

CALLISTO PHARMACEUTICALS INC  
Form 10-Q  
November 15, 2010

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark One)

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

**FOR THE QUARTERLY PERIOD ENDED: September 30, 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

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

Large accelerated filer       Accelerated filer       Non-accelerated filer       Smaller reporting company   
(Do not check if a smaller reporting company)

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

The number of the registrant's shares of common stock outstanding was 54,822,891 as of November 15, 2010.

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CALLISTO PHARMACEUTICALS, INC.

FORM 10-Q

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**INTRODUCTORY NOTE**

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

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

	September 30, 2010	December 31, 2009
	(Unaudited)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 596,988	\$ 7,207,612
Prepaid Research and Development	501,711	1,000,000
Prepaid expenses and other	101,637	61,630
State tax credit receivable	628,806	
<b>Total Current Assets</b>	<b>1,829,142</b>	<b>8,269,242</b>
Property and equipment, net	10,714	14,665
Security deposits	87,740	87,740
<b>Total Assets</b>	<b>\$ 1,927,596</b>	<b>\$ 8,371,647</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 4,125,749	\$ 3,079,798
Accrued expenses	1,311,002	727,679
Notes Payable	704,368	
<b>Total Current Liabilities</b>	<b>6,141,119</b>	<b>3,807,477</b>
Derivative financial instruments, at estimated fair value warrants	1,098,182	11,870,369
Notes Payable		487,130
Commitments and contingencies		
<b>Total Liabilities</b>	<b>7,239,301</b>	<b>16,164,976</b>
Stockholders' Deficit:		
Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized, 48,000 and 63,000 shares outstanding at September 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 September 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 September 30, 2010 and December 31, 2009, respectively	5,450	5,359
Additional paid-in capital	135,178,935	105,263,377
Deficit accumulated during development stage	(131,386,127)	(109,779,780)
<b>Total Callisto stockholders' equity (deficit)</b>	<b>3,798,364</b>	<b>(4,510,936)</b>
Noncontrolling interest	(9,110,069)	(3,282,393)

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Total stockholders' deficit	(5,311,705)	(7,793,329)
Total liabilities and stockholder's equity	\$ 1,927,596	\$ 8,371,647

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,		June 5, 1996 (Inception) to September 30, 2010
	2010	2009	2010	2009	2010
Revenues	\$	\$	\$	\$	\$
Costs and expenses:					
Research and development (1)	2,301,486	1,125,014	7,899,051	2,567,975	44,142,990
Government grants					(1,135,318)
Purchased in process research and development					6,944,553
General and administrative (1)	1,302,469	1,284,990	4,341,003	3,444,287	49,703,919
Loss from operations	(3,603,955)	(2,410,004)	(12,240,054)	(6,012,262)	(99,656,144)
Interest and investment income	933	10,939	25,084	11,164	914,419
State tax credit			628,806		628,806
Interest and other expense	(16,723)	(160,839)	(317,434)	(275,856)	(925,974)
Change in fair value of derivative instruments warrants	110,937	(5,735,936)	(15,530,425)	(22,472,503)	(22,353,163)
Net loss	(3,508,808)	(8,295,840)	(27,434,023)	(28,749,457)	(121,392,056)
Net Loss of subsidiary attributable to noncontrolling interest	1,792,485	743,755	5,827,676	1,899,498	9,110,069
Net loss attributable to controlling interest	(1,716,323)	(7,552,085)	(21,606,347)	(26,849,959)	(112,281,987)
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)		(136,889)	(136,889)
Series B Preferred stock conversion rate change accreted as a dividend		(1,678,703)		(1,678,703)	(1,678,703)
Cumulative effect of adopting ASC Topic 815 January 1, 2009					(1,903,900)
Net loss available to common stockholders	\$ (1,716,323)	\$ (9,367,677)	\$ (21,606,347)	\$ (28,665,551)	\$ (131,386,127)
<i>Weighted average shares outstanding:</i>					
basic and diluted	54,504,437	50,914,341	54,267,164	50,797,171	
<i>Net loss per common share:</i>					
basic and diluted	\$ (0.03)	\$ (0.18)	\$ (0.40)	\$ (0.56)	

(1) Patent costs reclassified from Research and Development to General and Administrative in 2009. See Note 2.

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





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

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

(Unaudited)

	Preferred Shares	Preferred Stock, Par Value	Common Shares	Common Stock, Par Value	Additional Paid in Capital
		\$		\$	\$
Balance at inception, June 5, 1996					
Net loss for the year					
Issuance of founder shares			2,642,500	264	528
Common stock issued			1,356,194	136	272
Common stock issued via private placement			1,366,667	137	1,024,863
Balance, December 31, 1996			5,365,361	537	1,025,663
Net loss for the year					
Common stock issued via private placement			1,442,666	144	1,081,855
Balance, December 31, 1997			6,808,027	681	2,107,518
Net loss for the year					
Amortization of Stock based Compensation					52,778
Common stock issued via private placement			1,416,667	142	1,062,358
Common stock issued for services			788,889	79	591,588
Common stock repurchased and cancelled			(836,792)	(84)	(96,916)
Balance, December 31, 1998			8,176,791	818	3,717,326
Net loss for the year					
Deferred Compensation stock options					9,946
Amortization of Stock based Compensation					
Common stock issued for services					3,168,832
Common stock issued via private placement			346,667	34	259,966
Balance, December 31, 1999			8,523,458	852	7,156,070
Net loss for the year					
Amortization of Stock based Compensation					
Common stock issued			4,560,237	455	250,889
Other					432
Preferred shares issued	3,485,299	348			5,986,302
Preferred stock issued for services	750,000	75			1,124,925
Balance, December 31, 2000	4,235,299	423	13,083,695	1,307	14,518,618
Net loss for the year					
Deferred Compensation stock Options					20,000
Amortization of Stock based Compensation					
Balance, December 31, 2001	4,235,299	423	13,083,695	1,307	14,538,618
Net loss for the year					
Amortization of Stock based Compensation					
Balance, December 31, 2002	4,235,299	\$ 423	13,083,695	\$ 1,307	\$ 14,538,618

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

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**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.



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

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

(Unaudited)

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

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**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.

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**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.

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**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.



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

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

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

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**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								(21,606,347)	(5,827,676)	(27,434,023)
Stock based compensation expense							611,845			611,845
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 controlled subsidiary							3,154,000			3,154,000
Warrants issued in connection with registered direct offering classified as derivative liability							(1,209,119)			(1,209,119)
Fees and expenses associated with direct offering of controlled subsidiary							(294,130)			(294,130)
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 September 30, 2010	48,000	\$ 5	1,009,166	\$ 101	54,504,437	\$ 5,450	\$ 135,178,935	\$ (131,386,127)	\$ (9,110,069)	\$ (5,311,705)

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



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

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

	Nine months ended September 30, 2010	Nine months ended September 30, 2009	Period from June 5, 1996 (inception) to September 30, 2010
Cash flows from operating activities:			
Net loss	\$ (27,434,023)	\$ (28,749,457)	\$ (121,392,056)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	3,951	4,172	106,518
Purchase discount accreted as interest income on U.S. Treasury bills			(26,950)
Stock-based compensation expense	611,845	976,886	19,466,570
Purchased in-process research and development (non-cash portion)			6,841,053
Interest expense accreted on notes	317,434	275,856	754,129
Stock-based liquidated damages			579,696
Change in fair value of derivative instruments warrants	15,530,425	22,472,503	22,353,163
Net liabilities assumed in excess of assets acquired in merger			(282,752)
Changes in operating assets and liabilities:			
Prepaid expenses	458,282	(30,054)	(603,348)
State tax credit receivable	(628,806)		(628,806)
Security deposit		(9,624)	(87,740)
Accounts payable and accrued expenses	1,670,398	379,742	5,425,375
Total adjustments	17,963,529	24,069,481	53,896,908
Net cash used in operating activities	(9,470,494)	(4,679,976)	(67,495,148)
Cash flows from investing activities:			
Short term investments purchased			(5,921,825)
Short term investments liquidated			5,948,775
Acquisition of equipment			(117,233)
Net cash used in investing activities			(90,283)
Cash flows from financing activities:			
Issuance of common and preferred stock			48,719,673
Finders fees and expenses	(294,130)	(245,000)	(3,608,302)
Proceeds from sale of 11% Notes		603,163	603,163
Proceeds of direct offering of majority owned subsidiary's common stock and warrants	3,154,000	7,232,500	22,149,100
Exercise of common stock warrants			318,785
Net cash provided by financing activities	2,859,870	7,590,663	68,182,419
Net (decrease) increase in cash and cash equivalents	(6,610,624)	2,910,687	596,988
Cash and cash equivalents at beginning of period	7,207,612	301,323	
Cash and cash equivalents at end of period	\$ 596,988	\$ 3,212,010	\$ 596,988

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



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

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

	Nine months ended September 30, 2010	Nine months ended September 30, 2009	Period from June 5, 1996 (inception) to September 30, 2010
Supplementary disclosure of cash flow information:			
Cash paid for taxes	\$ 57,754	\$ 35,248	\$ 300,324
Supplementary disclosure of non-cash investing and financing activities:			
Series A Preferred stock beneficial conversion feature accreted as a dividend		136,889	4,888,960
Series B Preferred stock beneficial conversion feature accreted as a dividend		1,678,703	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
Common stock issued to extend notes payable	\$ 100,196	\$	\$ 100,196

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

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**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.

In March 2010, Synergy initiated dosing in a Phase 2a randomized, double-blind, placebo-controlled, dose-escalation, cohort-design, multi-center clinical trial of plecanatide in patients with chronic constipation ("CC"). This Phase 2a clinical trial used modified Rome III criteria for enrollment, was designed primarily as a safety trial, but included measures of bowel function and patient-reported symptoms to provide us information on the pharmacodynamic effects of plecanatide on patients with CC. Seventy-eight evaluable patients were enrolled and dosed with placebo or plecanatide once-daily for 14 consecutive days at oral doses of 0.3 mg, 1.0 mg, 3.0 mg or 9.0 mg, respectively. Patients were monitored for a number of spontaneous and complete-spontaneous bowel movements, stool consistency using the Bristol Stool Form Scale, and ease of stool passage, abdominal discomfort, constipation severity and overall relief.

On October 6, 2010, Synergy announced the results of this Phase 2a clinical trial. Plecanatide given orally once daily, over 14 consecutive days, at doses of 0.3 mg, 1.0 mg, 3.0 mg and 9.0 mg improved bowel function in patients with CC. Benefits were observed in increased frequency of bowel movements, decreased straining and abdominal discomfort, and improvement in other associated clinical measures. Plecanatide treatment exhibited a favorable safety profile. No severe adverse events were observed, and notably no patients receiving plecanatide reported diarrhea. Additionally, no systemic absorption of plecanatide was detected in patients at any of the dose levels studied.

Synergy plans to initiate an approximately 450 patient, Phase 2b 28-day repeated-oral-dose, placebo-controlled clinical trial of plecanatide for the treatment of CC in the first quarter of 2011, and a Phase 2b 90-day clinical trial of plecanatide in IBS-C patients in third quarter of 2011.

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

These unaudited condensed consolidated financial statements include Callisto and subsidiaries: (1) Callisto Research Labs, LLC (including its wholly-owned subsidiary, Callisto Pharma, GmbH

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

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

**(Unaudited)**

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

(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.

During the quarter ended September 30, 2010 Callisto's ownership in its subsidiary, Synergy Pharmaceuticals, Inc. has decreased below 50% to 49.4%. However, because Callisto and Synergy continue to have certain common management, officers, directors and facilities, Callisto continues to exercise significant control over the operations of Synergy and consolidated Synergy's operations in its financial statements.

Certain items in the financial statements of the comparable prior periods have been reclassified to conform to the classification used for the three and nine months ended September 30, 2010. 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 nine months ended September 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 unaudited condensed consolidated financial statements as of September 30, 2010 and the audited consolidated financial statements as of 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 additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Net cash used in operating activities was \$9,470,494 during the nine months ended September 30, 2010 as compared to \$4,679,976 for the nine months ended September 30, 2009. During the nine months ended September 30, 2010 and 2009 Callisto incurred net losses available to common stockholders of \$21,606,347 and \$28,665,551, 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 nine months ended September 30, 2010 and 2009 and for the period from June 5, 1996 (inception) to September 30, 2010, was \$2,859,870, \$7,590,663 and \$68,182,419, respectively. As of September 30, 2010 Callisto had a working capital deficiency of \$4,311,977 compared to working capital of \$4,461,765 as of December 31, 2009.

On October 1, 2010 Synergy entered into a securities purchase agreement with an investor and raised gross proceeds of \$2,500,000 in a registered direct offering. Synergy paid a fee of \$50,000 to a



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

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

**(Unaudited)**

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

non-U.S. selling agent. Synergy sold to the investor 1,000,000 shares of its common stock and warrants to purchase 400,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investor was \$2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of \$2.75 per share.

On October 18, 2010 Synergy entered into a securities purchase agreement with certain investors and raised gross proceeds of \$1,525,000 in a registered direct offering. Synergy paid a fee of \$91,000 to a non-U.S. selling agent. Synergy sold 610,000 shares of its common stock and warrants to purchase 244,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investors was \$2.50 for each unit. The warrants expire after five years and each whole warrant has an exercise price of \$2.75 per share.

The October 1, 2010 and October 18, 2010 offerings were made pursuant to a shelf registration statement on Form S-3 (SEC File No. 333-163316, the base prospectus effective December 10, 2009), as supplemented by prospectus supplements filed with the Securities and Exchange Commission on October 1, 2010 and October 18, 2010.

On October 29, 2010 Synergy received notice from Internal Revenue Service that it was awarded a grant in the total amount of \$244,479 for qualified investments in a qualifying therapeutic discovery project under section 48D of the Internal Revenue Code for Agonists of Guanylate Cyclase-C.

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

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

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

**(Unaudited)**

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

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, 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.

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

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

(Unaudited)

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

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

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

***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 September 30,		Nine Months Ended September 30,		June 5, 1996 (Inception) to September 30,
	2010	2009	2010	2009	2010
Employees included in research and development	\$	\$ 6,303	\$ 5,345	\$ 20,244	\$ 2,692,157
Employees included in general and administrative	6,405	9,696	26,148	37,614	4,822,854
<b>Subtotal employee stock option grants</b>	<b>6,405</b>	<b>15,999</b>	<b>31,493</b>	<b>57,858</b>	<b>7,515,011</b>
Non-employee research and development					102,750
Non-employee general and administrative	(23,346)	(25,903)	24,111	58,600	9,858,123
<b>Subtotal non-employee stock option grants</b>	<b>(23,346)</b>	<b>(25,903)</b>	<b>24,111</b>	<b>58,600</b>	<b>9,960,873</b>
<b>Total stock based compensation expense</b>	<b>\$ (16,941)</b>	<b>\$ (9,904)</b>	<b>\$ 55,604</b>	<b>\$ 116,458</b>	<b>\$ 17,475,884</b>

The unrecognized compensation cost related to employee non-vested Callisto stock options outstanding at September 30, 2010, net of expected forfeitures, was \$51,207, to be recognized over a weighted average vesting period of approximately 2 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 nine months ended September 30, 2010 and 2009.

	Nine months ended September 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



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## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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

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

	Number of options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value
Balance outstanding, December 31, 2009	7,495,038	\$ 0.08 - 6.75	\$ 1.70	\$
Granted	855,000	\$ 0.26	\$ 0.26	
Forfeitures	(330,166)	\$ 0.20 - 6.75	\$ 3.86	
Balance outstanding, September 30, 2010	8,019,872	\$ 0.08 - 6.75	\$ 1.46	\$
Exercisable as of September 30, 2010	5,858,206	\$ 0.08 - 6.75	\$ 1.46	\$

*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. Synergy 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 September 30,		Nine Months Ended September 30		November 15, 2005 (inception) to September 30, 2010
	2010	2009	2010	2009	
Employees included in research and development	\$ 45,991	\$ 115,615	\$ 145,254	\$ 201,911	\$ 477,325
Employees included in general and administrative	46,553	185,133	164,501	297,902	635,397
Non-employees included in research and development	26,819	8,548	43,636	25,366	86,097
Non-employees included in general and administrative	59,473	196,847	202,850	335,249	791,867
Total stock-based compensation expense	\$ 178,836	\$ 506,143	\$ 556,241	\$ 860,428	\$ 1,990,686



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## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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

The estimated fair value of 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:

	Nine months ended September 30,	
	2010	2009
Risk free interest rate	2.31 to 2.71%	2.55 - 2.67%
Dividend yield	n/a	n/a
Expected volatility	90%	90%
Expected term	6 years	6 years

*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. Synergy 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, Synergy 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.

Table of Contents**CALLISTO PHARMACEUTICALS, INC.****(A Development Stage Company)****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Unaudited)****4. Accounting for share-based payments (Continued)**

The unrecognized compensation cost related to non-vested Synergy stock options outstanding at September 30, 2010, net of expected forfeitures, was \$470,839, to be recognized over the next three quarters.

On March 1, 2010, a majority of Synergy shareholders acting by written consent approved an amendment to the Plan increasing the number of shares reserved under the Plan to 15,000,000 shares.

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

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value
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	(75,000)	0.70	0.70	
Balance outstanding, September 30, 2010	8,604,016	\$ 0.25 - 0.95	\$ 0.51	\$ 17,158,986
Exercisable at September 30, 2010	2,722,469	\$ 0.25 - 0.95	\$ 0.29	\$ 6,029,305

(1)

These stock options will vest and become exercisable only upon a change of control of Synergy. Because of this contingent vesting Synergy did not record any stock based compensation expense on these stock options during the nine months ended September 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 Awards**

Restricted stock awards, 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 shares awarded are subject to a repurchase agreement, assumed by Synergy pursuant to the Exchange Transaction, whereby 50% of the shares 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 was expensed ratably by month over the 2 year service period ended July 3, 2008. As of July 3, 2010, we no longer have any restricted stock awards subject to repurchase.



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

The fair value of the 874,760 restricted stock units on July 3, 2008, the date of issuance, was \$524,856 of which \$1,077, \$64,705 and \$524,856 was recorded as stock-based compensation expense during the three and nine months ended September 30, 2010 and for the period from inception to September 30, 2010.

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 Synergy's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

Table of Contents**CALLISTO PHARMACEUTICALS, INC.****(A Development Stage Company)****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Unaudited)****5. Research and Development Expense**

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

In accordance with FASB ASC Topic 730-10-55, Research and Development, the Company recorded deferred research and development costs of \$501,711 and \$1.0 million as of September 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-304 and SP-333. In accordance with this guidance, the Company 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 June 30, 2010. As of September 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:

	September 30, 2010	December 31, 2009
Common Shares outstanding	54,504,437	53,608,111
Potentially dilutive common shares issuable upon:		
Exercise of warrants	83,802,576	84,842,576
Exercise of stock options	8,019,872	7,495,038
Conversion of Series A Convertible Preferred Stock	1,333,333	1,750,000
Conversion of Series B Convertible Preferred Stock	28,032,389	28,171,278
<b>Total fully diluted</b>	<b>175,692,607</b>	<b>175,867,003</b>

Table of Contents**CALLISTO PHARMACEUTICALS, INC.****(A Development Stage Company)****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Unaudited)****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 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 estimated 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, Callisto measured the fair value of the outstanding warrants through June 30, 2010, recognizing any changes in fair value of the derivative in earnings and then reclassified the derivative instrument liability into stockholders' equity.

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

	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, recorded as other expense (income) in the company's statement of operations		\$ 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, recorded as other expense (income) in the company's statement of operations		\$ (1,420,784)
6/30/2010	Reclass of derivative liability to stockholder's equity upon expiration of supplemental condition (price protection)		\$ (27,511,730)
9/30/2010	Balance of derivative financial instruments September 30, 2010	69,086,174	\$

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## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

**8. Derivative Financial Instruments (Continued)***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 nine months ended September 30, 2010:

Description	Balance at December 31, 2009	Unrealized losses	Reclassified	Balance as of September 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, Callisto measured the fair value of the outstanding warrants through 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 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 its 2010 registered direct offerings, must be recorded as derivative liabilities with a charge to additional paid in capital. In accordance with ASC Topic 815-40, the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded as other income (expense) in the Company's statement of operations. Synergy estimates the fair value of the warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability and change in fair value described above. The assumptions used to determine the fair value of the warrants during the nine months ended September 30, 2010 were:

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

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 Synergy's registered direct offering, which was an arms-length negotiated price. Expected volatility is based on historical volatility of Callisto's common

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## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

## 8. Derivative Financial Instruments (Continued)

stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates consistent with the expected term of the warrants.

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

Date	Description	New Warrants	Derivative Instrument Liability
6/30/2010	Initial relative fair value of warrants upon issuance	648,000	\$ 1,045,214
9/30/2010	Fair value of New Warrants issued during the quarter on date of issuance	103,703	\$ 163,905
9/30/2010	Change in fair value of warrants issued during the quarter ended September 30, 2010, recorded as other expense (income) in the company's statement of operations		\$ (110,937)
9/30/2010	Balance of derivative financial instruments liability	751,703	\$ 1,098,182

*Synergy Fair Value Measurements*

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of September 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 September 30, 2010
Derivative liabilities related to Warrants	\$	\$	\$ 1,098,182	\$ 1,098,182

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

Description	Balance at December 31, 2009	Fair Value of warrants upon issuance	Unrealized (gains) or losses	Balance as of September 30, 2010
Derivative liabilities related to Warrants	\$	\$ 1,209,119	\$ \$(110,937)	\$ 1,098,182

The unrealized gains or losses on the derivative liabilities will be classified in other income or expense as a change in derivative liabilities in the Company's statement of operations.

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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

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**CALLISTO PHARMACEUTICALS, INC.**

**(A Development Stage Company)**

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

**(Unaudited)**

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

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.

**9. 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 out