

CALLISTO PHARMACEUTICALS INC  
Form 10-Q  
May 15, 2008

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**UNITED STATES OF AMERICA  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, DC 20549

**FORM 10-Q**

(Mark One)

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

**FOR THE QUARTERLY PERIOD ENDED: MARCH 31, 2008**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number: 001-32325

**CALLISTO PHARMACEUTICALS, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

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

(Address of principal executive offices) (Zip Code)

**(212) 297-0010**

(Registrant's telephone number)

(Former Name, Former Address and Former Fiscal Year, if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller  
reporting company)

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

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The number of the registrant's shares of common stock outstanding was 47,218,161 as of May 14, 2008.

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**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, 2007 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. Financial Statements

CALLISTO PHARMACEUTICALS, INC.  
(A development stage company)

## CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2008	December 31, 2007
	(Unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 236,499	\$ 3,269,341
Short term investments	2,994,640	2,967,690
Prepaid expenses and other	29,518	88,820
	3,260,657	6,325,851
Property and equipment net	13,568	15,108
Security deposits	73,716	73,716
	\$ 3,347,941	\$ 6,414,675
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 3,363,083	\$ 3,254,992
Accrued expenses	1,083,195	1,366,333
	4,446,278	4,621,325
Stockholders' equity (deficit):		
Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized, 214,925 shares outstanding at March 31, 2008 with a liquidation preference of \$2,149,250 and 218,675 shares outstanding at December 31, 2007 with a liquidation preference of \$2,186,750	21	22
Series B convertible preferred stock, par value \$0.0001, 2,500,000 shares authorized, 1,137,050 shares outstanding at March 31, 2008 with a liquidation preference of \$11,370,500 and 1,147,050 shares outstanding at December 31, 2007 with a liquidation preference of \$11,470,500	114	115
Common stock, par value \$.0001, 225,000,000 shares authorized, 47,218,161 and 46,943,161 shares outstanding at March 31, 2008 and December 31, 2007, respectively	4,722	4,694
Additional paid-in capital	83,220,360	83,120,315
Deficit accumulated during development stage	(84,323,554)	(81,331,796)
	(1,098,337)	1,793,350
	\$ 3,347,941	\$ 6,414,675

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 Month Ended March 31, 2008	Three Months Ended March 31, 2007	For the period From June 5, 1996 (Inception) to March 31, 2008
Revenues	\$	\$	\$
Costs and expenses:			
Research and development	2,016,983	958,683	30,665,526
Government grant		(43,956)	(1,105,318)
Purchased in process research and development			6,944,553
General and administrative	1,020,312	940,182	35,687,151
Loss from operations	(3,037,295)	(1,854,909)	(72,191,912)
Interest and investment income	45,537	24,971	833,847
Other income (expense)			(171,846)
Change in fair value of Series B Preferred stock investor warrants from date of issuance to expiration of put option			2,591,005
Net loss	(2,991,758)	(1,829,938)	(68,938,906)
Series A Preferred stock beneficial conversion feature accreted as a dividend		(119,685)	(4,888,960)
Series B Preferred stock beneficial conversion feature accreted as a dividend			(10,495,688)
Net loss available to common stockholders	\$ (2,991,758)	\$ (1,949,623)	\$ (84,323,554)
Weighted average shares outstanding:			
basic and diluted	47,124,205	39,194,996	
Net loss per common share:			
basic and diluted	\$ (0.06)	\$ (0.05)	

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

**CALLISTO PHARMACEUTICALS, INC.**  
(A Development Stage Company)

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

(Unaudited)

	Preferred Shares	Preferred Stock, Par Value	Common Shares	Common Stock, Par Value	Additional Paid in Capital
Balance at inception, June 5, 1996		\$		\$	\$
Net loss for the year					
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)**

(Unaudited)

	<u>Unamortized Deferred Stock Based Compensation</u>	<u>Deficit Accumulated during the Development Stage</u>	<u>Total Stockholders' Equity</u>
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)**

(Unaudited)

	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)**

(Unaudited)

	<u>Common Stock</u>	<u>Common Stock Par Value</u>	<u>Additional Paid in Capital</u>	<u>Unamortized Deferred Stock Based Compensation</u>	<u>Deficit Accumulated during the Development Stage</u>	<u>Total Stockholders' Equity</u>
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 year					(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	\$ 39,910,186	\$ (2,302,534)	\$ (33,361,197)	\$ 4,249,377

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

**CALLISTO PHARMACEUTICALS, INC.**  
(A Development Stage Company)

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

(Unaudited)

	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	\$ 39,910,186	\$ (2,302,534)	\$ (33,361,197)	\$ 4,249,377
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)**

(Unaudited)

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity (Deficit)
Balance, December 31, 2005		\$	33,233,096	\$ 3,323	\$ 46,387,875	\$ (1,583,463)	\$ (45,140,654)	\$ (332,919)
Net loss for the year							(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 (DEFICIT)**

(Unaudited)

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Series B Convertible Preferred Shares	Series B 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 year								(7,887,265)	(7,887,265)
Stock based compensation expense							591,561		591,561
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	(395,450)	(40)			7,668,165	767	(727)		
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 December 31, 2007	218,675	\$ 22	1,147,050	\$ 115	46,943,161	\$ 4,694	\$ 83,120,315	(\$ 81,331,796)	\$ 1,793,350

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





**CALLISTO PHARMACEUTICALS, INC.**  
(A Development Stage Company)

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

(Unaudited)

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Series B Convertible Preferred Shares	Series B Convertible Preferred Stock	Common Shares	Common Stock Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders' Equity (Deficit)
Balance, December 31, 2007	218,675	\$ 22	1,147,050	\$ 115	46,943,161	\$ 4,694	\$ 83,120,315	\$ (81,331,796)	\$ 1,793,350
Net loss for the period								(2,991,758)	(2,991,758)
Stock based compensation expense							100,071		100,071
Conversion of Series A preferred stock to common stock	(3,750)	(1)			75,000	8	(7)		
Conversion of Series B preferred stock to common stock			(10,000)	(1)	200,000	20	(19)		
Balance March 31, 2008	214,925	\$ 21	1,137,050	\$ 114	47,218,161	\$ 4,722	\$ 83,220,360	\$ (84,323,554)	\$ (1,098,337)

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

**CALLISTO PHARMACEUTICALS, INC.**  
(A Development Stage Company)

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

	Three months ended March 31, 2008	Three months ended March 31, 2007	Period from June 5, 1996 (inception) to March 31, 2008
	<u>                    </u>	<u>                    </u>	<u>                    </u>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (2,991,758)	\$ (1,829,938)	\$ (68,938,906)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation	1,540		91,470
Purchase discount accreted as interest income on U.S. Treasury bills	(26,950)		(26,950)
Stock-based compensation expense	100,071	96,165	17,245,877
Purchased in-process research and development (non-cash portion)			6,841,053
Stock-based liquidated damages			579,696
Change in fair value of Series B preferred warrants from date of issuance to expiration of put option			(2,591,005)
<b>Changes in operating assets and liabilities:</b>			
Prepaid expenses	59,302	20,486	(29,518)
Security deposit			(73,716)
Accounts payable and accrued expenses	(175,047)	(275,869)	4,153,850
Total adjustments	(41,084)	(159,218)	26,190,757
<b>Net cash used in operating activities</b>	<b>(3,032,842)</b>	<b>(1,989,155)</b>	<b>(42,748,149)</b>
<b>Cash flows from investing activities:</b>			
Short term investments purchased			(5,921,825)
Short term investments liquidated			2,954,135
Acquisition of equipment			(105,037)
<b>Net cash used in investing activities</b>			<b>(3,072,727)</b>
<b>Cash flows from financing activities:</b>			
Issuance of common and preferred stock		280,000	48,719,673
Finders fees and expenses		(36,400)	(2,981,083)
Exercise of common stock warrants			318,785
<b>Net cash provided by financing activities</b>		<b>243,600</b>	<b>46,057,375</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(3,032,842)</b>	<b>(1,745,555)</b>	<b>236,499</b>
Cash and cash equivalents at beginning of period	3,269,341	3,904,232	
<b>Cash and cash equivalents at end of period</b>	<b>\$ 236,499</b>	<b>\$ 2,158,676</b>	<b>\$ 236,499</b>

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



**CALLISTO PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

	<b>Three months ended March 31, 2008</b>	<b>Three months ended March 31, 2007</b>	<b>Period from June 5, 1996 (inception) to March 31, 2008</b>
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Supplementary disclosure of cash flow information:</b>			
Cash paid for taxes	\$ 11,481	\$ 1,441	\$ 139,837
<b>Supplementary disclosure of non-cash investing and financing activities:</b>			
Series A Preferred stock beneficial conversion feature accreted as a dividend	\$	\$	\$ 4,888,960
Series B Preferred stock beneficial conversion feature accreted as a dividend	\$	\$	\$ 10,495,688

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

**CALLISTO PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Business overview:**

Callisto Pharmaceuticals, Inc. ("Callisto" or the "Company") is a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. Since inception in June of 1996, Callisto's efforts have been principally devoted to research and development, securing and protecting patents and raising capital. From inception through March 31, 2008, Callisto has sustained cumulative net losses available to common stockholders of \$84,323,554. Callisto's losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, stock based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees, as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception through March 31, 2008, Callisto has not generated any revenue from operations, expects to incur additional losses to perform further research and development activities and does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all.

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

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

The accompanying condensed consolidated financial statements of Callisto which include its wholly owned subsidiaries: (1) Callisto Research Labs, LLC (including its wholly owned subsidiary, Callisto Pharma, GmbH (Germany inactive)) and (2) Synergy Pharmaceuticals Inc. ("Synergy"), (including its wholly owned subsidiaries, Synergy Advanced Pharmaceuticals, Inc. and IgX, Ltd (Ireland inactive)), have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The results of operations of Synergy are included in the consolidated financial statements from May 1, 2003 to March 31, 2008. All intercompany balances and transactions have been eliminated. These condensed consolidated financial statements do not include all of the information and footnote disclosures required by GAAP for complete financial statements. These statements should be read in conjunction with Callisto's audited financial statements and notes thereto for the year ended December 31, 2007, included in Form 10-K filed with the SEC on March 28, 2008. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, primarily consisting of normal adjustments, necessary for the fair presentation of the balance sheet and results of operations for the interim periods. The results of operations for the three months ended March 31, 2008 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2008. The December 31, 2007 condensed consolidated balance sheet was derived from the audited consolidated financial statements as of that date.

The consolidated financial statements as of March 31, 2008 and December 31, 2007 have been prepared under the assumption that Callisto will continue as a going concern for the twelve months

**CALLISTO PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(Unaudited)

**2. Basis of presentation and going concern: (Continued)**

ending December 31, 2008. 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 its current cash expenditure levels.

Net cash used in operating activities was approximately \$3.0 million, \$2.0 million and \$42.7, for the three months ended March 31, 2008 and 2007 and for the period from June 5, 1996 (inception) to March 31, 2008, respectively. During the three months ended March 31, 2008 and 2007 Callisto incurred net losses available to common stockholders of approximately \$3.0 million, \$2.0 million, respectively. To date, Callisto's sources of cash have been primarily limited to the sale of equity securities. Net cash provided by financing activities for the three months ended March 31, 2008 and 2007 and for the period from June 5, 1996 (inception) to March 31, 2008, was approximately \$0, \$244,000 and \$46.1 million, respectively.

Callisto cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Callisto can raise additional funds by issuing equity securities, Callisto's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Callisto's ability to conduct its business. If Callisto is unable to raise additional capital when required or on acceptable terms, it may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of Callisto's product candidates. Callisto also may be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and relinquish licenses or otherwise dispose of rights to technologies, product candidates or products.

**3. Accounting for share-based payments**

Stock based compensation expense, related to employee and non-employee stock options, has been recognized in operating results as follow:

	<b>Three Months Ended March 31,</b>		<b>June 5, 1996 (Inception) to March 31, 2008</b>
	<b>2008</b>	<b>2007</b>	
<b>Stock based compensation expense</b>			
Employees included in research and development	\$ 12,651	\$ 17,846	\$ 2,633,928
Employees included in general and administrative	53,743	97,797	4,641,434
<b>Subtotal employee stock option grants</b>	<b>66,394</b>	<b>115,643</b>	<b>7,275,362</b>
Non-employee research and development	7,820		127,884
Non-employee general and administrative	25,858	(19,478)	9,842,632
<b>Subtotal non-employee stock option grants</b>	<b>33,678</b>	<b>(19,478)</b>	<b>9,970,515</b>
<b>Total stock based compensation expense</b>	<b>\$ 100,071</b>	<b>\$ 96,165</b>	<b>\$ 17,245,877</b>

**CALLISTO PHARMACEUTICALS, INC.**  
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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(Unaudited)

**3. Accounting for share-based payments (Continued)**

The estimated fair value of each employee stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the three months ended March 31, 2007. Callisto granted no stock options to employees during the quarter ended March 31, 2008.

	Three months ended March 31,	
	2008	2007
Risk free interest rate	n/a	4.68%
Dividend yield	n/a	0.0%
Expected volatility	n/a	60%
Expected term	n/a	6 years

The unrecognized compensation cost related to non-vested employee stock options outstanding at March 31, 2008 was \$219,492, to be recognized over a weighted average vesting period of approximately 1 year. The weighted average remaining term of all options outstanding at March 31, 2008 was 5.7 years as compared to 7.3 years at December 31, 2007.

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

	Number of options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value Per Share
Balance outstanding, December 31, 2007	8,241,207	\$ 0.66 - 6.75	\$ 1.70	
Granted		\$	\$	
Forfeitures	(50,000)	\$ 1.38	\$ 1.38	
Balance outstanding, March 31, 2008	8,191,207	\$ 0.66 - 6.75	\$ 1.70	\$ 0.00
Exercisable as of March 31, 2008	5,870,707	\$ 0.75 - 6.75	\$ 1.65	\$ 0.00

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. Recent Accounting Pronouncements**

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities-an amendment of FASB Statement No. 133" ("FAS 161"). FAS 161 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. The guidance in FAS 161 is effective for financial

CALLISTO PHARMACEUTICALS, INC.  
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

**4. Recent Accounting Pronouncements (Continued)**

statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. This Statement encourages, but does not require, comparative disclosures for earlier periods at initial adoption. The Company is currently assessing the impact of FAS 161.

In December 2007, the FASB ratified Emerging Issues Task Force ("EITF") Issue No. 07-1, " *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* ," ("EITF 07-1"), which provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure requirements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. Callisto is continuing to evaluate the impact of adopting the provisions EITF 07-1; however, it does not anticipate that adoption will have a material effect on Callisto's consolidated results of operations or financial position.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51*. SFAS No. 160 requires all entities to report noncontrolling (minority) interests in subsidiaries as equity in the consolidated financial statements. Its intention is to eliminate the diversity in practice regarding the accounting for transactions between an entity and noncontrolling interests. This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. Callisto does not expect that adoption of this Statement will have a material effect on its financial condition or results of operations.

In December 2007, the FASB issued SFAS No. 141(R), a revised version of SFAS No. 141, *Business Combinations*. The revision is intended to simplify existing guidance and converge rulemaking under U.S. GAAP with international accounting rules. This statement applies prospectively to business combinations where the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. Callisto does not expect that adoption of this Statement will have a material effect on its financial condition or results of operations.

In June 2007, the EITF of the FASB reached a consensus on Issue No. 07-3, " *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* " ("EITF 07-3"). EITF 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts would be recognized as an expense. This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2007 and earlier application is not permitted. This consensus was applied prospectively for new contracts entered into on or after the effective date and adoption did not have a material effect on Callisto's financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No.159, " *The Fair Value Option for Financial Assets and Financial Liabilities, including an Amendment to SFAS 115* " ("SFAS 159"). The fair value option established by SFAS 159 permits all entities to measure all eligible



**CALLISTO PHARMACEUTICALS, INC.**  
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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

**4. Recent Accounting Pronouncements (Continued)**

items at fair value at specified election dates. A business entity shall report all unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. The provisions of SFAS 159 are effective for fiscal years beginning after November 15, 2007. Callisto adopted SFAS 159 on January 1, 2008 and such adoption did not have a material effect on Callisto's financial statements, as Callisto did not elect this fair value option on any financial assets or liabilities.

In September 2006, the FASB issued SFAS No.157, "*Fair Value Measurements*" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 does not require any new fair value measurements. SFAS 157 emphasizes a "market-based" as opposed to an "entity-specific" measurement perspective, establishes a hierarchy of fair value measurement methods and expands disclosure requirements about fair value measurements including methods and assumptions and the impact on earnings. Originally, SFAS 157 was to be effective January 1, 2008 and applied prospectively. In February 2008, the FASB issued a Staff Position that partially defers the effective date of SFAS 157 for one year for certain nonfinancial assets and nonfinancial liabilities. Callisto adopted SFAS 157 on January 1, 2008 and such adoption did not have a material effect on Callisto's financial statements.

**5. Net Loss per Share**

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, "Earnings per Share," for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares since the inclusion of issuable shares pursuant to the exercise of stock options and warrants, and the conversion of 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 common shares outstanding as of:

	<u>March 31, 2008</u>	<u>March 31, 2007</u>
Common Shares outstanding	47,218,161	39,194,996
Potentially dilutive common shares issuable upon:		
Exercise of warrants	45,162,920	16,296,620
Exercise of stock options	8,191,207	8,388,375
Conversion of Series A Convertible Preferred Stock	4,298,500	8,031,033
Conversion of Series B Convertible Preferred Stock	22,741,000	
	<u>127,611,788</u>	<u>71,911,024</u>
Total fully diluted		

**6. Stockholders' equity (deficit)**

During the three months ended March 31, 2008, 3,750 shares of Series A Convertible Preferred Stock were converted to 75,000 shares of common stock and 10,000 shares of Series B Convertible

CALLISTO PHARMACEUTICALS, INC.  
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

**6. Stockholders' equity (deficit) (Continued)**

Preferred Stock were converted to 200,000 shares of common stock, at conversion price of \$0.50 per share.

On January 31, 2008, the Board of Directors approved a reassignment, as well as, a decrease in the exercise price, of the 1,323,822 warrants, previously assigned from Trilogy Capital Partners LLC to two unaffiliated entities, from \$1.03 per share to \$0.70 per share. The decrease in the exercise price was effective immediately and the reassignment will be effective at management's discretion. Callisto has determined that the price modifications was compensatory in accordance with SFAS 123R and the associated stock based compensation expense of \$45,086 was recorded during the quarter ended March 31, 2008. As of March 31, 2008 Callisto had not reassigned the warrants.

**7. Subsequent events**

On April 7, 2008, Callisto received notice from the staff of the American Stock Exchange ("AMEX") indicating that it intends to strike Callisto's common stock from listing on AMEX by filing a delisting application with the Securities and Exchange Commission. In its letter, AMEX stated that it has determined that Callisto has failed to comply with continued listing standards set forth in Sections 1003(a)(i), 1003(a)(ii) and 1003(a)(iii) of the AMEX Company Guide, respectively, which state, in relevant part, that AMEX will normally consider suspending dealings in, or removing from the list, securities of a company which (a) has stockholders' equity of less than \$2,000,000 if such company has sustained losses from continuing operations and/or net losses in two of its three most recent fiscal years; (b) has stockholders' equity of less than \$4,000,000 if such company has sustained losses from continuing operations and/or net losses in three of its four most recent fiscal years; or (c) has stockholders' equity of less than \$6,000,000 if such company has sustained losses from continuing operations and/or net losses in its five most recent fiscal years, respectively.

The AMEX rules provide for an appeal of the above decision, which Callisto has made, by requesting a hearing in accordance with appropriate procedures as outlined by the Company Guide. Callisto's common stock will continue to trade on the AMEX during the appeal process. If unsuccessful on appeal, Callisto intends to continue to trade on the Over-the-Counter Bulletin Board.

**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 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, 2007 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.

**OVERVIEW**

We are a development stage biopharmaceutical company focused primarily on the development of drugs to treat neuroendocrine cancer (including advanced carcinoid cancer), acute leukemia and gastrointestinal disorders and diseases. Our lead drug candidate in the clinic, Atiprimod, is an orally administered drug with antiproliferative and antiangiogenic activity. On November 7, 2006, we announced the initiation of a multi-center open-label Phase II clinical trial of Atiprimod for low-to-intermediate grade neuroendocrine cancers, primarily in advanced carcinoid cancer patients. This trial is based on earlier encouraging clinical results from a Phase I trial of Atiprimod in advanced cancer patients that showed stable disease and disease-related symptom relief in patients with advanced carcinoid cancer. On September 20, 2007, we announced that we had completed enrollment of the 40-patient Phase II clinical trial, 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 to permit those patients who had successfully completed a full year in the Phase II advanced carcinoid cancer trial, which only permitted dosing for up to one year, to continue to receive Atiprimod therapy. We are no longer dosing patients in the Phase I clinical trial of Atiprimod in relapsed or refractory multiple myeloma and have no plans at present to continue evaluating the drug in this disease indication, instead focusing on the clinical development of Atiprimod to treat advanced carcinoid cancer.

Our second drug candidate, L-Annamycin, earlier completed an initial Phase I/IIa clinical trial in relapsed or refractory leukemia patients with a prior sponsor. L-Annamycin is a novel compound from the anthracycline family of proven anti-cancer drugs, which has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart. L-Annamycin was in-licensed by us 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.

In October 2007 we announced a major strategic initiative to develop SP-304 (Guanilib), our guanylyl cyclase C (GC-C) receptor agonist, to treat gastrointestinal disorders, primarily chronic constipation and constipation-predominant irritable bowel syndrome (IBS-C). On April 2, 2008, we filed an investigational new drug (IND) application with the FDA. On May 2, 2008 we received notice from the FDA that our proposed study was deemed safe to proceed and we plan to initiate a Phase I clinical trial in volunteers during the quarter ended June 30, 2008. We also plan to open a Phase Ib trial of SP-304 (Guanilib) in late 2008.

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 March 31, 2008, we have sustained cumulative net losses available to common stockholders of \$84,323,554. Our losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, stock based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific advisory and financial consulting fees, as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception through March 31, 2008, 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 thus 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.

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

We had no off-balance sheet arrangements as of March 31, 2008.

#### **RESULTS OF OPERATIONS**

##### **THREE MONTHS ENDED MARCH 31, 2008 AND MARCH 31, 2007**

We had no revenues during the three months ended March 31, 2008 and 2007 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

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Research and development expenses increased \$1,058,300 or 110%, to \$2,016,983 for the three months ended March 31, 2008 from \$958,683 for the three months ended March 31, 2007. This increase in research and development expense was attributable to significantly higher SP-304 (Guanilib) program expenses. Program expenses are primarily incurred with outside contract research organizations ("CROs") and include pre-clinical animal testing, drug formulation, tableting, hospital patient costs, blood testing and FDA consultants. Our SP-304 (Guanilib) program expenses increased by \$1,449,701 up to \$1,475,947 for the three months ended March 31, 2008 from \$26,246 during the three months ended March 31, 2007. Partially offsetting these increased SP-304(Guanilib) research expenditures were lower Atiprimod program expenses which decreased by \$470,453 to \$29,556 for the three months ended March 31, 2008 from \$500,009 during the three months ended March 31, 2007.

Research and development in-house overhead, not allocated to specific programs, totaled approximately \$382,000 and \$235,000 during the three months ended March 31, 2008 and 2007, respectively, an increase of approximately \$150,000, or 62%. As a percent of our total research and development costs these non program specific overhead expenses represented 19% and 25% of total R&D expenses during the three months ended March 31, 2008 and 2007, respectively. This increase was attributable to higher compensation costs principally associated with hiring in-house clinical monitors.

On April 1, 2006 we received an \$885,641 biodefense partnership grant from the NIAID to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over the next two years. Government grant funding for the three months ended March 31, 2008 and 2007 was \$0 and \$43,956, respectively. This grant terminated on April 1, 2008 and we had approximately \$34,000 remaining unspent as of March 31, 2008. Under the terms of the grant we have 90 days to pay expenses related to work performed prior to termination.

General and administrative expenses for the three months ended March 31, 2008 increased \$80,130 or 8.5%, to \$1,020,312 for the three months ended March 31, 2008 from \$940,182 for the three months ended March 31, 2007. This increase was primarily due to higher corporate legal fees, as well as costs associated with our Sarbanes-Oxley compliance review and the related remediation actions undertaken during the quarter ended March 31, 2008.

Net loss for the three months ended March 31, 2008 was \$2,991,758 compared to a net loss of \$1,829,938 incurred for the three months ended March 31, 2007. The increased net loss is the result of higher research and development, and general and administrative expenses both of which are discussed above. Our net loss available to common stockholders for the three months ended March 31, 2008 was \$2,991,758 as compared to a net loss available to common stockholders of \$1,949,623 in the quarter ended March 31, 2007, during which period we accreted a beneficial conversion feature of \$119,685 as a dividend to the Series A preferred stockholders.

### LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2008 we had \$239,499 in cash and cash equivalents, compared to \$3,269,341 as of December 31, 2007. Net cash used in operating activities was approximately \$3.0 million and \$2.0 million for the three months ended March 31, 2008 and 2007 respectively. As of March 31, 2008 and December 31, 2007 we also had approximately \$3.0 million invested in U.S.Treasury bills, respectively, classified as *short term investments* on our balance sheet.

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. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at our current cash expenditure levels. To date, our sources of cash have been primarily limited to the sale of our equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all.

Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates.

On April 7, 2008, we received notice from the staff of the American Stock Exchange of their intent to strike our common stock from the American Stock Exchange by filing a delisting application with the SEC for failure to regain compliance with Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide and falling out of compliance with Section 1003(a)(iii) of the Company Guide with shareholders' equity of less than \$6,000,000 and losses from continuing operations and/or net losses in four of our five most recent fiscal years. We have a limited right to appeal the staff's determination and we have requested such an appeal. If we are delisted by the American Stock Exchange we may have more difficulty raising additional capital.

Our consolidated financial statements as of March 31, 2008 and December 31, 2007 have been prepared under the assumption that we will continue as a going concern for the twelve months ending December 31, 2008. Our independent registered public accounting firm has issued a report dated March 25, 2008 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.

#### **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 the notes to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options is designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage. Since inception through March 31, 2008 stock based compensation expense has totaled \$17,245,877 or 20% of our total accumulated deficit of \$84,323,554.

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, using the modified prospective method.

Prior to January 1, 2006, we had adopted SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). As provided for by SFAS 123, we had elected to continue to account for stock-based compensation according to the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"). Accordingly, compensation expense had been recognized to the extent of employee services rendered based on the intrinsic value of stock options granted under the plan. SFAS 123R did not change the way we account for non-employee stock-based compensation. We continue to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant.

For all fair value computations required for employee and non-employee stock-based compensation we use the Black-Scholes option-pricing model which requires assumptions for expected stock price volatility, expected term of the option, risk-free interest rate and expected dividend yield at the grant date. Our stock price has fluctuated from \$3.95 per share as of December 31, 2003 to \$0.38 per share as of March 31, 2008.

**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 securities held in short term investment accounts, commercial paper included in short term money market accounts and the FDIC insurance limit on our bank balances. At March 31, 2008 our money market balances totaled approximately \$200,000. In addition we held \$2,994,640 in US Treasury Bills at March 31, 2008, with a face value of \$3.0 million maturing May 1, 2008.

### **ITEM 4. CONTROLS AND PROCEDURES**

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of March 31, 2008, our Chief Executive Officer and Principal Financial Officer have concluded that 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 recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms.

In connection with the preparation of our annual financial statements, our management performed an assessment of the effectiveness of internal control over financial reporting as of December 31, 2007. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls. Based on this evaluation, management determined that, as of December 31, 2007, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management's assessment

were (i) a lack of sufficient internal accounting expertise to provide reasonable assurance that our financial statements and notes thereto, are prepared in accordance with generally accepted accounting principles (GAAP) and (ii) a lack of segregation of duties to ensure adequate review of financial statement preparation. In light of these material weaknesses, management concluded that, as of December 31, 2007, we did not maintain effective internal control over financial reporting. As defined by the Public Company Accounting Oversight Board Auditing Standard No. 5, a material weakness is a deficiency or a combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected

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 condensed consolidated financial statements as of and for the period ended March 31, 2008 include all adjustments identified as a result of the evaluation performed.

#### **CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING**

As of March 31, 2008 we are in the process of remediating the material weaknesses which existed at December 31, 2007. We have added financial staff resources to our accounting and finance department and implemented certain other controls and procedures which management believes will prevent the recurrence of the material weakness described above. However, it will require a period of time to determine the operating effectiveness of these newly implement internal controls over financial reporting. We plan to be testing and re-evaluating our controls periodically during 2008.

Other than described above there were no changes in our internal controls over financial reporting that could significantly affect internal controls over financial reporting during the quarter ended March 31, 2008.



**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, 2007, which could materially affect our business, financial condition or future results. There have been no other material changes to the risk factors disclosed in our Annual Report other than the following:

**THE LIQUIDITY OF YOUR STOCK DEPENDS IN PART ON CONTINUED LISTING OF OUR SHARES OF COMMON STOCK ON THE AMERICAN STOCK EXCHANGE.**

On April 7, 2008, we received notice from the staff of the American Stock Exchange of their intent to strike our common stock from the American Stock Exchange by filing a delisting application with the SEC for failure to regain compliance with Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide and falling out of compliance with Section 1003(a)(iii) of the Company Guide with shareholders' equity of less than \$6,000,000 and losses from continuing operations and/or net losses in four of our five most recent fiscal years. We have a limited right to appeal the staff's determination and we have requested such an appeal. If we are delisted by the American Stock Exchange you may experience difficulty in trading your shares of our common stock.

**ITEM 6. EXHIBITS**

(a)

Exhibits

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

**SIGNATURES**

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

**CALLISTO PHARMACEUTICALS, INC.**  
(Registrant)

Date: May 15, 2008

By: /s/ GARY S. JACOB

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Gary S. Jacob  
*Chief Executive Officer*

Date: May 15, 2008

By: /s/ BERNARD F. DENOYER

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Bernard F. Denoyer  
*Senior Vice President, Finance*  
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