

CALLISTO PHARMACEUTICALS INC

Form 10-Q

November 14, 2011

[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: September 30, 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

13-3894575

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(State or Other Jurisdiction of  
Incorporation or Organization)

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

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

(Address of principal executive offices) (Zip Code)

**(212) 297-0010**

(Registrant's telephone number)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  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

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   
(Do not check if a smaller reporting company)

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 November 11, 2011.



Table of Contents

CALLISTO PHARMACEUTICALS, INC.

FORM 10-Q

CONTENTS

	<b>Page Number</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u>	
<u>Financial Statements</u>	4
<u>Condensed Consolidated Balance Sheets as of September 30, 2011 (unaudited) and     December 31, 2010</u>	4
<u>Condensed Consolidated Statements of Operations for the Three Months and Nine     Months Ended September 30, 2011 and 2010 (unaudited) and the period June 5, 1996     (Inception) to September 30, 2011 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for     the period June 5, 1996 (Inception) to September 30, 2011 (unaudited)</u>	6
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended     September 30, 2011 and 2010 (unaudited) and for the period June 5, 1996 (Inception)     to September 30, 2011 (unaudited)</u>	15
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	17
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of     Operations</u>	28
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	32
<u>Item 4.</u>	
<u>Controls and Procedures</u>	32
<b><u>PART II OTHER INFORMATION</u></b>	34
<u>Item 6.</u>	
<u>Exhibits</u>	34
<u>Signatures</u>	35

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 control and similar words. Forward-looking statements include information concerning possible or assumed future business success or financial results. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Accordingly, we do not undertake any obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.**

**The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 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**

<b>ASSETS</b>			
Current Assets:			
Cash and cash equivalents	\$	67,473	\$ 1,708,982
Prepaid expenses and other		845,089	769,403
Tax credits receivable			781,127
<b>Total Current Assets</b>		<b>912,562</b>	<b>3,259,512</b>
Property and equipment, net		6,269	9,397
Security deposits		87,740	87,740
<b>Total Assets</b>	<b>\$</b>	<b>1,006,571</b>	<b>\$ 3,356,649</b>
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>			
Current Liabilities:			
Accounts payable	\$	6,216,462	\$ 4,755,361
Accrued expenses		2,456,901	2,311,050
<b>Total Current Liabilities</b>		<b>8,673,363</b>	<b>7,066,411</b>
Derivative financial instruments, at estimated fair value warrants		3,860,838	3,487,959
<b>Total Liabilities</b>		<b>12,534,201</b>	<b>10,554,370</b>
Commitments and contingencies			
Stockholders' Deficit:			
Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized, 8,000 shares issued and outstanding at September 30, 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 September 30, 2011 and December 31, 2010			
Common stock, par value of \$0.0001 per share: 225,000,000 shares authorized; 158,516,071 and 157,509,404 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively		15,852	15,751
Additional paid-in capital		144,565,901	139,496,452
Deficit accumulated during development stage		(140,348,549)	(135,573,268)
<b>Total Stockholders' Equity</b>		<b>4,233,205</b>	<b>3,938,936</b>
Non-controlling interest		(15,760,835)	(11,136,657)

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Total Stockholders' Deficit	(11,527,630)	(7,197,721)
Total Liabilities and Stockholders' Deficit	\$ 1,006,571	\$ 3,356,649

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

Table of Contents

## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		June 5, 1996 (Inception) to September 30, 2011
	2011	2010	2011	2010	
Revenues	\$	\$	\$	\$	\$
Costs and expenses:					
Research and development	3,882,802	2,301,486	7,610,829	7,899,051	53,443,310
Government grants					(1,135,318)
Purchased in process research and development					6,944,553
General and administrative	1,288,945	1,302,469	5,124,477	4,341,003	57,830,579
	(5,171,747)	(3,603,955)	(12,735,306)	(12,240,054)	(117,083,124)
Loss from operations					
Interest and investment income	3	933	57	25,084	914,939
State tax credit				628,806	1,025,606
Other income or expense	(4,425)	(16,723)	(10,631)	(317,434)	(941,878)
Loss on debt extinguishment					(2,099,892)
Change in fair value of derivative instruments warrants	4,382,796	110,937	3,346,421	(15,530,425)	(18,820,895)
Net loss	(793,373)	(3,508,808)	(9,399,459)	(27,434,023)	(137,005,244)
Net Loss of subsidiary attributable to noncontrolling interest	280,055	1,792,485	4,624,178	5,827,676	15,760,835
Net loss attributable to controlling interest	(513,318)	(1,716,323)	(4,775,281)	(21,606,347)	(121,244,409)
Series A Preferred stock beneficial conversion feature accrued as a dividend					(4,888,960)
Series B Preferred stock beneficial conversion feature accrued as a dividend					(10,495,688)
Series A Preferred stock conversion rate change accrued as a dividend					(136,889)
Series B Preferred stock conversion rate change accrued as a dividend					(1,678,703)
Cumulative effect of adopting ASC Topic 815 January 1, 2009					(1,903,900)



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Net loss available to common stockholders	\$	(513,318)	\$	(1,716,323)	\$	(4,775,281)	\$	(21,606,347)	\$	(140,348,549)
<i>Weighted average shares outstanding:</i>										
basic and diluted		158,516,071		54,504,437		158,225,741		54,267,164		
<i>Net loss per common share :</i>										
basic and diluted	\$	(0.00)	\$	(0.03)	\$	(0.03)	\$	(0.40)		

The accompanying notes are an integral part of these unaudited 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					

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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 unaudited 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

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Table of Contents

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

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

	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 unaudited 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 unaudited 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 unaudited 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 unaudited 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, Par Value	Series B Convertible Preferred Shares	Series B Convertible Preferred Stock, Par Value	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	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)
	218,675	22	1,147,050	115	46,943,161	4,694	83,120,315	(81,331,796)	1,793,350

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Balance, December 31, 2007										
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 unaudited 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)			

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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 derivative liability											(3,784,743)					(3,784,743)
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 unaudited 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	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, 2010	8,000	\$ 1	157,509,404	\$ 15,751	\$ 139,496,452	\$ (135,573,268)	\$ (11,136,657)	(7,197,721)
Net Loss						(4,775,281)	(4,624,178)	(9,399,459)
Stock based compensation expense					266,545			266,545
Common stock issued for services			850,000	85	532,915			533,000
Direct offering of common stock of controlled subsidiary					8,040,463			8,040,463
Fees and expenses associated with direct offering of controlled subsidiary					(661,051)			(661,051)
Warrants exercise			106,667	11	53,323			53,334
Warrants issued in connection with controlled subsidiary registered direct offering reclassified to derivative liability -net					(3,719,300)			(3,719,300)
Exercise of warrants-controlled subsidiary					415,309			415,309
Common stocks issued for settlement of directors fee			50,000	5	41,245			41,250
Sale of option to purchase shares of controlled subsidiary					100,000			100,000
Balance September 30, 2011	8,000	\$ 1	158,516,071	\$ 15,852	\$ 144,565,901	\$ (140,348,549)	\$ (15,760,835)	(11,527,630)

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





Table of Contents

## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30, 2011	Nine months ended September 30, 2010	Period from June 5, 1996 (inception) to September 30, 2011
Cash flows from operating activities:			
Net loss	\$ (9,399,459)	\$ (27,434,023)	\$ (137,005,244)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	3,128	3,951	110,963
Purchase discount accreted as interest income on U.S. Treasury bills			(26,950)
Stock-based compensation expense	574,545	611,845	20,283,921
Purchased in-process research and development (non-cash portion)			6,841,053
Interest expense on notes		317,434	759,400
Stock-based liquidated damages			579,696
Change in fair value of derivative instruments warrants	(3,346,421)	15,530,425	18,820,895
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	149,314	458,282	(620,089)
State tax credit receivable	781,127	(628,806)	
Security deposit			(87,740)
Accounts payable and accrued expenses	1,648,202	1,670,398	8,703,238
	(190,105)	17,963,529	57,181,527
Net cash used in operating activities	(9,589,564)	(9,470,494)	(79,823,717)
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 and exercise of warrants of controlled subsidiary	8,040,463	3,154,000	34,214,563
Proceeds from exercise of warrants of controlled subsidiary	415,309		415,309
Finders fees and expenses-combined	(661,051)	(294,130)	(4,443,354)

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Issuance of debt instruments converted to common stock				603,163
Exercise of common stock warrants	53,334			372,119
Proceeds from sale of option	100,000			100,000
Net cash provided by financing activities	7,948,055	2,859,870		79,981,473
Net (decrease) increase in cash and cash equivalents	(1,641,509)	(6,610,624)		67,473
Cash and cash equivalents at beginning of period	1,708,982	7,207,612		
Cash and cash equivalents at end of period	\$ 67,473	\$ 596,988	\$	67,473

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

Table of Contents

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

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

(Unaudited)

	Nine months ended September 30, 2011	Nine months ended September 30, 2010	Period from June 5, 1996 (inception) to September 30, 2011
Supplementary disclosure of cash flow information:			
Cash paid for taxes	\$ 6,481	\$ 57,754	\$ 18,490
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)
Director s fees settled for shares of common stock	41,250	41,125	82,375
Common stock issued to extend notes payable		100,196	100,196
Value of warrants classified as derivative liability - net	\$ 3,719,300	\$	\$ 8,243,634
Shares issued for consulting services recorded as prepaid and amortized over the service period	\$ 533,000	\$	\$ 533,000

The accompanying notes are an integral part of these unaudited 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 September 30, 2011, Callisto has sustained cumulative net losses available to common stockholders of \$140,348,549. 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 September 30, 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

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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.

### **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.

Table of Contents

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, primarily consisting of normal adjustments, necessary for the fair presentation of the balance sheet and results of operations for the interim periods. The results of operations for the three and nine months ended September 30, 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 September 30, 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 \$9,589,564 during the nine months ended September 30, 2011 as compared to \$9,470,494 for the nine months ended September 30, 2010 and \$79,823,717 during the period from June 5, 1996 (inception) to September 30, 2011. During the three months and nine months ended September 30, 2011 Callisto incurred net losses attributable to common stockholders of \$513,318 and \$4,775,281, respectively and \$140,348,549 during the period from June 5, 1996 (inception) to September 30, 2011. Net losses attributable to common shareholders for the three months and nine months ended September 30, 2010 were \$1,716,323 and \$21,606,347, respectively. To date, Callisto's sources of cash have been primarily limited to the sale of equity securities with warrants and issuance of debt instruments. Net cash provided by financing activities for the nine months ended September 30, 2011, nine months ended September 30, 2010, and for the period from June 5, 1996 (inception) to September 30, 2011, was \$7,948,055, \$2,859,870, and \$79,981,473, respectively.

Recent worldwide economic conditions, as well as domestic and international equity and credit markets, have significantly deteriorated and may remain depressed and volatile for the foreseeable future. These developments will make it more difficult to obtain additional equity or credit financing, when needed.

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.

### **3. Recent Accounting Pronouncements**

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income* (ASU 2011-05) which is intended to facilitate the convergence of U.S. GAAP and International Financial Reporting Standards (IFRS) as well as to increase the transparency of items reported in other comprehensive income. As a result of ASU 2011-05, all nonowner changes in stockholders' equity are required to be presented in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present other comprehensive income in the statement of changes in equity has been eliminated. ASU 2011-05 is effective for fiscal years beginning after December 15, 2011 and should be applied retrospectively. The Company expects to adopt this standard beginning in 2012. As ASU 2011-05 impacts presentation

only, it will have no effect on the Company's consolidated financial statements.

#### 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 The Company accounts for non-employee stock-based compensation. The Company 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* and accordingly the value of the stock compensation to non-employees is based upon the measurement date as determined at either a) the

Table of Contents

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 the Company's accumulated deficit position, no excess tax benefits have been recognized. The Company 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.

The Company 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.

*Callisto options*

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

	Three Months Ended September 30,		Nine Months Ended September 30,		June 5, 1996 (Inception) to September 30,	
	2011	2010	2011	2010	2011	
Employees included in research and development	\$	\$	\$	\$	\$ 2,692,259	
Employees included in general and administrative		2,426	6,405	23,202	26,148	4,852,166
Non-employee research and development						102,750
Non-employee general and administrative	109,412	(23,346)	244,059	24,111	10,182,859	
Total stock based compensation expense	\$ 111,838	\$ (16,941)	\$ 267,261	\$ 55,604	\$ 17,830,034	

The unrecognized compensation cost related to employee non-vested Callisto stock options outstanding at September 30, 2011, net of expected forfeitures, was \$32,851 to be recognized over a weighted average vesting period of approximately one year.



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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 nine months ended September 30, 2011 and 2010.

	Nine months ended September 30,	
	2011	2010
Risk free interest rate	1.85%	2.38%
Dividend yield	0%	0%
Expected volatility	90%	100%
Expected term	5 years	5 years
Weighted average grant date fair value	\$ 0.49	\$ 0.20

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

Table of Contents

	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	26,500	\$ 0.66	\$ 0.66		
Forfeitures	(563,000)	\$ 0.08-1.25	\$ 1.10		
Balance outstanding, September 30, 2011	7,435,372	\$ 0.08-3.60	\$ 1.49	\$ 208,615	3.64 years
Exercisable as of September 30, 2011	5,634,372	\$ 0.08-3.60	\$ 1.43	\$ 123,235	3.42 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 September 30,		Nine Months Ended September 30,		November 15, 2005 (inception) to September 30, 2011
	2011	2010	2011	2010	
Employees included in research and development	\$ 1,225	\$ 45,991	\$ 75,131	\$ 145,254	\$ 594,721
Employees included in general and administrative	1,487	46,553	91,220	164,501	772,706
Non-employees included in research and development	4,832	26,819	21,649	43,636	116,296
Non-employees included in general and administrative	3,184	59,473	119,284	202,850	970,164
Total stock-based compensation expense	\$ 10,728	\$ 178,836	\$ 307,284	\$ 556,241	\$ 2,453,887

There was no unrecognized share-based compensation related to time vested employee stock options at September 30, 2011. 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.

	Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010
Risk-free interest rate	(*)	2.31- 2.71%
Dividend yield	(*)	
Expected volatility	(*)	90%
Expected term (in years)	(*)	6.0 years

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(\*) 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:

Table of Contents

	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	(289,939)	\$0.25-0.70	\$ 0.52		
Balance outstanding, September 30, 2011	8,314,077	\$0.25-0.95	\$ 0.51	\$ 14,174,290	7.66 years
Exercisable at September 30, 2011	2,783,386	\$0.25-0.95	\$ 0.28	\$ 5,367,937	6.78 years

**5. Stockholder s Equity**

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 shares of Callisto common stock, with a fair value of \$533,000, as full compensation for their services, which has been recorded as prepaid expense and \$308,000 has been amortized over the term of the agreements for the nine months ended September 30, 2011.

On February 19, 2011 a Callisto warrant holder exercised his warrant to purchase 106,667 shares of Callisto common stock at an exercise price of \$0.50 per share yielding gross proceeds of \$53,334.

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. In accordance with ASC Topic 405-20, 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 and was recorded as a loss on extinguishment during the nine months ended September 30, 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 \$37, 709,699, plus the carrying value of Notes extinguished \$709,639, and (ii) the fair value of the common stock issued to the note \$40,519,831, 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.

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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:

Table of Contents

	11% Notes Payable	Interest expense
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	\$	\$ 322,705

On October 20, 2010 Callisto entered into an option agreement (the "Agreement") with a third party ("Optionee") granting the Optionee the right to purchase up to 2,000,000 shares of the common stock of Synergy Pharmaceuticals, Inc., currently owned by Callisto (the "Shares") at a purchase price of \$2.45 per share. On June 3, 2011 the Optionee paid Callisto \$100,000 in cash for this option which may be exercised at any time during the period from the date of the Agreement until (i) October 20, 2012 with respect to 1,000,000 Shares and (ii) October 20, 2015 with respect to 1,000,000 Shares. The Company recorded this sale as an equity transaction through additional paid in capital.

On March 4, 2011, Synergy closed a registered direct offering with a non-U.S. investor which raised gross proceeds of \$1,800,000. 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. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, the Company has determined that the warrants issued in connection with this registered direct offering must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

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, the Company has determined that the warrants issued in connection with this registered direct offering must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

From May 17 to May 23, 2011, Synergy entered into securities purchase agreements with certain investors to raise gross proceeds of \$1,199,997 in a registered direct offering. The Company issued to the investors 399,999 shares of its common stock and warrants to purchase 399,999 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, the Company has determined that the warrants issued in connection with this registered direct offering must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

On June 3, 2011, a Synergy warrant holder exercised his warrants and purchased a total of 160,000 shares of common stock. Synergy raised gross proceeds of \$415,309 as a result of the warrant exercise. The purchase price paid by the warrant holder was \$2.50 for 98,675 shares and \$2.75 for 61,235 shares. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, the Company had determined that the warrants exercised in connection with this transaction were derivative liabilities when issued and the Company had been marking this liability to market at the end of each reporting period. Upon the exercise of these warrants the fair value of the related derivative liability totaling \$486,328 was reclassified to Additional Paid in Capital. (See Note 8 Derivative Financial Instruments)

From June 3 to June 15, 2011, Synergy entered into securities purchase agreements with certain investors to raise gross proceeds of \$1,161,243 in a private placement. The Company issued to the investors 387,081 shares of its common stock and warrants to purchase 387,081 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. In connection with this transaction Synergy entered into a registration rights agreement with each of the investors pursuant to which Synergy agreed to register the shares of common stock and shares of common stock underlying the warrants in a resale registration statement to be filed within 45 days after the final closing of the private placement. 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 private placement must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

Table of Contents

On July 11, 2011, Synergy entered into a securities purchase agreement with an investor to raise gross proceeds of \$242,750 in a private placement. The Company issued to the investor 80,916 shares of its common stock and warrants to purchase 80,916 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. In connection with this transaction Synergy entered into a registration rights agreement with the investor pursuant to which Synergy agreed to register the shares of common stock and shares of common stock underlying the warrants in a resale registration statement to be filed within 45 days after the final closing of the private placement. 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 private placement must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

On July 28, 2011, Synergy entered into a securities purchase agreement with certain investors to raise gross proceeds of \$2,336,472 in a registered direct offering. The Company issued to the investors 667,563 shares of its common stock. The purchase price paid by the investors was \$3.50 for each share of common stock. Selling agent fees and expenses totaled approximately \$231,291 and there were no warrants issued in connection with this transaction.

For the nine months ended September 30, 2011, Synergy paid \$661,052 in selling agent fees and legal expenses related to the above financing transactions and issued 18,050 warrants to a selling agent which 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 16,050 warrants issued to selling agents were equity instruments upon issuance and 2,000 warrants were treated as derivative liabilities.

## **6. 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.

### *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 nine months ended September 30, 2011 are noted in the following table:



	Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010
Estimated fair value of stock	(*)	\$2.50-\$3.70
Expected warrant term	(*)	5 years
Risk-free interest rate	(*)	1.20-1.79%
Expected volatility	(*)	90%
Dividend yield	(*)	0%

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(\*) During the nine months ended and as of September 30, 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.

Table of Contents

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.

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

<b>Date</b>	<b>Description</b>	<b>New Warrants</b>	<b>Derivative Instrument Liability</b>
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 9/30/11	Balance of derivative financial instruments December 31, 2010 and September 30, 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 September 30, 2011 and December 31, 2010 Callisto had no financial instruments or related derivative liabilities requiring fair value measurements.

*Synergy Derivative Financial Instruments*

Effective January 1, 2009, Synergy 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.

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 its registered direct offerings and private placements must be recorded as derivative liabilities. Accordingly 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.

The Company estimates the fair value of the warrants using the Black-Scholes model in order to determine the associated derivative instrument liability and change in fair value described above. The range of assumptions used to determine the fair value of the warrants during each period indicated were as follows:

Table of Contents

	Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010
Estimated fair value of Synergy common stock	\$1.06-\$2.07	\$2.50-\$3.70
Expected warrant term	5-7 years	5 years
Risk-free interest rate	0.69-1.43%	1.20-1.79%
Expected volatility	90%	90%
Dividend yield	0%	0%

Estimated fair value of the stock is based on a Black-Scholes based apportionment of the unit price paid for the shares and warrants issued in Synergy's registered direct offerings, which resulting stock prices were deemed to be arms-length negotiated prices. Expected volatility is based on historical volatility of 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.

Certain of Synergy's warrants issued during the nine months ended September 30, 2011 contained a price protection clause which variable term required the Company to use a binomial model to determine fair value. The exercise price protection clause is effective on 833,333 warrants in the event of a subsequent equity sale at a price lower than \$3.25 per share of common stock, for a period of two years from date of issuance.

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
6/30/2011	Fair value of new warrants issued during the quarter	1,220,414	\$ 2,607,827
6/30/2011	Exercise of warrants during the quarter	(160,000)	\$ (486,328)
6/30/2011	Change in fair value of warrants during the quarter		\$ 697,660
6/30/2011	Balance of derivative financial instruments liability	2,937,352	\$ 7,958,506
9/30/2011	Fair value of new warrants issued during the quarter	80,916	\$ 285,128
9/30/2011	Change in fair value of warrants during the quarter		\$ (4,382,796)
9/30/2011	Balance of derivative financial instruments liability	3,018,268	\$ 3,860,838

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 September 30, 2011:



Table of Contents

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 Identical Assets and Liabilities (Level 1)			Balance as of September 30, 2011
	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)			Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)		
Derivative liabilities related to Warrants	\$	\$	\$ 3,487,959	\$ 3,487,959	\$	\$	\$ 3,860,838	\$ 3,860,838

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the nine months ended September 30, 2011:

Description	Balance at December 31, 2010	Fair Value of Warrants Exercised and Reclassified to Additional Paid in Capital	Fair value of New Warrants Issued During the Period	Unrealized (gains) or losses	Balance as of September 30, 2011
Derivative liabilities related to Warrants	\$ 3,487,959	\$ (486,328)	\$ 4,205,628	\$ (3,346,421)	\$ 3,860,838

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.

## 7. Research and Development Expense

Research and development costs include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, regulatory and scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring, insurance and FDA consultants.

In accordance with FASB ASC Topic 730-10-55, Research and Development, Synergy recorded prepaid research and development costs of \$485,600 and \$683,182 as of September 30, 2011 and December 31, 2010, respectively, for nonrefundable pre-payments for production of plecanatide drug substance and analytical testing services of our drug candidate plecanatide and SP-333. In accordance with this guidance, Synergy expenses prepaid research and development costs when drug compound is delivered and services are performed.

## 8. State Tax Credit Receivable

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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 nine months ended September 30, 2011 the Company collected \$531,127 of the New York State credit and the New York City tax credit of \$250,000.

### **9. 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:

Table of Contents

	September 30, 2011	September 30, 2010
Common Shares outstanding	158,516,071	54,504,437
Potentially dilutive common shares issuable upon:		
Exercise of warrants	7,203,260	83,802,576
Exercise of stock options	7,435,372	8,019,872
Conversion of Series A Convertible Preferred Stock	222,222	1,333,333
Conversion of Series B Convertible Preferred Stock		28,032,389
Total fully diluted	173,376,925	175,692,607

**10. Subsequent Events**

On October 4, 2011, Synergy entered into a securities purchase agreement with certain investors for the sale of 1,105,293 units in a registered direct offering, with each unit consisting of one share of common stock and one warrant to purchase 0.5 shares of common stock. The net proceeds to the Company from the sale of the units was \$2,166,248, after deducting placement agent fees and other estimated offering expenses payable by the Company. The purchase price paid by the investors was \$2.125 per unit. The warrants expire after five years and are exercisable at \$2.75 per share.

The October 4, 2011 transaction pricing resulted in the exercise price of the 833,333 warrants issued during May 2011 (the May Warrants) to be reduced to \$2.125 per share. No other outstanding warrants or common stock were affected by this subsequent equity sale at a lower price. The price protection rights attributable to the May Warrants remain in effect until May 2013. This exercise price reduction from \$3.25 per share to \$2.125 per share decreased the exercise proceeds attributable to the May Warrants by \$937,500.

On October 14, 2011, Synergy entered into securities purchase agreements with various investors for the sale of 273,824 units in a registered direct offering, with each unit consisting of one share of common stock and one warrant to purchase 0.5 shares of common stock. The net proceeds to the Company from the sale of the Units was \$525,326, after deducting placement agent fees and other estimated offering expenses payable by the Company. The purchase price paid by the investors was \$2.125 per Unit. The Warrants expire after five years and are exercisable at \$2.75 per share.

On October 28, 2011, Synergy entered into securities purchase agreements with various investors for the sale of 235,294 units in a registered direct offering, with each unit consisting of one share of common stock and one warrant to purchase 0.5 shares of common stock. The gross proceeds to the Company from the sale of the Units was \$500,000. The purchase price paid by the investors was \$2.125 per Unit. The Warrants expire after five years and are exercisable at \$2.75 per share.



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. 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.

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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.

### RECENT DEVELOPMENTS

On October 4, 2011, we entered into a securities purchase agreement with certain investors for the sale of 1,105,293 units in a registered direct offering, with each unit consisting of one share of common stock and one warrant to purchase 0.5 shares of common stock. The net proceeds from the sale of the units was \$2,166,248, after deducting placement agent fees and other estimated offering expenses payable by us. The purchase price paid by the investors was \$2.125 per unit. The warrants expire after five years and are exercisable at \$2.75 per share.

The October 4, 2011 transaction pricing resulted in the exercise price of the 833,333 warrants issued during May 2011 (the May Warrants) to be reduced to \$2.125 per share. No other outstanding warrants or common stock were affected by this subsequent equity

Table of Contents

sale at a lower price. The price protection rights attributable to the May Warrants remain in effect until May 2013. This exercise price reduction from \$3.25 per share to \$2.125 per share decreased the exercise proceeds attributable to the May Warrants by \$937,500.

On October 14, 2011, Synergy entered into securities purchase agreements with various investors for the sale of 273,824 units in a registered direct offering, with each unit consisting of one share of common stock and one warrant to purchase 0.5 shares of common stock. The net proceeds to the Company from the sale of the Units was \$525,326, after deducting placement agent fees and other estimated offering expenses payable by the Company. The purchase price paid by the investors was \$2.125 per Unit. The Warrants expire after five years and are exercisable at \$2.75 per share.

On October 28, 2011, Synergy entered into securities purchase agreements with various investors for the sale of 235,294 units in a registered direct offering, with each unit consisting of one share of common stock and one warrant to purchase 0.5 shares of common stock. The gross proceeds to the Company from the sale of the Units was \$500,000 by the Company. The purchase price paid by the investors was \$2.125 per Unit. The Warrants expire after five years and are exercisable at \$2.75 per share.

Our corporate headquarters totals approximately 3,800 square feet in suite 1609, located at 420 Lexington Avenue, New York, NY, which lease expired on June 30, 2011. On July 21, 2011 we extended our lease on Suite 1609 from June 30, 2011, to March 31, 2012; at a monthly rent of \$16,414.

**FINANCIAL OPERATIONS OVERVIEW**

From inception through September 30, 2011, we have sustained cumulative net losses attributable to common stockholders of \$140,348,549. 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 September 30, 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 \$9,589,563 during the nine months ended September 30, 2011 as compared to \$9,470,494 for the nine months ended September 30, 2010 and \$79,823,717 during the period from June 5, 1996 (inception) to September 30, 2011. During the three months and nine months ended September 30, 2011 Callisto incurred net losses attributable to common stockholders of \$513,318 and \$4,775,281, respectively and \$140,348,549 during the period from June 5, 1996 (inception) to September 30, 2011. Net losses attributable to common shareholders for the three months and nine months ended September 30, 2010 were \$513,318 and \$4,775,281, respectively. 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 nine months ended September 30, 2011 and 2010 and for the period from June 5, 1996 (inception) to September 30, 2011, was \$7,948,055, \$2,859,870, and \$79,981,473, 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.

#### **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.

Table of Contents

**CONTRACTUAL OBLIGATIONS AND COMMITMENTS**

For a discussion of our contractual obligations see (i) our Financial Statements and Notes to Consolidated Financial Statements Note 9. *Commitments and Contingencies* , and (ii) Item 7 Management Discussion and Analysis of Financial Condition and Results of Operations *Contractual Obligations and Commitments* , included in our Annual Report on Form 10-K as of December 31, 2010.

Our corporate headquarters totals approximately 3,800 square feet in Suite 1609, located at 420 Lexington Avenue, New York, NY, expired on June 30, 2011. On July 21, 2011 we extended our lease on Suite 1609 until March 31, 2012, at a monthly rent of \$16,414.

Other than the above lease extension there have been no changes in our contractual obligations and commitments during the three months ended September 30, 2011.

**OFF-BALANCE SHEET ARRANGEMENTS**

We had no off-balance sheet arrangements as of September 30, 2011.

**RESULTS OF OPERATIONS**

**THREE MONTHS ENDED September 30, 2011 AND September 30, 2010**

We had no revenues during the three months ended September 30, 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 for the three months ended September 30, 2011 increased \$1,581,316 or 68%, to \$3,882,802 from \$2,301,486 for the three months ended September 30, 2010. This increase was primarily due to i) program expenses including animal studies, analytical testing, clinical data monitoring of approximately \$2,700,000, as compared to \$1,404,000 during the three months ended September 31, 2010 (ii) drug production of approximately \$837,000, as compared to \$404,000 during the three months ended September 31, 2010, in support of ongoing and planned clinical trials, offset (iii) by lower scientific advisory fees and expenses of approximately \$347,000, as compared to \$486,000 during the three months ended September 30, 2010.

General and administrative expenses decreased \$13,524 or 1% to \$1,288,945 for the three months ended September 30, 2011 from \$1,302,469 for the three months ended September 30, 2010. This decrease was primarily due to approximately \$194,000 of lower facilities, and operational

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costs, offset by higher travel expenses and financial advisory fees and expenses related to our private placements and registered direct offerings and stock based compensation expenses, of approximately \$181,000, during the quarter ended September 30, 2011 as compared to the same period last year.

Net loss attributable to common stockholders for the three months ended September 30, 2011 decreased \$1,203,005 to \$513,318 compared to a net loss of \$1,716,323 incurred for the three months ended September 30, 2010. The decreased net loss is the result of higher research and development, and lower general and administrative expenses discussed above, plus the following non-operating expenses for the periods indicated:

	Quarter Ended 9/30/2011	Quarter Ended 9/30/2010	Change (\$)
Loss from operations	\$ (5,171,747)	\$ (3,603,955)	\$ (1,567,519)
Interest and dividend income	3	933	(930)
Other income or expense	(4,425)	(16,723)	12,298
Change in FV of financial instruments	4,382,796	110,937	4,271,859
Net loss attributable to noncontrolling interest	280,055	1,792,485	(1,512,430)
Net loss attributable to common stockholders	\$ (513,318)	\$ (1,716,323)	\$ 1,203,005

### NINE MONTHS ENDED SEPTEMBER 30, 2011 AND SEPTEMBER 30, 2010

We had no revenues during the nine months ended September 30, 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. Certain reclasses have been made in prior periods to conform to current year presentation (See note 2).

Research and development expenses for the nine months ended September 30, 2011 decreased \$288,212 or 4%, to \$7,610,829 from \$7,899,051 for the nine months ended September 30, 2010. This decrease was primarily due to i) \$1,930,000 of lower drug

Table of Contents

production, as a result of lower clinical trial activities, during the nine months ended September 31, 2010, offset by ii) \$1,640,000 of higher program expenses including animal studies, analytical testing, and clinical data monitoring to prepare us for the upcoming 90 day clinical trial, during the nine months ended September 31, 2010.

General and administrative expenses increased \$783,474 or 18%, to \$5,124,477 for the nine months ended September 30, 2011 from \$4,341,003 for the nine months ended September 30, 2010. This increase was primarily due to approximately \$650,000 of higher financial advisory fees and expenses related to our private placements and registered direct offerings during the nine months ended September 30, 2011.

Net loss attributable to common stockholders for the nine months ended September 30, 2011 decreased \$16,831,066 to \$4,775,281 compared to \$21,606,347 incurred for the nine months ended September 30, 2010. The decreased net loss is the result of lower research and development, and higher general and administrative expenses discussed above, plus the following non-operating items for the periods indicated:

	Nine Months Ended 09/30/2011	Nine Months Ended 09/30/2010	Change (\$)
Loss from operations	\$ (12,735,306)	\$ (12,240,054)	\$ (495,252)
Interest and dividend income	57	25,084	(25,027)
State tax credit		628,806	(628,806)
Interest (expense) on 11% Secured Notes and other income/(expenses)	(10,631)	(317,434)	306,803
Change in Fair Value of derivative instruments warrants	3,346,421	(15,530,425)	18,876,846
Net loss of majority owned subsidiary attributable to non-controlling interest	4,624,178	5,827,676	(1,203,498)
Net loss available to common stockholders	\$ (4,775,281)	\$ (21,606,347)	\$ 16,831,066

Table of Contents

**LIQUIDITY AND CAPITAL RESOURCES**

As of September 30, 2011, we had \$67,473 in cash and cash equivalents, compared to \$1,708,982 as of December 31, 2010. Net cash used in operating activities was \$9,589,563 for the nine months ended September 30, 2011 as compared to \$9,470,494 during the nine months ended September 30, 2010. Net cash provided by financing activities for the nine months ended September 30, 2011 was \$7,948,054, as compared to \$2,859,870 provided during the nine months ended September 30, 2010. As of September 30, 2011, we had a negative working capital of \$7,760,801 as compared to a negative working capital of \$3,806,899 on December 31, 2010.

We will be required to raise additional capital within the next year to complete the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. 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 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 we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

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

Our condensed consolidated financial statements as of September 30, 2011 and December 31, 2010 have been prepared under the assumption that we will continue as a going concern for the next twelve months. 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 negative outcome of this uncertainty.

**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 money market accounts and the FDIC insurance limit on our bank balances. At September 30, 2011, we had no balances in money market balances.

**ITEM 4. CONTROLS AND PROCEDURES**



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Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of September 30, 2011, our Chief Executive Officer and Principal Financial Officer have concluded that as of September 30, 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 a lack of (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