

CALLISTO PHARMACEUTICALS INC  
Form 10-Q  
May 16, 2011

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[Table of Contents](#)

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 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, 2011**

or

**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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes  No

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

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 the 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

The number of the registrant's shares of common stock outstanding was 158,516,071 as of May 12 2011.

---

Table of Contents

**CALLISTO PHARMACEUTICALS, INC.**

**FORM 10-Q**

**CONTENTS**

<b><u>PART I FINANCIAL INFORMATION</u></b>	<b><u>4</u></b>
<u>Item 1. Financial Statements</u>	<u>4</u>
<u>Condensed Consolidated Balance Sheets as of March 31, 2011 (unaudited) and December 31, 2010</u>	<u>4</u>
<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2011 and 2010 (unaudited) and the period June 5, 1996 (Inception) to March 31, 2011 (unaudited)</u>	<u>5</u>
<u>Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period June 5, 1996 (Inception) to March 31, 2011 (unaudited)</u>	<u>6</u>
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2011 and 2010 (unaudited) and for the period June 5, 1996 (Inception) to March 31, 2011 (unaudited)</u>	<u>15</u>
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>17</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>30</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>34</u>
<u>Item 4. Controls and Procedures</u>	<u>34</u>
<b><u>PART II OTHER INFORMATION</u></b>	<b><u>35</u></b>
<u>Item 6. Exhibits</u>	<u>35</u>
<u>Signatures</u>	<u>36</u>

Table of Contents

**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, 2010 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. All drug candidates to treat GI disorders and diseases, currently plecatanide and SP-333, are being developed exclusively by Synergy Pharmaceuticals, Inc., our controlled subsidiary ("Synergy"). Use of the terms "we", "our" or "us" in connection with GI drug candidates discussed herein refer to research and development activities and plans of Synergy.

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)****CONDENSED CONSOLIDATED BALANCE SHEETS**

	March 31, 2011 (Unaudited)	December 31, 2010
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 938,775	\$ 1,708,982
Prepaid expenses and other	1,034,505	769,403
Tax credits receivable	575,400	781,127
Total Current Assets	2,548,680	3,259,512
Property and equipment, net	8,080	9,397
Security deposits	87,740	87,740
Total Assets	\$ 2,644,500	\$ 3,356,649
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 4,426,817	\$ 4,755,361
Accrued expenses	2,433,716	2,311,050
Notes Payable	511,877	
Total Current Liabilities	7,372,410	7,066,411
Derivative financial instruments, at estimated fair value warrants	5,139,347	3,487,959
Total Liabilities	12,511,757	10,554,370
Commitments and contingencies		
Stockholders' Deficit:		
Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized, 8,000 shares outstanding at March 31, 2011 and December 31, 2010	1	1
Series B convertible preferred stock, par value \$0.0001, 2,500,000 shares		

authorized, no shares outstanding at Mach 31, 2011 and December 31, 2010		
Common stock, par value of \$.0001 per share: 225,000,000 shares authorized; 158,466,071 and 157,509,404 shares outstanding at March 31, 2011 and December 31, 2010, respectively	15,847	15,751
Additional paid-in capital	140,509,670	139,496,452
Deficit accumulated during development stage	(137,334,635)	(135,573,268)
<b>Total Stockholders' Equity (Deficit)</b>	<b>3,190,883</b>	<b>3,938,936</b>
Non-controlling interest	(13,058,140)	(11,136,657)
<b>Total Stockholders' Deficit</b>	<b>(9,867,257)</b>	<b>(7,197,721)</b>
 Total Liabilities and Stockholders' Equity (Deficit)	 \$ 2,644,500	 \$ 3,356,649

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

Table of Contents

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

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

	Three Months Ended March 31, 2011	Three Months Ended March 31, 2010	For the period June 5, 1996 (inception) to March 31, 2011
Revenues	\$	\$	\$
Costs and Expenses:			
Research and development	1,371,928	1,195,410	47,204,410
Government grants			(1,135,318)
Purchased in-process research and development			6,944,553
General and administrative	1,959,844	1,433,787	54,665,945
Loss from Operations	(3,331,772)	(2,629,197)	(107,679,590)
Interest and investment income	51	16,475	914,933
State tax credit		628,806	1,025,606
Interest and other expense	(12,414)	(284,169)	(943,661)
Loss on debt extinguishment			(2,099,892)
Change in fair value of derivative instruments	(338,715)	(17,062,145)	(22,506,031)
Net Loss	(3,682,850)	(19,330,230)	(131,288,635)
Net Loss of controlled subsidiary attributable to noncontrolling interest	1,921,483	1,165,057	13,058,140
Net loss attributable to controlling interest	(1,761,367)	(18,165,173)	(118,230,495)
Series A Preferred stock conversion rate change and beneficial conversion feature accreted as a dividend			(5,025,849)
Series B Preferred stock conversion rate change and beneficial conversion feature accreted as a dividend			(12,174,391)
Cumulative effect of adopting ASC Topic 815 January 1, 2009			(1,903,900)
Net loss attributable to common stockholders	\$ (1,761,367)	\$ (18,165,173)	\$ (137,334,635)
<i>Weighted Average Common Shares Outstanding</i>			
Basic and Diluted	157,645,404	53,869,123	
<i>Net Loss per Common Share</i>			
Basic and Diluted	\$ (0.01)	\$ (0.34)	

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

Table of Contents

**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					



Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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.

Table of Contents

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

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

	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.



Table of Contents

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

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

	Preferred Stock	Preferred Par Value	Common Stock	Common 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.

Table of Contents

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

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

	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 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.

Table of Contents

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

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

	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			176,249			176,249
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.

Table of Contents

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

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

	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			2,384,485
Beneficial conversion feature accreted as a dividend							(2,384,485)	(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.

Table of Contents

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

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

	Series A Convertible Preferred		Series B Convertible Preferred		Common Stock, Par	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders' Equity	
	Shares	Par Value	Shares	Par Value	Shares	Value			
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	4					279,997		280,001
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 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 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
Net loss for the year								(9,655,471)	(9,655,471)
Recapitalization of majority owned subsidiary via private placements of common stock							2,951,913		2,951,913
Minority interest in equity of subsidiary acquired							(42,824)		(42,824)
Stock-based compensation expense							589,063		589,063
Proceeds from issuance of 11% Notes attributable to detachable warrants							181,732		181,732
Conversion of Series A preferred stock to common stock	(120,675)	(12)			2,413,500	241	(229)		
Conversion of Series B preferred stock to common stock			(10,000)	(1)	200,000	20	(19)		
Balance, December 31, 2008	98,000	\$ 10	1,137,050	\$ 114	49,556,661	\$ 4,955	\$ 86,799,951	\$ (90,987,267)	\$ (4,182,237)

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



Table of Contents

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

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

(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	Non- Controlling Interest	Total Stockholders' Equity (Deficit)
Balance, December 31, 2008	98,000	\$ 10	1,137,050	\$ 114	49,556,661	4,955	\$ 86,799,951	\$ (90,987,267)		\$ (4,182,237)
Cumulative effect of adoption of ASC Topic 815							(181,732)	(1,903,900)		(2,085,632)
Net Loss								(15,073,021)	(3,282,393)	(18,355,414)
Stock based compensation expense							1,119,856			1,119,856
Conversion of Series A preferred stock to common stock	(35,000)	(4)			894,445	89	(85)			
Conversion of Series B preferred stock to common stock			(122,884)	(12)	2,963,236	296	(284)			
Private placements of common stock of majority owned subsidiary							15,970,100			15,970,100
Fees and expenses associated with private placements of majority owned subsidiary							(260,002)			(260,002)
Preferred Stock dividend attributable to reset of conversion price in conjunction with waiver of liquidation preference							1,815,592	(1,815,592)		
Cashless Conversion of Warrants to Common Stock					193,769	19	(19)			
Balance December 31, 2009	63,000	\$ 6	1,014,166	\$ 102	53,608,111	\$ 5,359	\$ 105,263,377	\$ (109,779,780)	\$ (3,282,393)	\$ (7,793,329)
Net Loss								(25,793,488)	(7,854,264)	(33,647,752)
Stock based compensation expense							854,651			854,651
Conversion of Series A preferred stock to common stock	(55,000)	(5)			1,527,777	153	(148)			
Conversion of Series B preferred stock to common stock			(1,014,166)	(102)	28,171,278	2,817	(2,715)			
Common shares in exchange for modification of convertible notes					265,770	27	100,169			100,196
Extinguishment on debt							2,809,531			2,809,531
Cashless conversion of Warrants to common stock upon extinguishment of convertible notes					72,355,769	7,236	(7,236)			
Warrants exchanged					1,505,699	151	(151)			
Direct offering of common stock of controlled subsidiary							7,179,000			7,179,000
Fair value of warrants issued in connection with controlled subsidiary registered direct offerings reclassified to							(3,784,743)			(3,784,743)

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

derivative liability												
Fees and expenses associated with direct offering of controlled subsidiary										(468,130)	(468,130)	
Reclassification of derivative liability to equity upon termination of price protection										27,511,730	27,511,730	
Common stock issued as settlement for director's fees				75,000	8					41,117	41,125	
Balance December 31, 2010	8,000	\$	1	\$	157,509,404	\$	15,751	\$	139,496,452	\$(135,573,268)	\$(11,136,657)	\$ (7,197,721)

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

Table of Contents

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

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

(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	Non- Controlling Interest	Total Stockholders' Equity (Deficit)
Net Loss								(1,761,367)	(1,921,483)	(3,682,850)
Stock based compensation expense							124,653			124,653
Common stock issued for services					850,000	85	532,915			533,000
Direct offering of common stock of controlled subsidiary							1,800,000			1,800,000
Fees and expenses associated with direct offering of controlled subsidiary							(185,000)			(185,000)
Fair value of warrants issued in connection with controlled subsidiary registered direct offerings reclassified to derivative liability							(1,312,673)			(1,312,673)
Warrants exercise					106,667	11	53,323			53,334
Balance March 31, 2011	8,000	\$ 1	\$		158,466,071	\$ 15,847	\$ 140,509,670	\$(137,334,635)	\$(13,058,140)	\$( 9,867,257)

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

Table of Contents

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

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

	Three months ended March 31, 2011	Three months ended March 31, 2010	Period from June 5, 1996 (inception) to March 31, 2011
<b>Cash flows from operating activities:</b>			
Net loss	\$ (3,682,850)	\$ (19,330,230)	\$ (131,288,635)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,317	1,317	109,152
Purchase discount accreted as interest income on U.S. Treasury bills			(26,950)
Stock-based compensation expense	124,653	278,097	19,834,029
Purchased in-process research and development (non-cash portion)			6,841,053
Interest expense on notes	11,877	284,169	771,277
Stock-based liquidated damages			579,696
Change in fair value of derivative instruments warrants	338,715	17,062,145	22,506,031
Loss on debt extinguishment			2,099,892
Net liabilities assumed in excess of assets acquired in merger			(282,752)
Changes in operating assets and liabilities:			
Prepaid expenses	267,898	(254,763)	(501,505)
State tax credit receivable	205,727	(628,806)	(575,400)
Security deposit			(87,740)
Accounts payable and accrued expenses	(205,878)	(666,085)	6,849,157
Net cash used in operating activities	(2,938,541)	(3,254,156)	(73,172,695)
Cash flows from investing activities:			
Short term investments purchased			(5,921,825)
Short term investments liquidated			5,948,775
Acquisition of equipment			(117,233)
Net cash used in investing activities			(90,283)
Cash flows from financing activities:			
Issuance of common and preferred stock			48,719,673
Issuance of common stock of controlled subsidiary	1,800,000		27,974,100
Finders fees and expenses combined	(185,000)		(3,967,302)
Issuance of debt instruments	500,000		1,103,163
Exercise of common stock warrants	53,334		372,119
Net cash provided by financing activities	2,168,334		74,201,753
Net (decrease) increase in cash and cash equivalents	(770,207)	(3,254,156)	938,775
	1,708,982	7,207,612	

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Cash and cash equivalents at beginning of  
period

Cash and cash equivalents at end of period	\$	938,775	\$	3,953,456	\$	938,775
--	----	---------	----	-----------	----	---------

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

Table of Contents

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

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)**

(Unaudited)

	Three months ended March 31, 2011	Three months ended March 31, 2010	Period from June 5, 1996 (inception) to March 31, 2011
Supplementary disclosure of cash flow information:			
Cash paid for taxes	\$ 12,009	\$	\$ 289,963
Supplementary disclosure of non-cash investing and financing activities:			
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
Series A Preferred stock conversion rate change accreted as a dividend			(136,889)
Series B Preferred stock conversion rate change accreted as a dividend			(1,678,703)
Common stock issued to extend notes payable			100,196
Value of warrants classified as derivative liability	1,312,673		5,139,347
Shares issued for prepaid consulting services	\$ 533,000	\$	\$ 533,000

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

Table of Contents

**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 has been on the development of drugs to treat gastrointestinal ("GI") disorders and diseases and rheumatoid arthritis (RA). Callisto was incorporated in the state of Delaware on June 5, 1996 (inception). Since inception, Callisto's efforts have been principally devoted to research and development, securing and protecting patents and raising capital.

From inception through March 31, 2011, Callisto has sustained cumulative net losses attributable to common stockholders of \$137,334,635. 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, 2011, Callisto has not generated any revenue from operations. The Company 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 not completing 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.

This Report on Form 10-Q for Callisto Pharmaceuticals, Inc. may contain forward-looking statements. Forward-looking statements are characterized by future or conditional verbs such as "may," "will," "expect," "intend," "anticipate," "believe," "estimate" and "continue" or similar words. 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. Such statements are only predictions and our actual results may differ materially from those anticipated in these forward-looking statements. 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. Factors that may cause such differences include, but are not limited to, those discussed elsewhere in this report, including the uncertainties associated with product development, the risk that products that appeared promising in early clinical trials do not demonstrate efficacy in larger-scale clinical trials, the risk that we will not obtain approval to market our products, the risks associated with dependence upon key personnel and the need for additional financing. We do not assume any obligation to update forward-looking statements as circumstances change. All drug candidates to treat gastro-intestinal ("GI") disorders and diseases, currently plecanatide and SP-333, are being developed exclusively by Synergy Pharmaceuticals, Inc., our controlled subsidiary ("Synergy"). Use of the terms "we", "our" or "us" in connection with GI drug candidates discussed herein refer to research and development activities and plans of Synergy.

Table of Contents

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

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

**(Unaudited)**

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

These condensed consolidated financial statements include Callisto and subsidiaries: (1) Callisto Research Labs, LLC (including its wholly-owned subsidiary, Callisto Pharma, GmbH (Germany inactive)), and (2) Synergy Pharmaceuticals, Inc. (including Synergy's wholly-owned subsidiaries, Synergy-DE, Synergy Advanced Pharmaceuticals, Inc. and IgX, Ltd (Ireland inactive)). 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, 2010, included in Form 10-K filed with the SEC on March 31, 2011. Certain items in the prior year's financial statements have been reclassified to conform to the current year's presentation.

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, 2011 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2011. The condensed consolidated balance sheet as of December 31, 2010 presented above was derived from the audited consolidated financial statements as of that date.

The condensed consolidated financial statements as of March 31, 2011 and December 31, 2010 have been prepared under the assumption that Callisto will continue as a going concern for the twelve months ending December 31, 2011. 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.

Net cash used in operating activities was \$2,938,541 during the three months ended March 31, 2011 as compared to \$3,254,156 for the three months ended March 31, 2010 and \$73,172,695 during the period from June 5, 1996 (inception) to March 31, 2011. During the three months ended March 31, 2011 and 2010 Callisto incurred net losses attributable to common stockholders of \$1,761,367 and \$18,165,173, respectively and \$137,334,635 during the period from June 5, 1996 (inception) to March 31, 2011. To date, Callisto's sources of cash have been primarily limited to the sale of equity securities and issuance of debt instruments. Net cash provided by financing activities for the three months ended March 31, 2011 and 2010 and for the period from June 5, 1996 (inception) to March 31, 2011, was \$2,168,334, \$0, and \$74,201,753, respectively.

Callisto will be required to raise additional capital within this year to complete the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Callisto cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Callisto raises 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 business. If Callisto is unable to raise additional capital when required or on acceptable terms, Callisto may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be



Table of Contents

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

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

**(Unaudited)**

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

desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that Callisto would otherwise seek to develop or commercialize ourselves on unfavorable terms.

**3. Recent Accounting Pronouncements**

In April 2010, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2010-13, "Compensation Stock Compensation (Topic 718) Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in Which the Underlying Equity Security Trades." ASU 2010-13 provides amendments to Topic 718 to clarify that an employee share-based payment award with an exercise price denominated in the currency of a market in which a substantial portion of the entity's equity securities trades should not be considered to contain a condition that is not a market, performance, or service condition. Therefore, an entity would not classify such an award as a liability if it otherwise qualifies as equity. The amendments in ASU 2010-13 are effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2010. Callisto adopted this standard on January 1, 2011 and such adoption did not have a material effect on its results of operation or its financial position.

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

ASC Topic 718 "*Compensation Stock Compensation*" requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated 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.

ASC Topic 718 did not change the way Callisto accounts for non-employee stock-based compensation. Callisto continues 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, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 "*Equity-Based Payment to Non-Employees*" whereas the value of the stock compensation is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly the fair value of these options is being "marked to market" quarterly until the measurement date is determined.

ASC Topic 718 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.

Callisto accounts for common stock, stock options, and warrants granted to employees and non-employees based on the fair market value of the instrument, using the Black-Scholes option pricing model based on assumptions for expected stock price volatility, term of the option, risk-free interest rate and expected dividend yield, at the grant date.

Table of Contents

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

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

(Unaudited)

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

*Callisto options*

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

	Three Months Ended March 31,		June 5, 1996 (Inception) to March 31, 2011
	2011	2010	
Employees included in research and development	\$	\$ 4,582	\$ 2,692,157
Employees included in general and administrative		5,886	9,858
Non-employee research and development			102,750
Non-employee general and administrative		(28,693)	75,282
			9,910,210
<b>Total stock based compensation expense</b>	<b>\$</b>	<b>(22,807)</b>	<b>\$ 89,722</b>
			<b>\$ 17,539,966</b>

The unrecognized compensation cost related to employee non-vested Callisto stock options outstanding at March 31, 2011, net of expected forfeitures, was \$40,540 to be recognized over a weighted average vesting period of approximately 1.75 years.

The estimated fair value of each Callisto 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, 2011 and 2010.

	Three months ended March 31,	
	2011	2010
Risk free interest rate	(*)%	2.38%
Dividend yield	(*)	n/a
Expected volatility	(*)%	100%
Expected term	(*)	5 years

(\*)

No options granted during the quarter ended March 31, 2011, see below

Table of Contents

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

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

(Unaudited)

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

A summary of stock option activity and of changes in Callisto 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	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2010	7,971,872	\$ 0.08 - 3.60	\$ 1.46	\$ 394,520	4.2 years
Granted		\$	\$		
Forfeitures	(557,000)	\$ 0.66 - 1.25	\$ 1.11		
Balance outstanding, March 31, 2011	7,414,872	\$ 0.08 - 3.60	\$ 1.49	\$ 277,280	4.1 years
Exercisable as of March 31, 2011	5,595,872	\$ 0.08 - 3.60	\$ 1.43	\$ 104,960	3.7 years

***Synergy Options***

Synergy adopted the 2008 Equity Compensation Incentive Plan (the "Plan") during the quarter ended September 30, 2008. Stock options granted under the Plan typically vest after three years of continuous service from the grant date and have a contractual term of ten years. Synergy did not issue stock options prior to the quarter ended September 30, 2008. Stock-based compensation expense related to Synergy options and restricted stock units have been recognized in operating results as follow:

	Three Months Ended March 31,		November 15, 2005 (inception) to March 31, 2011
	2011	2010	\$
Employees included in research and development	\$ 36,749	\$ 49,459	\$ 556,339
Employees included in general and administrative	44,618	58,955	726,099
Non-employees included in research and development	8,362	8,362	103,009
Non-employees included in general and administrative	57,731	71,599	908,616
Total stock-based compensation expense	\$ 147,460	\$ 188,375	\$ 2,294,063

The unrecognized compensation cost related to non-vested employee stock options outstanding at March 31, 2011, net of expected forfeitures, was \$159,826 to be recognized over a weighted-average remaining vesting period of approximately three months. This unrecognized cost does not include amounts related to stock options which vest upon change of control.

Table of Contents

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

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

(Unaudited)

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

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the following periods indicated.

	Three Months Ended March 31, 2011	Three Months Ended March 31, 2010
Risk-free interest rate	(*)	2.71%
Dividend yield	(*)	
Expected volatility	(*)	90%
Expected term (in years)	(*)	6.0 yrs

(\*)

No stock options granted during this period.

On March 1, 2010, a majority of Synergy's shareholders acting by written consent approved an amendment to the Plan increasing the number of shares reserved under the Plan to 15,000,000 shares. A summary of stock option activity and of changes in stock options outstanding under the Plan is presented below:

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2010	8,604,016	\$ 0.25 - 0.95	\$ 0.51	\$ 25,763,002	8.4 years
Granted					
Exercised					
Forfeited	(214,939)	\$ 0.25 - 0.70	\$ 0.46		
Balance outstanding, March 31, 2011	8,389,077	\$ 0.25 - 0.95	\$ 0.51	\$ 27,961,736	8.2 years
Exercisable at March 31, 2011	2,683,343	\$ 0.25 - 0.95	\$ 0.30	\$ 9,510,701	7.3 years

**5. Notes Payable**

On February 8, 2011, Synergy entered into a loan agreement (the "Agreement") with an investor (the "Lender"), pursuant to which the Lender agreed to lend an aggregate \$950,000 to Synergy. Simultaneously with the execution and delivery of the Agreement, Synergy issued a note to the Lender in the principal amount of \$500,000 (the "First Note"). Synergy had the option to issue an additional note to the Lender in the principal amount of \$450,000 beginning February 21, 2011 (the "Second Note" and with the First Note, the "Notes"). The Notes bear interest at 17% per annum and are payable on April 1, 2011. As of March 31, 2011 Synergy had not borrowed under the Second Note. The First Note principal and interest totaling \$511,877 was paid when due on April 1, 2011 and the loan agreement was terminated.



Table of Contents

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

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

**(Unaudited)**

**6. Research and Development Expense**

In accordance with FASB ASC Topic 730-10-55, "Research and Development", Synergy recorded research and development expense of \$ 407,445 and \$ 683,182 in prepaid research and development as of March 31, 2011 and December 31, 2010, respectively, for nonrefundable deposits on production of drug substance of our drug candidate plecanatide and analytical testing services of our drug candidate SP-333. In accordance with this guidance, Synergy expenses these advance payments when drug compound is delivered and services are performed.

**7. State Tax Credit Receivable**

As of December 31, 2010 Callisto had recorded a New York State Qualified Employer Tax Credit receivable totaling \$531,127 and Synergy had recorded a \$250,000 New York City biotechnology refundable tax credit. During the quarter ended March 31, 2011 the Company collected \$205,727 of the New York State credit and the balance of this credit \$325,400 was collected on April 5, 2011. The New York City tax credits of \$250,000 remains a receivable as of March 31, 2011.

**8. Net Loss per Share**

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, "Earnings per Share," for all periods presented. In accordance with ASC Topic 260, basic and diluted net loss per common share was determined by dividing net loss attributable 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:

	March 31, 2011	March 31, 2010
Common Shares outstanding	158,466,071	54,290,548
Potentially dilutive common shares issuable upon:		
Exercise of warrants	10,265,332	84,842,576
Exercise of Callisto stock options	7,414,872	8,350,038
Conversion of Series A Convertible Preferred Stock	222,222	1,333,333
Conversion of Series B Convertible Preferred Stock	0	1,014,166
<b>Total fully diluted</b>	<b>176,368,497</b>	<b>149,830,661</b>

**9. Derivative Financial Instruments**

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, "Derivatives and Hedging: Contracts in Entity's Own Equity" ("ASC Topic 815-40"). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity's own stock, which would qualify as a scope exception under ASC Topic 815-10.

Table of Contents

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

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

**(Unaudited)**

**9. Derivative Financial Instruments (Continued)**

*Callisto Derivative Instruments*

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40 and ASC Topic 815-10, certain warrants (the "New Warrants") issued in connection with the issuance of the 11% Notes are accounted for as derivative liabilities on the Company's Balance Sheet.

In accordance with ASC Topic 815-40, the New Warrants were re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value will be recorded as non-cash valuation adjustments within other income (expense) in the Company's statement of operations. The Company estimates the fair value of the New Warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability described above.

The Company estimates the fair value of the warrants using the Black-Scholes option pricing model. The assumptions used for the three months ended March 31, 2010 are noted in the following table:

	<b>Three Months Ended March 31, 2011</b>	<b>Three Months Ended March 31, 2010</b>
Expected warrant term	(*)	7.55 - 8.01 years
Risk-free interest rate	(*)	3.39%
Expected volatility	(*)	100%
Dividend yield	(*)	0%

(\*)

During the quarter ended and as of March 31, 2011 Callisto had no warrants outstanding which required liability accounting treatment in accordance with ASC Topic 815-40.

Expected volatility is based on historical volatility of the Company's common stock. The New Warrants have a transferability provision and based on guidance provided in SAB 107 for options issued with such a provision, we used the full contractual term as the expected term of the New Warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected term of the New Warrants.

On June 30, 2010, the price protection provision included in the New Warrants, which required derivative liability accounting, expired. As a result of the expiration of this provision, Callisto measured the fair value of the outstanding warrants through June 30, 2010, recognizing any changes in fair value of the derivative in earnings and then reclassified the derivative instrument liability as of June 30, 2010 into stockholders' equity. Subsequent to June 30, 2010 Callisto has accounted for the New Warrants as components of stockholders' equity until they were exchanged for common stock during the quarter ended December 31, 2010.

Table of Contents

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

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

(Unaudited)

**9. Derivative Financial Instruments (Continued)**

The following table sets forth the components of changes in the Company's long term derivative financial instruments liability balance for the periods indicated:

Date	Description	New Warrants	Derivative Instrument Liability
12/31/2009	Balance of derivative financial instruments December 31, 2009	68,883,536	\$ 11,870,369
3/31/2010	Change in fair value of New Warrants during the quarter ended March 31, 2010		17,062,145
3/31/2010	Balance of derivative financial instruments March 31, 2010	68,883,536	\$ 28,932,514
6/30/2010	Change in fair value of New Warrants during the quarter ended June 30, 2010		(1,420,784)
6/30/2010	Reclassification of derivative liability to stockholder's equity upon expiration of supplemental condition (price protection)		(27,511,730)
12/30/2010	New Warrants exchanged for common stock upon conversion of Notes	(68,883,536)	
12/31/2010 and 3/31/11	Balance of derivative financial instruments December 31, 2010 and March 31, 2011		\$

*Callisto Fair Value Measurements*

The unrealized losses on the derivative liabilities are recorded as a change in derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company performs a detailed analysis of the assets and liabilities that are subject to ASC Topic 820. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency were classified as Level 3. As of March 31, 2011 and December 31, 2010 Callisto had no financial instruments or related derivative liabilities requiring fair value measurements.

*Synergy Derivative Financial Instruments*

Based upon Synergy's analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that the warrants issued in connection with its registered direct offerings must be recorded as derivative liabilities. In accordance with ASC Topic 815-40, the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company's statement of operations.



Table of Contents

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

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

(Unaudited)

**9. Derivative Financial Instruments (Continued)**

Synergy estimates the fair value of the warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability and change in fair value described above. Synergy did not have derivative instruments outstanding during the quarter ended March 31, 2010. The range of assumptions used to determine the fair value of the warrants at the end of and during each period indicated were:

	Three Months Ended March 31, 2011	Three Months Ended March 31, 2010
Estimated fair value of Synergy common stock	\$2.43 - \$3.13	(*)
Expected warrant term	4.25 - 7.0 years	(*)
Risk-free interest rate	1.80% - 2.9%	(*)
Expected volatility	90%	(*)
Dividend yield		(*)

(\*)

No derivative instruments issued or outstanding during the quarter ended March 31, 2010. See table below

Estimated fair value of the stock is based on an apportionment of the unit price paid for the shares and warrants issued in Synergy's registered direct offerings, which were deemed to be arms-length negotiated prices. Expected volatility is based on historical volatility of the Synergy's common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants.

The following table sets forth the components of changes in the Synergy's derivative financial instruments liability balance for the periods indicated:

Date	Description	Warrants	Derivative Instrument Liability
12/31/2009	Balance of derivative financial instruments liability		\$
6/30/2010	Fair value of new warrants issued during the quarter	648,000	\$ 1,045,214
9/30/2010	Fair value of new warrants issued during the quarter	103,703	\$ 163,905
9/30/2010	Change in fair value of warrants during the quarter		\$ (110,937)
9/30/2010	Balance of derivative financial instruments liability	751,703	\$ 1,098,182
12/31/2010	Fair value of new warrants issued during the quarter	705,235	\$ 2,575,624
12/31/2010	Change in fair value of warrants during the quarter		\$ (185,847)
12/31/2010	Balance of derivative financial instruments liability	1,456,938	\$ 3,487,959
3/31/2011	Fair value of new warrants issued during the quarter	420,000	\$ 1,312,673
3/31/2011	Change in fair value of warrants during the quarter		\$ 338,715
3/31/2011	Balance of derivative financial instruments liability	1,876,938	\$ 5,139,347

Table of Contents

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

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

(Unaudited)

**9. Derivative Financial Instruments (Continued)**

*Synergy Fair Value Measurements*

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2010 and March 31, 2011:

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)			Balance as of December 31, 2010	Quoted Prices in Active Markets for Significant and Observable Inputs (Level 2)			Balance as of March 31, 2011
	Assets	Other	Significant and Unobservable Inputs (Level 3)		Assets	Other	Significant and Unobservable Inputs (Level 3)	
Derivative liabilities related to Warrants	\$	\$	\$ 3,487,959	\$ 3,487,959	\$	\$	\$ 5,139,347	\$ 5,139,347

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the three months ended March 31, 2011:

Description	Balance at December 31, 2010	Fair Value of warrants upon issuance	Unrealized (gains) or losses	Balance as of March 31, 2011
Derivative liabilities related to Warrants	\$ 3,487,959	\$ 1,312,673	\$ 338,715	\$ 5,139,347

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

**10. Stockholders' deficit**

On March 4, 2011, Synergy closed a financing with a non-U.S. investor which raised gross proceeds of \$1,800,000 in a registered direct offering. Synergy issued to the investor 600,000 shares of its common stock and warrants to purchase 420,000 shares of common stock. The purchase price paid by the investor was \$3.00 for each unit. The warrants expire after seven years and are exercisable at \$3.10 per share. Synergy paid fees to a non-US selling agent and legal expenses totaling \$185,000 on this offering.

On February 28, 2011 and March 8, 2011 Callisto entered into consulting agreements with two financial advisors who agreed to receive an aggregate of 850,000 of Callisto common stock, with a fair value of \$533,000, as full compensation for their services, which has been recorded as prepaid expense to be amortized over the term of the agreements.

Table of Contents

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

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

**(Unaudited)**

**10. Stockholders' deficit (Continued)**

On March 22, 2010, the Company reached an agreement with more than the requisite holders of 70% of the outstanding \$603,163 principal amount of 11% Secured Promissory Notes due April 15, 2010 (the "Notes") to extend the due date of the Notes to April 30, 2011. In exchange for the amendment, the Company agreed to issue to the note holders 15% of the amount of principal and interest due on the Notes as of March 31, 2010 payable in shares of common stock, or 265,770 shares of common stock. This modification of debt was considered "substantially different" and was accounted for as a modification of debt. The carrying value of the notes payable before modification in the amount of \$647,606 was extinguished and the fair value of the new debt in the amount \$671,103 was recorded. The difference between the carrying value and the fair value in the amount of \$23,497 was recorded as interest expense. The fair value of the shares totaled \$100,196 which cost was recorded as a loss on extinguishment during the three months ended March 31, 2010 and included in interest and other expense in the statement of operations.

On October 29, 2010, Callisto entered into a Note and Warrant Exchange Agreement with the holders of its Secured Promissory Notes due April 30, 2011 (the "Notes"), which were issued in December 2008 along with the related common stock purchase warrants exercisable for 68,883,536 shares of common stock (the "Warrants"), pursuant to which such holders exchanged the Notes plus accrued interest and the Warrants for an aggregate 72,355,770 shares of common stock.

The carrying value of the Notes extinguished, including accrued but unpaid interest, was \$709,639. In accordance with ASC Topic 405-20 Callisto calculated the difference between (i) the fair value of the Warrants received plus the carrying value of Notes extinguished and (ii) the fair value of the common stock issued to the note and warrant holders. This resulted in a loss of \$2,099,892 on extinguishment of the debt, which was recorded in the statement of operations during the quarter ended December 31, 2010.

Table of Contents

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

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

**(Unaudited)**

**10. Stockholders' deficit (Continued)**

The following table summarizes the financial impact of the 11% Notes payable and the related interest expense for the period from January 1, 2010 through December 31, 2010:

	<b>11% Notes Payable</b>	<b>Interest expense</b>
January 1, 2010	\$ 487,130	
Accretion of 11% Note discount to interest expense	144,116	144,116
11% nominal interest expense quarter ended March 31, 2010	16,360	16,360
Loss on extinguishment	23,497	23,497
Common shares issued in exchange for modification of notes payable		100,196
March 31, 2010	\$ 671,103	\$ 284,169
11% nominal interest expense quarter ended June 30, 2010	16,542	16,542
June 30, 2010	\$ 687,645	\$ 300,711
11% nominal interest expense quarter ended September 30, 2010	16,723	16,723
September 30, 2010	\$ 704,368	\$ 317,434
11% nominal interest expense through October 29, 2010	5,271	5,271
Extinguishment on Notes payable on October 29, 2010	(709,639)	
December 31, 2010 and March 31, 2011	\$	\$ 322,705

**11. Subsequent Events**

On April 1, 2011 Synergy repaid the First Note principal and interest totaling \$511,877 and the Agreement discussed in Note 5 above was terminated.

On May 2, 2011, Synergy entered into a securities purchase agreement with certain investors to raise gross proceeds of \$1,300,002 in a registered direct offering. The Company issued to the investors 433,334 shares of its common stock and warrants to purchase 433,334 shares of common stock. The purchase price paid by the investors was \$3.00 for each unit. The warrants expire after seven years and are exercisable at \$3.25 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that the warrants issued in connection with this registered direct offering must be recorded as derivative liabilities with a charge to additional paid in capital.

Table of Contents

**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, 2010 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. All drug candidates to treat GI disorders and diseases, currently plecanatide and SP-333, are being developed exclusively by Synergy Pharmaceuticals, Inc., our controlled subsidiary ("Synergy"). Use of the terms "we", "our" or "us" in connection with GI drug candidates discussed herein refer to research and development activities and plans of Synergy.

**BUSINESS OVERVIEW**

Callisto Pharmaceuticals, Inc. (which may be referred to as "Callisto", "the Company", "we" or "us") was incorporated under the laws of the State of Delaware in May 2003. We operate through two subsidiary companies: Synergy Pharmaceuticals Inc. and Callisto Research Labs, LLC, and we own two inactive subsidiaries, IgX, Ltd (Ireland) and Callisto Pharma, GmbH (Germany). Our principle corporate headquarters totals approximately 5,500 square feet, in two suites 1609 and 1701, located at 420 Lexington Avenue, New York, NY.

We are a development stage biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal ("GI") disorders and diseases and rheumatoid arthritis ("RA"). Our lead drug candidates are as follows:

- (1) Plecanatide, a guanylyl cyclase C ("GC-C") receptor agonist, to treat GI disorders, primarily chronic constipation ("CC") and constipation-predominant irritable bowel syndrome ("IBS-C").
- (2) SP-333, a second generation GC-C receptor agonist, SP-333, now in pre-clinical development to treat gastrointestinal inflammatory diseases.

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 not completing 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

Table of Contents

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.

**RECENT DEVELOPMENTS**

On May 2, 2011, we entered into a securities purchase agreement with certain investors to raise gross proceeds of \$1,300,002 in a registered direct offering. We issued to the investors 433,334 shares of our common stock and warrants to purchase 433,334 shares of common stock. The purchase price paid by the investors was \$3.00 for each unit. The warrants expire after seven years and are exercisable at \$3.25 per share.

On March 4, 2011, we closed a financing with a non-U.S. investor which raised gross proceeds of \$1,800,000 in a registered direct offering. Synergy issued to the investor 600,000 shares of our common stock and warrants to purchase 420,000 shares of common stock. The purchase price paid by the investor was \$3.00 for each unit. The warrants expire after seven years and are exercisable at \$3.10 per share. We paid fees to a non-US selling agent and legal expenses totaling \$175,000 on this offering.

**FINANCIAL OPERATIONS OVERVIEW**

From inception through March 31, 2011, we have sustained cumulative net losses attributable to common stockholders of \$137,334,635. Our losses have resulted primarily from expenditures incurred in connection with research and development activities related to the 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, 2011, 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.

Net cash used in operating activities was \$2,938,541 during the three months ended March 31, 2011 as compared to \$3,254,156 for the three months ended March 31, 2010 and \$73,172,695 during the period from June 5, 1996 (inception) to March 31, 2011. During the three months ended March 31, 2011 and 2010 Callisto incurred net losses attributable to common stockholders of \$1,761,367 and \$18,165,173, respectively and \$137,334,635 during the period from June 5, 1996 (inception) to March 31, 2011. To date, Callisto's sources of cash have been primarily limited to the sale of equity securities and issuance of debt instruments. Net cash provided by financing activities for the three months ended March 31, 2011 and 2010 and for the period from June 5, 1996 (inception) to March 31, 2011, was \$2,168,334, \$0, and \$74,201,753, respectively.

Callisto will be required to raise additional capital within this year to complete the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Callisto cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Callisto raises 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 business. If Callisto is unable to raise additional capital when required or on acceptable terms, Callisto may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) 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; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that Callisto would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Table of Contents**OFF-BALANCE SHEET ARRANGEMENTS**

We had no off-balance sheet arrangements as of March 31, 2011.

**RESULTS OF OPERATIONS****THREE MONTHS ENDED MARCH 31, 2011 AND MARCH 31, 2010**

We had no revenues during the three months ended March 31, 2011 and 2010 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 \$176,518 or 15% to \$1,371,928 for the three months ended March 31, 2011 from \$1,195,410 for the three months ended March 31, 2010. This increase in research and development expenses was entirely attributable to continuing the development of our plecanatide product candidate. These expenses included (i) program expenses including animal studies, analytical testing, clinical data monitoring and patient costs of approximately \$1,061,000, as compared to \$896,000 during the three months ended March 31, 2010, (ii) in-house staff salaries and wages, stock based compensation and employee benefits of approximately \$253,000, as compared to \$215,000 during the three months ended March 31, 2010 as we hired additional product development personnel, partially offset by (iii) lower scientific and regulatory advisory fees and expenses of approximately \$56,000, as compared to \$79,000 during the three months ended March 31, 2010.

General and administrative expenses for the three months ended March 31, 2011 increased \$526,057 or 37%, to \$1,959,844 for the three months ended March 31, 2011 from \$1,433,787 for the three months ended March 31, 2010. These expenses primarily include (i) higher facilities cost of approximately \$226,000 as compared to \$190,000 during the three months ended March 31, 2010, (ii) higher consultants and financial advisors fees of approximately \$1,269,000, as compared to \$282,000 during the three months ended March 31, 2010, partially offset by (iii) salaries and wages, stock based compensation and related employee benefits of approximately \$172,000, as compared to \$452,000 during the three months ended March 31, 2010 (iv) accounting, corporate legal and tax services of approximately \$247,000, as compared to \$454,000.

Net loss attributable to common stockholders for the three months ended March 31, 2011 decreased \$16,403,806 to \$1,761,367 compared to a net loss of \$18,165,173 incurred for the three months ended March 31, 2010. The increased net loss is the result of higher research and development, and general and administrative expenses discussed above, plus the following non-operating expenses for the periods indicated.

	Quarter Ended 03/31/2011	Quarter Ended 03/31/2010	Change (\$)
Loss from Operations	\$ (3,331,772)	\$ (2,629,197)	\$ (702,575)
Interest and dividend income	51	16,475	(16,424)
State tax credit		628,806	(628,806)
Interest expense and other expenses	(12,414)	(284,169)	271,755
Change in FV of financial instruments	(338,715)	(17,062,145)	16,723,430
Net loss attributable to noncontrolling interest	1,921,483	1,165,057	756,426
Net loss attributable to common stockholders	\$ (1,761,367)	\$ (18,165,173)	\$ 16,403,806

**LIQUIDITY AND CAPITAL RESOURCES**

As of March 31, 2011 we had \$938,775 in cash and cash equivalents, compared to \$1,708,982 as of December 31, 2010. Net cash used in operating activities was \$2,938,541 during the three months ended March 31, 2011 as compared to \$3,254,156 for the three months ended March 31, 2010. To date our

Table of Contents

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, 2011 and 2010 and for the period from June 5, 1996 (inception) to March 31, 2011, was \$2,168,334, \$0, and \$74,201,753, respectively.

As of March 31, 2011, we had a negative working capital of \$4,823,730, as compared to a negative working capital of \$3,806,899 on December 31, 2010.

On February 8, 2011, Synergy entered into a loan agreement (the "Agreement") with an investor (the "Lender"), pursuant to which the Lender agreed to lend an aggregate \$950,000 to us. Simultaneously with the execution and delivery of the Agreement, we issued a note to the Lender in the principal amount of \$500,000 (the "First Note") which was payable on April 1, 2011 and accrued interest at 17% per annum. The First Note principal and interest totaling \$511,877 was paid when due on April 1, 2011.

On March 4, 2011, Synergy closed a financing with a non-U.S. investor which raised gross proceeds of \$1,800,000 less a total of \$185,000 for offering expenses in connection with this registered direct offering. We issued to the investor 600,000 shares of Synergy common stock and warrants to purchase 420,000 shares of Synergy common stock. The purchase price paid by the investor was \$3.00 for each unit. The warrants expire after seven years and are exercisable at \$3.10 per share.

On May 2, 2011, Synergy entered into a securities purchase agreement with certain investors to raise gross proceeds of \$1,300,002 in a registered direct offering. Synergy issued to the investors 433,334 shares of Synergy common stock and warrants to purchase 433,334 shares of Synergy common stock. The purchase price paid by the investors was \$3.00 for each unit. The warrants expire after seven years and are exercisable at \$3.25 per share.

Worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain depressed for the foreseeable future. These developments make it more difficult for us to obtain additional equity or credit financing, when needed.

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, to fund the existing working capital deficit 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 equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more of product candidates; (ii) 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; or (iii) relinquish license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Our consolidated financial statements as of March 31, 2011 and December 31, 2010 have been prepared under the assumption that we will continue as a going concern for the twelve months ending December 31, 2011. Our independent registered public accounting firm has issued a report dated March 31, 2011 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



Table of Contents

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**

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 ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA of our Annual Report on Form 10-K as of and for year ended December 31, 2010, filed with the SEC on March 31, 2011. There have been no changes to our critical accounting policies since December 31, 2010.

**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, 2011 we had no balances in money market balances that was exposed to market risk.

**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, 2011, our Chief Executive Officer and Principal Financial Officer have concluded that as of March 31, 2011, 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, 2010. Management's assessment included an evaluation of the design of our internal control over financial reporting and the operational effectiveness of those controls. Based on this evaluation, management determined that, as of December 31, 2010, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management's assessment were (i) an effective whistle-blower program or other comparable mechanism and (ii) an ongoing program to manage identified fraud risks. As of December 31, 2010, we did not maintain effective internal control over financial reporting. As defined by Regulation S-X, Rule 1-02(a)(4), 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.

**CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING**

As of March 31, 2011, we are in the process of remediating the material weakness which existed at December 31, 2010. If these remedial measures are insufficient to address any of the identified material weaknesses or are not implemented effectively, or additional deficiencies arise in the future, material misstatements in our interim or annual financial statements may occur in the future.

There were no changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that could significantly affect internal controls over financial reporting during the quarter ended March 31, 2011.

Table of Contents

**PART II OTHER INFORMATION**

**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.

Table of Contents

**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 16, 2011

By:                   /s/ GARY S. JACOB

Gary S. Jacob  
*Chief Executive Officer*

Date: May 16, 2011

By:                   /s/ BERNARD F. DENOYER

Bernard F. Denoyer  
*Senior Vice President, Finance*