

CALLISTO PHARMACEUTICALS INC
Form 10-Q
November 16, 2009

Table of Contents

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: SEPTEMBER 30, 2009

or

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

For the transition period from _____ to _____
Commission File Number: 001-32325

CALLISTO PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

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

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

(Address of principal executive offices) (Zip Code)

(212) 297-0010

(Registrant's telephone number)

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

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

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

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Act. (Check one):

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

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

The number of the registrant's shares of common stock outstanding was 53,608,111 as of November 11, 2009.

Table of Contents

CALLISTO PHARMACEUTICALS, INC.

FORM 10-Q

CONTENTS

PART I FINANCIAL INFORMATION

<u>Item 1.</u>	<u>Financial Statements</u>	<u>2</u>
	<u>Condensed Consolidated Balance Sheets as of September 30, 2009 (unaudited) and December 31, 2008</u>	<u>2</u>
	<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2009 and 2008 (unaudited) and the period June 5, 1996 (Inception) to September 30, 2009 (unaudited)</u>	<u>3</u>
	<u>Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period June 5, 1996 (Inception) to September 30, 2009 (unaudited)</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2009 and 2008 (unaudited) and for the period June 5, 1996 (Inception) to September 30, 2009 (unaudited)</u>	<u>12</u>
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>14</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>26</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>32</u>
<u>Item 4T.</u>	<u>Controls and Procedures</u>	<u>32</u>
<u>PART II OTHER INFORMATION</u>		<u>34</u>
<u>Item 1.</u>	<u>Legal proceedings</u>	<u>34</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>34</u>
<u>Item 6.</u>	<u>Exhibits</u>	<u>34</u>
<u>Signatures</u>		<u>35</u>

Table of Contents

INTRODUCTORY NOTE

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

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2008 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.

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

	September 30, 2009	December 31, 2008
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 3,212,010	\$ 301,323
Cash in escrow		201,908
Prepaid expenses and other	89,810	59,756
Total Current Assets	3,301,820	562,987
Property and equipment, net	16,476	20,649
Security deposits	87,740	78,116
Total Assets	\$ 3,406,036	\$ 661,752
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Notes Payable secured short term	\$ 326,291	\$
Accounts payable	3,921,895	3,687,549
Accrued expenses	1,281,661	1,136,264
Total Current Liabilities	5,529,847	4,823,813
Notes payable secured long term		20,176
Derivative financial instruments, at estimated fair value warrants	24,929,129	
Total Liabilities	30,458,976	4,843,989
Commitments and contingencies		
Stockholders' Deficit:		
Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized, 88,000 and 98,000 shares outstanding at September 30, 2009 and December 31, 2008, respectively	9	10
Series B convertible preferred stock, par value \$0.0001, 2,500,000 shares authorized, 1,079,166 and 1,137,050 shares outstanding at September 30, 2009 and December 31, 2008, respectively	108	114
Common stock, par value of \$.0001 per share: 225,000,000 shares authorized; 50,914,341 and 49,556,661 shares outstanding at September 30, 2009 and December 31, 2008, respectively	5,091	4,955

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Additional paid-in capital	96,398,068	86,799,951
Deficit accumulated during development stage	(121,556,718)	(90,987,267)
Total Callisto Stockholders' Deficit	(25,153,442)	(4,182,237)
Non-controlling interest	(1,899,498)	
Total Stockholders' Deficit	(27,052,940)	(4,182,237)
Total Liabilities and Stockholders' Deficit	\$ 3,406,036	\$ 661,752

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30		Nine Months Ended September 30		June 5, 1996 (Inception) to September 30, 2009
	2009	2008	2009	2008	
Revenues	\$	\$	\$	\$	\$
Costs and expenses:					
Research and development	1,265,432	1,048,228	2,808,517	4,129,756	36,906,781
Government grants				(30,000)	(1,135,318)
Purchased in process research and development					6,944,553
General and administrative	1,144,572	1,253,268	3,203,745	3,291,196	42,182,350
Loss from operations	(2,410,004)	(2,301,496)	(6,012,262)	(7,390,952)	(84,898,366)
Interest and investment income	10,939	14,420	11,164	68,034	875,491
Other income (expense), net	(160,839)		(275,856)		(447,703)
Change in fair value of derivative instruments warrants	(5,735,936)		(22,472,503)		(19,881,498)
Net loss	(8,295,840)	(2,287,076)	(28,749,457)	(7,322,918)	(104,352,076)
Net Loss attributable to non-controlling interest	743,755	538,724	1,899,498	538,724	1,899,498
Net loss attributable to controlling interest	(7,552,085)	(1,748,352)	(26,849,959)	(6,784,194)	(102,452,578)
Series A Preferred stock beneficial conversion feature accreted as a dividend					(4,888,960)
Series B Preferred stock beneficial conversion feature accreted as a dividend					(10,495,688)
Series A Preferred stock conversion rate change accreted as a dividend	(136,889)		(136,889)		(136,889)
Series B Preferred stock conversion rate change accreted as a dividend	(1,678,703)		(1,678,703)		(1,678,703)
Cumulative effect of adopting ASC Topic 815 January 1, 2009					(1,903,900)
Net loss available to common stockholders	\$ (9,367,677)	\$ (1,748,352)	\$ (28,665,551)	\$ (6,784,194)	\$ (121,556,718)
<i>Weighted average shares outstanding:</i>					
basic and diluted	50,914,341	47,218,161	50,797,171	47,186,957	
<i>Net loss per common share:</i>					
basic and diluted	\$ (0.18)	\$ (0.04)	\$ (0.56)	\$ (0.14)	

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

(Unaudited)

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

(Unaudited)

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

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

(Unaudited)

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

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

(Unaudited)

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

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

(Unaudited)

	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity (Deficit)
Balance, December 31, 2004	29,219,102	\$ 2,922	\$ 39,910,186	\$ (2,302,534)	\$ (33,361,197)	\$ 4,249,377
Net loss for the year					(11,779,457)	(11,779,457)
Deferred stock-based compensation new grants			1,571,772	(1,571,772)		
Amortization of deferred stock-based compensation				2,290,843		2,290,843
Variable accounting for stock options			75,109			75,109
Common stock issued via private placement:						
March 2005	1,985,791	198	3,018,203			3,018,401
August 2005	1,869,203	187	1,812,940			1,813,127
Fees and expenses			(176,250)			(176,250)
Exercise of common stock warrant	125,000	13	128,737			128,750
Common stock issued for services	34,000	3	47,177			47,180
Balance, December 31, 2005	33,233,096	\$ 3,323	\$ 46,387,875	\$ (1,583,463)	\$ (45,140,654)	\$ (332,919)

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

(Unaudited)

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Common Stock	Common Stock Par Value	Additional Paid in Capital	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity (Deficit)
Balance, December 31, 2005		\$	33,233,096	\$ 3,323	\$ 46,387,875	\$ (1,583,463)	\$ (45,140,654)	\$ (332,919)
Net loss for the year							(12,919,229)	(12,919,229)
Reclassification of deferred unamortized stock-based compensation upon adoption of ASC Topic 718					(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
Fees and expenses					(561,808)			(561,808)
April 2006			666,667	67	799,933			800,000
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
Fees and expenses	11,775	1			(448,909)			(448,908)
Detachable warrants					2,384,485			
Beneficial conversion feature accreted as a dividend							(2,384,485)	
Balance, December 31, 2006	586,125	\$ 58	39,194,996	\$ 3,919	\$ 61,290,509	\$	\$ (60,444,368)	\$ 850,118

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

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

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

	Series A Convertible Preferred Shares	Series A Convertible Preferred Stock	Series B Convertible Preferred Shares	Series B Convertible Preferred Stock	Common 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 for the period								(26,849,959)	(1,899,498)	(28,749,457)
Stock based compensation expense							976,886			976,886
Conversion of Series A preferred stock to common stock	(10,000)	(1)			200,000	20	(19)			
Conversion of Series B preferred stock to common stock			(57,884)	(6)	1,157,680	116	(110)			
Private placements of common stock of majority owned subsidiary							7,232,500			7,232,500
Fees and expenses associated with private placements of majority owned subsidiary							(245,000)			(245,000)
Preferred Stock dividend attributable to reset of conversion price in conjunction with waiver of liquidation preference							1,815,592	(1,815,592)		
Balance September 30, 2009	88,000	\$ 9	1,079,166	\$ 108	50,914,341	\$ 5,091	\$ 96,398,068	\$ (121,556,718)	\$ (1,899,498)	\$ (27,052,940)

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30, 2009	Nine months ended September 30, 2008	Period from June 5, 1996 (inception) to September 30, 2009
Cash flows from operating activities:			
Net loss	\$ (28,749,457)	\$ (7,322,918)	\$ (104,352,076)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	4,172	4,620	100,756
Purchase discount accreted as interest income on U.S. Treasury bills		(26,950)	(26,950)
Stock-based compensation expense	976,886	368,405	18,711,755
Purchased in-process research and development (non-cash portion)			6,841,053
Interest expense on notes payable	275,856		275,856
Stock-based liquidated damages			579,696
Change in fair value of derivative instruments warrants	22,472,503		19,881,498
Changes in operating assets and liabilities:			
Prepaid expenses	(30,054)	(2,131)	(89,810)
Security deposit	(9,624)		(87,740)
Accounts payable and accrued expenses	379,742	(399,335)	4,868,304
Total adjustments	24,069,481	(55,391)	51,054,418
Net cash used in operating activities	(4,679,976)	(7,378,309)	(53,297,658)
Cash flows from investing activities:			
Short term investments purchased			(5,921,825)
Short term investments liquidated		2,994,640	5,948,775
Acquisition of equipment		(12,196)	(117,233)
Net cash provided by (used in) investing activities		2,982,444	(90,283)
Cash flows from financing activities:			
Issuance of common and preferred stock			48,719,673
Finders fees and expenses			(2,981,083)
Proceeds from sale of 11% Notes	603,163		603,163
Proceeds of private placement of majority owned subsidiary's common stock	7,232,500	3,025,000	10,257,500
Fees and expenses on private placement of majority owned subsidiary common stock	(245,000)	(73,087)	(318,087)
Exercise of common stock warrants			318,785
Net cash provided by financing activities	7,590,663	2,951,913	56,599,951
Net increase (decrease) in cash and cash equivalents	2,910,687	(1,443,952)	3,212,010
Cash and cash equivalents at beginning of period	301,323	3,269,341	
Cash and cash equivalents at end of period	\$ 3,212,010	\$ 1,825,389	\$ 3,212,010

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30, 2009	Nine months ended September 30, 2008	Period from June 5, 1996 (inception) to September 30, 2009
Supplementary disclosure of cash flow information:			
Cash paid for taxes	\$ 35,248	\$ 31,816	\$ 196,973
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	\$	\$ 136,889
Series B Preferred stock conversion rate change accreted as a dividend	\$ 1,678,703	\$	\$ 1,678,703

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Business overview:

Callisto Pharmaceuticals, Inc. ("Callisto" or the "Company") is a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. Since inception on June 5, 1996, Callisto's efforts have been principally devoted to research and development, securing and protecting patents and raising capital. From inception through September 30, 2009, Callisto has sustained cumulative net losses available to common stockholders of \$121,556,718. 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, regulatory, scientific and financial consulting fees, change in fair value of derivative financial instruments (warrants), as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception on June 5, 1996 through September 30, 2009, Callisto has not generated any revenue from operations, expects to incur additional losses to perform further research and development activities and does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all.

Callisto's product development efforts are thus in their early stages and Callisto cannot make estimates of the costs or the time they will take to complete. The risk of completion of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, the nature and timing of costs and competing technologies being developed by organizations with significantly greater resources.

2. Basis of presentation and going concern:

These unaudited condensed consolidated financial statements include Callisto and subsidiaries, (1) Synergy Pharmaceuticals, Inc. consolidated ("Synergy") (a majority owned subsidiary) and (2) Callisto Research Labs, LLC (a wholly-owned but inactive subsidiary). All intercompany balances and transactions have been eliminated. These unaudited 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, 2008, included in Form 10-K filed with the SEC on April 15, 2009. 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, 2009 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2009. The condensed consolidated balance sheet as of December 31, 2008 was derived from the audited consolidated financial statements as of that date.

The condensed consolidated financial statements as of September 30, 2009 and December 31, 2008 have been prepared under the assumption that Callisto will continue as a going concern for the twelve months ending December 31, 2009. 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,

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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

ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Callisto will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at its current cash expenditure levels.

Net cash used in operating activities was \$4,679,976 during the nine months ended September 30, 2009 as compared to \$7,378,309 for the nine months ended September 30, 2008. To date, Callisto's sources of cash have been primarily limited to the sale of equity securities. Net cash provided by financing activities for the nine months ended September 30, 2009 was \$7,590,663 as compared to \$2,951,913 for the nine months ended September 30, 2008. Included in net cash provided by financing activities for the nine months ended September 30, 2009 was primarily the Synergy private placement of 10,332,144 shares of unregistered Synergy common stock at \$0.70 per share to private investors for aggregate proceeds of \$7,232,500. Fees to selling agents and other costs of capital associated with the sale of certain common stock were \$245,000. Net cash provided by financing activities for the nine months ended September 30, 2008 reflects the Synergy private placement of 5,041,667 shares of unregistered common stock at \$0.60 per share to private investors for aggregate proceeds of \$3,025,000. Fees to selling agents and other costs of capital associated with the sale of this common stock were \$73,087.

As of September 30, 2009 Callisto had a working capital deficit of \$2,228,027 as compared to a deficit of \$4,260,826 as of December 31, 2008, accordingly Callisto will be required to raise additional capital within the next year to complete the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Callisto cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Callisto raises additional funds by issuing equity securities, Callisto's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Callisto's ability to conduct business. If Callisto is unable to raise additional capital when required or on acceptable terms, Callisto may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that Callisto would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Recent worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult to obtain additional equity or credit financing, when needed. Callisto has accordingly taken steps to conserve cash which include extending payment terms to our suppliers as well as substantial management and staff salary cuts and deferrals. These actions may not be sufficient to allow the Company time to raise additional capital.

3. Recent Accounting Pronouncements

In August 2009, the FASB issued Accounting Standards Update No. 2009-05, "Measuring Liabilities at Fair Value" ("ASU 2009-05"). ASU 2009-05 amends ASC Topic 820 and clarifies that,

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Recent Accounting Pronouncements (Continued)

where a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: 1) a valuation technique that uses a) the quoted price of the identical liability when traded as an asset or b) quoted prices for similar liabilities or similar liabilities when traded as assets and/or 2) a valuation technique that is consistent with the principles of ASC Topic 820. ASU 2009-05 also clarifies that, when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability. The adoption of ASU 2009-05 did not have a material impact on the Company's financial statements.

In June 2009, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2009-01, "Generally Accepted Accounting Principles" (ASC Topic 105), by the Codification which establishes the FASB Accounting Standards Codification (the "Codification" or "ASC") as the single source of authoritative GAAP. All existing accounting standards in effect prior to the Codification were superseded. All other accounting guidance not included in the Codification will be considered non-authoritative. The Codification also includes all relevant SEC guidance organized using the same topical structure in separate sections within the Codification. The Codification does not change GAAP and does not impact the Company's financial statements. Beginning with the financial statements and the notes thereto included in this quarterly report, all references to authoritative accounting literature (including references related to periods prior to the establishment of the Codification) will be referenced in accordance with the Codification.

In May 2009, the FASB issued guidance within ASC Topic 855, "Subsequent Events," relating to subsequent events. This guidance establishes principles and requirements for subsequent events. This guidance defines the period after the balance sheet date during which events or transactions that may occur would be required to be disclosed in a company's financial statements. Public entities are required to evaluate subsequent events through the date that financial statements are issued. This guidance also provides guidelines for evaluating whether or not events or transactions occurring after the balance sheet date should be recognized in the financial statements. This guidance requires disclosure of the date through which subsequent events have been evaluated. The Company has evaluated subsequent events immediately prior to the date of issuance of this report.

In April 2009, the FASB issued guidance within ASC Topic 825, "Financial Instruments Overall," concerning interim disclosures about fair value instruments. This guidance requires that disclosures about the fair value of a company's financial instruments be made whenever summarized financial information for interim reporting periods is made. The provisions of this guidance are effective for interim periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's financial statements.

Effective January 1, 2009, the Company adopted ASC Topic 810, "*Non-controlling Interests in Consolidated Financial Statements.*" This statement amends Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to establish accounting and reporting standards for a non-controlling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. This statement clarifies that a non-controlling interest in a subsidiary is an ownership in the consolidated entity that should be reported as equity in the consolidated financial statements. The adoption of ASC Topic 810 impacted the presentation and disclosure of noncontrolling (minority) interests in the

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Recent Accounting Pronouncements (Continued)

Company's condensed consolidated financial statements. ASC Topic 810 was applied prospectively. The noncontrolling (minority) interest relates to the third party shareholders of Synergy who own approximately 41% of Synergy as of September 30, 2009. The net loss attributable to the Synergy non-controlling interest totaled \$1,899,498 during the nine months ended September 30, 2009. This amount was recorded as a reduction in net loss and stockholder's deficit in the condensed consolidated financial statements prospectively after adoption of ASC Topic 810 on January 1, 2009. The net loss attributable to the non-controlling interest of \$1,139,746 for the period from July 14, 2008 (inception of non-controlling interest) to December 31, 2008 was not retrospectively adjusted in Callisto's Consolidated Financial Statements for the period ended and as of December 31, 2008 because the non-controlling interest had been reduced to zero. If this amount had been recorded, Callisto's net loss available to common stockholders would have been reduced by \$1,139,746 to \$89,847,521 from inception through December 31, 2008.

4. Accounting for share-based payments

The Company periodically issues stock options and warrants to employees and non-employees in capital raising transactions, for services and for financing costs. The Company adopted ASC Topic 718 for employee awards effective January 1, 2006, and is using the modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of ASC Topic 718 for all share-based payments granted after the effective date and (b) based on the requirements of ASC Topic 718 for all awards granted to employees prior to the effective date of ASC Topic 718 that remained unvested on the effective date.

The Company accounts for stock option and warrant grants issued and vesting to non-employees in accordance with ASC Topic 505: "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and ASC Topic 505 "Accounting Recognition for Certain Transactions involving Equity Instruments Granted to Other Than 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.

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for share-based payments (Continued)

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, 2009
	2009	2008	2009	2008	
Employees included in research and development	\$ 6,303	\$ 10,408	\$ 20,244	\$ 33,354	\$ 2,682,128
Employees included in general and administrative	9,696	28,741	37,614	133,684	4,787,568
Subtotal employee stock option grants	15,999	39,149	57,858	167,038	7,469,696
Non-employee research and development		(20,891)		(17,317)	102,750
Non-employee general and administrative	(25,903)	17,447	58,600	17,535	9,898,998
Subtotal non-employee stock option grants	(25,903)	(3,444)	58,600	221	10,001,748
Total stock based compensation expense	\$ (9,904)	\$ 35,705	\$ 116,458	\$ 167,259	\$ 17,471,444

The unrecognized compensation cost related to employee non-vested Callisto stock options outstanding at September 30, 2009, net of expected forfeitures, was \$26,604, to be recognized over a weighted average vesting period of approximately five months. The weighted-average remaining term of all options outstanding at September 30, 2009 was 4.6 years as compared to 5.1 years at December 31, 2008.

The estimated fair value of each employee stock option award was determined on the date of grant using the Black-Scholes option valuation model. Callisto granted no stock options to employees, and no stock options were exercised, during the three and nine months ended September 30, 2009 and 2008. A summary of stock option activity and of changes in Callisto stock options outstanding under Callisto's plans is presented below:

	Number of options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value as of September 30, 2009
Balance outstanding, December 31, 2008	7,938,538	\$ 0.08 - 6.75	\$ 1.72	\$
Granted		\$	\$	
Forfeitures	(301,666)	\$ 0.75 - 1.95	\$ 1.81	
Balance outstanding, September 30, 2009	7,636,872	\$ 0.08 - 6.75	\$ 1.72	\$
Exercisable as of September 30, 2009	5,856,706	\$ 0.47 - 6.75	\$ 1.61	\$

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for share-based payments (Continued)

Synergy Options

Synergy adopted The 2008 Equity Compensation Incentive Plan (the "Plan") on July 3, 2008. Stock options granted under the Plan typically vest after three years of continuous service from the grant date and have a contractual term of ten years. Synergy did not issue stock options prior to the quarter ended September 30, 2008. Synergy granted no stock options during the quarter ended September 30, 2009. Synergy periodically issues stock options to employees and non-employees and has adopted ASC Topic 718 for employee awards on July 3, 2008 concurrently with adoption of the Plan. Prior to that date Synergy had not issued any stock options. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505: "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and ASC Topic 505 "Accounting Recognition for Certain Transactions Involving Equity Instruments Granted to Other Than Employees" whereas the value of the stock compensation is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete.

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

	Three Months Ended September 30,		Nine Months Ended September 30		November 15, 2005 (inception) to September 30, 2009
	2009	2008	2009	2008	
Employees included in research and development	\$ 115,615	\$ 37,009	\$ 201,911	\$ 37,009	281,440
Employees included in general and administrative	185,133	55,409	297,902	55,409	410,629
Non-employees included in research and development	8,548		25,366		33,914
Non-employees included in general and administrative	196,847	108,728	335,249	108,728	514,328
Total stock-based compensation expense	\$ 506,143	\$ 201,146	\$ 860,428	\$ 201,146	\$ 1,240,311

The unrecognized compensation cost related to non-vested employee stock options outstanding at September 30, 2009, net of expected forfeitures, was \$1,104,724, to be recognized over a weighted-average remaining vesting period of approximately one year.

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Accounting for share-based payments (Continued)

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

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value
Balance outstanding, December 31, 2008	4,080,016	\$ 0.25 - 0.95	\$ 0.29	\$ 8,933,935
Granted				
Exercised				
Forfeited				
Balance outstanding, September 30, 2009	4,080,016	\$ 0.25 - 0.95	\$ 0.29	\$ 11,300,344
Exercisable at September 30, 2009	1,381,587	\$ 0.25 - 0.60	\$ 0.28	\$ 3,847,259

Synergy Restricted Stock Units

Restricted Stock Units, which issue to the holder a specified number of shares of Synergy common stock are accounted for as stock based compensation in accordance with ASC Topic 718 in the same manner as stock options using fair value at the date of grant. Subject to a repurchase agreement, according to which, 50% of the units are released after 1 year of continuous service and the remaining 50% are released after 2 years of continuous service from the grant date.

On July 3, 2008, 874,760 restricted stock units were issued by Synergy-DE and assumed by Synergy as part of the Exchange Transaction and are subject to a repurchase agreement, as defined. These restricted stock units were issued to certain officers and a consultant of Synergy. The fair value of each Synergy restricted stock unit is estimated on the grant date based on the price paid by shareholders participating in Synergy's July 14, 2008 private placement. As of September 30, 2009 there were 874,760 Synergy restricted stock units outstanding. The fair value of the 874,760 Synergy restricted stock units on the date of grant was \$524,856 of which \$230,361 and \$327,960 was recorded as stock-based compensation expense during the three and nine months ended September 30, 2009. As of September 30, 2009 the unrecognized fair value of the 165,485 unvested stock units was \$99,290 to be amortized over 9 months. The intrinsic value of the 874,760 outstanding restricted stock units was \$2,676,766 as of September 30, 2009, measured using the closing stock price of \$ 3.06 per share as of that date.

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

5. Net Loss per Share

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

5. Net Loss per Share (Continued)

common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares since the inclusion of issuable shares pursuant to the exercise of stock options and warrants, and the conversion of preferred stock would have been antidilutive. The following table sets forth the potentially dilutive effect of all outstanding derivative instruments which were not included in weighted average common shares outstanding as of:

	September 30, 2009	September 30, 2008
Common Shares outstanding	50,914,341	47,218,161
Potentially dilutive common shares issuable upon:		
Exercise of warrants	85,048,089	43,852,920
Exercise of stock options	7,636,872	7,911,038
Conversion of Series A Convertible Preferred Stock	1,760,000	4,298,500
Conversion of Series B Convertible Preferred Stock	21,583,320	22,741,000
Total fully diluted	166,942,622	126,021,619

6. Derivative Financial Instruments

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

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, certain warrants (the "New Warrants") issued in connection with the issuance of the 11% Notes (see Note 8 below) must now be treated as derivative liabilities in the Company's statement of financial position. Prior to the adoption of ASC Topic 815-40, the Company accounted for the Warrants as components of stockholders' equity.

Consistent with ASC Topic 815's requirements, the Company recognized the cumulative effect of the change in accounting principle to reduce the opening balance of the deficit accumulated during the development stage for fiscal year 2009. The cumulative effect adjustment of \$1,903,900 represents the difference between the amounts recognized in the statement financial position before initial application of ASC Topic 815 on January 1, 2009 and the initial fair value of the warrants. Additionally, the initial relative fair value of the Warrants, aggregating \$181,732, which were initially recorded as additional paid-in capital upon issuance, was reclassified to long-term liabilities upon adoption of Topic 815. (See Note 8.) The total amount recognized at initial issuance of \$2,085,632 was determined based on the estimated fair value of the New Warrants using a Black-Scholes option pricing model.

Prospectively, the New Warrants will be re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value will be recorded as non-cash valuation adjustments within other income (expense) in the Company's statement of operations. The Company estimates the fair value of the New Warrants using the Black-Scholes option pricing model in order to

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

6. Derivative Financial Instruments (Continued)

determine the associated derivative instrument liability described above. The assumptions used for the three and nine months ended September 30, 2009 are noted in the following table:

	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
Expected option term	7.25 years	7.25 to 8 years
Risk-free interest rate	2.93%	2.27% to 3.33%
Expected volatility	100%	150% to 200%
Dividend yield	0%	0%

Expected volatility is based on historical volatility of the Company's common stock. The New Warrants have a transferability provision and based on guidance provided in ASC Topic 718 for options issued with such a provision, we used the full contractual term as the expected term of the New Warrants. The risk free rate is based on the U.S. Treasury security rates consistent with the expected term of the New Warrants.

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

Date	Description	New Warrants	Derivative Instrument Liability
12/31/2008	Initial relative fair value of New Warrants, upon issuance	23,216,230	\$ 181,732
01/01/2009	Cumulative effect adjustment upon adoption of ASC Topic 815		\$ 1,903,900
01/01/2009	Fair value of New Warrants upon adoption of ASC Topic 815	23,216,230	\$ 2,085,632
03/31/2009	Change in fair value of warrants outstanding on December 31, 2008 during the quarter ended March 31, 2009		\$ (232,505)
01/31/2009	Fair value of New Warrants issued during the quarter ended March 31, 2009, on date of issuance	5,633,726	\$ 562,270
03/31/2009	Change in fair value of New Warrants issued during the quarter ended March 31, 2009		\$ (112,662)
03/31/2009	Balance of derivative financial instruments March 31, 2009	28,849,956	\$ 2,302,735
06/30/2009	Change in fair value of warrants outstanding on March 31, 2009, during the quarter ended June 30, 2009		\$ 5,712,513
06/17/2009	Fair value of New Warrants issued during the quarter ended June 30, 2009, on date of issuance	40,236,218	\$ 4,365,620
06/30/2009	Change in fair value of New Warrants issued during the quarter ended June 30, 2009		\$ 6,812,325
06/30/2009	Balance of derivative financial instruments June 30, 2009	69,086,174	\$ 19,193,193
09/30/2009	Change in fair value of New Warrants issued during the quarter ended September 30, 2009		\$ 5,735,936
09/30/2009	Balance of derivative financial instruments September 30, 2009	69,086,174	\$ 24,929,129

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

7. Fair Value Measurements

The unrealized losses on the derivative liabilities are classified in other income or (expenses) as a change in derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company performs a detailed analysis of the assets and liabilities that are subject to ASC Topic 820. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of September 30, 2009:

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of September 30, 2009
Derivative liabilities related to Warrants	\$	\$	\$ 24,929,129	\$ 24,929,129

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the nine months ended September 30, 2009:

Description	Balance at December 31, 2008	Cumulative Effect of the Adoption of ASC Topic 820 (See Note 4)	Unrealized Losses	Balance as of September 30, 2009
Derivative liabilities related to Warrants	\$	\$ 2,085,632	\$ 22,843,497	\$ 24,929,129

8. Stockholders' deficit

During the nine months ended September 30, 2009 Synergy sold 10,332,144 shares of unregistered common stock at \$0.70 per share to private investors, pursuant to a Securities Purchase Agreement, for aggregate proceeds of \$7,232,500. There were no warrants issued in connection with these transactions. Synergy incurred \$235,000 in fees to selling agents and \$10,000 in legal fees in connection with certain of these transactions. Pursuant to the Securities Purchase Agreement the investors agreed to be subject to a lock-up until August 15, 2010 and Synergy agreed to price protection for the investors in the event of subsequent sales of equity securities as defined, until February 15, 2011. In accordance with the guidance contained in ASC Topic 815-40, the Company has determined that the price protection provisions are embedded derivatives that require bifurcation and recognition at fair value in the company's financial statements. The Company has determined that the fair value of the derivatives is immaterial. As of September 30, 2009 Callisto owns approximately 59% of Synergy's outstanding shares.

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

8. Stockholders' deficit (Continued)

On September 16, 2009, the Company amended the Series A and Series B Convertible Preferred Stock to eliminate the liquidation preference and decrease the conversion price of the Series A and B Convertible Preferred Stock to \$0.36 per share from \$0.50 per share. The closing price of the Company's common stock on September 16, 2009 was \$0.20 per share. This modification resulted in the prospective issuance of an additional 684,444 and 8,393,513 of Callisto common stock in the event of the conversion of the remaining Series A and B Preferred Stock, respectively. The additional shares of Callisto common stock, valued at the share price on the date of the modification, have been accounted for as a dividend on the Series A and B Convertible Preferred Stock totaling \$136,889 and \$1,678,703, respectively, during the three months ended September 30, 2009.

During the nine months ended September 30, 2009, 10,000 shares of Series A Convertible Preferred Stock were converted to 200,000 shares of common stock and 57,884 shares of Series B Convertible Preferred Stock were converted to 1,157,680 shares of common stock, at conversion price of \$0.50 per share.

On December 30, 2008, Callisto entered into a securities purchase and exchange agreement ("Purchase Agreement") with several investors, each of whom were holders of record as of November 4, 2008 of outstanding warrants to purchase shares of the Company's common stock, exercisable at \$0.50 or \$0.70 per share until August 2, 2010 ("Series B Warrants"). The Series B Warrants were issued in connection with the private placement of the Company's Series B Preferred Shares on August 2, 2007. During the period from December 30, 2008 to June 17, 2009, pursuant to the Purchase Agreement, Callisto issued \$603,163 principal amount of 11% Secured Notes due April 15, 2010 ("11% Notes"). Interest on the 11% Notes is due at maturity and repayment of the 11% Notes is secured by a pledge of up to 2,292,265 shares of the common stock of Synergy owned by Callisto. Pursuant to the Purchase Agreement, Callisto issued 69,086,174 common stock purchase warrants (see Note 6) ("New Warrants") in exchange for the surrender and cancellation of 26,938,800 outstanding Series B Warrants. The New Warrants have an exercise price, subject to certain anti-dilution adjustments, of \$0.02 per share and are exercisable at any time on or prior to December 31, 2016. In connection with the issuance of \$349,880 of the \$603,163 11% Notes in June 2009, Callisto entered into an additional security agreement granting all of the holders of the 11% Notes a security interest in the Atiprimod technology acquired by the Company in December 2008.

The proceeds from the issuance of these instruments were allocated to the 11% Notes and the New Warrants based upon the relative fair values of the 11% Notes and the New Warrants. The New Warrants had a fair value of \$6,781,471 upon issuance, measured utilizing the Black Scholes fair value methodology using assumptions ranging from 7.5 to 8 years for expected term, volatility of 150% to 200%, no dividends and risk free interest rates ranging from 1.76% to 3.33%. This resulted in a debt discount of \$552,728 apportioned to the New Warrants recorded as additional paid in capital and the balance of \$20,176 was reflected on the Company's balance sheet as long term notes as of December 31, 2008. The debt discount of \$552,728 will be accreted to the 11% Notes as interest expense over the life of the 11% Notes and such accretion totaled \$144,116 and \$244,131 for the three and nine months ended September 30, 2009, respectively.

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

8. Stockholders' deficit (Continued)

The following table summarizes the financial impact of the 11% Notes payable and the related interest expense for the period from December 30, 2008 through September 30, 2009:

	11% Notes Payable	Interest expense
11% Notes issued during the year ended December 31, 2008	\$ 201,908	\$
Apportionment of net proceeds to New Warrants recorded as additional paid in capital (11% Note discount)	(181,732)	
11% Notes balance at December 31, 2008	20,176	
11% Notes issued during the three months ended March 31, 2009	51,375	
Accretion of 11% Note discount to interest expense	34,800	34,800
11% nominal interest expense	6,685	6,685
11% Notes balance March 31, 2009	\$ 113,036	\$ 41,485
11% Notes issued during the three months ended June 30, 2009	349,880	
Apportionment of net proceeds to New Warrants recorded as additional paid in capital (11% Note discount)	(370,996)	
Accretion of 11% Note discount to interest expense	65,215	65,215
11% nominal interest expense	8,317	8,317
11% Notes Balance June 30, 2009	\$ 165,452	\$ 115,017
Accretion of 11% Note discount to interest expense	144,116	144,116
11% nominal interest expense	16,723	16,723
11% Notes Balance September 30, 2009	\$ 326,291	\$ 275,856

9. Subsequent events

On October 30, 2009, Synergy sold 9,389,428 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$6,572,600, pursuant to a Securities Purchase Agreement dated as of October 30, 2009. On November 5, 2009, Synergy sold 1,114,286 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$780,000, pursuant to a Securities Purchase Agreement dated as of November 5, 2009. On November 12, 2009, Synergy sold 1,664,284 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$1,165,000, pursuant to a Securities Purchase Agreement dated as of November 12, 2009.

Table of Contents

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

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

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2008 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.

Callisto Pharmaceuticals, Inc. (which may be referred to as "Callisto", "the Company", "we" or "us") was incorporated under the laws of the State of Delaware in May 2003. Our principal offices are located at 420 Lexington Avenue, Suite 1609, New York, NY 10170. We are a development stage biopharmaceutical company focused primarily on the development of drugs to treat neuroendocrine cancer (including advanced carcinoid cancer), rheumatoid arthritis ("RA"), acute leukemia and gastrointestinal ("GI") disorders and diseases. Our current drug candidates are as follows:

1. SP-304, a guanylyl cyclase C ("GC-C") receptor agonist, to treat GI disorders, primarily chronic constipation ("CC") and constipation-predominant irritable bowel syndrome ("IBS-C"), currently being developed by our majority-owned subsidiary, Synergy Pharmaceuticals, Inc. ("Synergy").
2. Atiprimod, an orally administered drug with antiproliferative and antiangiogenic activity.
3. L-Annamycin, a novel compound from the anthracycline family of proven anti-cancer drugs, which has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart.

From inception through September 30, 2009, we have sustained cumulative net losses available to common stockholders of \$121,556,718. Our 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 and the change in fair value of derivative financial instruments. From inception through September 30, 2009, 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.

Table of Contents

Our product development efforts are thus in their early stages and we cannot make estimates of the costs or the time they will take to complete. The risk of completion of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, our ability to raise additional capital, the nature and timing of research and development expenses and competing technologies being developed by organizations with significantly greater resources.

We will be required to raise additional capital within the next year to complete the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Recent Developments

On October 30, 2009, Synergy closed a private placement of 9,389,428 shares of Common Stock to certain investors (the "Investors") at a per share price of \$0.70 for aggregate gross proceeds of \$6,572,600 pursuant to a Securities Purchase Agreement dated as of October 30, 2009. On November 5, 2009, Synergy sold 1,114,286 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$780,000, pursuant to a Securities Purchase Agreement dated as of November 5, 2009. On November 12, 2009, Synergy sold 1,664,284 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$1,165,000, pursuant to a Securities Purchase Agreement dated as of November 12, 2009.

On September 16, 2009, the Company amended the Series A and Series B Convertible Preferred Stock to eliminate the liquidation preference and decrease the conversion price of the Series A and B Convertible Preferred Stock to \$0.36 per share from \$0.50 per share. The closing price of the Company's common stock on September 16, 2009 was \$0.20 per share. This modification resulted in the prospective issuance of an additional 684,444 and 8,393,513 of Callisto common stock in the event of the conversion of the remaining Series A and B Preferred Stock, respectively.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2009.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2009 AND SEPTEMBER 30, 2008

We had no revenues during the three months ended September 30, 2009 and 2008 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 increased \$217,204 or 21% to \$1,265,432 for the three months ended September 30, 2009 from \$1,048,228 for the three months ended September 30, 2008. This increase in research and development expense was attributable to re-accelerating the development work

Table of Contents

on Synergy's SP-304 candidate as Synergy was able to continue to raise capital during the quarter. This was partially offset by a significant curtailment of Callisto's cancer drug development due to lack of funding. Program expenses include those incurred with outside contract research organizations ("CROs") for pre-clinical animal testing, drug formulation, tableting as well as hospital patient costs, blood testing and FDA consultants. Our SP-304 program expenses increased by approximately \$586,000 to approximately \$1,105,000 for the three months ended September 30, 2009 from approximately \$519,000 during the three months ended September 30, 2008, principally due to commencement of animal studies in the third quarter. Offsetting this were lower Atiprimod program expenses which decreased by approximately \$304,000 for the three months ended September 30, 2009 and lower Annamycin program expenses which decreased by approximately \$19,000. Research and development in-house overhead, not allocated to specific programs, totaled approximately \$143,000 and \$189,000 during the three months ended September 30, 2009 and 2008, respectively. This decrease of \$46,000 was primarily attributable to completion of our cancer trial during 2008.

General and administrative expenses for the three months ended September 30, 2009 decreased \$108,696 or 9%, to \$1,144,572 from \$1,253,268 for the three months ended September 30, 2008. This decrease was primarily due to decreased accounting and audit fees by approximately \$109,000, (ii) reduced professional fees including investment banking and public relations, lower by approximately \$76,000 and (iii) lower salaries and other employment related cost, down approximately \$55,000. These lower cash based expenditure during the three months ended September 30, 2009 were partially offset by higher non-cash stock based compensation expense which increased by approximately \$155,000 to approximately \$366,000 during the three months ended September 30, 2009, attributable to lowering our fair value forfeiture rate assumptions because of new estimates.

Our loss from operation increased \$108,508 or 5% for the three months ended September 30, 2009 to \$2,410,004 from \$2,301,496 for the three months ended September 30, 2008 due to higher research and development, partially offset by lower general and administrative expenses discussed above.

Net loss available to common stockholders for the three months ended September 30, 2009 increased \$7,619,325 or 436% to \$9,367,677 compared to a net loss of \$1,748,352 incurred for the three months ended September 30, 2008. The increased net loss is the result of higher loss from operations discussed above, plus (i) higher interest expense of \$160,839 attributable to our 11% Notes, (ii) a \$5,735,936 non-cash charge incurred to mark to market the estimated fair value of our derivative financial instruments during the three months ended September 30, 2009 and (iii) Series A and B Convertible Preferred Stock dividends totaling \$1,815,592 resulting from the reset of the conversion price from \$0.50 per share to \$0.36 per share; partially offset by (iv) a higher credit of \$743,755 for the net losses attributable to the non-controlling interest in Synergy, our majority owned subsidiary, as compared to a credit of \$538,724 for the three months ended September 30 2008.

NINE MONTHS ENDED SEPTEMBER 30, 2009 AND SEPTEMBER 30, 2008

We had no revenues during the nine months ended September 30, 2009 and 2008 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 decreased \$1,321,239 or 32% to \$2,808,517 for the nine months ended September 30, 2009 from \$4,129,756 for the nine months ended September 30, 2008. This decrease in research and development expense was attributable to a curtailment of all development program expenses due to lack of funding. Program expenses include those incurred with outside CRO's for pre-clinical animal testing, drug formulation, tableting as well as hospital patient costs, blood testing and FDA consultants. Our most active program was SP-304 where expenses decreased by approximately \$123,000 to approximately \$2,553,000 for the nine months ended September 30, 2009 from approximately \$2,676,000 during the nine months ended September 30, 2008,

Table of Contents

Also lower were Atiprimod program expenses which decreased by approximately \$483,000 to \$20,000 for the nine months ended September 30, 2009 and lower Annamycin program expenses which decreased by approximately \$162,000 to approximately \$86,000 for the nine months ended September 30, 2009 from approximately \$248,000 during the nine months ended September 30, 2008. Research and development in-house overhead, not allocated to specific programs, totaled approximately \$149,000 and \$702,000 during the nine months ended September 30, 2009 and 2008, respectively. This decrease of \$553,000 was primarily attributable to lower clinical monitor salaries and travel due to the completion of our cancer trials during 2008.

General and administrative expenses for the nine months ended September 30, 2009 decreased \$87,451 or 3%, to \$3,203,745 from \$3,291,196 for the nine months ended September 30, 2008. This decrease was primarily due to (i) decreased accounting and audit fees, reduced by approximately \$125,000, (ii) reduced professional fees including investment banking and public relations, lower by approximately \$147,000, (iii) lower facilities and related overhead, down approximately \$164,000 and (iv) lower salaries and other employment related cost, down approximately \$11,000. These lower cash based expenditure during the nine months ended September 30, 2009 were partially offset by higher non-cash stock based compensation expense which increased by approximately \$414,000 to approximately \$729,000 during the nine months ended September 30, 2009, attributable to lowering our fair value forfeiture rate assumptions on Synergy stock options based on new estimates.

Our loss from operation decreased \$1,378,690 or 19% for the nine months ended September 30, 2009 to \$6,012,262 from \$7,390,952 for the nine months ended September 30, 2008 due to lower research and development and lower general and administrative expenses discussed above.

Net loss available to common stockholders for the nine months ended September 30, 2009 increased \$21,881,357 or 323% to \$28,665,551 compared to a net loss of \$6,784,194 incurred for the nine months ended September 30, 2008. The increased net loss is the result of lower loss from operations discussed above, more than offset by (i) interest income lower by \$56,870 attributable to lower cash balances, (ii) higher interest expense of \$275,856 attributable to our 11% Notes, (iii) a \$22,472,503 non-cash charge incurred to record and then mark to market the estimated fair value of our derivative financial instruments during the nine months ended September 30, 2009 and (iv) Series A and B Convertible Preferred Stock dividends totaling \$1,815,592 resulting from the reset of the conversion price from \$0.50 per share to \$0.36 per share; partially offset by (v) a credit of \$1,899,498 for the net losses attributable to the non-controlling interest in Synergy, our majority owned subsidiary, as compared to a credit of \$538,724 for the nine months ended September 30 2008.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2009 we had \$3,212,010 in cash and cash equivalents, compared to \$301,323 as of December 31, 2008. We had a working capital deficit of \$2,228,027 as of September 30, 2009 as compared to a working capital deficit of \$4,260,826 as of December 31, 2008. Net cash used in operating activities was \$4,679,976 during the nine months ended September 30, 2009 as compared to \$7,378,309 for the nine months ended September 30, 2008. To date, our sources of cash have been primarily limited to the sale of equity securities. Net cash provided by financing activities for the nine months ended September 30, 2009 was \$7,590,663 as compared to \$2,951,913 for the nine months ended September 30, 2008.

On October 30, 2009, Synergy sold 9,389,428 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$6,572,600, pursuant to a Securities Purchase Agreement dated as of October 30, 2009. On November 5, 2009, Synergy sold 1,114,286 shares of unregistered common stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$780,000, pursuant to a Securities Purchase Agreement dated as of November 5, 2009. On November 12, 2009, Synergy sold 1,664,284 shares of unregistered common

Table of Contents

stock to certain investors, at a per share price of \$0.70, for aggregate gross proceeds of \$1,165,000, pursuant to a Securities Purchase Agreement dated as of November 12, 2009.

On September 16, 2009, the Company amended the Series A and Series B Convertible Preferred Stock to eliminate the liquidation preference and decrease the conversion price of the Series A and B Convertible Preferred Stock to \$0.36 per share from \$0.50 per share. The closing price of the Company's common stock on September 16, 2009 was \$0.20 per share. This modification resulted in the prospective issuance of an additional 684,444 and 8,393,513 of Callisto common stock in the event of the conversion of the remaining Series A and B Preferred Stock, respectively.

Worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult for us to obtain additional equity or credit financing, when needed. We have accordingly taken steps to conserve our cash which include extending payment terms to our vendors and suppliers as well as management and staff cuts and salary deferrals. These actions may not be sufficient to allow us time to raise additional capital.

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of pharmaceutical research and development programs. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates, to fund the existing working capital deficit and to continue to fund operations at our current cash expenditure levels. To date, our sources of cash have been primarily limited to the sale of equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more of product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Our consolidated financial statements as of September 30, 2009 and December 31, 2008 have been prepared under the assumption that we will continue as a going concern for the twelve months ending December 31, 2009. Our independent registered public accounting firm has issued a report dated April 15, 2009 that included an explanatory paragraph referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

CRITICAL ACCOUNTING POLICIES

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 years ended December 31, 2008 and 2007, filed with the SEC on April 15, 2009.

Table of Contents

Derivative Instruments Liability

Effective January 1, 2009, we adopted ASC Topic 815, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock" ("ASC Topic 815"). ASC Topic 815 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.

Based upon our analysis of the ASC Topic 815 criteria, certain warrants (the "New Warrants") issued in connection with the issuance of the 11% Notes must now be treated as derivative liabilities in our balance sheet. Prior to the adoption of ASC Topic 815, we accounted for the Warrants as components of stockholders' equity. Prospectively, the New Warrants will be re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value will be recorded as non-cash valuation adjustments within other income (expense) in the our statement of operations. (See Note 6, 7 and 8 to our condensed consolidated financial statements for a more detailed discussion of the financial impact of these accounting policies).

During the nine months ended September 30, 2009 the change in estimated fair value of derivative financial instruments has resulted in an expense of \$22,472,503 or approximately 78% of our net loss available to common stockholders of \$28,665,551.

Research and Development

We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all and therefore our research and development costs are expensed as incurred. These include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of our proposed products, purchase of in-process research and development, regulatory and scientific consulting fees, contract research and royalty payments to outside suppliers, facilities and universities as well as legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products. While certain of our research and development costs may have future benefits, our policy of expensing all research and development expenditures is predicated on the fact that we have no history of successful commercialization of biopharmaceutical products to base any estimate of the number of future periods that would be benefited.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

There have been no changes in our contractual obligations and commitments during the three months ended September 30, 2009.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk on the fair values of certain assets is related to credit risk associated with securities held in money market accounts and the FDIC insurance limits on our bank balances. At September 30, 2009, we had approximately \$3,100,000 in money market balances.

ITEM 4T. 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, 2009, our Chief Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were not effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the

Table of Contents

Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms.

In connection with the preparation of our annual financial statements, our management performed an assessment of the effectiveness of internal control over financial reporting as of December 31, 2008. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls. Based on this evaluation, management determined that, as of December 31, 2008, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management's assessment were (i) a lack of sufficient internal accounting expertise to provide reasonable assurance that our financial statements and notes thereto, are prepared in accordance with generally accepted accounting principles (GAAP) and (ii) a lack of segregation of duties to ensure adequate review of financial statement preparation. In light of these material weaknesses, management concluded that, as of December 31, 2008, we did not maintain effective internal control over financial reporting. As defined by the Public Company Accounting Oversight Board Auditing Standard No. 5, 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.

The condensed consolidated financial statements as of and for the period ended September 30, 2009 include all adjustments identified as a result of the evaluation performed.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As of September 30, 2009 we have added financial staff resources to our accounting and finance department to improve controls surrounding both the segregations of duties and accounting expertise. Management believes this will substantially reduce the risk of a material misstatement resulting from the material weaknesses described above. However, it will require a period of time to determine the operating effectiveness of these newly implemented internal controls over financial reporting.

Other than described above there were no changes in our internal controls over financial reporting that could significantly affect internal controls over financial reporting during the three months ended September 30, 2009.

Table of Contents

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

There have been no material changes from the legal proceedings disclosed in our Form 10-K for the year ended December 31, 2008.

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2008.

ITEM 6. EXHIBITS

(a)

Exhibits

- 31.1 Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
- 31.2 Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

