CALLISTO PHARMACEUTICALS INC Form 10-Q August 15, 2011 Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q
(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED: June 30, 2011
or

o 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 x No o

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 x No o

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 o

Accelerated filer o

Non-accelerated filer o (Do not check if a smaller reporting company)

Smaller reporting company x

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

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.

FORM 10-Q

CONTENTS

		Page
<u>PART I FINANCIAL INFORMATIO</u> N		4
Item 1.	<u>Financial Statements</u>	4
	Condensed Consolidated Balance Sheets as of June 30, 2011 (unaudited) and	
	<u>December 31, 2010</u>	4
	Condensed Consolidated Statements of Operations for the Three Months and Six	
	Months Ended June 30, 2011 and 2010 (unaudited) and the period June 5, 1996	
	(Inception) to June 30, 2011 (unaudited)	5
	Condensed Consolidated Statements of Changes in Stockholders	,
	period June 5, 1996 (Inception) to June 30, 2011 (unaudited)	6
	Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30,	
	2011 and 2010 (unaudited) and for the period June 5, 1996 (Inception) to June 30, 2011	
	(unaudited)	15
	Notes to Condensed Consolidated Financial Statements (unaudited)	17
<u>Item 2.</u>	Management's Discussion and Analysis of Financial Condition and Results of	
	<u>Operations</u>	28
<u>Item 3.</u>	Quantitative and Qualitative Disclosures About Market Risk	31
<u>Item 4.</u>	Controls and Procedures	31
<u>PART II OTHER INFORMATIO</u> N		33
<u>Item 6.</u>	<u>Exhibits</u>	33
<u>Signatures</u>		34

2

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

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

3

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2011 (Unaudited)	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 598,104	\$ 1,708,982
Prepaid expenses and other	969,399	769,403
Tax credits receivable	250,000	781,127
Total Current Assets	1,817,503	3,259,512
Property and equipment, net	6,763	9,397
Security deposits	87,740	87,740
Total Assets	\$ 1,912,006	\$ 3,356,649
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current Liabilities:		
Accounts payable	\$ 4,382,375	\$ 4,755,361
Accrued expenses	2,306,145	2,311,050
Total Current Liabilities	6,688,520	7,066,411
Derivative financial instruments, at estimated fair value warrants	7,958,506	3,487,959
Total Liabilities	14,647,026	10,554,370
Commitments and contingencies		
Stockholders Deficit:		
Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized,		
8,000 shares outstanding at June 30, 2011 and December 31, 2010	1	1
Series B convertible preferred stock, par value \$0.0001, 2,500,000 shares authorized,		
no shares outstanding at June 30, 2011 and December 31, 2010		
Common stock, par value of \$.0001 per share: 225,000,000 shares authorized;		
158,516,071 and 157,509,404 shares outstanding at June 30, 2011 and December 31,		
2010, respectively	15,852	15,751
Additional paid-in capital	142,565,138	139,496,452
Deficit accumulated during development stage	(139,835,231)	(135,573,268)
Total Stockholders Equity	2,745,760	3,938,936
Non-controlling interest	(15,480,780)	(11,136,657)

Total Stockholders Deficit	(12,735,020)	(7,197,721)
Total Liabilities and Stockholders Deficit	\$ 1,912,006 \$	3,356,649

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Mor		ıded		Six Mor Ju	June 5, 1996 (Inception) to	
	2011	,	2010		2011	2010	June 30, 2011
Revenues	\$	\$	\$;		\$ \$	
Costs and expenses:							
Research and development	2,356,099		4,402,155		3,728,027	5,597,565	49,560,509
Government grants							(1,135,318)
Purchased in process research and development							6,944,553
General and administrative	1,875,688		1,604,747		3,835,532	3,038,534	56,541,633
Loss from operations	(4,231,787)		(6,006,902)		(7,563,559)	(8,636,099)	(111,911,377)
Interest and investment income	3		7,675		54	24,150	914,936
State tax credit						628,806	1,025,606
Interest and other expense	6,208		(16,542)		(6,206)	(300,711)	(937,453)
Loss on debt extinguishment							(2,099,892)
Change in fair value of derivative							
instruments warrants	(697,660)		1,420,784		(1,036,375)	(15,641,361)	(23,203,691)
Net loss	(4,923,236)		(4,594,985)		(8,606,086)	(23,925,215)	(136,211,871)
Net Loss of subsidiary attributable to							
noncontrolling interest	2,422,640		2,870,134		4,344,123	4,035,191	15,480,780
Net loss attributable to controlling							
interest	(2,500,596)		(1,724,851)		(4,261,963)	(19,890,024)	(120,731,091)
Series A Preferred stock beneficial							
conversion feature accreted as a							
dividend							(4,888,960)
Series B Preferred stock beneficial							
conversion feature accreted as a							
dividend							(10,495,688)
Series A Preferred stock conversion							
rate change accreted as a dividend							(136,889)
Series B Preferred stock conversion							
rate change accreted as a dividend							(1,678,703)
Cumulative effect of adopting ASC							
Topic 815 January 1, 2009							(1,903,900)
Net loss available to common							
stockholders	\$ (2,500,596)	\$	(1,724,851) \$	i	(4,261,963)	\$ (19,890,024) \$	(139,835,231)

Weighted average shares outstanding:					
basic and diluted	158,506,181	54,420,023	158,078,170	54,146,561	
Net loss per common share:					
basic and diluted	\$ (0.02)	\$ (0.03) \$	(0.03)	\$ (0.37)	

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					
Amorazation 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

CALLISTO PHARMACEUTICALS, INC. (A Development Stage Company)

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

	nortized 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	(552)	(1,684,965)	(1,684,965)
Amortization of Stock based Compensation	332	(1,00.1,700)	332
Balance, December 31, 2002	\$ \$	(12,711,483) \$	1,828,865

CALLISTO PHARMACEUTICALS, INC. (A Development Stage Company)

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

	Preferred Stock	Preferred Stock Par Value	Common Stock	C	Stock Additional Par Paid in		Unamortized Accumulat Deferred during th		Deficit Accumulated during the Development Stage	Si	Total tockholders 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

CALLISTO PHARMACEUTICALS, INC. (A Development Stage Company)

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

	Common Stock	Common Stock Par Value		Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Si	Total tockholders 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

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

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

	Common Stock		Common Stock Par Value		Additional Paid in Capital		Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	S	Total tockholders Equity (Deficit)
Balance, December 31,		_		_		_			_	
2004	29,219,102	\$	2,922	\$	39,910,186	\$	(2,302,534) \$. , , ,	\$	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)

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN

STOCKHOLDERS EQUITY (DEFICIT) (Continued)

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders Equity (Deficit)
Balance, December 31,								
2005		\$	33,233,096	\$ 3,323	\$ 46,387,87	75 \$ (1,583,463)		(, ,
Net loss for the year							(12,919,229)	(12,919,229)
Reclassification of deferred unamortized stock-based compensation upon								
adoption of FAS 123R					(1,583,46	53) 1,583,463		
Stock based compensation								
expense					2,579,43	31		2,579,431
Common stock issued via private placement:								
February 2006			4,283,668	428	5,139,78	32		5,140,210
Finders fees and expenses					(561,80	08)		(561,808)
April 2006			666,667	67	799,93	33		800,000
Finders fees and expenses					(41,00	00)		(41,000)
Waiver and Lock-up								
Agreement			740,065	74	579,62	22		579,696
Common stock issued for								
services			87,000	9	121,10)1		121,110
Exercise of common stock								
warrants			184,500	18	190,01	.7		190,035
Series A convertible								
preferred stock issued via								
private placement:	574,350	57			5,743,44	13		5,743,500
Finders fees and expenses	11,775	1			(448,90	09)		(448,908)
Detachable warrants					2,384,48	35		