CALLISTO PHARMACEUTICALS INC
Form 10-Q
November 19, 2012
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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: September 30, 2012

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	**13-3894575**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

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

(Address of principal executive offices) (Zip Code)

(212) 297-0010

(Registrant s telephone number)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 158,965,565 as of November 19, 2012.

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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 plan, may, will, expect, intend, anticipate, believe, estimate 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 this report and in our Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the Securities Exchange Commission on March 30, 2012. 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.

On May 9, 2012, Callisto deconsolidated Synergy and derecognized the Synergy assets, liabilities, and non-controlling interest from its financial statements. All drug candidates to treat GI disorders and diseases, currently plecanatide and SP-333, are being developed exclusively by Synergy Pharmaceuticals, Inc., our former 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.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2012 (Unaudited)	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 120	$ 13,244,961
Prepaid expenses and other		796,028
Tax credits receivable		377,865
Total Current Assets	120	14,418,854
Equity investment in Synergy	114,453,453	
Property and equipment, net		5,774
Security deposits	73,715	87,740
Total Assets	$ 114,527,288	$ 14,512,368
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 1,625,092	$ 3,206,827
Accrued expenses	114,343	1,457,427
Total Current Liabilities	1,739,435	4,664,254
Derivative financial instruments, at estimated fair value warrants		3,325,114
Due to related party	2,655,594	
Total Liabilities	4,395,029	7,989,368
Commitments and contingencies		
Stockholders Deficit:		
Series A convertible preferred stock, par value $0.0001, 700,000 shares authorized, none shares outstanding at September 30, 2012 and 8,000 shares outstanding at December 31, 2011		1
Common stock, par value of $.0001 per share: 225,000,000 shares authorized; 158,965,565 and 158,516,071 shares outstanding at September 30, 2012 and December 31, 2011 respectively	15,897	15,852
Additional paid-in capital	169,221,471	168,531,201
Deficit accumulated during development stage	(59,105,109)	(142,366,313)
Total Callisto Stockholders Equity	110,132,259	26,180,741

Non-controlling interest				(19,657,741)
Total Stockholders Equity		110,132,259		6,523,000
	$	114,527,288	$	14,512,368

The accompanying notes are an integral part of these unaudited 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
	2012	2011	2012	2011	September 30, 2012
Revenues	$	$	$	$	$
Costs and expenses:					
Research and development		3,882,802	7,880,230	7,610,829	66,974,747
Government grants			3,508		(1,131,810)
Purchased in process research and development					6,944,553
General and administrative	418,001	1,288,945	3,176,502	5,124,477	63,549,160
Loss from operations	(418,001)	(5,171,747)	(11,060,240)	(12,735,306)	(136,336,650)
Gain on deconsolidation of Synergy			120,393,000		120,393,000
Loss related to equity method investment	(3,360,997)		(5,750,997)		(5,750,997)
Interest and investment income		3	20,942	57	937,519
Tax credit (expense)	(72,807)		(297,770)		1,067,008
Other income or expense	(40,000)	(4,425)	45,180	(10,631)	(869,503)
Loss on debt extinguishment					(2,099,892)
Change in fair value of derivative instruments		4,382,796	(431,170)	3,346,421	(17,341,455)
Net income/(loss)	(3,891,805)	(793,373)	102,918,945	(9,399,459)	(40,000,970)
Add: Net loss of subsidiary attributable to non-controlling interest		280,055	6,957,805	4,624,178	26,615,546
Net income/(loss) attributable to Callisto	(3,891,805)	(513,318)	109,876,750	(4,775,281)	(13,385,424)
Series A Preferred stock conversion rate change and beneficial conversion feature accreted as a dividend					(5,025,849)
Series B Preferred stock conversion rate change and beneficial conversion feature accreted as a dividend					(12,174,391)
Cumulative effect of adopting ASC Topic 815 January 1, 2009					(1,903,900)
Net income/(loss) available to Callisto common stockholders	$ (3,891,805)	$ (513,318)	$ 109,876,750	$ (4,775,281)	$ (32,489,564)

Weighted average common shares outstanding				
basic	158,866,092	158,516,071	158,633,596	158,225,741
diluted	158,866,092	158,516,071	159,201,398	158,225,741
Net income/(loss) per common share				
Basic	$ (0.02)	$ (0.00)	$ 0.69	$ (0.03)
Diluted	$ (0.02)	$ (0.00)	$ 0.69	$ (0.03)

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

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

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

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

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

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

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

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

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

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CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

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

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

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

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CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN

STOCKHOLDERS EQUITY (DEFICIT) (Continued)

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

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

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CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN

STOCKHOLDERS EQUITY (DEFICIT) (Continued)

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

Minority interest in equity of subsidiary acquired							(42,824)		(42,824)
Stock-based compensation expense							589,063		589,063
Proceeds from issuance of 11% Notes attributable to detachable warrants							181,732		181,732
Conversion of Series A preferred stock to common stock	(120,675)	(12)			2,413,500	241	(229)		
Conversion of Series B preferred stock to common stock			(10,000)	(1)	200,000	20	(19)		
Balance, December 31, 2008	98,000	$ 10	1,137,050	$ 114	49,556,661	$ 4,955	$ 86,799,951	$ (90,987,267)	$ (4,182,237)

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

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

(Unaudited)

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Series B Convertible Preferred Shares	Series B Convertible Preferred Stock	Common Shares	Common Stock Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Non-Controlling Interest	Total Stockholders Equity (Deficit)
Balance, December 31, 2008	98,000	$ 10	1,137,050	$ 114	49,556,661	4,955	$ 86,799,951	$ (90,987,267)	$	$ (4,182,237)
Cumulative effect of adoption of ASC Topic 815							(181,732)	(1,903,900)		(2,085,632)
Net Loss								(15,073,021)	(3,282,393)	(18,355,414)
Stock based compensation expense							1,119,856			1,119,856
Conversion of Series A preferred stock to common stock	(35,000)	(4)			894,445	89	(85)			
Conversion of Series B preferred stock to common stock			(122,884)	(12)	2,963,236	296	(284)			
Private placements of common stock of majority owned subsidiary							15,970,100			15,970,100
Fees and expenses associated with private placements of majority owned subsidiary							(260,002)			(260,002)
Preferred Stock dividend attributable to reset of conversion price in conjunction with waiver of liquidation preference							1,815,592	(1,815,592)		
Cashless Conversion of Warrants to Common Stock					193,769	19	(19)			
Balance December 31, 2009	63,000	$ 6	1,014,166	$ 102	53,608,111	$ 5,359	$ 105,263,377	$ (109,779,780)	$ (3,282,393)	$ (7,793,329)
Net Loss								(25,793,488)	(7,854,264)	(33,647,752)
							854,651			854,651

Stock based compensation expense									
Conversion of Series A preferred stock to common stock	(55,000)	(5)			1,527,777	153	(148)		
Conversion of Series B preferred stock to common stock			(1,014,166)	(102)	28,171,278	2,817	(2,715)		
Common shares in exchange for modification of convertible notes					265,770	27	100,169		100,196
Extinguishment on debt							2,809,531		2,809,531
Cashless conversion of Warrants to common stock upon extinguishment of convertible notes					72,355,769	7,236	(7,236)		
Warrants exchanged					1,505,699	151	(151)		
Direct offering of common stock of controlled subsidiary							7,179,000		7,179,000
Fair value of warrants issued in connection with controlled subsidiary registered direct offerings reclassified to derivative liability							(3,784,743)		(3,784,743)
Fees and expenses associated with direct offering of controlled subsidiary							(468,130)		(468,130)
Reclassification of derivative liability to equity upon termination of price protection							27,511,730		27,511,730
Common stock issued as settlement for director s fees					75,000	8	41,117		41,125
Balance December 31, 2010	8,000	$ 1		$	157,509,404	$ 15,751	$ 139,496,452	$ (135,573,268)	$ (11,136,657) $ (7,197,721)

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

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

(Unaudited)

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Series B Convertible Preferred Shares	Series B Convertible Preferred Stock	Common Shares	Common Stock Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Non-Controlling Interest	Total Stockholders Equity (Deficit)
Balance December 31, 2010	8,000	$ 1			157,509,404	$ 15,751	$ 139,496,452	$ (135,573,268)	$ (11,136,657)	(7,197,721)
Net Loss								(6,793,045)	(8,521,084)	(15,314,129)
Stock based compensation expense							424,168			424,168
Common stock issued for services					850,000	85	532,915			533,000
Value of common stock issued by controlled subsidiary for consulting services provided							341,295			341,295
Placement of common stock of controlled subsidiary							34,369,064			34,369,064
Fees and expenses associated with direct offering of controlled subsidiary							(2,148,384)			(2,148,384)
Warrant exercise					106,667	11	53,323			53,334
Warrants issued in connection with controlled subsidiary registered direct offering reclassified to derivative liability-net							(5,094,186)			(5,094,186)
Exercise of warrants-controlled subsidiary							415,309			415,309
Common stocks issued for settlement of directors fee					50,000	5	41,245			41,250
Sale of option to purchase shares of controlled subsidiary							100,000			100,000
Balance December 31, 2011	8,000	1			158,516,071	15,852	168,531,201	(142,366,313)	(19,657,741)	6,523,000
Net income/(loss) for the period								109,876,750	(6,957,805)	102,918,945
							497,651			497,651

Stock based compensation expense									
Value of common stock issued by controlled subsidiary for services rendered						92,663			92,663
Common stock issued in settlement of directors fees				227,272	23	99,977			100,000
Reclassification of non-controlling interest upon deconsolidation May 9, 2012							(26,615,546)	26,615,546	
Conversion of Series A preferred stock to common stock	(8,000)	(1)		222,222	22	(21)			
Balance September 30, 2012		$	$	158,965,565	$ 15,897	$ 169,221,471	$ (59,105,109)	$	$ 110,132,259

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, 2012	Nine months ended September 30, 2011	Period from June 5, 1996 (inception) to September 30, 2012
Cash flows from operating activities:			
Net income/(loss)	$ 102,918,945	$ (9,399,459)	$ (40,000,970)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation		3,128	111,458
Purchase discount accreted as interest income on U.S.Treasury bills			(26,950)
Stock-based compensation expense	665,315	574,545	21,598,154
Purchased in-process research and development			6,841,053
Interest expense on notes			759,400
Loss on disposal of property and equipment	5,774		5,774
Stock-based liquidated damages			579,696
Change in fair value of derivative instruments warrants	431,170	(3,346,421)	17,341,455
Loss on debt extinguishment			2,099,892
Net liabilities assumed in excess of assets acquired in merger			(282,752)
Gain on deconsolidation of Synergy	(120,393,000)		(120,393,000)
Loss related to equity method investment	5,750,997		5,750,997
Changes in operating assets and liabilities:			
Prepaid expenses	721,028	149,314	
Tax credit receivable	377,865	781,127	
Security deposit	14,025		(73,715)
Accounts payable and accrued expenses	(6,392,554)	1,648,202	(1,698,426)
Due to related party	2,655,594		2,655,594
Total Adjustments	(116,163,786)	(190,105)	(64,731,370)
Net cash used in operating activities	(13,244,841)	(9,589,564)	(104,732,340)
Cash flows from investing activities:			
Short term investments purchased			(5,921,825)
Short term investments liquidated			5,948,775
Acquisition of equipment			(117,233)
Net cash used in investing activities			(90,283)
Cash flows from financing activities:			
Issuance of common and preferred stock			48,719,673
Issuance of common stock of controlled subsidiary		8,040,463	60,543,163
Proceeds from exercise of warrants of controlled subsidiary		415,309	415,309
Selling Agent fees and expenses-combined		(661,051)	(5,930,684)
Proceeds from sale of 11% Notes			603,163
Exercise of common stock warrants		53,334	372,119
Proceeds from sale of option		100,000	100,000
Net cash provided by financing activities		7,948,055	104,822,743
Net (decrease) increase in cash and cash equivalents	(13,244,841)	(1,641,509)	120
Cash and cash equivalents at beginning of period	13,244,961	1,708,982	

Cash and cash equivalents at end of period	$ 120	$ 67,473	$ 120

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

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

(Unaudited)

	Nine months ended September 30, 2012	Nine months ended September 30, 2011	Period from June 5, 1996 (inception) to September 30, 2012
Supplementary disclosure of cash flow information:			
Cash paid for taxes	$ 304,251	$ 6,481	$ 629,135
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	100,000	41,250	182,375
Cash received in escrow for June 30, 2010 direct registered offering			
Accrued finders fees related to direct registered offering			
Common stock issued to extend notes payable			100,196
Value of warrants classified as derivative liability net	$	$ 3,719,300	$ 20,331,912
Value of shares issued for services	$	$ 533,000	$ 625,663

The accompanying notes are an integral part of these unaudited 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:

Callisto Pharmaceuticals, Inc. (which may be referred to as Callisto , the Company) is a development stage biopharmaceutical company incorporated under the laws of the State of Delaware on June 5, 1996 (inception). Since inception, Callisto s efforts have been principally devoted to research and development, securing and protecting patents and raising capital.

From inception through September 30, 2012, Callisto has sustained cumulative net losses attributable to common stockholders of $32,489,564. Callisto s losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, stock-based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees, as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception through September 30, 2012, Callisto has not generated any revenue from operations.

Callisto - Synergy Merger

On July 20, 2012, Callisto entered into an Agreement and Plan of Merger (the Merger Agreement) with Synergy Pharmaceuticals, Inc., a Delaware corporation (Synergy). Pursuant to the Merger Agreement, following the satisfaction or waiver of each of the applicable conditions set forth in the Merger Agreement, Callisto and Synergy will merge (the Merger), whereupon Callisto s separate corporate existence will cease and Synergy will continue as the surviving corporation of the Merger. Callisto is Synergy s largest shareholder.

On October 15, 2012, Callisto entered into Amendment No. 1 to the above Agreement and Plan of Merger, dated July 20, 2012 with Synergy Pharmaceuticals, Inc., a Delaware corporation. Pursuant to the Amendment, the parties have agreed to, among other things, increase the exchange ratio from .17 to .1799 and change the lock-up provision such that each share of Synergy common stock received in connection with the merger shall be subject to a lock-up beginning on the effective date of the merger and ending on the earlier of (i) twenty-four (24) months after such date, (ii) a Change in Control (as defined in the Merger Agreement), or (iii) written consent of Synergy, at Synergy s sole discretion, provided Synergy s consent shall apply to all shares of Synergy s common stock issued pursuant to the merger.

The consummation of the Merger is subject to various customary closing conditions, including but not limited to, (i) approval by Callisto s and Synergy s stockholders, (ii) the Registration Statement on Form S-4 shall have been declared effective by the SEC and (iii) the shares of Synergy s common stock to be issued in the Merger shall have been approved for listing on The NASDAQ Capital Market. Upon consummation of the Merger the related party balances due to Synergy, $2,655,594 as of September 30, 2012, will be eliminated.

Completion of the merger is anticipated to occur during the first quarter of 2013, although there can be no assurance the merger will occur within the expected timeframe or at all.

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2. Basis of presentation and going concern:

These condensed consolidated financial statements include Callisto and one subsidiary Callisto Research Labs, LLC (including its wholly-owned subsidiary, Callisto Pharma, GmbH (Germany 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, 2011, included in Form 10-K filed with the SEC on March 30, 2012. Certain items in the prior year s financial statements have been reclassified to conform to the current year s presentation.

Deconsolidation

On May 9, 2012, Callisto s controlled subsidiary, Synergy, closed an underwritten public offering of 10 million shares of common stock at an offering price of $4.50 per share, resulting in gross proceeds of $45 million before deducting underwriting discounts, commissions and other estimated offering expenses of approximately $3 million. As a result Callisto s equity ownership decreased to approximately 34% of Synergy and Callisto determined that it no longer had control over the operations and decision making of Synergy. Therefore, Callisto deconsolidated Synergy and derecognized the Synergy assets, liabilities, and non-controlling interest from its financial statements.

As of the date of deconsolidation, May 9, 2012, Callisto began accounting for its investment in Synergy under the equity method and accordingly recognized its share of Synergy losses in the amount of $3,360,997 and $5,750,997 for the quarter and nine months ended September 30, 2012. No dividends have been received from Synergy since inception. As of September 30, 2012, Callisto s investment in Synergy was $114,453,453.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, primarily consisting of normal adjustments, necessary for the fair presentation of the balance sheet and results of operations for the interim periods. The results of operations for the three and nine months ended September 30, 2012 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2012. The condensed consolidated balance sheet as of December 31, 2011 presented above was derived from the audited consolidated financial statements as of that date.

The condensed consolidated financial statements as of September 30, 2012 and December 31, 2011 have been prepared under the assumption that Callisto will continue as a going concern for the twelve months ending December 31, 2012. 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 $13,244,841 during the nine months ended September 30, 2012 as compared to $9,589,564 for the nine months ended September 30, 2011 and $104,732,340 during the period from June 5, 1996 (inception) to September 30, 2012. During the three months and nine months ended September 30, 2012 Callisto reported a net loss attributable to common stockholders of $3,891,805 and net income of $109,876,750, respectively. The net loss of attributable to common stockholders recorded during the period from June 5, 1996 (inception) to September 30, 2012 was $32,489,564. The gain recognized upon deconsolidation of $120,393,000 is reflected in net losses for the nine month ended and the period from inception to September 30, 2012. To date, Callisto s sources of cash have been primarily limited to the

sale of equity securities and issuance of debt instruments. No cash was provided by financing activities for the nine months ended September 30, 2012; and for the period from June 5, 1996 (inception) to September 30, 2012, financing activities provided $104,822,743

3. Recent Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income* (ASU 2011-05) which is intended to facilitate the convergence of U.S. GAAP and International Financial Reporting Standards (IFRS) as well as to increase the transparency of items reported in other comprehensive income. As a result of ASU 2011-05, all non-owner changes in stockholders equity are required to be presented in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present other comprehensive income in the statement of changes in equity has been eliminated. ASU 2011-05 is effective for fiscal years beginning after December 15, 2011 and should be applied retrospectively. The Company adopted this standard on January 1, 2012 and the adoption did not have a material impact on the Company s consolidated financial statements.

In May 2011, FASB issued ASU No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs. ASU 2011-04 amends Topic 820 to provide common fair value measurement and disclosure requirements in U.S. Generally Accepted Accounting Principles (U.S. GAAP) and International Financial Reporting Standards. Consequently, the amendments change the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements, as well as providing guidance on how fair value should be applied where its use is already required or permitted by other standards within U.S. GAAP. ASU No. 2011-04 is to be applied prospectively, and early adoption is not permitted. For public entities, the amendments are effective during interim and annual periods beginning after December 15, 2011. The adoption of ASU No. 2011-04 on January 1, 2012 did not have a material impact on the Company s consolidated financial statements.

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In December 2011, the FASB issued ASU 2011-11, Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities. ASU 2011-11 provides for additional disclosures of both gross information and net information about both instruments and transactions eligible for offset in the statement of financial position and instruments and transactions subject to an agreement similar to a master netting arrangement. This scope would include derivatives, sale and repurchase agreements and reverse sale and repurchase agreements, and securities borrowing and securities lending arrangements. The amendments in this Update are effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods, and disclosures required by these amendments should be provided retrospectively for all comparative periods presented. The adoption of ASU No. 2011-11 is not expected to have a material impact on the Company s consolidated financial statements.

4. Accounting for share-based payments

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

ASC Topic 718 did not change the way 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 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,
	2012	2011	2012	2011	2012
Employees included in research and development	$	$	$	$	$ 2,692,157
Employees included in general and administrative	5,900	2,426	17,572	23,202	4,875,833
Subtotal employee stock option grants	5,900	2,426	17,572	23,202	7,567,990
Non-employee research and development					102,750
Non-employee general and administrative	9,213	109,412	91,596	244,509	10,402,618
Subtotal non-employee stock option grants	9,213	109,412	91,596	244,509	10,505,368
Total stock based compensation expense	$ 15,113	$ 111,838	$ 109,168	$ 267,261	$ 18,073,358

The unrecognized compensation cost related to employee non-vested Callisto stock options outstanding at September 30, 2012, net of expected forfeitures, was $9,824 to be recognized over a weighted average vesting period of approximately 4 months. No options were granted during the quarter ended September 30, 2012.

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The estimated fair value of each Callisto stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the six months ended September 30, 2011.

	Nine months ended September 30,	
	2012	**2011**
Risk free interest rate	(*)%	1.85%
Dividend yield	(*)	n/a
Expected volatility	(*)%	90%
Expected term	(*)	5 years

(*) No options were granted during nine months ended September 30, 2012.

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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	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2011	7,435,372	$ 0.08 - 3.60	$ 1.49	$ 7,200	3.39
Granted		$	$		
Forfeitures		$	$		
Balance outstanding, September 30, 2012	7,435,372	$ 0.08 - 3.60	$ 1.49	$ 360,215	2.64
Exercisable as of September 30, 2012	5,907,372	$ 0.08 - 3.60	$ 1.37	$ 250,155	2.42

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. ASC Topic 718 did not change the way Synergy accounts for non-employee stock-based compensation. Synergy continues to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 *Equity -Based Payment to Non-Employees* and accordingly the value of the stock compensation to non-employees is based upon the measurement date as determined at either a) the 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 Synergy s accumulated deficit position, no excess tax benefits have been recognized. Synergy 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.

Synergy adopted the 2008 Equity Compensation Incentive Plan (the Plan) during the quarter ended September 30, 2008. Stock options granted under the Plan typically vest after three years of continuous service from the grant date and have a contractual term of ten years.

Three Months Ended September 30,		Nine Months Ended September 30		November 15, 2005 (inception) to September 30,
2012 (1)	2011	2012 (1)	2011	2012 (1)
$	$	$ 164,460	$	$ 791,242

Employees included in research and development						
Employees included in general and administrative		2,426	127,013	23,202		901,424
Non-employees included in research and development						168,096
Non-employees included in general and administrative		109,412	264,674	244,059		1,664,034
Total stock-based compensation expense	$	$ 111,838	$ 556,147	$ 267,261	$	3,524,796

(1) On May 9, 2012, Callisto deconsolidated Synergy and derecognized the Synergy assets, liabilities, and non-controlling interest from its financial statements. Accordingly stock based compensation expense for Synergy is not included subsequent to that date.

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5. Investment in Synergy

On May 9, 2012, Callisto s controlled subsidiary, Synergy, closed an underwritten public offering of 10 million shares of common stock at an offering price of $4.50 per share, resulting in gross proceeds of $45 million before deducting underwriting discounts, commissions and other estimated offering expenses of approximately $3 million. As a result, Callisto s equity ownership decreased to approximately 34% of Synergy and Callisto determined that it no longer had control over the operations and decision making of Synergy. Therefore, Callisto deconsolidated Synergy and derecognized the Synergy assets, liabilities, and non-controlling interest from its financial statements.

As of the date of deconsolidation, May 9, 2012, Callisto began accounting for its investment in Synergy under the equity method and accordingly recognized its share of Synergy losses in the amount of $3,360,997 and $5,750,997 for the three months and nine months ended September 30, 2012, respectively. No dividends have been paid by Synergy from inception to September 30, 2012. The balance of the investment in Synergy carried on Callisto s balance sheet, using the equity method of accounting as of September 30, 2012, was $114,453,453.

The following table summarizes financial information of Synergy at September 30, 2012.

Income Statement data:

	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2012	November 15, 2005 (inception) to September 30, 2012
Loss from Operations	$ (10,088,770)	$ (26,702,794)	$ (102,917,092)
Total Other Income/(Expense)	203,483	(763,585)	5,913,516
Net Loss	(9,885,287)	(27,466,379)	(97,075,397)

Balance Sheet data:

	September 30, 2012 (unaudited)
Cash and cash equivalents	$ 17,244,049
Available-for-sales securities short term	20,123,315
Due from related party (Callisto Pharmaceuticals)	2,655,594
Total Assets	41,329,685
Total Current Liabilities	4,975,195
Derivative financial instruments, at estimated fair value-warrants	4,663,395
Total Liabilities	9,638,590
Total Stockholders Equity	31,691,095

6. Research and Development Expense

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

In accordance with FASB ASC Topic 730-10-55, Research and Development, Synergy recorded prepaid research and development costs of $577,745 as of December 31, 2011, for nonrefundable pre-payments for production of drug substance and analytical testing services for its drug candidates. In accordance with this guidance, Synergy expenses deferred research and development costs when drug compound is delivered and services are performed. As of September 30, 2012 Synergy s assets and liabilities have been deconsolidated and as a result there are no prepaid research and development costs on the balance sheet. See Note 5 above.

7. Income Taxes

For the nine months ended September 30, 2012 Callisto recorded $225,000 of New York State investment tax expense related to the tax years 2009 to 2011.

8. 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. For the three months ended September 30, 2012 and 2011 and for the nine months ended September 30, 2011, 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

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antidilutive. For the nine months ended September 30 diluted weighted-average shares were computed using the Treasury Stock Method, since the inclusion of issuable shares pursuant to the exercise of stock options and warrants, and the conversion of preferred stock was dilutive.

The following table sets forth the potentially dilutive effect of all outstanding equity instruments:

	September 30, 2012	September 30, 2011
Common Shares outstanding	158,965,565	158,516,071
Potentially dilutive common shares issuable upon:		
Exercise of warrants	988,741	7,203,260
Exercise of Callisto stock options	7,435,372	7,435,372
Conversion of Series A Convertible Preferred Stock		222,222
Total fully diluted pro-forma	167,389,678	173,376,925

9. Derivative Financial Instruments

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, Derivatives and Hedging: Contracts in Entity s Own Equity (ASC Topic 815-40). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity s own stock, which would qualify as a scope exception under ASC Topic 815-10.

Synergy Derivative Financial Instruments

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, Derivatives and Hedging: Contracts in Entity s Own Equity (ASC Topic 815-40). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity s own stock, which would qualify as a scope exception under ASC Topic 815-10.

Based upon the Company s analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that certain warrants issued in connection with sale of its common stock must be classified as derivative instruments. In accordance with ASC Topic 815-40, these warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company s statement of operations. The Company estimates the fair value of certain 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 range of assumptions used to determine the fair value of the warrants at each period end during the periods indicated below were:

	January 1, 2012 to May 9, 2012 (1)	Nine Months Ended September 30, 2011
Estimated fair value of Synergy common stock	$4.05-$4.75	$2.56-$3.30
Expected warrant term	2.4 - 5.7 years	5 - 7 years

Risk-free interest rate	0.32%-1.33%	1.18%-2.5%
Expected volatility	60%	90%
Dividend yield		

(1) Synergy s assets and liabilities have been deconsolidated as of May 9, 2012 and as a result there was no derivative instrument liability on the balance sheet as of September 30 2012. Changes in fair values of Synergy derivative instruments have been recorded through May 9, 2012.

Estimated fair value of stock is the closing market price of the Company s common stock on the date of warrant issuance and at the end of each reporting period when the derivative instruments are marked to market. Expected volatility is based on historical volatility of Synergy s common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants and the date of grant or quarterly revaluation.

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Certain of Synergy s warrants issued during the nine months ended September 30, 2011 contained a price protection clause which variable term required the Company to use a binomial model to determine fair value. There were no such price protected warrants issued during the nine months ended September 30, 2012. The range of assumptions used to determine the fair value of the warrants was as follows:

	Jan 1 to May 9, 2012	Nine months ended, September 30, 2011
Estimated fair value of stock	$3.28 - $4.50	$2.72 - $3.78
Expected warrant term	4.4 4.6 years	6.59 - 7 years
Risk-free interest rate	0.72% - 1.03%	1.18% - 2.50%
Expected volatility	60%	90%
Dividend yield		

In the Binomial model, the assumption for estimated fair value of the stock is based on a Black-Scholes based apportionment of the unit price paid for the shares and warrants issued in Synergy s most recent registered direct offerings, which resulting stock prices were deemed to be arms-length negotiated prices. Expected volatility is based on historical volatility of Synergy s common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants.

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

Date	Description	Warrants		Derivative Instrument Liability
12/31/2010	Balance of derivative financial instruments liability	728,469	$	3,487,959
3/31/2011	Fair value of new warrants issued during the quarter	210,000	$	1,312,673
3/31/2011	Change in fair value of warrants during the quarter recognized as other expense in the statement of operations		$	338,715
3/31/2011	Balance of derivative financial instruments liability	938,469	$	5,139,347
6/30/2011	Fair value of new warrants issued during the quarter	611,207	$	2,607,827
6/30/2011	Exercise of warrants during the quarter	(80,000)	$	(486,328)
6/30/2011	Change in fair value of warrants during the quarter recognized as other expense in the statement of operations		$	697,660
6/30/2011	Balance of derivative financial instruments liability	1,469,676	$	7,958,506
9/30/2011	Fair value of new warrants issued during the quarter	40,458	$	285,128
9/30/2011	Change in fair value of warrants during the quarter recognized as other income in the statement of operations		$	(4,382,796)
9/30/2011	Balance of derivative financial instruments liability	1,510,134	$	3,860,838
12/31/2011	Fair value of new warrants issued during the quarter	1,810,294	$	3,082,203
12/31/2011	Reclass of derivative liability to equity during the quarter	(1,055,268)	$	(1,707,317)
12/31/2011	Change in fair value of warrants during the quarter recognized as other income in the statement of operations		$	(1,910,610)
12/31/2011	Balance of derivative financial instruments liability	2,265,160	$	3,325,114
3/31/2012	Change in fair value of warrants during the quarter recognized as other income in the statement of operations			(7,946)
3/31/2012	Balance of derivative financial instruments liability	2,265,160		3,317,168

5/9/12	Change in fair value of warrants during the quarter recognized as other income in the statement of operations		439,116
5/9/12	Reclassification due to deconsolidation	(2,265,160)	(3,756,284)
9/30/2012	Balance of derivative financial instruments liability		

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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 December 31, 2011 and September 30, 2012:

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 December 31, 2011	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, 2012	
Derivative liabilities related to Warrants	$	$	$ 3,325,114	$ 3,325,114	$	$	$	$	*

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 September 30, 2012:

Description	Balance at December 31, 2011	Fair Value of warrants upon issuance	Unrealized (gains) or losses	Balance as of September 30, 2012 (*)
Derivative liabilities related to Warrants	$ 3,325,114	$	$	$

(*) Synergy s assets and liabilities have been deconsolidated as of May 9, 2012 and as a result there was no derivative instrument liability on the Callisto s balance sheet as of September 30 2012. Changes in fair values of Synergy derivative instruments have been recorded through May 9, 2012.

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities in the Company s statement of operations. A financial instrument s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

10. Stockholder s Equity

On January 30, 2012 Synergy issued 26,250 unregistered shares of its common stock to its corporate counsel for professional services rendered. The shares had a fair value on the date of issuance of $3.53 per share and $92,663 was recorded as legal expense during the quarter ended March 31, 2012.

On July 13, 2012 Callisto issued 227,272 unregistered shares of its common stock to two independent directors in settlement of director s fees payable. The value of the services rendered was $50,000 to each director for past services rendered to Callisto.

On August 3, 2012 8,000 shares of Series A Convertible Preferred Stock were converted to 222,222 shares of common stock at a conversion price of $0.36 per share. As of September 30, 2012 Callisto had no Series A or Series B Convertible Preferred Stock outstanding.

11. Related Parties

As of September 30, 2012 Callisto owns 34% of Synergy s outstanding shares.

As of September 30, 2012 Synergy had advanced Callisto $2,655,594 which is Callisto s share of Synergy payments for common operating costs since July 2008 that Callisto was unable to fund. The indebtedness as of December 31, 2011 is evidenced by an unsecured promissory note which bears interest at 6% per annum..

As of September 30, 2012 and December 31, 2011, the balances due to Synergy are comprised of the following amounts at the dates indicated:

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	September 30, 2012	December 31, 2011
Rent, utilities and property taxes	$ 114,313	$ 90,166
Insurance and other facilities related overhead	311,215	249,635
Independent accountants and legal fees	696,519	510,331
Financial printer and transfer agent fees	268,356	217,476
Salaries and consulting fees	329,660	289,270
Income taxes	297,725	
Merger fairness opinion	210,000	
Working capital advances, net of repayments	427,806	184,578
Total due from Callisto	$ 2,655,594	$ 1,541,456

Upon consummation of the Merger the related party balances due to Synergy $2,655,594 as of September 30, 2012, will be eliminated.

12. Contingencies

On August 9, 2012, a purported stockholder class action complaint was filed in the Supreme Court for the State of New York, captioned Shona Investments v. Callisto Pharmaceuticals, Inc., et al., Civil Action No. 652783/2012. The complaint names as defendants, Callisto, each member of the Board of Callisto (the ***Individual Defendants***) and Synergy. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that Synergy aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs attorneys fees and costs. Callisto and Synergy believe the plaintiffs allegations lack merit and will contest them.

On August 31, 2012, a purported stockholder class action complaint was filed in the Court of Chancery of the State of Delaware, captioned Gary Wagner v. Gary S. Jacob, Inc., et al., Case No. 7820-VCP. The complaint names as defendants, Callisto, the Individual Defendants and Synergy. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that Synergy aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs attorneys fees and costs. Callisto and Synergy believe the plaintiffs allegations lack merit and will contest them.

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13. Subsequent Events

On October 15, 2012, Callisto entered into Amendment No. 1 to the Agreement and Plan of Merger, dated July 20, 2012 with Synergy. Pursuant to the Amendment, the parties have agreed to, among other things, increase the exchange ratio from .17 to .1799 and change the lock-up provision such that each share of Synergy common stock received in connection with the merger shall be subject to a lock-up beginning on the effective date of the merger and ending on the earlier of(i) twenty-four (24) months after such date, (ii) a Change in Control (as defined in the Merger Agreement), or (iii) written consent of Synergy, at Synergy s sole discretion, provided Synergy s consent shall apply to all shares of the Synergy s common stock issued pursuant to the merger.

As Callisto does not meet the definition of a business under ASC 805, the merger will not be accounted for as a business combination. The merger is expected to be accounted for as a recapitalization of Synergy, affected through exchange of Callisto shares for Synergy shares, and the cancellation of Synergy shares held by Callisto. The excess of Synergy shares issued to Callisto shareholders over the Synergy shares held by Callisto is the result of a discount associated with the restricted nature of the Synergy shares to be received by Callisto shareholders. Therefore, considering this discount, the share exchange has been determined to be equal from a fair value stand point. Upon the effective date of the Merger, Synergy will account for the merger by assuming Callisto s net liabilities. Synergy s financial statements will reflect the operations of Callisto prospectively and will not be restated retroactively to reflect the historical financial position or results of operations of Callisto.

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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, 2011 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., (Synergy). Use of the terms we , our or us in connection with GI drug candidates discussed herein refer to research and development activities and plans of Synergy.

BUSINESS OVERVIEW

We are a development stage biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal (GI) disorders and diseases and was incorporated under the laws of the State of Delaware on June 5, 1996 (inception). Since inception, our efforts have been principally devoted to research and development, securing and protecting patents Synergy and raising capital.

Callisto - Synergy Merger

On July 20, 2012, Callisto entered into an Agreement and Plan of Merger (the Merger Agreement) with Synergy Pharmaceuticals Inc., a Delaware corporation (Synergy). Pursuant to the Merger Agreement, following the satisfaction or waiver of each of the applicable conditions set forth in the Merger Agreement, Callisto and Synergy will merge (the Merger), whereupon Callisto s separate corporate existence will cease and Synergy will continue as the surviving corporation of the Merger. Callisto is Synergy s largest shareholder.

On October 15, 2012, Callisto entered into Amendment No. 1 to the above Agreement and Plan of Merger, dated July 20, 2012 with Synergy. Pursuant to the Amendment, the parties have agreed to, among other things, increase the exchange ratio from .17 to .1799 and change the lock-up provision such that each share of Synergy common stock received in connection with the merger shall be subject to a lock-up beginning on the effective date of the merger and ending on the earlier of (i) twenty-four (24) months after such date, (ii) a Change in Control (as defined in the Merger Agreement), or (iii) written consent of Synergy, at Synergy s sole discretion, provided Synergy s consent shall apply to all shares of

Synergy s common stock issued pursuant to the merger.

The consummation of the Merger is subject to various customary closing conditions, including but not limited to, (i) approval by Callisto s and Synergy s stockholders, (ii) the Registration Statement on Form S-4 shall have been declared effective by the SEC and (iii) the shares of Synergy s common stock to be issued in the Merger shall have been approved for listing on The NASDAQ Capital Market. Upon consummation of the Merger the related party balances due to Synergy, $2,655,594 as of September 30, 2012, will be eliminated.

Completion of the merger is anticipated to occur during the first quarter of 2013, although there can be no assurance the merger will occur within the expected timeframe or at all.

Critical Accounting Policies

Investment in Synergy

We account for our investment in Synergy under the equity method of accounting, as we do not have the elements of control that would require consolidation. The investment is adjusted quarterly for equity in Synergy s net income or loss.

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FINANCIAL OPERATIONS OVERVIEW

From inception through September 30, 2012, we have sustained cumulative net losses attributable to common stockholders of $32,489,564. Our losses have resulted primarily from expenditures incurred in connection with research and development activities related to the application and filing for regulatory approval of proposed products, stock-based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees, as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception through September 30, 2012, 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 $13,244,841 during the nine months ended September 30, 2012 as compared to $9,589,564 for the nine months ended September 30, 2011 and $104,732,340 during the period from June 5, 1996 (inception) to September 30, 2012. During the three months and nine months ended September 30, 2012 we incurred net loss attributable to common stockholders of $3,891,805, net income of $109,876,750, respectively, and a net loss of $32,489,564 during the period from June 5, 1996 (inception) to September 30, 2012.

To date, our sources of cash have been primarily limited to the sale of equity securities and issuance of debt instruments. Net cash provided by financing activities for the nine months ended September 30, 2011 and for the period from June 5, 1996 (inception) to September 30, 2012, was $7,948,055 and $104,822,743 respectively. There was no cash provided by our financing activities during the nine months ended September 30, 2012.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2012.

RESULTS OF OPERATIONS

THREE MONTHS ENDED September 30, 2012 AND September 30, 2011

We had no revenues during the three months ended September 30, 2012 and 2011 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Callisto incurred no research and development expenses for the three months ended September 30, 2012 as compared to $3,882,802 for the three months ended September 30, 2011. This decrease was the result of the Synergy deconsolidation, effective May 9th, 2012. During the three

months ended September 30, 2011, Callisto incurred no research and development expenses other than those attributable to Synergy.

General and administrative expenses decreased $870,944 or 67%, to $418,001 for the three months ended September 30, 2012 from $1,288,945 for the three months ended September 30, 2011. This decrease was the result of the Synergy deconsolidation, effective May 9th, 2012. The difference of $ 870,944 represented Synergy related 2011 expense, not included during the three months ended September 30, 2012 as a result of the deconsolidation.

Net loss attributable to common stockholders for the three months ended September 30, 2012 increased $3,378,487 to $3,891,805 compared to a net loss of $513,318 incurred for the three months ended September 30, 2012. The increased loss is primary the result of gain of $4,382,796 from changes in the fair value of derivative instruments during the three month ended September 30, 2011. No such gains were during the three month ended September 30, 2012.

NINE MONTHS ENDED SEPTEMBER 30, 2012 AND SEPTEMBER 30, 2011

We had no revenues during the nine months ended September 30, 2012 and 2011 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the nine months ended September 30, 2012 increased $269,401or 3.5%, to $7,880,230 from $7,610,829 for the nine months ended September 30, 2011. The $7,880,230 during the nine months this year included approximately four months of Synergy s research and development expenses incurred prior to the deconsolidation, while $$7,610,829 during the nine months last year included nine months of Synergy s expenses. This increase of $269,401 was primary due to Synergy s increased development cost prior to deconsolidation on May 9, 2012.

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General and administrative expenses decreased $1,947,975 or 38%, to $3,176,502 for the nine months ended September 30, 2012 from $5,124,477 for the nine months ended September 30, 2011. The nine months ended September 30, 2012 included approximately four month of Synergy s general and administrative expenses, while during the nine months last year included nine months of Synergy s expenses. The difference of $1,974,975 represented approximately five months of Synergy s general and administrative expense, incurred subsequent to the deconsolidation on May 9, 2012 and therefore not included in our general and administrative expense.

Net income attributable to common stockholders for the nine months ended September 30, 2012 of $109,876,750, compared to a net loss of $4,775,281 incurred for the nine months ended September 30, 2011. The increase is primary due to the $120,393,000 gain recognized on the deconsolidation of Synergy on May 9, 2012, net of a $5,750,997 loss recognized in our investment in Synergy using the equity method for the period May 10, 2012 through September 30, 2012.

LIQUIDITY AND CAPITAL RESOURCES

We had $120 in cash and cash equivalents as of September 30, 2012, compared to $13,244,961 as of December 31, 2011, which includes Synergy. On May 9, 2012, Synergy closed an underwritten public offering of 10 million shares of common stock at an offering price of $4.50 per share, resulting in gross proceeds of $45 million before deducting underwriting discounts, commissions and other estimated. As a result our equity ownership in Synergy decreased to approximately 34% and we determined that we no longer had control over the operations and decision making of Synergy. Therefore, we deconsolidated Synergy and derecognized the Synergy assets, liabilities, and non-controlling interest from our financial statements as of May 9, 2012.

Our condensed consolidated financial statements as of September 30, 2012 and December 31, 2011 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 that included an explanatory paragraph referring to our recurring losses from operations 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. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA of our Annual Report on Form 10-K as of and for year ended December 31, 2011, filed with the SEC on March 30, 2012.

On May 9, 2012, Callisto s controlled subsidiary, Synergy, closed an underwritten public offering of 10 million shares of common stock at an offering price of $4.50 per share, resulting in gross proceeds of $45 million before deducting underwriting discounts, commissions and other estimated offering expenses of approximately $3 million. As a result, Callisto s equity ownership decreased to approximately 34% of Synergy and Callisto determined that it no longer had control over the operations and decision making of Synergy. Therefore, Callisto deconsolidated Synergy and derecognized the Synergy assets, liabilities, and non-controlling interest from its financial statements as of May 9, 2012 began accounting for its investment in Synergy under the equity method

Except for the above there have been no changes to our critical accounting policies since December 31, 2011.

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 September 30, 2012 we have no balances in money market accounts.

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 September 30, 2012, our Chief Executive Officer and Principal Financial Officer have concluded that as of September 30, 2012, 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.

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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, 2011. 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, 2011, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management s assessment were (i) an ineffective whistle-blower program or other comparable mechanism and (ii) a failure to maintain an ongoing program to manage identified fraud risks. As of December 31, 2011, we did not maintain effective internal control over financial reporting. As defined by Regulation S-X, Rule 1-02(a)(4), a material weakness is a deficiency or a combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected.

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

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

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 September 30, 2012.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On August 9, 2012, a purported stockholder class action complaint was filed in the Supreme Court for the State of New York, captioned Shona Investments v. Callisto Pharmaceuticals, Inc., et al., Civil Action No. 652783/2012. The complaint names as defendants, Callisto, each member of the Board of Callisto (the ***Individual Defendants***) and Synergy. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that Synergy aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs attorneys fees and costs. Callisto and Synergy believe the plaintiffs allegations lack merit and will contest them.

On August 31, 2012, a purported stockholder class action complaint was filed in the Court of Chancery of the State of Delaware, captioned Gary Wagner v. Gary S. Jacob, Inc., et al., Case No. 7820-VCP. The complaint names as defendants, Callisto, the Individual Defendants and Synergy. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that Synergy aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs attorneys fees and costs. Callisto and Synergy believe the plaintiffs allegations lack merit and will contest them.

Other than the above, there have been no material changes from the legal proceedings disclosed in our Form 10-K for the year ended December 31, 2011.

ITEM 1A. RISK FACTORS

On July 20, 2012, Callisto and Synergy entered into Merger Agreement which was amended on October 15, 2012. The following risk factors are in addition to the risk factors disclosed in our Form 10-K for the year ended December 31, 2011.

RISKS RELATED TO THE MERGER

All of Callisto s executive officers and all but one of its directors have conflicts of interest that may influence them to support or approve the merger without regard to your interests.

All of the Callisto officers will be employed by the combined company and certain directors will continue to serve on the board of directors of the combined company following the consummation of the merger. In addition, all of the Callisto officers and some of the directors have a direct

or indirect financial interest in both Callisto and Synergy. These interests, among others, may influence such executive officers and directors of Callisto to support or approve the merger.

The exchange ratio is not adjustable based on the market price of Synergy common stock so the merger consideration at the closing may have a greater or lesser value than it had at the time the merger agreement was signed.

The parties to the merger agreement have set the exchange ratio for the Callisto common stock and the exchange ratio is not adjustable. Any changes in the market price of Synergy common stock will not affect the number of shares holders of Callisto common stock will be entitled to receive upon consummation of the merger. Therefore, if the market price of Synergy common stock declines from the market price on the date of the merger agreement prior to the consummation of the merger, Callisto stockholders could receive merger consideration with considerably less value. Similarly, if the market price of Synergy common stock increases from the market price on the date of the merger agreement prior to the consummation of the merger, Callisto stockholders could receive merger consideration with considerably more value than their shares of Callisto common stock and the Synergy stockholders immediately prior to the merger will not be compensated for the increased market value of the Synergy common stock. The merger agreement does not include a price-based termination right. Because the exchange ratio does not adjust as a result of changes in the value of Synergy common stock, for each one percentage point that the market value of Synergy common stock rises or declines, there is a corresponding one percentage point rise or decline, respectively, in the value of the total merger consideration issued to the Callisto stockholders. For example, on July 20, 2012, the date of the execution of the merger agreement, the closing price of Synergy common stock, as reported on The NASDAQ Capital Market, was $4.34 per share. Assuming that a total of 28,597,905 shares of Synergy common stock are issued to Callisto stockholders upon the closing of the merger at a per share value of $4.34 per share (excluding the value of assumed stock options and warrants), the aggregate merger consideration to be issued to Callisto stockholders in

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the merger would be approximately $124.1 million. If, however, the closing price of Synergy common stock on the date of closing of the merger had declined from $4.34 per share to, for example, $3.46 per share, a decline of 20%, the aggregate merger consideration to be issued to Callisto stockholders in the merger would decrease approximately $24.8 million to approximately $99.3 million in total.

The combined company s stock price is expected to be volatile, and the market price of its common stock may drop following the merger.

The market price of the combined company s common stock could be subject to significant fluctuations following the merger. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the combined company s common stock.

In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the combined company s profitability and reputation.

The market price of the combined company s common stock may decline as a result of the merger.

The market price of the combined company s common stock may decline as a result of the merger if the combined company does not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by Synergy or Callisto or investors, financial or industry analysts.

The combined company may not experience the anticipated strategic benefits of the merger

The respective management of Synergy and Callisto believes that the merger would provide certain strategic benefits that may not be realized by each of the companies operating as standalones. Specifically, Synergy believes the merger would provide certain strategic benefits which would enable Synergy to accelerate its business plan through an increased access to capital in the public equity markets. There can be no assurance that these anticipated benefits of the merger will materialize or that if they materialize will result in increased stockholder value or revenue stream to the combined company.

During the pendency of the merger, Synergy and Callisto may not be able to enter into certain transactions with another party because of restrictions in the merger agreement, which could adversely affect their respective businesses.

Covenants in the merger agreement impede the ability of Synergy and Callisto to complete certain transactions that are not in the ordinary course of business, pending completion of the merger. As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors because the parties will have been prevented from entering into arrangements with possible financial and or other benefits to them.

In addition, any such transactions could be favorable to such party s stockholders.

If the conditions to the merger are not met, the merger will not occur.

Even if the merger is approved by the stockholders of Synergy and Callisto, specified conditions must be satisfied or waived in order to complete the merger, including, among others:

- the filing and effectiveness of a registration statement under the Securities Act of 1933, as amended, in connection with the issuance of Synergy common stock in the merger;

- the respective representations and warranties of Synergy and Callisto, shall be true and correct in all material respects as of the date of the merger agreement and the closing;

- each executive of Synergy or any of its subsidiaries and Callisto or any of its subsidiaries shall have delivered a waiver of rights to payments, bonuses, vesting, acceleration or other similar rights that are or may be triggered by the merger;

- no material adverse effect with respect to Synergy or Callisto or its subsidiaries shall have occurred since the date of the merger agreement and the closing of the merger;

- performance or compliance in all material respects by Synergy and Callisto with their respective covenants and obligations in the merger agreement;

- Callisto shall have obtained any consents and waivers of approvals required in connection with the merger; and

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- no material adverse effect with respect to Synergy or Callisto or its subsidiaries shall have occurred since the date of the merger agreement.

Synergy and Callisto cannot assure you that all of the conditions to the merger will be satisfied. If the conditions to the merger are not satisfied or waived, the merger will not occur or will be delayed, and Synergy and Callisto each may lose some or all of the intended benefits of the merger.

If there are Callisto stockholders that exercise their appraisal rights, the surviving corporation in the merger will be responsible for the resulting cash payment obligation.

If the merger is completed, holders of Callisto common stock are entitled to appraisal rights under Section 262 of the DGCL, or Section 262, provided that they comply with the conditions established by Section 262. If there are Callisto stockholders who exercise such rights and complete the process required by the DGCL, Synergy, as the surviving company in the merger, will be obligated to pay such stockholders the pre-merger cash value of their Callisto stock as determined by the Delaware Court of Chancery.

Should the merger not qualify as tax free reorganization, Callisto stockholders may recognize capital gain or loss with respect to the shares received in the merger.

In connection with the merger, Callisto received a tax opinion of Wilk Auslaunder LLP that the merger will be treated as a reorganization within the meaning of Section 368 of the Internal Revenue Code of 1986, as amended. The failure of the merger to qualify as a reorganization within the meaning of Section 368(a) of the Code would result in a Callisto stockholder recognizing capital gain or loss with respect to the shares of Callisto stock surrendered by such stockholder equal to the difference between the stockholder s basis in the shares and the fair market value, as of the effective time of the merger, of the Synergy stock received in exchange for the Callisto stock on the closing date of the merger. In such event, a stockholder s aggregate basis in the Synergy common stock so received would equal its fair market value and such stockholder s holding period would begin the day after the merger. A dissenting stockholder who receives cash will be required to recognize gain or loss in the same manner as described above.

Synergy and Callisto will incur substantial expenses whether or not the merger is completed.

Synergy and Callisto will incur substantial expenses related to the merger whether or not the merger is completed. Synergy currently expects to incur approximately $325,000 in transactional expenses and Callisto currently expects to incur approximately $300,000 in transactional expenses.

The merger agreement limits Callisto s ability to pursue alternative business combinations.

Certain no shop provisions included in the merger agreement make it difficult for Callisto to sell its business to a party other than Synergy. These provisions include the general prohibition on Callisto soliciting any acquisition transaction. These provisions might discourage a third party with an interest in acquiring all of or a significant part of Callisto from considering or proposing an acquisition, including a proposal that might be more advantageous to the stockholders of Callisto.

Although Brean Murray Carret & Co. s opinion was given to Callisto s board of directors on July 20, 2012, the date of the execution of the merger agreement, and re-issued on October 11, 2012, it does not reflect any changes in market and economic circumstances after July 20, 2012.

To the extent there may have been any changes in the operations and prospects of Synergy or Callisto and/or changes in general market and economic conditions subsequent to July 20, 2012, which could make Callisto s value now greater than its value as of July 20, 2012 (the date of the merger agreement and of the analysis conducted by Brean Murray Carret & Co (Brean Murray)), any such developments will have no effect whatsoever on Brean Murray s opinion or the exchange ratio for Callisto common stock, which was been fixed at $0.1799 under the merger agreement, as amended. Brean Murray s opinion, including the October 11, 2012 re-issued opinion, was based on financial, economic, monetary, market and other conditions and circumstances as in effect on, and the information made available to them on, July 20, 2012, the date of the execution of the merger agreement. While neither the Callisto nor Synergy board of directors is aware of any changes in the operations and prospects of Synergy or Callisto and/or changes in general market and economic conditions subsequent to July 20, 2012, which could make Callisto s value greater than its value as of July 20, 2012 (the date of the merger agreement and the analysis conducted by Brean Murray), or lead to the conclusion that the consideration to be received in the merger by Callisto s shareholders is not fair, there can be no assurance given that changes in the operations and prospects of Synergy or Callisto and/or changes in general market and economic conditions subsequent to July 20, 2012, could make Callisto s value, on the effective date of the merger greater than its value as of July 20, 2012. Brean Murray has undertaken no obligation to update its opinion for changes subsequent to July 20, 2012.

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The merger and related transactions are subject to approval by the stockholders of both Synergy and Callisto.

In order for the merger to be completed, both Synergy s and Callisto s stockholders must approve the merger agreement, which requires the affirmative vote of the holders of at least a majority of the outstanding shares of Callisto common stock entitled to vote. In addition, under applicable NASDAQ rules, Synergy s stockholders must approve the issuance of the shares of Synergy common stock to Callisto stockholders as part of the merger consideration. Approval of the issuance of shares of Synergy common stock to Callisto stockholders requires approval by a majority of the outstanding shares of Synergy common stock entitled to vote.

Several lawsuits have been filed against Callisto and Synergy challenging the merger, and an adverse ruling in any such lawsuit may delay or prevent the merger from being completed.

Callisto, members of Callisto s board of directors, or director defendants, and Synergy have been named as defendants in a number of putative class action lawsuits brought by certain Callisto stockholders challenging the merger and generally alleging, among other things, that the director defendants, aided and abetted by Synergy, breached their fiduciary duties to Callisto stockholders by entering into the merger agreement for merger consideration each plaintiff claims is inadequate and pursuant to a process the plaintiff claims to be flawed. The lawsuits seek, among other things, to enjoin the defendants from consummating the merger on the agreed-upon terms or to rescind the merger to the extent already implemented, as well as damages, expenses, and attorney s fees. The existence of these lawsuits could delay the completion of, or jeopardize Callisto s and Synergy s ability to complete, the merger.

RISKS RELATED TO SYNERGY AND CALLISTO AS A COMBINED ENTITY

Risks Related to the Business of Synergy and the Combined Entity

Synergy s business and stock price may be adversely affected if the acquisition of Callisto is not completed.

Synergy s acquisition of Callisto is subject to several customary conditions, including the effectiveness of this registration statement and the approvals of the transaction by the stockholders of Callisto and Synergy.

If Synergy s acquisition of Callisto is not completed, Synergy could be subject to a number of risks that may adversely affect Synergy s business and stock price, including:

- the current market price of shares of Synergy s common stock reflects a market assumption that the acquisition will be completed;

- Synergy must pay costs related to the merger; and

- Synergy would not realize the benefits it expects from acquiring Callisto.

Synergy is at an early stage of development as a company, currently has no source of revenue and may never become profitable.

Synergy is a development stage biopharmaceutical company. Currently, it has no products approved for commercial sale and, to date, it has not generated any revenue. Its ability to generate revenue depends heavily on:

- demonstration in current and future clinical trials that its product candidate, plecanatide for the treatment of CC and IBS-C, is safe and effective;

- its ability to seek and obtain regulatory approvals, including with respect to the indications it is seeking;

- successful manufacture and commercialization of its product candidates; and

- market acceptance of its products.

All of Synergy s existing product candidates are in various stages of development and will require extensive additional preclinical and clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before they could provide Synergy with any revenue. As a result, if Synergy does not successfully develop, achieve regulatory approval and commercialize plecanatide, it will be unable to generate any revenue for many years, if at all. Synergy does not anticipate that it will generate revenue for several years, at the earliest, or that it will achieve profitability for at least several years after generating material revenue, if at all. If Synergy is unable to generate revenue, it will not become profitable, and it may be unable to continue its operations.

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Synergy does not have any products that are approved for commercial sale and therefore does not expect to generate any revenues from product sales in the foreseeable future, if ever.

Synergy currently does not have any products that are approved for commercial sale. To date, Synergy has funded its operations primarily from sales of its securities. Synergy has not received, and does not expect to receive for at least the next several years, if at all, any revenues from the commercialization of its product candidates. To obtain revenues from sales of its product candidates, Synergy must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential. Synergy may never succeed in these activities, and may not generate sufficient revenues to continue its business operations or achieve profitability.

Synergy has incurred significant losses since inception and anticipates that it will incur continued losses for the foreseeable future.

As of September 30, 2012, Synergy had an accumulated deficit of $97,075,397. As of December 31, 2011, Synergy had an accumulated deficit of $69,609,018. Synergy expects to incur significant and increasing operating losses for the next several years as it expands its research and development, continues its clinical trials of plecanatide for the treatment of GI disorders, acquires or licenses technologies, advances other product candidates into clinical development, including SP-333, completes clinical trials, seeks regulatory approval and, if it receives FDA approval, commercializes its products. Because of the numerous risks and uncertainties associated with product development efforts, Synergy is unable to predict the extent of any future losses or when it will become profitable, if at all. If Synergy is unable to achieve and then maintain profitability, the market value of its common stock will likely decline.

Synergy s independent registered public accounting firm has expressed substantial doubt about its ability to continue as a going concern, which may hinder its ability to obtain future financing.

Synergy s consolidated financial statements as of December 31, 2011 were prepared under the assumption that it will continue as a going concern for the next twelve months. Synergy s independent registered public accounting firm has issued a report that included an explanatory paragraph referring to its recurring losses from operations and expressing substantial doubt in its ability to continue as a going concern without additional capital becoming available. Synergy s ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Synergy will need to raise substantial additional capital to fund its operations, and its failure to obtain funding when needed may force Synergy to delay, reduce or eliminate its product development programs.

During the nine months ended September 30, 2012, Synergy s operating activities used net cash of $23,070,861. During the twelve months ended December 31, 2011, Synergy s operating activities used net cash of $21,231,254. Synergy expects to continue to spend substantial amounts to:

- continue clinical development of plecanatide to treat GI disorders;
- continue development of other product candidates, including SP-333;
- finance its general and administrative expenses;
- prepare regulatory approval applications and seek approvals for plecanatide and other product candidates, including SP-333;
- license or acquire additional technologies;
- manufacture product for clinical trials;
- launch and commercialize its product candidates, if any such product candidates receive regulatory approval; and
- develop and implement sales, marketing and distribution capabilities.

Synergy will be required to raise additional capital to complete the development and commercialization of its current product candidates and to continue to fund operations at the current cash expenditure levels. Synergy future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of its clinical trials and other development activities;
- any future decisions Synergy may make about the scope and prioritization of the programs it pursues;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

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- the costs of manufacturing product;

- the costs and timing of regulatory approval;

- the costs of establishing sales, marketing and distribution capabilities;

- the effect of competing technological and market developments;

- the terms and timing of any collaborative, licensing and other arrangements that Synergy may establish; and

- general market conditions for offerings from biopharmaceutical companies.

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

Synergy cannot be certain that funding will be available on acceptable terms, or at all. To the extent that Synergy raises additional funds by issuing equity securities, its stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impacts Synergy s ability to conduct its business. If Synergy is unable to raise additional capital when required or on acceptable terms, it may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of its product candidates. Synergy also may be required to:

- seek collaborators for its product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and/or

- relinquish license or otherwise dispose of rights to technologies, product candidates or products that it would otherwise seek to develop or commercialize itself on unfavorable terms.

Synergy is largely dependent on the success of its lead product candidate, plecanatide, and it cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized.

Synergy currently has no products for sale, and it cannot guarantee that it will ever have any drug products approved for sale. Synergy and its product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. Synergy is not permitted to market any of its product candidates in or outside the United States until it receives approval of a new drug application, or NDA, for a product candidate from the FDA or the equivalent approval from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. Synergy currently has one lead product candidate, plecanatide for the treatment of GI disorders, and the success of its business currently depends on its successful development, approval and commercialization. This product candidate has not completed the clinical development process; therefore, Synergy has not yet submitted an NDA or foreign equivalent, or received marketing approval for this product candidate anywhere in the world.

The clinical development program for plecanatide may not lead to commercial products for a number of reasons, including if Synergy fails to obtain necessary approvals from the FDA or foreign regulatory authorities because its clinical trials fail to demonstrate to their satisfaction that this product candidate is safe and effective. Synergy may also fail to obtain the necessary approvals if it has inadequate financial or other resources to advance its product candidates through the clinical trial process. Any failure or delay in completing clinical trials or obtaining regulatory approval for plecanatide in a timely manner would have a material adverse impact on Synergy s business and its stock price.

Synergy will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact its business.

A pharmaceutical product cannot be marketed in the U.S. or other countries until it has completed rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names Synergy intends to use for its product candidates will require approval from the FDA regardless of whether Synergy has secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of Synergy s proposed product brand names, it may be required to adopt an alternative brand name for its product candidates. If Synergy adopts an alternative brand name, it would lose the benefit of its existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Synergy may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit its ability to commercialize its product candidates.

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Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Synergy s product candidates may not prove to be safe and efficacious in clinical trials and may not meet all the applicable regulatory requirements needed to receive regulatory approval. In order to receive regulatory approval for the commercialization of its product candidates, Synergy must conduct, at its own expense, extensive preclinical testing and clinical trials to demonstrate safety and efficacy of these product candidates for the intended indication of use. Clinical testing is expensive, can take many years to complete, if at all, and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials of new drugs do not necessarily predict the results of later-stage clinical trials. The design of Synergy s clinical trials is based on many assumptions about the expected effects of its product candidates, and if those assumptions are incorrect may not produce statistically significant results. Preliminary results may not be confirmed on full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of Synergy s product candidates may not be sufficient to support the filing of an NDA or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, Synergy cannot determine if or when it will have an approved product for commercialization or achieve sales or profits.

Delays in clinical testing could result in increased costs to Synergy and delay its ability to generate revenue.

Synergy may experience delays in clinical testing of its product candidates. Synergy does not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs approved for the conditions Synergy is investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of Synergy s product candidates versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing its clinical trials will increase Synergy s costs, slow down its product development and timeliness and approval process and delay its ability to generate revenue.

The FDA s expectations for clinical trials may change over time, complicating the process of obtaining evidence to support approval of Synergy s product candidates.

In March 2010, the FDA s Center for Drugs Evaluation and Research, or CDER, released a draft guidance entitled: Irritable Bowel Syndrome Clinical Evaluation of Products for Treatment to assist the product sponsors developing new drugs for the treatment of IBS. In pertinent part, this document provides recommendations for IBS clinical trial design and endpoints, and describes the need for the future development of patient-reported outcome, or PRO, instruments for use in IBS clinical trials. The clinical trials Synergy has planned for plecanatide are designed to follow the recommendations included in this draft guidance. Synergy cannot predict when the draft guidance will be finalized and, if it is finalized, whether the final version will include the same recommendations, or whether its currently planned clinical trials of plecanatide will meet the final recommendations.

When finalized, the guidance document will represent the FDA s thinking on the clinical evaluation of products for the treatment of IBS. FDA guidance documents, however, do not establish legally enforceable requirements, should be viewed only as recommendations, and may be changed at any time. Therefore, even insofar as Synergy intends to follow the recommendations provided in the draft guidance document and the final guidance document when revealed, Synergy cannot be sure that the FDA will accept the results of its clinical research even if such research follows the recommendations in the guidance document.

Synergy may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of its product candidates.

Synergy s clinical trials may be suspended at any time for a number of reasons. For example, it may voluntarily suspend or terminate its clinical trials if at any time it believes that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of Synergy s clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of Synergy s product candidates and could result in the FDA or other regulatory authorities denying further development or approval of its product candidates for any or all targeted indications. Ultimately, some or all of Synergy s product candidates may prove to be

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unsafe for human use. Moreover, Synergy could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in Synergy s clinical trials.

If Synergy fails to comply with healthcare regulations ,it could face substantial enforcement actions, including civil and criminal penalties and its business, operations and financial condition could be adversely affected.

As a developer of pharmaceuticals, even though Synergy does not intend to make referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse, false claims and patients privacy rights are and will be applicable to Synergy s business. Synergy could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which it conducts its business. The laws include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If Synergy s operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, it may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of its operations. Any penalties, damages, fines, curtailment or restructuring of Synergy s operations could adversely affect its ability to operate its business and its financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against Synergy for violation of these laws, even if it successfully defends against it, could cause

Synergy to incur significant legal expenses and divert management s attention from the operation of its business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If Synergy is unable to satisfy regulatory requirements, it may not be able to commercialize its product candidates.

Synergy needs FDA approval prior to marketing its product candidates in the United States. If it fails to obtain FDA approval to market its product candidates, it will be unable to sell its product candidates in the United States and Synergy will not generate any revenue.

The FDA s review and approval process, including among other things, evaluation of preclinical studies and clinical trials of a product candidate as well as the manufacturing process and facility, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-designed and well-controlled pre-clinical testing and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. Synergy cannot predict if or when it will submit an NDA for approval for any of its product candidates currently under development. Any approvals Synergy may obtain may not cover all of the clinical indications for which it is seeking approval or may contain significant limitations on the conditions of use.

The FDA has substantial discretion in the NDA review process and may either refuse to file Synergy s NDA for substantive review or may decide that its data is insufficient to support approval of its product candidates for the claimed intended uses. Following any regulatory approval of its product candidates, Synergy will be subject to continuing regulatory obligations such as safety reporting, required and additional post marketing obligations, and regulatory oversight of promotion and marketing. Even if Synergy receives regulatory approvals, the FDA may subsequently seek to withdraw approval of Synergy s NDA if it determines that new data or a reevaluation of existing data show the product is unsafe for use under the conditions of use upon the basis of which the NDA was approved, or based on new evidence of adverse effects or

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adverse clinical experience, or upon other new information. If the FDA does not file or approve Synergy s NDA or withdraws approval of its NDA, the FDA may require that Synergy conducts additional clinical trials, preclinical or manufacturing studies and submit that data before it will reconsider Synergy s application. Depending on the extent of these or any other requested studies, approval of any applications that Synergy submits may be delayed by several years, may require Synergy to expend more resources than it has available, or may never be obtained at all.

Synergy will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of its products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product in those countries. The approval process varies and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. Synergy cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere.

If Synergy s product candidates are unable to compete effectively with marketed drugs targeting similar indications as its product candidates, Synergy s commercial opportunity will be reduced or eliminated.

Synergy faces competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of its competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than Synergy does. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Synergy s commercial opportunity will be reduced or eliminated if its competitors develop and commercialize GI drugs that are safer, more effective, have fewer side effects or are less expensive than Synergy s product candidates. These potential competitors compete with Synergy in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies and technology licenses complementary to Synergy s programs or advantageous to its business.

If approved and commercialized, plecanatide will compete with at least two currently approved prescription therapies for the treatment of CC and IBS-C, Amitiza and Linzess. In addition, over-the-counter products are also used to treat certain symptoms of CC and IBS-C. Synergy believes other companies are developing products that will compete with plecanatide should they be approved by the FDA. For example, velusetrag, is being developed by Theravance, Inc. and has completed Phase 2 clinical trials for CC. To Synergy s knowledge, other potential competitors are in earlier stages of development. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for plecanatide.

Synergy expects that its ability to compete effectively will depend upon its ability to:

- successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;

- maintain a proprietary position for its products and manufacturing processes and other related product technology;

- attract and retain key personnel;

- develop relationships with physicians prescribing these products; and

- build an adequate sales and marketing infrastructure for its product candidates.

Because Synergy will be competing against significantly larger companies with established track records, it will have to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, its products, if approved, are competitive to other products. If Synergy is unable to compete effectively in the GI drug market and differentiate its products from other marketed GI drugs, it may never generate meaningful revenue.

Synergy currently has no sales and marketing organization. If it is unable to establish a direct sales force in the United States to promote its products, the commercial opportunity for its products may be diminished.

Synergy currently has no sales and marketing organization. If any of its product candidates are approved by the FDA, it intends to market that product through its own sales force. Synergy will incur significant additional expenses and commit significant additional management resources to establish this sales force. Synergy may not be able to establish these capabilities despite these additional expenditures. It will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If Synergy elects to rely on third parties to sell its product candidates in the United States, it may receive less revenue than if it sold its products directly. In addition, although Synergy would intend to use due diligence in monitoring their activities, it may have little or no control over the sales efforts

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of those third parties. In the event Synergy is unable to develop its own sales force or collaborate with a third party to sell its product candidates, it may not be able to commercialize its product candidates which would negatively impact its ability to generate revenue.

Synergy may need others to market and commercialize its product candidates in international markets.

Currently, Synergy does not have any plans to enter international markets. In the future, if appropriate regulatory approvals are obtained, Synergy intends to commercialize its product candidates in international markets. However, Synergy has not decided how to commercialize its product candidates in those markets. Synergy may decide to build its own sales force or sell its products through third parties. If Synergy decides to sell its product candidates in international markets through a third party, it may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to Synergy than if it marketed its product candidates entirely on its own. If Synergy is unable to enter into a marketing arrangement for its product candidates in international markets, it may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If Synergy fails to enter into marketing arrangements for its products and is unable to develop an effective international sales force, itsability to generate revenue would be limited.

If the manufacturers upon whom Synergy relies fail to produce plecanatide and its product candidates, including SP-333, in the volumes that it requires on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, Synergy may face delays in the development and commercialization of its product candidates.

Synergy does not currently possess internal manufacturing capacity. It currently utilizes the services of contract manufacturers to manufacture its clinical supplies. With respect to the manufacturing of plecanatide, Synergy has executed supply agreements with two contract manufacturers sufficient to meet its foreseeable clinical trial requirements. Any curtailment in the availability of plecanatide, however, could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

Synergy continues to pursue additional API and drug product supply agreements with other manufacturers. Synergy may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions with the contract manufacturers. Synergy may not be able to enter into long-term agreements on commercially reasonable terms, or at all. If Synergy changes or adds manufacturers, the FDA and comparable foreign regulators may require approval of the changes. Approval of these changes could require new testing by the manufacturer and compliance inspections to ensure the manufacturer is conforming to all applicable laws and regulations, including good manufacturing practices, or GMP. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary for the production of Synergy s product candidates. Peptide manufacturing is a highly specialized manufacturing business. While Synergy believes it will have long term arrangements with a sufficient number of contract manufacturers, if it loses a manufacturer, it would take Synergy a substantial amount of time to identify and develop a relationship, and seek regulatory approval, where necessary, for an alternative manufacturer.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of Synergy s clinical trials, increase the costs associated

with conducting its clinical trials and, depending upon the period of delay, require Synergy to commence new clinical trials at significant additional expense or to terminate a clinical trial.

Synergy is responsible for ensuring that each of its contract manufacturers comply with the GMP requirements of the FDA and other regulatory authorities from which it seeks to obtain product approval. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer s compliance with GMP requirements. Synergy is responsible for regularly assessing a contract manufacturer s compliance with GMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations. Manufacturers of plecanatide and other product candidates, including SP-333, may be unable to comply with these GMP requirements and with other FDA and foreign regulatory requirements, if any.

While Synergy will oversee compliance by its contract manufacturers, ultimately it will not have control over its manufacturers compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of plecanatide or other product candidates is compromised due to a manufacturers failure to adhere to applicable laws or for other reasons, Synergy may not be able to obtain regulatory approval for or successfully commercialize plecanatide or other product candidates, and it may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of plecanatide or other product candidates, entail higher costs or result in Synergy being unable to effectively commercialize

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plecanatide or other product candidates. Furthermore, if Synergy s manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, it may be unable to meet demand for any approved products and would lose potential revenues.

Synergy may not be able to manufacture its product candidates in commercial quantities, which would prevent it from commercializing its product candidates.

To date, Synergy s product candidates have been manufactured in small quantities for preclinical studies and clinical trials. If any of Synergy s product candidates is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, it will need to manufacture such product candidate in larger quantities. Synergy may not be able to increase successfully the manufacturing capacity for any of its product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If Synergy is unable to increase successfully the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Synergy s product candidates require precise, high quality manufacturing. Synergy s failure to achieve and maintain these high quality manufacturing standards in collaboration with its third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm its business, financial condition and results of operations.

Materials necessary to manufacture Synergy s product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of its product candidates.

Synergy relies on the third-party manufacturers of its product candidates to purchase from third-party suppliers the materials necessary to produce the bulk active pharmaceutical ingredients, or APIs, and product candidates for its clinical trials, and it will rely on such manufacturers to purchase such materials to produce the APIs and finished products for any commercial distribution of its products if it obtains marketing approval. Suppliers may not sell these materials to Synergy s manufacturers at the time they need them in order to meet Synergy s required delivery schedule or on commercially reasonable terms, if at all. Synergy does not have any control over the process or timing of the acquisition of these materials by its manufacturers. Moreover, it currently does not have any agreements for the production of these materials. If Synergy s manufacturers are unable to obtain these materials for its clinical trials, testing of the affected product candidate would be delayed, which may significantly impact its ability to develop the product candidate. If Synergy or its manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of Synergy s products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm Synergy s ability to generate revenues from such product and achieve or sustain profitability.

Synergy s product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting Synergy s potential to generate revenues.

If one of Synergy s product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payors and its profitability and growth will depend on a number of factors, including:

- demonstration of safety and efficacy;

- changes in the practice guidelines and the standard of care for the targeted indication;

- relative convenience and ease of administration;

- the prevalence and severity of any adverse side effects;

- budget impact of adoption of Synergy s product on relevant drug formularies and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;

- pricing and cost effectiveness, which may be subject to regulatory control;

- effectiveness of Synergy s or any of its partners sales and marketing strategies;

- the product labeling or product insert required by the FDA or regulatory authority in other countries; and

- the availability of adequate third-party insurance coverage or reimbursement.

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If any product candidate that Synergy develops does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Synergy s ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including its ability to produce a product at a competitive price and its ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, Synergy s ability to generate revenues from that product would be substantially reduced. In addition, its efforts to educate the medical community and third-party payors on the benefits of its product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

Guidelines and recommendations published by various organizations can impact the use of Synergy s products.

Government agencies promulgate regulations and guidelines directly applicable to Synergy and to its products. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of Synergy s products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of Synergy s proposed products.

If product liability lawsuits are successfully brought against Synergy, it may incur substantial liabilities and may be required to limit commercialization of its product candidates.

Synergy faces an inherent risk of product liability lawsuits related to the testing of its product candidates, and will face an even greater risk if it sells its product candidates commercially. Currently, Synergy is not aware of any anticipated product liability claims with respect to its product candidates. In the future, an individual may bring a liability claim against Synergy if one of its product candidates causes, or merely appears to have caused, an injury. If Synergy cannot successfully defend itself against the product liability claim, it may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for Synergy s product candidates;
- injury to its reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;

- initiation of investigations by regulators;

- substantial monetary awards to patients or other claimants;

- distraction of management s attention from Synergy s primary business;

- product recalls;

- loss of revenue; and

- the inability to commercialize its product candidates.

Synergy has clinical trial liability insurance with a $5,000,000 aggregate limit. Synergy intends to expand its insurance coverage to include the sale of commercial products if marketing approval is obtained for its product candidates. Synergy s current insurance coverage may prove insufficient to cover any liability claims brought against it. In addition, because of the increasing costs of insurance coverage, Synergy may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy liabilities that may arise.

Synergy s failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair its ability to grow.

As part of its growth strategy, Synergy intends to develop and market additional products and product candidates. It is pursuing various therapeutic opportunities through its pipeline. Synergy may spend several years completing its development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which Synergy allocates its resources may not end up

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being successful. In addition, because Synergy s internal research capabilities are limited, it may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to it. The success of this strategy depends partly upon its ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. Failure of this strategy would impair Synergy s ability to grow.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with Synergy for the license or acquisition of product candidates and approved products. Synergy has limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into its current infrastructure. Moreover, Synergy may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or it may fail to realize the anticipated benefits of such efforts. Synergy may not be able to acquire the rights to additional product candidates on terms that it finds acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of Synergy s business and diversion of its management s time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with its operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

Further, any product candidate that Synergy acquires may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Even if Synergy s product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product s indicated uses or impose ongoing requirements for potentially costly post-approval studies. Plecanatide and other product candidates, including SP-333, would also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP, regulations. If Synergy or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing. If Synergy, its product candidates or the manufacturing facilities for its product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by Synergy;

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- impose restrictions on operations, including costly new manufacturing requirements;

- seize or detain products or request us to initiate a product recall; or

- pursue and obtain an injunction.

Drugs approved to treat IBS have been subject to considerable post-market scrutiny, with consequences up to and including voluntary withdrawal of approved products from the market. This may heighten FDA scrutiny of Synergy s product candidates before or following market approval.

Products approved for the treatment of IBS have been subject to considerable post-market scrutiny. For example, in 2007, Novartis voluntarily discontinued marketing Zelnorm (tegaserod), a product approved for the treatment of women with IBS-C, after the FDA found an increased risk of serious cardiovascular events associated with the use of the drug. Earlier, in 2000, Glaxo Wellcome withdrew Lotronex (alosetron), which was approved for women with severe diarrhea-prominent IBS, after the manufacturer received numerous reports of adverse events or AEs, including ischemic colitis, severely obstructed or ruptured bowel, or death. In 2002, the FDA approved the manufacturer s application to make Lotronex available again, on the condition that the drug only be made available through a restricted marketing program.

Although plecanatide is being investigated for IBS, plecanatide is from a different pharmacologic class than Zelnorm or Lotronex, and would not be expected to share the same clinical risk profile as those agents. Nevertheless, because these products are in the same or related therapeutic classes, it is possible that the FDA will have heightened scrutiny of plecanatide or any other agent under development for IBS. This could delay product approval, increase the cost of Synergy s clinical development program, or increase the cost of post-market study commitments for its IBS product candidates, including plecanatide.

Even if Synergy s product candidates receive regulatory approval in the United States, it may never receive approval to commercialize them outside of the United States.

In the future, Synergy may seek to commercialize plecanatide and/or other product candidates, including SP-333, in foreign countries outside of the United States. In order to market any products outside of the United States, Synergy must establish and comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the United States. The time required to obtain approval in other jurisdictions might differ from that required to obtain FDA approval. The regulatory approval process in other jurisdictions may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that plecanatide or other product candidates may not be approved for all indications for use included in proposed labeling or for any indications at all, which could limit the uses of plecanatide or other product candidates and have an adverse effect on Synergy s products commercial potential or require costly post-marketing studies.

Synergy relies on third parties to conduct its clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, Synergy may not be able to seek or obtain regulatory approval for or commercialize its product candidates.

Synergy has agreements with third-party contract research organizations, or CROs, under which it has delegated to the CROs the responsibility to coordinate and monitor the conduct of its clinical trials and to manage data for its clinical programs. Synergy, its CROs and its clinical sites are required to comply with current Good Clinical Practices, or GCPs, regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where it is conducting clinical trials. Synergy has an ongoing obligation to monitor the activities conducted by its CROs and at its clinical sites to confirm compliance with these requirements. In the future, if Synergy, its CROs or its clinical sites fail to comply with applicable GCPs, the clinical data generated in its clinical trials may be deemed unreliable and the FDA may require Synergy to perform additional clinical trials before approving oitsmarketing applications. In addition, Synergy s clinical trials must be conducted with product produced under cGMP regulations, and will require a large number of test subjects. Synergy s failure to comply with these regulations may require it to repeat clinical trials, which would delay the regulatory approval process.

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to Synergy s clinical protocols, regulatory requirements or for other reasons, Synergy s clinical trials may be extended, delayed or terminated, and it may not be able to obtain regulatory approval for or successfully commercialize its product candidates. As a result, its financial results and the commercial prospects for its product candidates would be harmed, its costs could increase, and its ability to generate revenue could be delayed.

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If Synergy fails to attract and keep senior management and key scientific personnel, it may be unable to successfully develop its product candidates, conduct its clinical trials and commercialize its product candidates.

Synergy s success depends in part on its continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on its ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. Synergy is highly dependent upon its senior management and scientific staff, particularly Gary S. Jacob, Ph.D., its President and Chief Executive Officer and Kunwar Shailubhai, Ph.D., its Chief Scientific Officer. The loss of services of Dr. Jacob or one or more of Synergy s other members of senior management could delay or prevent the successful completion of its planned clinical trials or the commercialization of its product candidates.

The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. Synergy will need to hire additional personnel as it expands its clinical development and commercial activities. It may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies.

Synergy will need to increase the size of its organization, and it may experience difficulties in managing growth.

Synergy is a small company with fourteen employees as of October 18, 2012. To continue its clinical trials and commercialize its product candidates, it will need to expand its employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Over the next 12 months depending on the progress of its planned clinical trials, Synergy plans to add additional employees to assist it with its clinical programs. Synergy s future financial performance and its ability to commercialize its product candidates and to compete effectively will depend, in part, on its ability to manage any future growth effectively. To that end, Synergy must be able to:

- manage development efforts effectively;
- manage its clinical trials effectively;
- integrate additional management, administrative, manufacturing and sales and marketing personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

Synergy may not be able to accomplish these tasks, and its failure to accomplish any of them could harm its financial results and impact its ability to achieve development milestones.

Reimbursement may not be available for Synergy s product candidates, which would impede sales.

Market acceptance and sales of Synergy s product candidates may depend on coverage and reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for Synergy s products as well as levels at which these payers pay directly for its products, where applicable, could affect whether Synergy is able to commercialize these products. Synergy cannot be sure that reimbursement will be available for any of these products. Also, Synergy cannot be sure that coverage or reimbursement amounts will not reduce the demand for, or the price of, its products. Synergy has not commenced efforts to have its product candidates reimbursed by government or third party payors. If coverage and reimbursement are not available or are available only at limited levels, Synergy may not be able to commercialize its products.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If Synergy s products are or become subject to government regulation that limits or prohibits payment for its products, or that subjects the price of its products to governmental control, it may not be able to generate revenue, attain profitability or commercialize its products.

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also impose strict prior authorization requirements and/or refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse patients for their use of newly-approved drugs, which in turn will put pressure on the pricing of drugs.

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Healthcare reform measures could hinder or prevent Synergy s product candidates commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect Synergy s ability to set prices for its products which it believes are fair, and its ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit Synergy s potential revenue, and it may need to revise its research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect Synergy s ability to sell its products profitably.

For example, in March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA. This law will substantially change the way healthcare is financed by both government health plans and private insurers, and significantly impact the pharmaceutical industry. The PPACA contains a number of provisions that are expected to impact Synergy s business and operations in ways that may negatively affect its potential revenues in the future. For example, the PPACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which Synergy believes will increase the cost of its products. In addition, as part of the PPACA s provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the donut hole), Synergy will be required to provide a discount on branded prescription drugs equal to 50% of the government-negotiated price, for drugs provided to certain beneficiaries who fall within the donut hole. Similarly, PPACA increases the level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% and requires collection of rebates for drugs paid by Medicaid managed care organizations. The PPACA also includes significant changes to the 340B drug discount program including expansion of the list of eligible covered entities that may purchase drugs under the program. At the same time, the expansion in eligibility for health insurance benefits created under PPACA is expected to increase the number of patients with insurance coverage who may receive Synergy s products. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on Synergy s business, they could have a material adverse effect on Synergy s business and financial condition.

Congress periodically adopts legislation like the PPACA and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, that modifies Medicare reimbursement and coverage policies pertaining to prescription drugs. Implementation of these laws is subject to ongoing revision through regulatory and subregulatory policies. Congress also may consider additional changes to Medicare policies, potentially including Medicare prescription drug policies, as part of ongoing budget negotiations. While the scope of any such legislation is uncertain at this time, there can be no assurances that future legislation or regulations will not decrease the coverage and price that Synergy may receive for its proposed products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for Synergy to go through the process of seeking coverage and reimbursement from Medicare and private payors. Synergy s proposed products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow Synergy to sell its proposed products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidates that Synergy develops and may further limit its commercial opportunities. Synergy s results of operations could be materially adversely affected by proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA s exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

Except for those risk factors discussed above there have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2011.

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.

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31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2012, filed on November 19, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows (iv) the Condensed Consolidated Statement of Stockholders Equity (Deficit) and (v) the Notes to Consolidated Financial Statements tagged as blocks of text.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CALLISTO PHARMACEUTICALS, INC.
(Registrant)

Date: November 19, 2012	By:	/s/ GARY S. JACOB
		Gary S. Jacob *Chief Executive Officer*
Date: November 19, 2012	By:	/s/ BERNARD F. DENOYER
		Bernard F. Denoyer *Senior Vice President, Finance*