

CALLISTO PHARMACEUTICALS INC
Form 10-Q
August 15, 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: June 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
(State or Other Jurisdiction of
Incorporation or Organization)

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

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

(Address of principal executive offices) (Zip Code)

(212) 297-0010

(Registrant's telephone number)

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

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

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

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 August 12, 2011.

Table of Contents

CALLISTO PHARMACEUTICALS, INC.

FORM 10-Q

CONTENTS

	Page
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	
<u>Financial Statements</u>	4
<u>Condensed Consolidated Balance Sheets as of June 30, 2011 (unaudited) and December 31, 2010</u>	4
<u>Condensed Consolidated Statements of Operations for the Three Months and Six Months Ended June 30, 2011 and 2010 (unaudited) and the period June 5, 1996 (Inception) to June 30, 2011 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period June 5, 1996 (Inception) to June 30, 2011 (unaudited)</u>	6
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2011 and 2010 (unaudited) and for the period June 5, 1996 (Inception) to June 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>	31
<u>Item 4.</u>	
<u>Controls and Procedures</u>	31
<u>PART II OTHER INFORMATION</u>	33
<u>Item 6.</u>	
<u>Exhibits</u>	33
<u>Signatures</u>	34

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

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

	June 30, 2011	December 31, 2010
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 598,104	\$ 1,708,982
Prepaid expenses and other	969,399	769,403
Tax credits receivable	250,000	781,127
Total Current Assets	1,817,503	3,259,512
Property and equipment, net	6,763	9,397
Security deposits	87,740	87,740
Total Assets	\$ 1,912,006	\$ 3,356,649
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current Liabilities:		
Accounts payable	\$ 4,382,375	\$ 4,755,361
Accrued expenses	2,306,145	2,311,050
Total Current Liabilities	6,688,520	7,066,411
Derivative financial instruments, at estimated fair value warrants	7,958,506	3,487,959
Total Liabilities	14,647,026	10,554,370
Commitments and contingencies		
Stockholders' Deficit:		
Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized, 8,000 shares outstanding at June 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 June 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 outstanding at June 30, 2011 and December 31, 2010, respectively	15,852	15,751
Additional paid-in capital	142,565,138	139,496,452
Deficit accumulated during development stage	(139,835,231)	(135,573,268)
Total Stockholders' Equity	2,745,760	3,938,936
Non-controlling interest	(15,480,780)	(11,136,657)

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Total Stockholders' Deficit	(12,735,020)	(7,197,721)
Total Liabilities and Stockholders' Deficit	\$ 1,912,006	\$ 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 June 30,		Six Months Ended June 30,		June 5, 1996 (Inception) to June 30, 2011
	2011	2010	2011	2010	
Revenues	\$	\$	\$	\$	\$
Costs and expenses:					
Research and development	2,356,099	4,402,155	3,728,027	5,597,565	49,560,509
Government grants					(1,135,318)
Purchased in process research and development					6,944,553
General and administrative	1,875,688	1,604,747	3,835,532	3,038,534	56,541,633
Loss from operations	(4,231,787)	(6,006,902)	(7,563,559)	(8,636,099)	(111,911,377)
Interest and investment income	3	7,675	54	24,150	914,936
State tax credit				628,806	1,025,606
Interest and other expense	6,208	(16,542)	(6,206)	(300,711)	(937,453)
Loss on debt extinguishment					(2,099,892)
Change in fair value of derivative instruments warrants	(697,660)	1,420,784	(1,036,375)	(15,641,361)	(23,203,691)
Net loss	(4,923,236)	(4,594,985)	(8,606,086)	(23,925,215)	(136,211,871)
Net Loss of subsidiary attributable to noncontrolling interest	2,422,640	2,870,134	4,344,123	4,035,191	15,480,780
Net loss attributable to controlling interest	(2,500,596)	(1,724,851)	(4,261,963)	(19,890,024)	(120,731,091)
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)
Cumulative effect of adopting ASC Topic 815 January 1, 2009					(1,903,900)
Net loss available to common stockholders	\$ (2,500,596)	\$ (1,724,851)	\$ (4,261,963)	\$ (19,890,024)	\$ (139,835,231)

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

*Weighted average shares
outstanding:*

basic and diluted	158,506,181	54,420,023	158,078,170	54,146,561
-------------------	-------------	------------	-------------	------------

Net loss per common share :

basic and diluted	\$ (0.02)	\$ (0.03)	\$ (0.03)	\$ (0.37)
-------------------	-----------	-----------	-----------	-----------

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					

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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)**

	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)
Balance, December 31, 2007	218,675	22	1,147,050	115	46,943,161	4,694	83,120,315	(81,331,796)	1,793,350
Net loss for the year								(9,655,471)	(9,655,471)
Recapitalization of majority owned subsidiary via private placements of common stock							2,951,913		2,951,913
Minority interest in equity of subsidiary acquired							(42,824)		(42,824)
							589,063		589,063

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Stock-based compensation expense									
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)			

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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						(4,261,963)	(4,344,123)	(8,606,086)
Stock based compensation expense					294,444			294,444
Common stock issued for services			850,000	85	532,915			533,000
Direct offering of common stock of controlled subsidiary					5,461,242			5,461,242
Fees and expenses associated with direct offering of controlled subsidiary					(395,620)			(395,620)
Warrants exercise			106,667	11	53,323			53,334
Warrants issued in connection with controlled subsidiary registered direct offering reclassified to derivative liability -net					(3,434,172)			(3,434,172)
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 June 30, 2011	8,000	\$ 1	158,516,071	\$ 15,852	\$ 142,565,138	\$ (139,835,231)	\$ (15,480,780)	\$ (12,735,020)

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)

	Six months ended June 30, 2011	Six months ended June 30, 2010	Period from June 5, 1996 (inception) to June 30, 2011
Cash flows from operating activities:			
Net loss	\$ (8,606,086)	\$ (23,925,215)	\$ (136,211,871)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,634	2,634	110,469
Purchase discount accreted as interest income on U.S.Treasury bills			(26,950)
Stock-based compensation expense	469,444	449,951	20,178,820
Purchased in-process research and development (non-cash portion)			6,841,053
Interest expense on notes		300,711	759,400
Stock-based liquidated damages			579,696
Change in fair value of derivative instruments warrants	1,036,375	15,641,361	23,203,691
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	158,004	848,825	(611,399)
State tax credit receivable	531,127	(628,806)	(250,000)
Security deposit			(87,740)
Accounts payable and accrued expenses	(336,641)	1,204,000	6,718,394
Net cash used in operating activities	(6,745,143)	(6,106,539)	(76,979,297)
Cash flows from investing activities:			
Short term investments purchased			(5,921,825)
Short term investments liquidated			5,948,775
Acquisition of equipment			(117,233)
Net cash used in investing activities			(90,283)
Cash flows from financing activities:			
Issuance of common and preferred stock			48,719,673
Issuance of common stock of controlled subsidiary	5,461,242	255,000	31,635,342
Proceeds from exercise of warrants of controlled subsidiary	415,309		415,309
Finders fees and expenses-combined	(395,620)	(25,000)	(4,177,922)
Issuance of debt instruments			
Exercise of common stock warrants	53,334		372,119
Proceeds from sale of note			603,163
Proceeds from sale of stock option	100,000		100,000

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Net cash provided by financing activities	5,634,265	230,000	77,667,684
Net (decrease) increase in cash and cash equivalents	(1,110,878)	(5,876,539)	598,104
Cash and cash equivalents at beginning of period	1,708,982	7,207,612	
Cash and cash equivalents at end of period	\$ 598,104	\$ 1,331,073	\$ 598,104

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)

	Six months ended June 30, 2011	Six months ended June 30, 2010	Period from June 5, 1996 (inception) to June 30, 2011
Supplementary disclosure of cash flow information:			
Cash paid for taxes	\$ 5,147	\$ 33,120	\$ 17,156
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	41,250	82,500
Cash received in escrow for June 30, 2010 direct registered offering		2,499,000	
Accrued finders fees related to direct registered offering		261,630	
Common stock issued to extend notes payable			100,196
Value of warrants classified as derivative liability - net	\$ 3,434,172	\$	\$ 7,958,506
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 June 30, 2011, Callisto has sustained cumulative net losses available to common stockholders of \$139,835,231. 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 June 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

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.

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 six months ended June 30, 2011 are not necessarily indicative of the results of

Table of Contents

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 June 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 \$6,745,143 during the six months ended June 30, 2011 as compared to \$6,106,539 for the six months ended June 30, 2010 and \$76,979,297 during the period from June 5, 1996 (inception) to June 30, 2011. During the three months and six months ended June 30, 2011 Callisto incurred net losses attributable to common stockholders of \$2,500,596 and \$4,261,963, respectively and \$139,835,231 during the period from June 5, 1996 (inception) to June 30, 2011. Net losses attributable to common shareholders for the three months and six months ended June 30, 2010 were \$1,724,851 and \$19,890,024, 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 six months ended June 30, 2011 and 2010 and for the period from June 5, 1996 (inception) to June 30, 2011, was \$5,634,265, \$230,000, and \$77,667,684, respectively.

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 investor was \$3.00 for each unit. The warrants expire after seven years and are exercisable at \$3.25 per share. Synergy also paid a selling agent \$16,993 and issued 6,503 warrants in connection with this transaction.

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 \$287,000 and there were no warrants issued in connection with this transaction.

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.

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

4. Accounting for share-based payments

ASC Topic 718 *Compensation - Stock Compensation* requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. ASC Topic 718 did not change the way 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

Table of Contents

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

	Three Months Ended June 30,		Six Months Ended June 30,		June 5, 1996 (Inception) to June 30,
	2011	2010	2011	2010	2011
Employees included in research and development	\$	\$ 764	\$	\$ 5,345	\$ 2,692,259
Employees included in general and administrative	14,890	9,885	20,776	19,743	4,849,740
Non-employee research and development					102,750
Non-employee general and administrative	180,703	27,825	152,010	47,458	10,090,910
Total stock based compensation expense	\$ 195,593	\$ 17,176	\$ 172,886	\$ 72,546	\$ 17,735,659

The unrecognized compensation cost related to employee non-vested Callisto stock options outstanding at June 30, 2011, net of expected forfeitures, was \$38,861 to be recognized over a weighted average vesting period of approximately six months.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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 six months ended June 30, 2011 and 2010.

	Six months ended June 30,	
	2011	2010
Risk free interest rate	1.85%	2.38%
Dividend yield	n/a	n/a
Expected volatility	100%	100%
Expected term	5 years	5 years

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Table of Contents

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

	Number of options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2010	7,971,872	\$ 0.08 - 3.60	\$ 1.46	\$ 394,520	4.2 years
Granted	26,500	\$ 0.66	\$ 0.66		
Forfeitures	(563,000)	\$ 0.08-1.25	\$ 1.10		
Balance outstanding, June 30, 2011	7,435,372	\$ 0.08-3.60	\$ 1.49	\$ 322,315	3.89 years
Exercisable as of June 30, 2011	5,610,372	\$ 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 June 30,		Six Months Ended June 30		November 15, 2005 (inception) to June 30, 2011
	2011	2010	2011	2010	
Employees included in research and development	\$ 37,157	\$ 49,804	\$ 73,906	\$ 99,263	\$ 593,496
Employees included in general and administrative	45,115	58,994	89,733	117,948	771,219
Non-employees included in research and development	8,456	8,455	16,818	16,817	111,464
Non-employees included in general and administrative	58,370	71,778	116,101	143,377	966,982
Total stock-based compensation expense	\$ 149,098	\$ 189,031	\$ 296,558	\$ 377,405	\$ 2,443,161

The unrecognized compensation cost related to non-vested employee stock options outstanding at June 30, 2011, net of expected forfeitures, was \$10,727 to be recognized over a weighted-average remaining vesting period of approximately three months. This unrecognized compensation cost does not include amounts related to stock options which vest upon change of control.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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.

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

(*) No stock options granted during this period.

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

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, June 30, 2011	8,314,077	\$ 0.25-0.95	\$ 0.51	\$ 29,887,896	7.91 years
Exercisable at June 30, 2011	2,683,343	\$ 0.25-0.95	\$ 0.30	\$ 10,208,371	7.04 years

5. Notes Payable

On February 8, 2011, Synergy entered into a loan agreement (the Agreement) with an investor (the Lender), pursuant to which the Lender agreed to lend an aggregate \$950,000 to Synergy. Simultaneously with the execution and delivery of the Agreement, Synergy borrowed and issued a note to the Lender in the principal amount of \$500,000 (the First Note). Synergy had, but never exercised, the option to issue an additional note to the Lender in the principal amount of \$450,000 beginning February 21, 2011 (the Second Note and with the First Note, the Notes). The Notes bore interest at 17% per annum and were payable on April 1, 2011. The First Note principal and interest totaling \$511,877 was paid when due on April 1, 2011 and the loan agreement was terminated.

6. 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 of Callisto common stock, with a fair value of \$533,000, as full compensation for their services, which has been recorded as prepaid expense to be amortized over the term of the agreements.

On February 19, 2011 a Callisto warrant holder exercised his warrant to purchase 107,667 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. The carrying value of the notes payable before modification in the amount of \$647,606 was extinguished and the fair value of the new debt in the amount \$671,103 was recorded. The difference between the carrying value and the fair value in the amount of \$23,497 was recorded as interest expense. The fair value of the shares totaled \$100,196 which cost was recorded as a loss on extinguishment during the six months ended June 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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

aggregate 72,355,770 shares of common stock.

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

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:

	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

Table of Contents

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, the Company 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

For the six months ended June 30, 2011, Synergy paid \$395,620 in selling agent fees and legal expenses related to the above financing transactions and issued 11,547 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, the Company has determined that these warrants issued to selling agents were equity instruments upon issuance.

7. 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 six months ended June 30, 2010 are noted in the following table:

	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010
Expected warrant term	(*)	7.5-8 years
Risk-free interest rate	(*)	2.7 to 3.4%
Expected volatility	(*)	100%
Dividend yield	(*)	n/a

(*) During the six months ended and as of June 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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

New Warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected term of the New Warrants.

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

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

Table of Contents

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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:

	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010
Estimated fair value of Synergy common stock	2.56-3.30	2.64
Expected warrant term	5-7 years	5 years
Risk-free interest rate	1.18%-2.5%	1.79%
Expected volatility	90%	90%
Dividend yield		

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.

Table of Contents

Certain of Synergy's warrants issued during the six months ended June 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. Except for this variable exercise price the input assumptions to this methodology were the same as used in our Black Scholes model indicated above.

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

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 June 30, 2011:

Description	December 31, 2010			June 30, 2011		
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Derivative liabilities related to Warrants	\$	\$	\$ 3,487,959	\$	\$	\$ 7,958,506
			\$ 3,487,959			\$ 7,958,506

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the six months ended June 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 June 30, 2011
Derivative liabilities related to Warrants	\$ 3,487,959	\$ (486,328)	\$ 3,920,500	\$ 1,036,375	\$ 7,958,506

Table of Contents

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.

8. 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 \$574,691 and \$683,182 as of June 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.

9. State Tax Credit Receivable

As of December 31, 2010 Callisto had recorded a New York State Qualified Employer Tax Credit receivable totaling \$531,127 and Synergy had recorded a \$250,000 New York City biotechnology refundable tax credit. During the quarter ended March 31, 2011 the Company collected \$205,727 of the New York State credit and the balance of this credit \$325,400 was collected on April 5, 2011. The New York City tax credit of \$250,000 which remained a receivable as of June 30, 2011 was received on August 11, 2011.

10. 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:

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

	June 30, 2011	June 30, 2010
Common Shares outstanding	158,516,071	54,504,437
Potentially dilutive common shares issuable upon:		
Exercise of warrants	9,290,248	84,842,576
Exercise of Callisto stock options	7,435,371	8,344,038
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	175,463,912	177,056,773

11. Subsequent Events

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. Synergy 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. Synergy also paid a selling agent \$16,993 and issued 9,547 warrants, with the same terms as the investor warrants, in connection with this transaction. 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

Table of Contents

criteria contained in ASC Topic 815-40, the Company 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. Synergy 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 \$287,000 and there were no warrants issued in connection with this transaction.

Table of Contents

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and other financial information appearing elsewhere in this quarterly report. In addition to historical information, the following discussion and other parts of this quarterly report contain forward-looking statements. You can identify these statements by forward-looking words such as may, will, expect, intend, anticipate, believe, estimate and continue or similar words. Forward-looking statements include information concerning possible or assumed future business success or financial results. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Accordingly, we do not undertake any obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2010 and other periodic reports filed with the SEC. Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of the Company, please be advised that Callisto's actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements. All drug candidates to treat GI disorders and diseases, currently plecanatide and SP-333, are being developed exclusively by Synergy Pharmaceuticals, Inc., our controlled subsidiary (Synergy). Use of the terms we , our or us in connection with GI drug candidates discussed herein refer to research and development activities and plans of Synergy.

BUSINESS OVERVIEW

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

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

(1) Plecanatide, a guanylyl cyclase C (GC-C) receptor agonist, to treat GI disorders, primarily chronic constipation (CC) and constipation-predominant irritable bowel syndrome (IBS-C).

(2) SP-333, a second generation GC-C receptor agonist, SP-333, now in pre-clinical development to treat gastrointestinal inflammatory diseases.

Callisto's product development efforts are thus in their early stages and Callisto cannot make estimates of the costs or the time they will take to complete. The risk of not completing of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent 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 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. Synergy 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 Synergy common stock. Selling agent fees and expenses totaled approximately \$287,000 and there were no warrants issued in connection with this transaction.

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. Synergy issued to the investor 80,916 shares of its common stock and warrants to purchase 80,916 shares of its 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 \$3.25 per share. Synergy also paid a selling agent \$16,993 and issued 9,547 warrants, with the same terms as the investor warrants, in connection with this transaction.

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.

Table of Contents

FINANCIAL OPERATIONS OVERVIEW

From inception through June 30, 2011, we have sustained cumulative net losses attributable to common stockholders of \$139,835,231. 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 June 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 \$6,745,143 during the six months ended June 30, 2011 as compared to \$6,106,539 for the six months ended June 30, 2010 and \$76,979,297 during the period from June 5, 1996 (inception) to June 30, 2011. During the three months and six months ended June 30, 2011 Callisto incurred net losses attributable to common stockholders of \$2,500,596 and \$4,261,963, respectively and \$139,835,231 during the period from June 5, 1996 (inception) to June 30, 2011. Net losses attributable to common shareholders for the three months and six months ended June 30, 2010 were \$1,724,851 and \$19,890,024, 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 six months ended June 30, 2011 and 2010 and for the period from June 5, 1996 (inception) to June 30, 2011, was \$5,634,265, \$230,000, and \$77,667,684, 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.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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, which lease expired on June 30, 2011. On July 21, 2011 we extended its 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 June 30, 2011.

OFF-BALANCE SHEET ARRANGEMENTS

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

RESULTS OF OPERATIONS

THREE MONTHS ENDED June 30, 2011 AND June 30, 2010

We had no revenues during the three months ended June 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.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Table of Contents

Research and development expenses for the three months ended June 30, 2011 decreased \$2,046,056 or 46%, to \$2,356,099 from \$4,402,155 for the three months ended June 30, 2010. This decrease was primarily due to lower drug production expenses of approximately \$2,060,000 as a result of lower clinical trial activities for plecanatide during the three months ended June 30, 2011. Our Phase 2a 28 day clinical trial concluded during the third quarter of 2010 and our next Phase 2/3 90 day clinical trial is scheduled to begin during the third quarter of 2011.

General and administrative expenses increased \$270,941 or 17%, to \$1,875,688 for the three months ended June 30, 2011 from \$1,604,747 for the three months ended June 30, 2010. This increase was primarily due to (i) approximately \$ 330,000 of higher financial advisory expenses related to our private placements and registered direct offerings, offset by (ii) approximately \$53,000 of lower travel and patent legal expenses in the quarter ended June 30, 2011 as compared to the same period last year.

Net loss attributable to common stockholders for the three months ended June 30, 2011 decreased \$775,745 to \$2,500,596 compared to a net loss of \$1,724,851 incurred for the three months ended June 30, 2010. The increased net loss is the result of higher research and development, and general and administrative expenses discussed above, plus the following non-operating expenses for the periods indicated:

	Quarter Ended 6/30/2011	Quarter Ended 6/30/2010	Change (\$)
Loss from Operations	\$ (4,231,787)	\$ (6,006,902)	\$ 1,775,115
Interest and dividend income	3	7,675	(7,672)
Interest (expense) and other income	6,208	(16,542)	22,750
Change in FV of financial instruments	(697,660)	1,420,784	(2,118,444)
Net loss attributable to noncontrolling interest	2,422,640	2,870,134	(447,494)
Net loss attributable to common stockholders	\$ (2,500,596)	\$ (1,724,851)	\$ (775,745)

SIX MONTHS ENDED JUNE 30, 2011 AND JUNE 30, 2010

We had no revenues during the six months ended June 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 six months ended June 30, 2011 decreased \$1,869,538 or 33%, to \$ 3,728,027 from \$5,597,565 for the six months ended June 30, 2010. This decrease was primarily due to (i) lower drug production expenses of approximately \$2,200,000 as a result of lower clinical trial activities during the three months ended June 30, 2011. Our Phase 2a 28 day clinical trial concluded during the third quarter of 2010 and our next Phase 2/3 90 day clinical trial is scheduled to begin during the third quarter of 2011; offset by (ii) higher program expenses, including animal studies, analytical testing, and clinical start-up expenses which increased by approximately \$440,000 during the six months ended June 30, 2011 to approximately \$3,100,000.

General and administrative expenses increased \$796,998 or 26%, to \$3,835,532 for the six months ended June 30, 2011 from \$3,038,534 for the six months ended June 30, 2010. This increase was primarily due to (i) \$760,000 of higher financial advisory accounting services related to our private placements and registered direct offerings.

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Net loss attributable to common stockholders for the six months ended June 30, 2011 decreased \$15,628,061 to \$4,261,963 compared to \$19,890,024 incurred for the six months ended June 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:

	Six Months Ended 06/30/2011	Six Months Ended 06/30/2010	Change (\$)
Loss from operations	\$ (7,563,559)	\$ (8,636,099)	\$ 1,072,540
Interest and dividend income	54	24,150	(24,096)
State tax credit		628,806	(628,806)
Interest (expense) on 11% Secured Notes and other income/(expenses)	(6,206)	(177,018)	170,812
Interest expense attributable to extinguishment of debt		(123,693)	123,693
Change in Fair Value of derivative instruments warrants	(1,036,375)	(15,641,361)	14,604,986
Net loss of majority owned subsidiary attributable to non-controlling interest	4,344,123	4,035,191	308,932
Net loss available to common stockholders	\$ (4,261,963)	\$ (19,890,024)	\$ 15,628,061

Table of Contents

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2011, we had \$598,104 in cash and cash equivalents, compared to \$1,708,982 as of December 31, 2010. Net cash used in operating activities was \$6,745,143 for the six months ended June 30, 2011 as compared to \$6,106,539 during the six months ended June 30, 2010. Net cash provided by financing activities for the six months ended June 30, 2011 was \$5,634,265, as compared to \$230,000 provided during the six months ended June 30, 2011. As of June 30, 2011, we had a negative working capital of \$4,871,017 as compared to a negative working capital of \$3,806,899 on December 31, 2010.

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. Synergy issued to the investors 667,563 shares of our 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 \$287,000 and there were no warrants issued in connection with this transaction.

On July 11, 2011, Synergy entered into a securities purchase agreement with a certain investor to raise gross proceeds of \$242,750 in a private placement. Synergy issued to the investor 80,916 shares of our common stock and warrants to purchase 80,916 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 \$3.25 per share.

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 June 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 June 30, 2011, we had no balances in money market balances.

ITEM 4. CONTROLS AND PROCEDURES

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of June 30, 2011, our Chief Executive Officer and Principal Financial Officer have concluded that as of June 30, 2011, our disclosure controls and procedures were not effective in

Table of Contents

ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms.

In connection with the preparation of our annual financial statements, our management performed an assessment of the effectiveness of internal control over financial reporting as of December 31, 2010. Management's assessment included an evaluation of the design of our internal control over financial reporting and the operational effectiveness of those controls. Based on this evaluation, management determined that, as of December 31, 2010, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management's assessment were (i) an effective whistle-blower program or other comparable mechanism and (ii) an ongoing program to manage identified fraud risks. As of December 31, 2010, we did not maintain effective internal control over financial reporting. As defined by Regulation S-X, Rule 1-02(a)(4), a material weakness is a deficiency or a combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the relationship between the benefit of desired controls and procedures and the cost of implementing new controls and procedures.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As of June 30, 2011, we are in the process of remediating the material weakness which existed at December 31, 2010. If these remedial measures are insufficient to address any of the identified material weaknesses or are not implemented effectively, or additional deficiencies arise in the future, material misstatements in our interim or annual financial statements may occur in the future.

There were no changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that could significantly affect internal controls over financial reporting during the quarter ended June 30, 2011.

Table of Contents

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

There have been no material changes from the legal proceedings disclosed in our Form 10-K for the year ended December 31, 2010.

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2010.

ITEM 6. EXHIBITS

(a) Exhibits

- 31.1 Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
- 31.2 Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101 Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2011, filed on August 15, 2011, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows (iv) the Condensed Consolidated Statement of Stockholders Equity (Deficit) and (v) the Notes to Consolidated Financial Statements tagged as blocks of text.

