

CALLISTO PHARMACEUTICALS INC  
Form 10-Q  
August 16, 2010

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, 2010**

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller  
reporting company)

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

The number of the registrant's shares of common stock outstanding was 54,504,437 as of August 13, 2010.

---

Table of Contents

CALLISTO PHARMACEUTICALS, INC.

FORM 10-Q

CONTENTS

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements</u>	<u>2</u>
<u>Condensed Consolidated Balance Sheets as of June 30, 2010 (unaudited) and December 31, 2009</u>	<u>2</u>
<u>Condensed Consolidated Statements of Operations for the Three Months and Six Months Ended June 30, 2010 and 2009 (unaudited) and the period June 5, 1996 (Inception) to June 30, 2010 (unaudited)</u>	<u>3</u>
<u>Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period June 5, 1996 (Inception) to June 30, 2010 (unaudited)</u>	<u>4</u>
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2010 and 2009 (unaudited) and for the period June 5, 1996 (Inception) to June 30, 2010 (unaudited)</u>	<u>12</u>
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>14</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>28</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>33</u>
<u>Item 4. Controls and Procedures</u>	<u>33</u>
<b><u>PART II OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	<u>35</u>
<u>Item 1A. Risk Factors</u>	<u>35</u>
<u>Item 6. Exhibits</u>	<u>35</u>
<u>Signatures</u>	<u>36</u>

Table of Contents

**INTRODUCTORY NOTE**

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

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2009 and other periodic reports filed with the SEC. Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of the Company, please be advised that Callisto's actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements. All drug candidates to treat GI disorders and diseases, currently plecatanide (previously designated as SP-304) and SP-333, are being developed exclusively by Synergy Pharmaceuticals, Inc., our 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, 2010 (Unaudited)	December 31, 2009
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 1,331,073	\$ 7,207,612
Cash in escrow	2,499,000	
Prepaid Research and Development	176,260	1,000,000
Prepaid expenses and other	36,545	61,630
State tax credit receivable	628,806	
 Total Current Assets	 4,671,684	 8,269,242
Property and equipment, net	12,031	14,665
Security deposits	87,740	87,740
	\$ 4,771,455	\$ 8,371,647
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 4,030,930	\$ 3,079,798
Accrued expenses	1,201,052	727,679
 Total Current Liabilities	 5,231,982	 3,807,477
Notes Payable	687,645	487,130
Derivative financial instruments, at estimated fair value warrants	1,045,214	11,870,369
Commitments and contingencies		
Stockholders' Deficit:		
Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized, 48,000 and 63,000 shares outstanding at June 30, 2010 and December 31, 2009, respectively	5	6
Series B convertible preferred stock, par value \$0.0001, 2,500,000 shares authorized, 1,009,166 and 1,014,166 shares outstanding at June 30, 2010 and December 31, 2009	101	102
Common stock, par value of \$.0001 per share: 225,000,000 shares authorized; 54,504,437 and 53,608,111 shares outstanding at June 30, 2010 and December 31, 2009, respectively	5,450	5,359
Additional paid-in capital	134,788,446	105,263,377
Deficit accumulated during development stage	(129,669,804)	(109,779,780)

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Total Callisto Stockholders' Equity /(Deficit)	5,124,198	(4,510,936)
Noncontrolling interest	(7,317,584)	(3,282,393)
Total Deficit	(2,193,386)	(7,793,329)
	\$ 4,771,455	\$ 8,371,647

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

Table of Contents

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

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		June 5, 1996 (Inception) to June 30, 2010
	2010	2009	2010	2009	2010
Revenues	\$	\$	\$	\$	\$
Costs and expenses:					
Research and development (1)	4,402,155	1,103,727	5,597,565	1,442,961	41,841,504
Government grants					(1,135,318)
Purchased in process research and development					6,944,553
General and administrative (1)	1,604,747	1,143,931	3,038,534	2,159,295	48,401,450
Loss from operations	(6,006,902)	(2,247,658)	(8,636,099)	(3,602,256)	(96,052,189)
Interest and investment income	7,675	14	24,150	225	913,486
State tax credit			628,806		628,806
Interest and other expense	(16,542)	(73,532)	(300,711)	(115,018)	(909,251)
Change in fair value of derivative instruments warrants	1,420,784	(16,519,465)	(15,641,361)	(16,736,568)	(22,464,100)
Net loss	(4,594,985)	(18,840,641)	(23,925,215)	(20,453,617)	(117,883,248)
Net Loss of subsidiary attributable to noncontrolling interest	2,870,134	836,853	4,035,191	1,155,743	7,317,584
Net loss attributable to controlling interest	(1,724,851)	(18,003,788)	(19,890,024)	(19,297,874)	(110,565,664)
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	\$ (1,724,851)	\$ (18,003,788)	\$ (19,890,024)	\$ (19,297,874)	\$ (129,669,804)
<i>Weighted average shares outstanding:</i>					
basic and diluted	54,420,023	50,846,570	54,146,561	50,737,615	
<i>Net loss per common share :</i>					
basic and diluted	\$ (0.03)	\$ (0.35)	\$ (0.37)	\$ (0.38)	

(1) Patent costs reclassified. See Note 2.

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





Table of Contents

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

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

(Unaudited)

	Preferred Shares	Preferred Stock, Par Value	Common Shares	Common Stock, Par Value	Additional Paid in Capital
Balance at inception, June 5, 1996		\$		\$	\$
Net loss for the year					
Issuance of founder shares			2,642,500	264	528
Common stock issued			1,356,194	136	272
Common stock issued via private placement			1,366,667	137	1,024,863
Balance, December 31, 1996			5,365,361	537	1,025,663
Net loss for the year					
Common stock issued via private placement			1,442,666	144	1,081,855
Balance, December 31, 1997			6,808,027	681	2,107,518
Net loss for the year					
Amortization of Stock based Compensation					52,778
Common stock issued via private placement			1,416,667	142	1,062,358
Common stock issued for services			788,889	79	591,588
Common stock repurchased and cancelled			(836,792)	(84)	(96,916)
Balance, December 31, 1998			8,176,791	818	3,717,326
Net loss for the year					
Deferred Compensation stock options					9,946
Amortization of Stock based Compensation					
Common stock issued for services					3,168,832
Common stock issued via private placement			346,667	34	259,966
Balance, December 31, 1999			8,523,458	852	7,156,070
Net loss for the year					
Amortization of Stock based Compensation					
Common stock issued			4,560,237	455	250,889
Other					432
Preferred shares issued	3,485,299	348			5,986,302
Preferred stock issued for services	750,000	75			1,124,925
Balance, December 31, 2000	4,235,299	423	13,083,695	1,307	14,518,618
Net loss for the year					
Deferred Compensation stock Options					20,000
Amortization of Stock based Compensation					
Balance, December 31, 2001	4,235,299	423	13,083,695	1,307	14,538,618
Net loss for the year					
Amortization of Stock based Compensation					

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Balance, December 31, 2002	4,235,299	\$	423	13,083,695	\$	1,307	\$	14,538,618
----------------------------	-----------	----	-----	------------	----	-------	----	------------

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

Table of Contents

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

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

(Unaudited)			
	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance at inception, June 5, 1996	\$	\$	\$
Net loss for the year		(404,005)	(404,005)
Issuance of founder shares			792
Common stock issued			408
Common stock issued via private placement			1,025,000
Balance, December 31, 1996		(404,005)	622,195
Net loss for the year		(894,505)	(894,505)
Common stock issued via private placement			1,081,999
Balance, December 31, 1997		(1,298,510)	809,689
Net loss for the year		(1,484,438)	(1,484,438)
Amortization of Stock based Compensation			52,778
Common stock issued			1,062,500
Common stock issued for services			591,667
Common Stock repurchased and cancelled			(97,000)
Balance, December 31, 1998		(2,782,948)	935,196
Net loss for the year		(4,195,263)	(4,195,263)
Deferred Compensation stock options	(9,946)		
Amortization of Stock based Compensation	3,262		3,262
Common stock issued for services			3,168,832
Common stock issued via private placement			260,000
Balance, December 31, 1999	(6,684)	(6,978,211)	172,027
Net loss for the year		(2,616,261)	(2,616,261)
Amortization of Stock based Compensation	4,197		4,197
Common stock issue			251,344
Other			432
Preferred shares issued			5,986,650
Preferred stock issued for services			1,125,000
Balance, December 31, 2000	(2,487)	(9,594,472)	4,923,389
Net loss for the year		(1,432,046)	(1,432,046)
Deferred Compensation stock options	(20,000)		
Amortization of Stock based Compensation	22,155		22,155
Balance, December 31, 2001	(332)	(11,026,518)	3,513,498
Net loss for the year		(1,684,965)	(1,684,965)
Amortization of Stock based Compensation	332		332
Balance, December 31, 2002	\$	\$ (12,711,483)	\$ 1,828,865

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



Table of Contents

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

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

(Unaudited)

	Preferred Stock	Preferred Stock Par Value	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance December 31, 2002	4,235,299	\$ 423	13,083,695	\$ 1,307	\$ 14,538,618	\$	\$ (12,711,483)	\$ 1,828,865
Net loss for the year							(13,106,247)	(13,106,247)
Conversion of preferred stock in connection with the Merger	(4,235,299)	(423)	4,235,299	423				
Common stock issued to former Synergy stockholders			4,329,927	432	6,494,458			6,494,890
Common stock issued in exchange for Webtronics common stock			1,503,173	150	(150)			
Deferred Compensation stock options					9,313,953	(9,313,953)		
Amortization of deferred Stock based Compensation						3,833,946		3,833,946
Private placement of common stock, net			2,776,666	278	3,803,096			3,803,374
Balance, December 31, 2003		\$	25,928,760	\$ 2,590	\$ 34,149,975	\$ (5,480,007)	\$ (25,817,730)	\$ 2,854,828

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

Table of Contents

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

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

(Unaudited)

	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance, December 31, 2003	25,928,760	\$ 2,590	\$ 34,149,975	\$ (5,480,007)	\$ (25,817,730)	\$ 2,854,828
Net loss for the year					(7,543,467)	(7,543,467)
Amortization of deferred Stock-based compensation expense				3,084,473		3,084,473
Variable accounting for stock options			(816,865)			(816,865)
Stock-based compensation net of forfeitures			240,572	93,000		333,572
Common stock issued via private placements, net	3,311,342	331	6,098,681			6,099,012
Warrant and stock-based compensation for services in connection with the Merger			269,826			269,826
Common stock returned from former Synergy stockholders	(90,000)	(9)	(159,083)			(159,092)
Stock issued for patent rights	25,000	3	56,247			56,250
Common stock issued for services	44,000	7	70,833			70,840
Balance, December 31, 2004	29,219,102	\$ 2,922	\$ 39,910,186	\$ (2,302,534)	\$ (33,361,197)	\$ 4,249,377

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

Table of Contents

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

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

(Unaudited)

	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity (Deficit)
Balance, December 31, 2004	29,219,102	\$ 2,922	\$ 39,910,186	\$ (2,302,534)	\$ (33,361,197)	\$ 4,249,377
Net loss for the year					(11,779,457)	(11,779,457)
Deferred stock-based compensation new grants			1,571,772	(1,571,772)		
Amortization of deferred stock-based compensation				2,290,843		2,290,843
Variable accounting for stock options			75,109			75,109
Common stock issued via private placement:						
March 2005	1,985,791	198	3,018,203			3,018,401
August 2005	1,869,203	187	1,812,940			1,813,127
Finders fees and expenses			176,249			176,249
Exercise of common stock warrant	125,000	13	128,737			128,750
Common stock issued for services	34,000	3	47,177			47,180
Balance, December 31, 2005	33,233,096	\$ 3,323	\$ 46,387,875	\$ (1,583,463)	\$ (45,140,654)	\$ (332,919)

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

Table of Contents

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

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

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity (Deficit)
Balance, December 31, 2005		\$	33,233,096	\$ 3,323	\$ 46,387,875	\$ (1,583,463)	\$ (45,140,654)	\$ (332,919)
Net loss for the year							(12,919,229)	(12,919,229)
Reclassification of deferred unamortized stock-based compensation upon adoption of FAS 123R					(1,583,463)	1,583,463		
Stock based compensation expense					2,579,431			2,579,431
Common stock issued via private placement:								
February 2006			4,283,668	428	5,139,782			5,140,210
Finders fees and expenses					(561,808)			(561,808)
April 2006			666,667	67	799,933			800,000
Finders fees and expenses					(41,000)			(41,000)
Waiver and Lock-up Agreement			740,065	74	579,622			579,696
Common stock issued for services			87,000	9	121,101			121,110
Exercise of common stock warrants			184,500	18	190,017			190,035
Series A convertible preferred stock issued via private placement:	574,350	57			5,743,443			5,743,500
Finders fees and expenses	11,775	1			(448,909)			(448,908)
Detachable warrants					2,384,485			2,384,485
Beneficial conversion feature accreted as a dividend							(2,384,485)	(2,384,485)
Balance, December 31, 2006	586,125	\$ 58	39,194,996	\$ 3,919	\$ 61,290,509	\$	\$ (60,444,368)	\$ 850,118

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



Table of Contents

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

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

	Series A Convertible		Series B Convertible		Common Shares	Common Stock, Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
	Series A Preferred Convertible Shares	Series A Preferred Stock, Par Value	Series B Preferred Convertible Shares	Series B Preferred Stock, Par Value					
Balance, December 31, 2006	586,125	\$ 58		\$	39,194,996	\$ 3,919	\$ 61,290,509	\$ (60,444,368)	\$ 850,118
Net loss for the year								(7,887,265)	(7,887,265)
Stock-based compensation expense							591,561		591,561
Common stock issued for services					80,000	8	36,792		36,800
Series A convertible preferred stock, issued via private placement	28,000	4					279,997		280,001
Finders fees and expenses, Series A private placement							(36,400)		(36,400)
Conversion of Series A preferred stock to common stock	(395,450)	(40)			7,668,165	767	(727)		
Beneficial conversion feature accreted as a dividend to Series A preferred stock							2,504,475	(2,504,475)	
Series B convertible preferred stock, issued via private placement			1,147,050	115			11,470,385		11,470,500
Finders fees and expenses, Series B private placement							(920,960)		(920,960)
Beneficial conversion feature accreted as a dividend to Series B preferred stock							10,495,688	(10,495,688)	
Change in fair value of Series B warrants from date of issuance to expiration of put option							(2,591,005)		(2,591,005)
Balance, December 31, 2007	218,675	22	1,147,050	115	46,943,161	4,694	83,120,315	(81,331,796)	1,793,350
Net loss for the year								(9,655,471)	(9,655,471)
Recapitalization of majority owned subsidiary via private placements of common stock							2,951,913		2,951,913
Minority interest in equity of subsidiary acquired							(42,824)		(42,824)
Stock-based compensation expense							589,063		589,063
Proceeds from issuance of 11% Notes attributable to detachable warrants							181,732		181,732
Conversion of Series A preferred stock to common stock	(120,675)	(12)			2,413,500	241	(229)		
Conversion of Series B preferred stock to common stock			(10,000)	(1)	200,000	20	(19)		
Balance, December 31, 2008	98,000	\$ 10	1,137,050	\$ 114	49,556,661	\$ 4,955	\$ 86,799,951	\$ (90,987,267)	\$ (4,182,237)

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

Table of Contents

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

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

	Series A Convertible Preferred Shares	Series A Non-convertible Preferred Stock	Series B Convertible Preferred Shares	Series B Non-convertible Preferred Stock	Common Stock Shares	Common Stock Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Non- Controlling Interest	Total Stockholders' Equity (Deficit)
Balance, December 31, 2008	98,000	\$ 10	1,137,050	\$ 114	49,556,661	\$ 4,955	\$ 86,799,951	\$ (90,987,267)		\$ (4,182,237)
Cumulative effect of adoption of ASC Topic 815							(181,732)	(1,903,900)		(2,085,632)
Net Loss								(15,073,021)	(3,282,393)	(18,355,414)
Stock based compensation expense							1,119,856			1,119,856
Conversion of Series A preferred stock to common stock	(35,000)	(4)			894,445	89	(85)			
Conversion of Series B preferred stock to common stock			(122,884)	(12)	2,963,236	296	(284)			
Private placements of common stock of majority owned subsidiary							15,970,100			15,970,100
Fees and expenses associated with private placements of majority owned subsidiary							(260,002)			(260,002)
Preferred Stock dividend attributable to reset of conversion price in conjunction with waiver of liquidation preference							1,815,592	(1,815,592)		
Cashless Conversion of Warrants to Common Stock					193,769	19	(19)			
Balance December 31, 2009	63,000	6	1,014,166	102	53,608,111	5,359	105,263,377	(109,779,780)	(3,282,393)	(7,793,329)
Net Loss								(19,890,024)	(4,035,191)	(23,925,215)
Stock based compensation expense							449,951			449,951
Conversion of Series A preferred stock to common stock	(15,000)	(1)			416,667	42	(41)			
Conversion of Series B preferred stock to common stock			(5,000)	(1)	138,889	14	(13)			
Direct offering of common stock of majority owned subsidiary							2,754,000			2,754,000
Warrants issued in connection with registered direct offering classified as derivative liability							(1,045,214)			(1,045,214)
Fees and expenses associated with direct offering of majority owned subsidiary							(286,630)			(286,630)
Reclassification of derivative liability to equity							27,511,730			27,511,730
Common stock issued as settlement for director's fees					75,000	8	41,117			41,125
Common stock issued in exchange for modification of notes payable					265,770	27	100,169			100,196
Balance June 30, 2010	48,000	\$ 5	1,009,166	\$ 101	54,504,437	\$ 5,450	\$ 134,788,446	\$ (129,669,804)	\$ (7,317,584)	\$ (2,193,386)

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

Table of Contents

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

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(Unaudited)**

	Six months ended June 30, 2010	Six months ended June 30, 2009	Period from June 5, 1996 (inception) to June 30, 2010
<b>Cash flows from operating activities:</b>			
Net loss	\$ (23,925,215)	\$ (20,453,617)	\$ (117,883,248)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation	2,634	3,349	105,201
Purchase discount accreted as interest income on U.S.Treasury bills			(26,950)
Stock-based compensation expense	449,951	480,648	19,304,676
Purchased in-process research and development (non-cash portion)			6,841,053
Interest expense accreted on notes	300,711	115,018	737,406
Stock-based liquidated damages			579,696
Change in fair value of derivative instruments warrants	15,641,361	16,736,568	22,464,099
Net liabilities assumed in excess of assets acquired in merger			(282,752)
<b>Changes in operating assets and liabilities:</b>			
Prepaid expenses	848,825	59,756	(212,805)
State tax credit receivable	(628,806)		(628,806)
Security deposit			(87,740)
Accounts payable and accrued expenses	1,204,000	882,233	4,958,977
<b>Total adjustments</b>	<b>17,818,676</b>	<b>18,277,572</b>	<b>53,752,055</b>
<b>Net cash used in operating activities</b>	<b>(6,106,539)</b>	<b>(2,176,045)</b>	<b>(64,131,193)</b>
<b>Cash flows from investing activities:</b>			
Short term investments purchased			(5,921,825)
Short term investments liquidated			5,948,775
Acquisition of equipment			(117,233)
<b>Net cash used in investing activities</b>			<b>(90,283)</b>
<b>Cash flows from financing activities:</b>			
Issuance of common and preferred stock			48,719,673
Finders fees and expenses	(25,000)	(157,927)	(3,339,172)
Proceeds from sale of 11% Notes		603,163	603,163
Proceeds of direct offering of majority owned subsidiary's common stock	255,000	5,138,500	19,250,100
Exercise of common stock warrants			318,785
<b>Net cash provided by financing activities</b>	<b>230,000</b>	<b>5,583,736</b>	<b>65,552,549</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(5,876,539)</b>	<b>3,407,691</b>	<b>1,331,073</b>
Cash and cash equivalents at beginning of period	7,207,612	301,323	
<b>Cash and cash equivalents at end of period</b>	<b>\$ 1,331,073</b>	<b>\$ 3,709,014</b>	<b>\$ 1,331,073</b>

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

Table of Contents

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

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

	Six months ended June 30, 2010	Six months ended June 30, 2009	Period from June 5, 1996 (inception) to June 30, 2010
Supplementary disclosure of cash flow information:			
Cash paid for taxes	\$ 33,120	\$ 17,891	\$ 275,690
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	41,125		41,125
Cash received in escrow for June 30, 2010 direct registered offering	2,499,000		2,499,000
Accrued finders fees related to direct registered offering	\$ 261,630	\$	\$ 261,630

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

Table of Contents

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Business overview:**

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 (previously designated as SP-304) and SP-333, are being developed exclusively by Synergy Pharmaceuticals, Inc., our 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, 2009, included in Form 10-K filed with the SEC on March 31, 2010. 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.

Certain items in the comparable prior period's financial statements have been reclassified to conform to the current period's presentation. Specifically, legal costs associated with patent applications and maintenance have been classified as general and administrative expense, where previously these costs were classified as research and development expense in our statement of operations. The results of operations for the three and six months ended June 30, 2010 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2010. The condensed consolidated balance sheet as of December 31, 2009 presented above was derived from the audited consolidated financial statements as of that date.

The condensed consolidated financial statements as of June 30, 2010 and December 31, 2009 have been prepared under the assumption that Callisto will continue as a going concern for the next twelve months. Callisto's ability to continue as a going concern is dependent upon its ability to obtain

Table of Contents

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

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

**(Unaudited)**

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

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 \$6,106,539 during the six months ended June 30, 2010 as compared to \$2,176,045 for the six months ended June 30, 2009. During the six months ended June 30, 2010 and 2009 Callisto incurred net losses available to common stockholders of \$19,890,024 and \$19,297,874, respectively. To date, Callisto's sources of cash have been primarily limited to the sale of equity securities and issuance of 11% Notes. Net cash provided by financing activities for the six months ended June 30, 2010 and 2009 and for the period from June 5, 1996 (inception) to June 30, 2010, was \$230,000, \$5,583,736 and \$65,552,549, respectively. As of June 30, 2010 Callisto had a working capital deficit of \$560,298 compared to a working capital of \$4,461,765 as of December 31, 2009.

Worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult for us 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 FASB issued ASU 2010-13, "Compensation - Stock Compensation (Topic 718) Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in Which the Underlying Equity Security Trades." ASU 2010-13 provides amendments to Topic 718 to clarify that an employee share-based payment award with an exercise price denominated in the currency of a market in which a substantial portion of the entity's equity securities trades should not be considered to contain a condition that is not a market, performance, or service condition. Therefore, an entity would not classify such an award as a liability if it otherwise qualifies as equity. The amendments in ASU 2010-13 are effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2010. Callisto expects that the adoption of this standard will not have a material effect on its results of operation or its financial position.

In January 2010, the FASB issued Accounting Standards Update ("ASU") 2010-06, "Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements" ("ASU 2010-06"). ASU 2010-06 includes new disclosure requirements related to fair value measurements, including transfers in and out of Levels 1 and 2 and information about purchases, sales,

Table of Contents

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

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

**(Unaudited)**

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

issuances and settlements for Level 3 fair value measurements. This update also clarifies existing disclosure requirements relating to levels of disaggregation and disclosures of inputs and valuation techniques. The provisions of ASU 2010-06 are effective for periods beginning after December 15, 2009. The disclosures relating to Level 3 activity are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years. The adoption of ASU 2010-06 did not have a material impact on the Company's financial statements.

In January 2010, the FASB issued ASU 2010-02, *Accounting and Reporting for Decreases in Ownership of a Subsidiary a Scope Clarification* ("ASU 2010-02"), in response to practice issues entities encountered in applying the decrease in ownership provisions of SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* (codified in ASC 810-10, *Consolidation*). ASU 2010-02 clarifies that the decrease in ownership provisions of ASC 810-10 and related guidance apply to (a) a subsidiary or group of assets that is a business or nonprofit activity, (b) a subsidiary or group of assets that is a business or nonprofit activity for a noncontrolling interest in an entity (including an equity method investee or joint venture) and (c) an exchange of a group of assets that constitutes a business or nonprofit activity for a noncontrolling interest in an entity (including an equity method investee or joint venture). In addition, ASU 2010-02 clarifies that the decrease in ownership guidance does not apply to sales of in-substance real estate or conveyances of oil and gas mineral rights, even if these transactions involve businesses. Finally, the ASU expands the disclosures required upon deconsolidation of a subsidiary. The adoption of ASU 2010-02 on January 1, 2010 did not have a material impact on the Company's financial statements.

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

ASC Topic 718 "*Compensation - Stock Compensation*" requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award.

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

ASC Topic 718 requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to Callisto's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

Callisto accounts for common stock, stock options, and warrants granted to employees and non-employees based on the fair market value of the instrument, using the Black-Scholes option pricing

Table of Contents

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

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

**(Unaudited)**

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

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, 2010
	2010	2009	2010	2009	
Employees included in research and development	\$ 764	\$ 7,009	\$ 5,345	\$ 13,941	\$ 2,692,157
Employees included in general and administrative	9,885	9,591	19,743	27,918	4,816,449
<b>Subtotal employee stock option grants</b>	<b>10,648</b>	<b>16,600</b>	<b>25,088</b>	<b>41,859</b>	<b>7,508,606</b>
Non-employee research and development					102,750
Non-employee general and administrative	(27,825)	91,842	47,458	84,503	9,881,469
<b>Subtotal non-employee stock option grants</b>	<b>(27,825)</b>	<b>91,842</b>	<b>47,458</b>	<b>84,503</b>	<b>9,984,219</b>
<b>Total stock based compensation expense</b>	<b>\$ (17,176)</b>	<b>\$ 108,442</b>	<b>\$ 72,546</b>	<b>\$ 126,362</b>	<b>\$ 17,492,825</b>

The unrecognized compensation cost related to employee non-vested Callisto stock options outstanding at June 30, 2010, net of expected forfeitures, was \$57,612, to be recognized over a weighted average vesting period of approximately 1.4 years.

The estimated fair value of each Callisto stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the six months ended June 30, 2010 and 2009.

	Six months ended June 30,	
	2010	2009
Risk free interest rate	2.38%	No awards
Dividend yield	n/a	No awards
Expected volatility	100%	No awards
Expected term	5 years	No awards

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	Intrinsic Value
----------------------	--------------------------------	---------------------------------	--------------------



Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

				<b>Price Per Share</b>	
Balance outstanding, December 31, 2009	7,495,038	\$	0.08 - 6.75	\$	1.70 \$
Granted	855,000	\$	0.26	\$	0.26
Forfeitures	(6,000)	\$	0.20	\$	0.20
Balance outstanding, June 30, 2010	8,344,038	\$	0.08 - 6.75	\$	1.56 \$
Exercisable as of June 30, 2010	6,074,372	\$	0.08 - 6.75	\$	1.54 \$

17

---

Table of Contents

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

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

(Unaudited)

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

*Synergy Options*

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.

Synergy adopted the 2008 Equity Compensation Incentive Plan (the "Plan") on July 3, 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 periodically issues stock options to employees and non-employees and has adopted ASC Topic 718 for employee awards on July 3, 2008. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 Equity-Based Payment to Non-Employees whereas the value of the stock compensation is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete.

Stock-based compensation expense, including all options and restricted stock units, has been recognized in operating results as follow:

	Three Months Ended June 30,		Six Months Ended June 30		November 15, 2005
	2010	2009	2010	2009	(inception) to June 30, 2010
Employees included in research and development	\$ 49,804	\$ 43,055	\$ 99,263	\$ 86,296	\$ 431,334
Employees included in general and administrative	58,994	56,695	117,948	112,769	588,842
Non-employees included in research and development	8,455	8,455	16,817	16,817	59,279
Non-employees included in general and administrative	71,778	69,585	143,377	138,404	732,395
<b>Total stock-based compensation expense</b>	<b>\$ 189,031</b>	<b>\$ 177,790</b>	<b>\$ 377,405</b>	<b>\$ 354,286</b>	<b>\$ 1,811,850</b>

The estimated fair value of each Synergy stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions:

	Six months ended June 30,	
	2010	2009
Risk free interest rate	2.31 to 2.71%	No awards
Dividend yield	n/a	No awards
Expected volatility	90%	No awards
Expected term	6 years	No awards

Table of Contents

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

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

**(Unaudited)**

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

*Risk-free interest rate* Based upon observed US Treasury yield curve interest rates for Treasury instruments with maturities which correspond to the expected term of Synergy's employee stock options at the date of grant.

*Dividend yield* Synergy has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future.

*Expected volatility* Based on the historical volatility of similar publicly traded stocks in Synergy's industry segment with comparable market capitalization and stage of development.

*Expected term* Synergy has had no stock options exercised since inception. The expected option term represents the period that stock-based awards are expected to be outstanding based on the simplified method provided in Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment*, ("SAB No. 107"), which averages an award's weighted-average vesting period and expected term for "plain vanilla" share options. Under SAB No. 107, options are considered to be "plain vanilla" if they have the following basic characteristics: (i) granted "at-the-money"; (ii) exercisability is conditioned upon service through the vesting date; (iii) termination of service prior to vesting results in forfeiture; (iv) limited exercise period following termination of service; and (v) options are non-transferable and non-hedgeable.

In December 2007, the SEC issued SAB No. 110, *Share-Based Payment*, ("SAB No. 110"). SAB No. 110 was effective January 1, 2008 and expresses the views of the Staff of the SEC with respect to extending the use of the simplified method, as discussed in SAB No. 107, in developing an estimate of the expected term of "plain vanilla" share options in accordance with ASC Topic 718. The Company will continue to use the simplified method until it has the historical data necessary to provide a reasonable estimate of expected life in accordance with SAB No. 107, as amended by SAB No. 110. For the expected term, the Company has "plain-vanilla" stock options, and therefore used a simple average of the vesting period and the contractual term for options granted subsequent to January 1, 2006 as permitted by SAB No. 107.

*Forfeitures* ASC Topic 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Synergy's estimated future unvested option forfeitures is based on the historical experience of its majority shareholder, Callisto.

The unrecognized compensation cost related to non-vested stock options outstanding at June 30, 2010, net of expected forfeitures, was \$631,405, to be recognized over the next three quarters.

On March 1, 2010, a majority of our 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.

Table of Contents

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

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

(Unaudited)

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

A summary of stock option activity and of changes in stock options outstanding under the Plan is presented below:

A summary of stock option activity and of changes in stock options outstanding under the Plan is presented below:

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value
Balance outstanding, December 31, 2009	4,214,016	\$ 0.25 - 0.95	\$ 0.30	\$ 22,320,436
Granted	4,465,000(1)	0.70	0.70	
Exercised				
Forfeited				
Balance outstanding, June 30, 2010	8,679,016	\$ 0.25 - 0.95	\$ 0.51	\$ 63,987,092
Exercisable at June 30, 2010	1,417,420	\$ 0.25 - 0.95	\$ 0.29	\$ 10,753,665

(1)

These stock options will vest and become exercisable only upon a change of control of the company. Because of this contingent vesting the Company did not record any stock based compensation expense on these stock options during the six months ended June 30, 2010. The weighted average fair value of these stock options at the date of grant was \$6.77 per share as calculated by the Black-Scholes model, using the assumptions noted in the table above.

**Synergy Restricted Stock Units**

Restricted stock units, which entitle the holder to earn, at the end of a vesting term, a specified number of shares of Synergy common stock are accounted for as stock based compensation in accordance with ASC Topic 718 in the same manner as stock options using fair value at the date of issuance. Restricted stock units are subject to a repurchase agreement, assumed by Synergy pursuant to the Exchange Transaction, whereby 50% of the units vest after 1 year of continuous service and the remaining 50% vest after 2 years of continuous service from the issuance date. The fair value at the date of issuance is being expensed ratably by month over the 2 year service period since July 2008. As of June 30, 2010 there were 874,760 restricted stock units outstanding. These units were originally issued on July 3, 2008 and are included in shares outstanding. The fair value of the 874,760 restricted stock units on the date of issuance was \$524,856 of which \$31,275, \$63,628 and \$523,779 was recorded as stock-based compensation expense during the three and six months ended June 30, 2010 and for the period from inception to June 31, 2010, leaving \$1,077 unrecognized as of June 30, 2010, to be expensed in the quarter ended September 30, 2010.

**5. Research and Development Expense**

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

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

Table of Contents

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

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

**(Unaudited)**

**5. Research and Development Expense (Continued)**

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 \$176,260 and \$1.0 million as of June 30, 2010 and December 31, 2009, respectively, for nonrefundable pre-payments for production of plecanatide drug substance and analytical testing services of our drug candidate SP-333. In accordance with this guidance, Synergy expenses deferred research and development costs when drug compound is delivered and services are performed.

**6. State Tax Credit Receivable**

During the quarter ended March 31, 2010, Callisto determined that it was eligible for New York State's Qualified Emerging Technology Company Tax Credit for the tax years ended December 31, 2006, 2007, and 2008 totaling \$628,806. On April 23, 2010 Callisto filed amended tax returns for the above mentioned tax years, and reflected this receivable and credit in our financial statements for the quarter ended March 31, 2010. As of June 30, 2010, this receivable was still outstanding.

**7. 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:

	June 30, 2010	June 30, 2009
Common Shares outstanding	54,504,437	50,914,341
Potentially dilutive common shares issuable upon:		
Exercise of warrants	84,842,576	85,050,964
Exercise of stock options	6,074,372	7,903,358
Conversion of Series A Convertible Preferred Stock	1,333,333	1,760,000
Conversion of Series B Convertible Preferred Stock	28,032,389	21,583,320
<b>Total fully diluted</b>	<b>174,787,107</b>	<b>167,212,163</b>

**8. Derivative Financial Instruments**

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, "Derivatives and Hedging: Contracts in Entity's Own Entity" ("ASC Topic 815-40"). ASC Topic 815-40 clarifies the

Table of Contents

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

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

**(Unaudited)**

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

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, certain warrants (the "New Warrants") issued in connection with the issuance of the 11% Notes were to be treated as derivative liabilities on the Company's Balance Sheet. Prior to the adoption of ASC Topic 815-40, the Company accounted for the warrants as components of stockholders' equity. 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 was 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.

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, we 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 into stockholders' equity.

The Company estimated the fair value of the New Warrants using the Black-Scholes option pricing model. The assumptions used for the three and six months ended June 30, 2010 are noted in the following table:

	Six Months Ended June 30, 2010	Six Months Ended June 30, 2009
Expected option term	7.5 to 8.0 years	7.5 to 8.0 years
Risk-free interest rate	2.7% to 3.4%	2.27% to 3.33%
Expected volatility	100%	150% to 200%
Dividend yield	0%	0%

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

Table of Contents

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

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

(Unaudited)

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

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

Date	Description	New Warrants	Derivative Instrument Liability
12/31/2009	Balance of derivative financial instruments December 31, 2009	69,086,174	\$ 11,870,369
3/31/2010	Change in fair value of New Warrants outstanding on December 31, 2009, during the quarter ended March 31, 2010		\$ 17,062,145
3/31/2010	Balance of derivative financial instruments March 31, 2010	69,086,174	\$ 28,932,514
6/30/2010	Change in fair value of New Warrants outstanding during the quarter ended June 30, 2010		\$ (1,420,784)
6/30/2010	Reclass of derivative liability to stockholder's equity upon expiration of supplemental condition (price protection)		\$ (27,511,730)
6/30/2010	Balance of derivative financial instruments June 30, 2010	69,086,174	\$

*Synergy Derivative Instruments*

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 the issuance of the June 30, 2010 registered direct offering, must be recorded as derivative liabilities with a charge to additional paid in capital. In accordance with ASC Topic 815-40, the warrants will be 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 warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability described above. The assumptions used to determine the fair value of the warrants as of June 30, 2010 were:

	June 30, 2010
Estimated fair value of stock	\$2.64
Expected warrant term	5 years
Risk-free interest rate	1.79%
Expected volatility	90%
Dividend yield	0%

Estimated fair value of the stock is based on an apportionment of the \$4.25 unit price paid for the shares and warrants issued June 30, 2010 in the Company's registered direct offering, which was an arms-length negotiated price.

Expected volatility is based on the historical volatility of similar publicly traded stocks in Synergy's industry segment with comparable market capitalization and stage of development. 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 consistent with the expected term of the warrants.



Table of Contents

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

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

(Unaudited)

**9. Fair Value Measurements**

*Callisto Fair Value Measurements*

The following table sets forth a summary of changes in the fair value of the Callisto's Level 3 liabilities for the six months ended June 30, 2010:

Description	Balance at December 31, 2009	Unrealized losses	Reclassified	Balance as of June 30, 2010
Derivative liabilities related to warrants	\$ 11,870,369	\$ 15,641,361	\$ (27,511,730)	\$

The unrealized losses on the derivative liabilities are classified in other expenses as a change in derivative liabilities in the Company's statement of operations. On June 30, 2010, the price protection clause expired. As a result, we measured the fair value of the outstanding warrants as of June 30, 2010, recognized any changes in value in earnings and then reclassified the derivative instrument liability into stockholder's equity. (See Note 8 above)

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.

*Synergy Fair Value Measurements*

The following table presents the Company's liabilities, arising from Synergy's derivative liabilities discussed above (See Note 7), that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of June 30, 2010:

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of June 30, 2010
Derivative liabilities related to Warrants	\$	\$	\$ 1,045,214	\$ 1,045,214

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, 2010:

Description	Balance at December 31, 2009	Unrealized losses	Balance as of June 30, 2010
Derivative liabilities related to Warrants	\$	\$	\$ 1,045,214

Table of Contents

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

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

**(Unaudited)**

**9. Fair Value Measurements (Continued)**

The unrealized losses on the derivative liabilities are classified in other expenses 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 reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

**10. Stockholders' deficit**

On December 30, 2008, Callisto entered into a securities purchase and exchange agreement ("Purchase Agreement") with several investors, each of whom were holders of record as of November 4, 2008 of outstanding warrants to purchase shares of the Company's common stock, exercisable at \$0.50 or \$0.70 per share until August 2, 2010 ("Series B Warrants"). The Series B Warrants were issued in connection with the private placement of the Company's Series B Preferred Shares on August 2, 2007. During the period from December 30, 2008 to June 17, 2009, pursuant to the Purchase Agreement, Callisto issued \$603,163 principal amount of 11% Secured Notes due April 15, 2010 ("11% Notes"). Interest on the 11% Notes is due at maturity and repayment of the 11% Notes is secured by a pledge of up to 2,292,265 shares of the common stock of Synergy owned by Callisto. Pursuant to the Purchase Agreement, Callisto issued 69,086,174 common stock purchase warrants ("New Warrants") in exchange for the surrender and cancellation of 26,938,800 outstanding Series B Warrants. The New Warrants have an exercise price, subject to certain anti-dilution adjustments, of \$0.02 per share and are exercisable at any time on or prior to December 31, 2016.

In connection with the issuance of \$349,880 of the \$603,163 11% Notes in June 2009, Callisto entered into an additional security agreement granting all of the holders of the 11% Notes a security interest in the Atiprimod technology acquired by the Company in December 2008.

The proceeds from the issuance of these instruments were allocated to the 11% Notes and the New Warrants based upon the relative fair values of the 11% Notes and the New Warrants. The New Warrants had a fair value of \$6,781,471 upon issuance, measured utilizing the Black Scholes fair value methodology using assumptions ranging from 7.5 to 8 years for expected term, volatility of 150% to 200%, no dividends and risk free interest rates ranging from 1.76% to 3.33%. This resulted in a debt discount of \$552,728 apportioned to the New Warrants which was being accreted to the 11% Notes as interest expense over the life of the 11% Notes.

On June 30, 2010, the price protection provision included in the New Warrants expired. As a result, we measured the fair value of the outstanding warrants as of June 30, 2010, recognized any changes in value in earnings and then reclassified the derivative instrument liability into stockholder's equity. (See Note 8 above)

Table of Contents

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

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

**(Unaudited)**

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

The following table summarizes the financial impact of the 11% Notes payable and the related interest expense for the period from December 30, 2009 through June 30, 2010:

	<b>11% Notes Payable</b>	<b>Interest expense</b>
11% Notes Balance December 31, 2009	\$ 487,130	\$ 436,693
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
11% Notes balance March 31, 2010	\$ 671,103	\$ 284,169
11% nominal interest expense quarter ended June 30, 2010	16,542	16,542
11% Notes balance June 30, 2010	\$ 687,645	\$ 300,711

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

On June 30, 2010, Synergy entered into securities purchase agreements to sell securities to non-U.S. investors and raise gross proceeds of approximately \$2,754,000 in a registered direct offering. Synergy sold 648,000 units at \$4.25 per share to investors. Each unit consists of one share of Synergy's common stock and one warrant to purchase one additional share of Synergy common stock. The warrants expire after five years and are exercisable at \$4.50 per share. In accordance with ASC 815-40, "Derivatives and Hedging Contracts in Entity's Own Equity" the warrants have been classified as a derivative liability.

The offering was made pursuant to a shelf registration statement on Form S-3 (the base prospectus effective December 10, 2009), as supplemented by a prospectus supplement filed with the Securities and Exchange Commission on June 23, 2010. As of June 30, 2010, Synergy had received proceeds of \$255,000, less legal fees of \$25,000 associated with this offering, and the remaining \$2,499,000 was held in escrow account and received by Synergy on July 2 and July 8, 2010. In July 2010, the Synergy paid an aggregate \$261,630 to selling agents in connection with this placement, of which the entire amount was accrued as of and for the period ended June 30, 2010.

Table of Contents

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

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

**(Unaudited)**

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

During the six months ended June 30, 2010, 15,000 shares of Callisto's Series A Convertible Preferred Stock were converted to 416,667 shares of common stock and 5,000 shares of Series B Convertible Preferred Stock were converted to 138,889 shares of common stock.

**11. Subsequent Events**

On July 13, 2010 Synergy issued 1,061,867 shares of its common stock as consideration for an agreement by certain holders of its common stock to extend their lock-up of such shares from August 15, 2010 to January 15, 2011 or enter into a lock-up agreement until such date, as the case may be. This issuance was approved by Synergy's Board of Directors on June 22, 2010 and represents 5% of the shares of previously issued common stock currently subject to a lock-up agreement or being requested to lock-up, as the case maybe. The fair value of the common stock issued to accomplish this lock-up extension totaled \$2,798,020, based on the estimated fair value of the shares issued in connection with the June 30, 2010 registered direct offering (See Note 10). This amount will be charged to additional paid in capital as a cost of facilitating the registered direct offering discussed above.

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, 2009 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 majority-owned 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.

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.

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

- (1) plecanatide (previously designated as SP-304), 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.
- (3) Atiprimod, an orally administered drug with antiproliferative, anti-inflammatory and antiangiogenic activity.

**RECENT DEVELOPMENTS**

On June 30, 2010, Synergy entered into securities purchase agreements to sell securities to non-U.S. investors and raised gross proceeds of approximately \$2,754,000 in a registered direct offering. Synergy sold 648,000 units at \$4.25 per share to investors. Each unit consists of one share of our Synergy common stock and one warrant to purchase one additional share of Synergy common stock. The warrants expire after five years and are exercisable at \$4.50 per share. The offering was made pursuant to a shelf registration statement on Form S-3 (the base prospectus effective December 10,

Table of Contents

2009), as supplemented by a prospectus supplement filed with the Securities and Exchange Commission on June 23, 2010. As of June 30, 2010, we had received proceeds of \$255,000, less legal fees of \$25,000 associated with this offering. The remaining \$2,499,000 was held in escrow and received from escrow on July 2 and July 8, 2010. In July 2010, the Company paid an aggregate \$261,630 to selling agents in connection with this placement, of which the entire amount was accrued as of and for the period ended June 30, 2010.

On March 19, 2010, we initiated a Phase 2a 14-day repeated-oral-dose, placebo-controlled, dose-escalation trial of plecanatide (previously designated SP-304) in CC patients. We expect to obtain meaningful topline data from this by trial late summer of 2010, and use those data to establish doses for follow-up Phase 2b clinical trials in CC and IBS-C. We plan to open a 24-day repeated-oral-dose trial of plecanatide in CC patients in the autumn of 2010, and a 90-day trial of plecanatide in IBS-C patients in the second quarter of 2011.

An Investigational New Drug application ("IND") for SP-333 is planned for the fourth quarter of 2010 and we plan to open the first human trial of SP-333 in volunteers in early 2011.

**FINANCIAL OPERATIONS OVERVIEW**

From inception through June 30, 2010, we have sustained cumulative net losses available to common shareholders of \$129,669,804. Our losses have resulted primarily from expenditures 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, 2010, 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 \$6,106,539 during the six months ended June 30, 2010 as compared to \$2,176,045 for the six months ended June 30, 2009. During the six months ended June 30, 2010 and 2009 Callisto incurred net losses attributable to common stockholders of \$19,890,024 and \$19,297,874, respectively. To date, Callisto's sources of cash have been primarily limited to the sale of equity securities and issuance of 11% Notes. Net cash provided by financing activities for the six months ended June 30, 2010 and 2009 and for the period from June 5, 1996 (inception) to June 30, 2010, was \$230,000, \$5,583,736 and \$65,552,549, respectively.

**OFF-BALANCE SHEET ARRANGEMENTS**

We had no off-balance sheet arrangements as of June 30, 2010.

**RESULTS OF OPERATIONS**

**THREE MONTHS ENDED JUNE 30, 2010 AND JUNE 30, 2009**

We had no revenues during the three months ended June 30, 2010 and 2009 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 increased \$3,298,428 or 299% to \$4,402,155 for the three months ended June 30, 2010 from \$1,103,727 for the three months ended June 30, 2009. This increase was primarily due to (i) higher program expenses, including animal studies, analytical testing, clinical data monitoring and patient costs, which increased by approximately \$1,821,000 during the three

Table of Contents

months ended June 30, 2010 to approximately \$1,862,000 related to our continuing Phase 2a trial of plecanatide in CC patients which began March 19, 2010, (ii) drug production increased approximately \$1,300,000 to approximately \$2,200,000 in support of ongoing and planned clinical trials, (iii) scientific advisors fees and expenses increased approximately \$55,000 to approximately \$93,000 and (iv) staff compensation cost increased approximately \$100,000 to \$223,259 as we hired additional product development personnel.

General and administrative expenses for the three months ended June 30, 2010 increased \$460,816 or 40%, to \$1,604,747 for the three months ended June 30, 2010 from \$1,143,931 for the three months ended June 30, 2009. This increase was primarily due to (i) approximately \$265,000 of higher financial advisory and travel expenses related to our public offerings and (ii) approximately \$180,000 of increased facilities overhead, (iii) approximately \$94,000 of higher patent legal expenses, offset by approximately \$110,000 of lower stock based compensation expense.

Loss from operations for the three months ended June 30, 2010 increased \$3,759,244 to \$6,006,902 compared to a net loss from operations of \$2,247,658 incurred for the three months ended June 30, 2009. The increased loss is the result of higher research and development, and general and administrative expenses discussed above, plus the following non-operating expenses for the quarters ended June 30, 2009 and 2010.

	Quarter Ended 06/30/2010	Quarter Ended 06/30/2009	Change (\$) 06/30/2010
Loss from operations	\$ (6,006,902)	\$ (2,247,658)	\$ (3,759,244)
Interest and dividend income	7,675	14	7,661
Interest expense on 11% Secured Notes	(16,542)	(73,532)	56,990
Change in Fair Value of derivative instruments warrants	1,420,784	(16,519,465)	17,940,249
Net loss of majority owned subsidiary attributable to non-controlling interest	2,870,134	836,853	2,033,281
Net loss available to common stockholders	\$ (1,724,851)	\$ (18,003,788)	\$ 16,278,937

**SIX MONTHS ENDED JUNE 30, 2010 AND JUNE 30, 2009**

We had no revenues during the six months ended June 30, 2010 and 2009 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 increased \$4,154,604 or 288% to \$5,597,565 for the six months ended June 30, 2010 from \$1,442,961 for the six months ended June 30, 2009. This increase was primarily due to (i) higher program expenses, including animal studies, analytical testing, clinical data monitoring and patient costs, which increased by approximately \$2,660,000 during the six months ended June 30, 2010 to approximately \$2,780,000 related to our Phase 2a clinical trial of plecanatide in CC patients which began March 19, 2010, (ii) drug production increased approximately \$1,300,000 to approximately \$2,200,000 in support of ongoing and planned clinical trials, (iv) scientific advisors fees and expenses increased approximately \$75,000 to approximately \$172,000 and (v) staff compensation cost increased approximately \$164,000 to approximately \$430,000 as we hired additional product development personnel.

General and administrative expenses for the six months ended June 30, 2010 increased \$879,239 or 41%, to \$3,038,534 for the six months ended June 30, 2010 from \$2,159,295 for the six months ended June 30, 2009. This increase was primarily due to (i) approximately \$316,000 of higher financial advisory and travel expenses related to Synergy's public offerings, (ii) approximately \$262,000 of increased facilities overhead and (iii) higher staff salaries, wages and benefits which increased by

Table of Contents

approximately \$60,000, (iv) approximately \$286,000 of higher patent legal expense in the six months ended June 30, 2010 as compared to the same period last year, offset by approximately \$65,000 of lower stock based compensation expense.

Loss from operations for the six months ended June 30, 2010 increased \$5,033,843 to \$8,636,099 compared to a net loss from operations of \$3,602,256 incurred for the six months ended June 30, 2009. 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 six months ended June 30, 2009 and 2010.

	Six Months Ended 06/30/2010	Six Months Ended 06/30/2009	Change (\$) 06/30/2010
Loss from operations	\$ (8,636,099)	\$ (3,602,256)	\$ (5,033,843)
Interest and dividend income	24,150	225	23,925
State tax credit	628,806		628,806
Interest expense on 11% Secured Notes	(177,018)	(115,018)	(62,000)
Interest expense attributable to extinguishment of debt	(123,693)		(123,693)
Change in Fair Value of derivative instruments warrants	(15,641,361)	(16,736,568)	1,095,207
Net loss of majority owned subsidiary attributable to non-controlling interest	4,035,191	1,155,743	2,879,448
Net loss available to common stockholders	\$ (19,890,024)	\$ (19,297,874)	\$ (592,150)

**LIQUIDITY AND CAPITAL RESOURCES**

As of June 30, 2010 we had \$1,331,073 in cash and cash equivalents, compared to \$7,207,612 as of December 31, 2009. We had working capital deficit of \$560,298 as of June 30, 2010.

Net cash used in operating activities was \$6,106,539 during the six months ended June 30, 2010 as compared to \$2,176,045 for the six months ended June 30, 2009. During the six months ended June 30, 2010 and 2009 Callisto incurred net losses attributable to common stockholders of \$19,890,024 and \$19,297,874, respectively. To date, Callisto's sources of cash have been primarily limited to the sale of equity securities and issuance of 11% Notes. Net cash provided by financing activities for the six months ended June 30, 2010 and 2009 and for the period from June 5, 1996 (inception) to June 30, 2010, was \$230,000, \$5,583,736 and \$65,552,549, respectively.

On June 30, 2010, Synergy entered into securities purchase agreements to sell securities to non-U.S. investors and raise gross proceeds of approximately \$2,754,000 in a registered direct offering. Synergy sold 648,000 units at \$4.25 per share to investors. Each unit consisted of one share of our common stock and one warrant to purchase one additional share of common stock. The warrants expire after five years and are exercisable at \$4.50 per share. The offering was made pursuant to a shelf registration statement on Form S-3 (the base prospectus effective December 10, 2009), as supplemented by a prospectus supplement filed with the Securities and Exchange Commission on June 23, 2010. As of June 30, 2010, Synergy had received proceeds of \$255,000, less legal fees of \$25,000 associated with this placement which was included in our cash and cash equivalents. The remaining \$2,499,000 was held in escrow and received on July 2, 2010 and July 8, 2010. In July 2010, Synergy also paid an aggregate \$261,630 to selling agents in connection with this offering.

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



Table of Contents

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of pharmaceutical research and development programs. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates, to fund the existing working capital deficit and to continue to fund operations at our current cash expenditure levels. To date, our sources of cash have been primarily limited to the sale of equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution.

Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more of product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Our consolidated financial statements as of June 30, 2010 and December 31, 2009 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our independent registered public accounting firm has issued a report dated March 31, 2010 that included an explanatory paragraph referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**CRITICAL ACCOUNTING POLICIES**

We prepare our financial statements in conformity with accounting principles generally accepted in the U.S. The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and contingent liabilities, at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Because of the uncertainty of factors surrounding the estimates or assumptions used in the preparation of the consolidated financial statements, actual results may vary from these estimates.

**Share-Based Payments**

We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options is designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage. Since inception through June 30, 2010 stock-based compensation expense has totaled \$19,304,676 or 17% of our net loss available to common shareholders of \$129,669,804.

Upon adoption of ASC Topic 718, we selected the Black-Scholes option pricing model as the most appropriate model for determining the estimated fair value for stock-based awards. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Expected volatility was calculated based on our historical volatility. Our stock price has fluctuated from \$3.95 per share as of December 31, 2003 to \$0.41 per share as of June 30, 2010. The expected term was determined based on the simplified method provided in ASC Topic 718 "*Share-Based Payment*".

Table of Contents

The risk-free interest rate is based on observed interest rate appropriate for the expected term of our stock options. Forfeitures are estimated, based on our historical experience, at the time of grant.

**Research and Development**

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 ASC Topic 730-10-55-2. Also, as prescribed by this guidance the costs of patent applications and filings are legal in nature and classified as general and administrative expense.

We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all and therefore our research and development costs are expensed as incurred. While certain of our research and development costs may ultimately have future benefits, our policy of expensing all research and development expenditures is predicated on (i) the fact that we have no history of successful commercialization of biopharmaceutical products to base any estimate of the number of future periods that would be benefited and (ii) recoverability is highly uncertain at our stage of development.

In June 2007, the EITF of the FASB reached a consensus on ASC Topic 730, *Research and Development* ("ASC Topic 730"). In accordance with ASC Topic 730-10-55 non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts are recognized as an expense. We adopted ASC Topic 730-10-55 on January 1, 2008 and the adoption did not have a material effect on our consolidated financial position, results of operations or cash flows.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk on the fair values of certain assets is related to credit risk associated with securities held in short term investment accounts, commercial paper included in short term money market accounts and the FDIC insurance limit on our bank balances. At June 30, 2010 we had \$630,000 in money market balances that was exposed to market risk.

**ITEM 4. CONTROLS AND PROCEDURES**

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of June 31, 2010, our Chief Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were not effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms.

In connection with the preparation of our annual financial statements, our management performed an assessment of the effectiveness of internal control over financial reporting as of December 31, 2009. 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, 2009, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management's assessment were (i) a lack of sufficient internal accounting expertise to provide reasonable assurance that our financial statements and notes thereto, are prepared in accordance with generally accepted accounting principles (GAAP)

Table of Contents

and (ii) a lack of segregation of duties to ensure adequate review of financial statement preparation. In light of these material weaknesses, management concluded that, as of December 31, 2009, 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.

Management, in coordination with the input, oversight and support of our Audit Committee, has identified the following measures to strengthen our internal control over financial reporting and to address the material weaknesses described above. During the quarter ended December 31, 2009 we hired a controller to: (i) prepare annual and quarterly consolidated financial statements, (ii) prepare annual and quarterly account reconciliations and (iii) prepare annual and quarterly journal entries. This hire allows for better segregation of duties within our financial department. During the quarter ended June 30, 2010 we also retained a GAAP advisor to assist management with accounting and reporting matters. While these remedial actions have been implemented, they may not be in place for a sufficient period of time to help us certify that material weaknesses have been fully remediated as of the end of calendar year 2010. We will continue to develop our remediation plans and implement additional measures during calendar year 2010 and possibly into calendar year 2011.

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, 2010, we are in the process of remediating certain material weakness which existed at December 31, 2009. If the remedial measures described above 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. We are currently working to improve and simplify our internal processes and implement enhanced controls, as discussed above, to address the material weaknesses in our internal control over financial reporting and to remedy the ineffectiveness of our disclosure controls and procedures. A key element of our remediation effort is the ability to recruit and retain qualified individuals to support our remediation efforts. While our Audit Committee and Board of Directors have been supportive of our efforts by supporting the hiring of a controller in our finance department as well as funding efforts to improve our financial reporting system, improvement in internal control will be hampered if we can not recruit and retain more qualified professionals.

Other than described above, 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, 2010.

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, 2009.

**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, 2009.

**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.

