. We plan to release interim data from the advanced carcinoid cancer trials in the first quarter of 2008, and also plan to arrange to meet with the FDA on the design of a registration trial in the first quarter of 2008.

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 after confirming activity of the drug candidate in our current Phase II human clinical trials in advanced carcinoid cancer.

ORPHAN DRUG STATUS OF ATIPRIMOD

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. 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.

2. 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/m2. 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/m2. A second Phase II study of L-Annamycin was performed in 13 women with doxorubicin-resistant breast cancer. The median number of prior chemotherapy regimes was two, and six patients had two or more organ sites of involvement. L-Annamycin was administered at 190-250 mg/m2 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 acute 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 was 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) was determined. A major goal of the trial was to confirm the MTD reported from the previous sponsor for use in adult ALL patients. The clinical data from our studies indicate that the MTD reported by the previous sponsor which indicated that patients could be dosed as high as 280 mg/m2/day for 3 consecutive days in ALL patients was too high. We utilized a uniform validated reconstitution method that we believe delivers a more uniform liposomal drug product when infused into patients. This infusion methodology is being utilized across all study sites. We recently reached an MTD of 150 mg/m2/day given for 3 consecutive days in the adult trial and are currently evaluating patients in the fixed-dose portion of the trial.

In February, 2007, we opened a Phase I trial of L-Annamycin in pediatric relapsed or refractory ALL or AML patients. Based on the information from the ongoing adult trial, we initiated this trial at 130 mg/m2/day given for three consecutive days. The trial is a multi-center, open-label, single-agent, dose-escalation study that is utilizing POETIC a consortium of ten pediatric cancer centers located in the U.S. and Canada. The trial is presently open at four clinical sites in the U.S. We have not yet established the MTD in children. We plan to review future development of this drug once data from the adult trial are available. The key Callisto employee responsible for coordinating this L-Annamycin program with our clinical sites, Dr. Donald Picker, former Executive Vice President of Research & Development, resigned from the Company in December, 2006. Consequently, work on this clinical program was impacted until his replacement was able to assume Dr. Picker's responsibilities.

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 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 L-ANNAMYCIN

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.

3. GUANILIB TO TREAT GASTROINTESTINAL DISORDERS

We announced on October 3, 2007 a major strategic initiative to develop Guanilib, Callisto's guanylyl cyclase C receptor agonist, to treat gastrointestinal disorders, primarily chronic constipation

and constipation-predominant irritable bowel syndrome (IBS-C). Guanilib was developed by our scientists based on structure-function studies performed in-house. A patent covering composition of matter and therapeutic applications of Guanilib was granted by the U.S. Patent and Trademark Office on May 9, 2006.

Guanilib is an analog of uroguanylin, a natural gastro-intestinal hormone produced in the gut that is a key regulator of intestinal function. Uroguanylin works by activating a unique receptor on intestinal cells. The receptor, called the guanylate cyclase C (GC-C) receptor, promotes fluid and ion transport in the gastro-intestinal (GI) tract. Under normal conditions, the receptor is activated by the natural hormones uroguanylin and guanylin. Activation of the receptor leads to the transport of chloride and bicarbonate into the intestine, and water is carried with these ions into the lumen of the intestine, thereby producing a looser stool.

PRECLINICAL STUDIES

Guanilib has been demonstrated to be superior to uroguanylin in its biological activity, protease stability and pH characteristics. Guanilib acts in an identical manner as the natural hormone as an agonist (i.e. activator) of the GC-C receptor found on the epithelial cells of the colon. Upon activation, the GC-C receptor promotes intracellular synthesis of cGMP, which in turn eventually activates the cystic fibrosis transmembrane receptor (CFTR) within the epithelial cells. Activation of CFTR leads to secretion of salts and water into the intestine, resulting in a looser intestine content that is more easily transported through the bowel. Recent animal studies performed with Guanilib have demonstrated the drugs potential to enhance intestinal motility.

Guanilib has also undergone pre-clinical animal studies as a treatment for gastrointestinal 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 animal models of ulcerative colitis.

DEVELOPMENT PLAN

We currently have a major preclinical program underway to support the filing of an investigational new drug (IND) application with FDA in the first quarter of 2008. The plan is to evaluate Guanilib's clinical potential first in chronic constipation and IBS-C. The initial Phase I trial is planned to be performed in volunteers in early 2008. The purpose of this trial is to establish the safety of the drug when given as a single oral dose. We also expect to demonstrate that Guanilib is not systemically absorbed (i.e. taken up in the blood and distributed throughout the body) which means that the compound is likely to be very safe in clinical use. We also plan to open a Phase Ib trial of Guanilib in chronic constipation patients in late 2008.

MANUFACTURING OF GUANILIB

A practical, efficient and cost effective method for producing Guanilib on a commercial scale is currently being developed by a contract research organization (CRO). The CRO currently has a 100 gram-scale GMP production run of Guanilib underway which is scheduled for release in January 2008. We plan to enter into a supply contract for Guanilib in 2008 to support future clinical and preclinical studies after evaluating competitive bids and quality of drug substance from a small group of potential commercial suppliers.

4. 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. The intention in 2007 was to work with key scientists at the University of Texas M.D. Anderson Cancer Center to bring forward a pre-clinical candidate for development in the clinic. The key Callisto employee responsible for coordinating this program with scientists at M.D. Anderson Cancer Center, Dr. Donald Picker, former Executive Vice President of Research & Development, resigned from the Company in December, 2006. Consequently, work on this program has been scaled back until we are able to hire an expert or utilize the services of a consultant to take over Dr. Picker's responsibilities.

5. SUPERANTIGEN-BASED BIOTERORRISM 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 has been extended through April, 2008 and as of September 30, 2007 we had $98,392 of funding remaining. Because the bioterrorism program is not a core activity of ours, we plan to terminate further development work upon the expiration of the research grant in April, 2008.

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 November 12, 2007, we had 9 full-time and 3 part-time employees.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2007.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2007 AND SEPTEMBER 30, 2006

We had no revenues during the three months ended September 30, 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 increased $281,792 or 25%, to $1,420,886 for the three months ended September 30, 2007 from $1,139,094 for the three months ended September 30, 2006. This increase was primarily due to our research and development overhead not allocated to specific programs, principally in-house staff related expenses, increasing by $239,000 to approximately $361,000 during the three months ended September 30, 2007, from approximately $122,000 during the three months ended September 30, 2006. This increase is primarily attributable to a shift away from out-sourced clinical monitoring activities to in-house staff.

In addition our program specific research and development expenditures were increased during the quarter ended September 30, 2007 and refocused onto the development of Guanilib. Guanilib development spending during the quarter ended September 30, 2007 increased by approximately $362,000 or 575% to approximately $425,000, as compared to approximately $63,000 expended during three months ended September 30, 2006. All other program specific development expenses decreased approximately $319,000 in the three months ended September 30, 2007 as compared to the same period of 2006, specifically: (i) Atiprimod development expenditures of approximately $416,000 during the three months ended September 30, 2007 were $32,000 or 7% lower than the $448,000 level of spending during the three months ended September 30, 2006, (i) costs related to the development of L-Annamycin were reduced by approximately $111,000, or 34%, to approximately $212,000 and (ii) Degrasyns development spending was curtailed approximately $176,000 or 97% down to approximately $6,000 during the three months ended September 30, 2007.

General and administrative expenses for the three months ended September 30, 2007 increased $616,560 or 77% to $1,417,363 during the three months ended September 30, 2007 as compared to $800,803 for the three months ended September 30, 2006. This increase was principally due to (i) higher investor relations and corporate finance advisory expenses totaling approximately $474,000, (ii) approximately $54,000 in higher SEC legal expenses primarily associated with the filing of our Form S-3 registration statement covering the sale of the common stock underlying the Series A and B Convertible Preferred Stock, (iii) approximately $60,000 in higher corporate legal fees associated with employment related litigations and (iv) during the three months ended September 30, 2006 we reversed approximately $57,000 of Sarbanes-Oxley compliance testing expenses recorded during the year ended December 31, 2005. We had no such reversal (credit) during the three months ended September 30, 2007.

Net loss for the three months ended September 30, 2007 was $83,164 compared to a net loss of $1,930,146 incurred for the three months ended September 30, 2006. The decreased net loss is the result of a $2,591,005 change in the fair value the warrants issued to our Lead Investors in the Series B Preferred Stock private placement, from the date of issue through the expiration date of the Put Option, partially offset by higher research and development and general and administrative expenses discussed above. In addition liquidated damages, associated with the late filing of registration statements required by our Series A Preferred Stock private placement, totaling $177,010 were incurred during the three months ended September 30, 2006. We had no such expenses during the nine months ended September 30, 2007 because the required registration statements have since been filed with the SEC.

During the three months ended September 30, 2007 we accreted a beneficial conversion dividend to the Series B Preferred stockholders upon issuance of $10,495,688. Our Series B Preferred Stock

private placement reset the conversion price of the then remaining Series A Preferred Stock and reset the exercise price of the then remaining Series A Warrants from $0.75 per share to $0.50 per share. This modification required the accretion of $2,384,790 in additional beneficial conversion dividend to the Series A Preferred stockholders during the quarter ended September 30, 2007. The resulting net loss available to common stockholders was $12,962,642 in the quarter ended September 30, 2007, as compared to a net loss available to common stockholders of $1,930,146 reported for the three months ended September 30, 2006, during which period we had no preferred stock transactions and thus no beneficial conversion features that needed to be accreted as a dividend.

NINE MONTHS ENDED SEPTEMBER 30, 2007 AND SEPTEMBER 30, 2006

We had no revenues during the nine months ended September 30, 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 $1,490,920 or 30%, to $3,498,604 for the nine months ended September 30, 2007 from $4,898,524 for the nine months ended September 30, 2006. This decrease was primarily due to our program specific research and development expenditures which were curtailed approximately $1,220,000 during the nine months ended September 30, 2007 while we refocused our activities and efforts on the development of Guanilib, our most promising pre-clinical drug candidate.

Guanilib development spending during the nine months ended September 30, 2007 was increased to approximately $726,000, higher by $363,000 or 100% from approximately $363,000 during the nine months ended September 30, 2006.

All other program specific development expenses decreased approximately $1,583,000 in the nine months ended September 30, 2007 as compared to the nine months ended September 30, 2006, specifically:

(i) Atiprimod development expenditures of approximately $1,293,000 during the nine months ended September 30, 2007 were $235,000 or 15% lower than the $1,528,000 level of spending during the nine months ended September 30, 2006,

(ii) L-Annamycin costs were reduced by approximately $682,000, or 56%, to approximately $531,000 during the nine months ended September 30, 2007, from approximately $1,213,000, during the six months ended September 30, 2006, and

(iii) Degrasyns development spending was significantly reduced by approximately $665,000 or 98% to approximately $13,000 during the nine months ended September 30, 2007, from approximately $678,000, during the six months ended September 30, 2006.

Our research and development overhead not allocated to specific programs, principally in-house staff related expenses were also reduced approximately $283,000 or 23% to approximately $936,000 during the nine months ended September 30, 2007, from approximately $1,219,000 during the nine months ended September 30, 2006. Included in research and development overhead was stock based compensation expense, associated with options granted to employees, which decreased approximately $413,000 or 89% from approximately $466,000 in the nine months ended September 30, 2006 to approximately $53,000 in the nine months ended September 30, 2007. This lower stock-based compensation during 2007 is primarily attributable to the full vesting during 2006 of certain options granted in 2003.

General and administrative expenses for the nine months ended September 30, 2007 were also reduced to $3,350,519, a decrease of $616,493 or 16%, from $4,012,012 for the nine months ended September 30, 2006. This decrease was primarily due to reduced spending on investor relations by

approximately $150,000 and lower stock based compensation expense associated with options granted to employees decreased approximately $546,000 or 69%. This lower stock-based compensation during 2007 is primarily attributable to the full vesting during 2006 of certain options granted in 2003 that are no longer being expensed in 2007.

Net loss for the nine months ended September 30, 2007 was $6,550,384 compared to a net loss of $9,720,946 incurred for the nine months ended September 30, 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, (i) non-employee stock-based compensation expense during the nine months ended September 30, 2007 decreased by approximately $876,000 from the nine months period ended September 30, 2006 which included approximately $734,000 associated with the Trilogy Capital stock options which completely vested on June 30, 2006, (ii) other expense for the nine months ended September 30, 2006 was $334,446 due to liquidated damages incurred for failure to register shares of the Company's common stock sold in a private placement in February and April 2006, which expense did not exist for the nine months ended September 30, 2007, and (iii) we recorded a $2,591,005 change in the fair value of the warrants issued to our Lead Investors in the Series B Preferred Stock private placement, from the date of issue through September 30, 2007, the expiration date of the Put Option.

During the nine months ended September 30, 2007 we accreted a beneficial conversion dividend to the Series B Preferred stockholders of $10,495,688 and we also accreted a beneficial conversion dividend to the Series A preferred stockholders of $2,504,475, resulting in a net loss available to common stockholders of $16,959,542 in the nine months ended September 30, 2007. This compared to a net loss available to common stockholders of $9,720,946 reported for the nine months ended September 30, 2007, during which period we had no preferred stock transactions and thus no beneficial conversion features that needed to be accreted as a dividend.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2007 we had $226,613 in cash and cash equivalents, compared to $3,904,232 as of December 31, 2006. This decrease in cash of $3,677,619 during the nine months ended September 30, 2007 was principally the result of cash used in operating activities of $5,990,759; partially offset by private placements of Series A and B Convertible preferred stock yielding net proceeds of $2,313,140. In addition on September 30, 2007 we had $8,480,000 of proceeds from our Series B Preferred Stock placement in escrow, which funds were released October 1, 2007 (see below).

In August 2007, we closed a private placement of 1,147,050 shares of Series B Convertible Preferred Stock (the "Series B Preferred Stock") and 22,941,000 warrants (the "Warrants") to certain investors (the "Investors") for aggregate gross proceeds of $11,470,500 pursuant to a Securities Purchase Agreement dated as of August 2, 2007 (the "SPA"). Each share of Series B Preferred Stock was immediately convertible into that number of shares of common stock determined by dividing the stated value of $10.00 of such share of Series B Preferred Stock by $0.50 (the "Conversion Price"), at the option of the holder, at any time and from time to time. The Warrants are immediately exercisable at $0.70 per share and are exercisable at any time within three years from the date of issuance. In connection with this transaction we paid aggregate fees and expenses of $920,960 and issued warrants to purchase 2,473,900 shares of common stock at $0.50 per share and 2,473,900 shares of common stock at $0.70 per share to certain selling agents. The warrants will expire three years after issuance.

Subsequent to closing, $8,480,000 of the net proceeds were placed into escrow at the request of RAB Special Situations (Master) Fund Limited and Absolute Octane Master Fund Limited (collectively, the "Lead Investors"), each of which invested $5,000,000 in the private placement. Pursuant to a Put Option Agreement, the Lead Investors had the right until October 30, 2007 to

require redemption by us of all of the Series B Convertible Preferred Stock and 85% of the Warrants purchased by them only upon the occurrence of any of the following events:

i. We shall have not received the approval of its common stockholders of the issuance of shares of Common Stock issuable upon the conversion of the Series B Convertible Preferred Stock or the exercise of the Warrants (the "Underlying Shares") by 5:00 pm New York time on September 30, 2007. Such approval was obtained at a meeting of stockholders held on September 26, 2007.

or

ii. The American Stock Exchange shall not have approved the Listing of Additional Securities application filed by us relating to the Underlying Shares by 5:00 pm New York time on September 30, 2007 (for a reason other than the Lead Investors failing to timely provide American Stock Exchange with information reasonably requested by Amex Listing Qualification as part of their review of the application); The American Stock Exchange approved our Listing of Additional Securities on September 26, 2007.

or

iii. The American Stock Exchange delists our Common Stock on or before 5:00 pm New York time on September 30, 2007. As of September 30, 2007 our stock continued to be listed on the American Stock Exchange.

Having satisfied these conditions the Put Option expired as of September 30, 2007 and the net proceeds placed in escrow at closing were released on October 1, 2007. At least 50% of the net proceeds from the sale of the Series B Preferred Stock to the Lead Investors shall be dedicated to the development and clinical trials of Guanilib and the remaining net proceeds shall be used for working capital purposes.

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 traunche 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 1,228,761warrants 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.

As a result of the August 2, 2007 Series B Preferred Stock financing the conversion price of Series A Preferred Stock and the exercise price of the Series A Warrants was reset from $0.75 per

share to $0.50 per share as per the antidilution rights discussed above. The proceeds from any prospective exercise of the 8,031,333 Series A Warrants outstanding on the date of reset was decreased by approximately $2.0 million.

On April 24, 2007, Callisto entered into a services agreement with Barretto Pacific Corporation ("Barretto") to provide, beginning May 1, 2007, investor relations services. Callisto agreed to pay Barretto a fee of $120,000 over a seven month period and issue 80,000 shares of restricted common stock. During the three months ended June 30, 2007 Callisto paid $20,000 of this fee and issued the 80,000 shares of common stock. The fair value of the common shares issued to Barretto was $55,200, of which $36,800 was accounted for as stock-based compensation expense during the three months ended June 30, 2007. On August 2, 2007 Callisto and Barretto entered into a Termination and Release Agreement cancelling any further obligations to pay fees beyond the $20,000 paid in June 2007 and Barretto returned the 80,000 shares of common stock. No stock based compensation was recorded on these shares during the quarter ended September 30, 2007.

On September 25, 2007 Synergy, a wholly owned subsidiary, entered into a Service Agreement with Capebio, LLC ("Capebio") to provide research and development services for the commercialization of non-oncology related gastrointestinal pharmaceutical products under the Guanilib patent. The Service Agreement is for a minimum term of eleven months starting October 1, 2007 during which period Synergy paid an initial fee of $55,000 and is obligated to pay $26,000 per month through August 31, 2008. In addition Capebio will be eligible for a bonus of $58,000 if certain performance milestones are achieved by December 31, 2007 and Synergy is required to establish an escrow of $250,000 in favor of Capebio to guarantee specific performance under the Service Agreement.

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

To date, our sources of cash have been primarily limited to the sale of our equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of financial condition and results of operations are based upon our condensed consolidated financial statements, which have been prepared by us without audit in

accordance with the rules and regulations of the Securities and Exchange Commission. The preparation of our financial statements requires us to make estimates that affect the reported amounts of assets, liabilities, revenue and expense, and related disclosure of contingent assets and liabilities. We base our accounting estimates on historical experience and other factors that are believed to be reasonable under the circumstances. However, actual results may vary from these estimates under different assumptions or conditions. The following is a summary of our critical significant accounting policies and estimates.

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in Note 3 of the notes to our consolidated financial statements included in our Annual Report on Form 10-K 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 September 30, 2007 stock based compensation expense has totaled $16,780,756 or 22% of our accumulated net losses available to common stockholders of $77,403,910.

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 $.50 per share as of September 30, 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 September 30, 2007 our money market balances totaled approximately $200,000.

ITEM 4. CONTROLS AND PROCEDURES

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of September 30, 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 September 30, 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 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 September 30, 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On September 26, 2007, we held our 2007 Annual Meeting of Stockholders. A description of each matter and a tabulation of the votes for each of the matters follow:

1. Proposal to elect seven directors to our Board of Directors to serve for the ensuing year or until their successors are duly elected and qualified or until their earlier resignation or removal.

	Votes	
Nominee	**For**	**Abstain**
Gabriele M. Cerrone	28,979,151	218,708
Gary S. Jacob	29,006,246	191,613
Christoph Bruening	28,985,446	212,413
John P. Brancaccio	28,986,346	211,513
Stephen K. Carter	29,007,996	189,863
Randall K. Johnson	29,007,996	189,863
Riccardo Dalla-Favera	28,985,846	212,013

2. Proposal to approve the potential issuance of up to 50,919,800 shares of our common stock (issuable upon the conversion of 1,147,050 shares of Series B Convertible Preferred Stock and the exercise of 27,978,800 common stock purchase warrants) at a price below fair market value issued in connection with a private placement conducted in August 2007.

Votes		
For	**Against**	**Abstain**
21,067,967	170,555	7,948,766

3. Proposal to amend our Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock, par value $.0001 per share, from 150,000,000 shares to 225,000,000 shares

Votes		
For	**Against**	**Abstain**
28,775,732	391,020	31,104

4. Proposal to ratify the appointment of BDO Seidman, LLP as our independent registered public accountants for the year ending December 31, 2007.

	Votes		
For	**Against**		**Abstain**
29,072,635	60,364 40		64,856

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: November 14, 2007 By: /s/ GARY S. JACOB

Gary S. Jacob
Chief Executive Officer

Date: November 14, 2007 By: /s/ BERNARD F. DENOYER

Bernard F. Denoyer
Vice President, Finance

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