

CALLISTO PHARMACEUTICALS INC
Form 10-Q
August 14, 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: JUNE 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

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 June 30, 2009 (unaudited) and December 31, 2008</u>	<u>2</u>
	<u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2009 and 2008 (unaudited) and the period June 5, 1996 (Inception) to June 30, 2009 (unaudited)</u>	<u>2</u>
	<u>Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period June 5, 1996 (Inception) to June 30, 2009 (unaudited)</u>	<u>3</u>
	<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2009 and 2008 (unaudited) and for the period June 5, 1996 (Inception) to June 30, 2009 (unaudited)</u>	<u>4</u>
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>12</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>14</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>27</u>
<u>Item 4T.</u>	<u>Controls and Procedures</u>	<u>33</u>

PART II OTHER INFORMATION

<u>Item 1</u>	<u>Legal proceedings</u>	<u>35</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>35</u>
<u>Item 6.</u>	<u>Exhibits</u>	<u>35</u>
<u>Signatures</u>		<u>36</u>

Table of Contents

INTRODUCTORY NOTE

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

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

	June 30, 2009 (Unaudited)	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 3,709,014	\$ 301,323
Cash in escrow		201,908
Prepaid expenses and other		59,756
Total Current Assets	3,709,014	562,987
Property and equipment, net	17,300	20,649
Security deposits	78,116	78,116
Total Assets	\$ 3,804,430	\$ 661,752
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Notes Payable secured short term	\$ 165,452	\$
Accounts payable	4,413,050	3,687,549
Accrued expenses	1,293,000	1,136,264
Total Current Liabilities	5,871,502	4,823,813
Notes payable secured long term		20,176
Derivative financial instruments, at estimated fair value warrants	19,193,193	
Total Liabilities	25,064,695	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 with a liquidation preference of \$880,000 and \$980,000 at June 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 with a liquidation preference of \$10,791,660 and \$11,370,500 at June 30, 2009 and December 31, 2008, respectively	108	114
Common stock, par value of \$.0001 per share: Authorized 225,000,000 shares at December 31, 2008; 50,914,341 and 49,556,661 shares outstanding at June 30, 2009 and December 31, 2008, respectively	5,091	4,955

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Additional paid-in capital	92,079,311	86,799,951
Deficit accumulated during development stage	(112,189,041)	(90,987,267)
Total Stockholders' Deficit	(20,104,522)	(4,182,237)
Non-controlling interest	(1,155,743)	
Total Deficit	(21,260,265)	(4,182,237)
Total Liabilities and Stockholders' Deficit	\$ 3,804,430	\$ 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 June 30		Six Months Ended June 30,		June 5, 1996
	2009	2008	2009	2008	(Inception) to June 30, 2009
Revenues	\$	\$	\$	\$	\$
Costs and expenses:					
Research and development	1,145,063	1,064,545	1,543,085	3,081,528	35,641,349
Government grants		(30,000)		(30,000)	(1,135,318)
Purchased in process research and development					6,944,553
General and administrative	1,102,595	1,017,615	2,059,171	2,037,927	41,037,777
Loss from operations	(2,247,658)	(2,052,160)	(3,602,256)	(5,089,455)	(82,488,361)
Interest and investment income	14	8,077	225	53,614	864,552
Other income (expense), net	(73,532)		(115,018)		(286,864)
Change in fair value of derivative instruments - warrants	(16,519,465)		(16,736,568)		(14,145,563)
Net loss	(18,840,641)	(2,044,083)	(20,453,617)	(5,035,841)	(96,056,236)
Net Loss attributable to non-controlling interest	836,853		1,155,743		1,155,743
Net loss attributable to controlling interest	(18,003,788)	(2,044,083)	(19,297,874)	(5,035,841)	(94,900,493)
Series A Preferred stock beneficial conversion feature accreted as a dividend					(4,888,960)
Series A Preferred stock beneficial conversion feature accreted as a dividend					(10,495,688)
Net loss available to common stockholders	\$(18,003,788)	\$(2,044,083)	\$(19,297,874)	\$(5,035,841)	\$(110,285,141)
Weighted average shares outstanding:					
basic and diluted	50,846,570	47,218,161	50,737,615	47,171,183	
Net loss per common share:					
basic and diluted	\$ (0.35)	\$ (0.04)	\$ (0.38)	\$ (0.11)	

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					

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Amortization of Stock based
Compensation

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

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

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

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

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 FAS 123R					(1,583,463)	1,583,463		
Stock based compensation expense					2,579,431			2,579,431
Common stock issued via private placement:								
February 2006			4,283,668	428	5,139,782			5,140,210
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 Convertible Preferred Shares	Series A Convertible Preferred Stock, Par Value	Series B Convertible Preferred Shares	Series B Convertible Preferred Stock, Par Value	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance, December 31, 2006	586,125	\$ 58		\$	39,194,996	\$ 3,919	\$ 61,290,509	\$ (60,444,368)	\$ 850,118
Net loss for the year								(7,887,265)	(7,887,265)
Stock-based compensation expense							591,561		591,561
Common stock issued for services					80,000	8	36,792		36,800
Series A convertible preferred stock, issued via private placement	28,000	4					279,997		280,001
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 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 EITF Issue 07-05							(181,732)	(1,903,900)		(2,085,632)
Net loss for the period								(19,297,874)	(1,155,743)	(20,453,617)
Stock based compensation expense							480,648			480,648
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							5,138,500			5,138,500
Fees and expenses associated with private placements							(157,927)			(157,927)
Balance June 30, 2009	88,000	\$ 9	1,079,166	\$ 108	50,914,341	\$ 5,091	\$92,079,311	\$(112,189,041)	\$(1,155,743)	(21,260,265)

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six months ended June 30, 2009	Six months ended June 30, 2008	Period from June 5, 1996 (inception) to June 30, 2009
Cash flows from operating activities:			
Net loss	\$ (20,453,617)	\$ (5,035,841)	\$ (96,056,236)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	3,349	3,080	99,933
Purchase discount accreted as interest income on U.S. Treasury bills		(26,950)	(26,950)
Stock-based compensation expense	480,648	131,554	18,215,517
Purchased in-process research and development (non-cash portion)			6,841,053
Interest expense on notes payable	115,018		115,018
Stock-based liquidated damages			579,696
Change in fair value of derivative instruments warrants	16,736,568		14,145,563
Minority interest in net losses of majority owned subsidiary			(335,252)
Changes in operating assets and liabilities:			
Prepaid expenses	59,756	(33,303)	
Security deposit			(78,116)
Accounts payable and accrued expenses	882,233	(357,265)	5,706,047
Total adjustments	18,277,572	(282,884)	45,262,510
Net cash used in operating activities	(2,176,045)	(5,318,725)	(50,793,727)
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			(117,233)
Net cash used in investing activities		2,994,640	(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	5,138,500		8,090,413
Fees and expenses on private placement of majority owned subsidiary common stock	(157,927)		(157,927)
Exercise of common stock warrants			318,785
Net cash provided by financing activities	5,583,736		54,593,023

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Net increase (decrease) in cash and cash equivalents	3,407,691	(2,324,085)	3,709,014
Cash and cash equivalents at beginning of period	301,323	3,269,341	
Cash and cash equivalents at end of period	\$ 3,709,014	\$ 945,256	\$ 3,709,014

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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six months ended June 30, 2009	Six months ended June 30, 2008	Period from June 5, 1996 (inception) to June 30, 2009
Supplementary disclosure of cash flow information:			
Cash paid for taxes	\$ 17,891	\$ 11,481	\$ 179,615
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

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 in June of 1996, Callisto's efforts have been principally devoted to research and development, securing and protecting patents and raising capital. From inception through June 30, 2009, Callisto has sustained cumulative net losses available to common stockholders of \$110,285,141. 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 June 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 six months ended June 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 June 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, ultimately, to generate revenue. The financial statements do not include any adjustments that might

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)

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 \$2,176,045 during the six months ended June 30, 2009 as compared to \$5,318,725 for the six months ended June 30, 2008 and \$50,793,727 for the period from June 5, 1996 (inception) to June 30, 2009. 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 six months ended June 30, 2009 was \$5,583,736 as compared to \$0 for the six months ended June 30, 2008 and \$54,593,023 for the period from June 5, 1996 (inception) to June 30, 2009. Included in net cash provided by financing activities for the six months ended June 30, 2009 was primarily the Synergy private placement of 7,340,715 shares of unregistered common stock at \$0.70 per share to private investors for aggregate proceeds of \$5,138,500. Fees to selling agents and other costs of capital associated with the sale of certain common stock were \$157,927.

As of June 30, 2009 Callisto had a working capital deficit of \$1,997,036 as compared to \$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.

On July 2, 2009, Synergy sold 1,870,000 shares of unregistered common stock, to certain investors at a price of \$0.70 per share for aggregate gross proceeds of \$1,309,000. On July 6, 2009, Synergy sold 921,429 shares of unregistered common stock, to certain investors at a per share price of \$0.70 for aggregate gross proceeds of \$645,000. In July 2009 Synergy incurred fees to selling agents of \$87,073 in connection with its July 2009 private placements.

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.

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Recent Accounting Pronouncements

In June 2009, the FASB issued SFAS No. 168, *"The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162"* ("SFAS 168"), to formally establish the FASB Accounting Standards Codification ("Codification") to become the source of authoritative U.S. generally accepted accounting principles recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission ("SEC") under authority of federal securities laws are also sources of authoritative U.S. GAAP for SEC registrants. The subsequent issuances of new standards will be in the form of Accounting Standards Updates that will be included in the Codification. Generally, the Codification is not expected to change U.S. GAAP. All other accounting literature excluded from the Codification will be considered non-authoritative. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Company will adopt SFAS 168 for our quarter ending September 30, 2009. All future references to authoritative accounting literature will be references in accordance with the Codification.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events* ("SFAS 165"). SFAS 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued. SFAS 165 is effective for interim or annual financial periods ending after June 15, 2009, and is being applied prospectively. The Company adopted SFAS 165 on June 30, 2009 and has evaluated subsequent events through the date of the issuance of this report.

In April 2009, the FASB issued FSP 107-1 and Accounting Principles Board ("APB") 28-1, *Interim Disclosures about Fair Value of Financial Instruments* ("FSP 107-1"). FSP 107-1 amends SFAS No. 107, *Disclosures About Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FSP 107-1 also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods. FSP 107-1 was effective for interim reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. FSP 107-1 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP 107-1 requires comparative disclosures only for periods ending after initial adoption. The Company adopted the provisions of FSP FAS 107-1 on June 30, 2009, and its requirements are reflected herein.

In April 2009, the FASB issued FSP 115-2 and 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments* ("FSP 115-2 and 124-2"). FSP 115-2 and 124-2 amends the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. FSP 115-2 and 124-2 does not amend existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. FSP 115-2 and 124-2 is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. FSP 115-2 and 124-2 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP 115-2 and 124-2 requires comparative disclosures only for periods ending after

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Recent Accounting Pronouncements (Continued)

initial adoption. Callisto adopted FSP FAS 115-2 and FAS 124-2 on June 30, 2009 and the adoption did not have a material effect on its consolidated financial position, results of operations or cash flows.

In April 2009, the FASB issued FSP 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* (FSP 157-4"). FSP 157-4 provides additional guidance for estimating fair value in accordance with SFAS 157 when the volume and level of activity for the asset or liability have significantly decreased. FSP 157-4 also includes guidance on identifying circumstances that indicate a transaction is not orderly. FSP 157-4 is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. FSP 157-4 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP 157-4 requires comparative disclosures only for periods ending after initial adoption. Callisto adopted FSP FAS 157-4 on June 15, 2009 and the adoption did not have a material effect on its consolidated financial position, results of operations or cash flows.

Effective January 1, 2009, the Company adopted SFAS No. 160, *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 SFAS 160 impacted the presentation and disclosure of noncontrolling (minority) interests in the Company's condensed consolidated financial statements. SFAS 160 was applied prospectively. The noncontrolling (minority) interest relates to the third party shareholders of Synergy who own 38.9% of Synergy as of June 30, 2009. The net loss attributable to the Synergy non-controlling interest totaled \$1,155,743 during the six months ended June 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 SFAS No. 160 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.

In June 2008, the FASB ratified the consensus reached on Emerging Issues Task Force ("EITF") Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* ("EITF No. 07-05"). EITF No. 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities.* The Company adopted EITF No. 07-05 on January 1, 2009. See Note 6 below.

In February 2008, the FASB issued FSP No. 157-2, *Partial Deferral of the Effective Date of Statement 157*, ("FSP No. 157-2"). FSP No. 157-2 delays the effective date of SFAS No. 157, *Fair Value Measurements* ("SFAS No. 157") for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. Recent Accounting Pronouncements (Continued)

annually) to fiscal years beginning after November 15, 2008. The Company adopted SFAS No. 157 for nonfinancial assets and nonfinancial liabilities on January 1, 2009 and the adoption did not have a material impact on its consolidated financial position, results of operations or cash flows.

In December 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, ("EITF No. 07-1"), which provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure requirements. EITF No. 07-1 is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company adopted the provisions of EITF No. 07-1 on January 1, 2009 and the adoption did not have a material impact on its consolidated financial position, results of operations or cash flows.

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 SFAS No. 123R 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 SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of APB No. 25 for all awards granted to employees prior to the effective date of SFAS No. 123R 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 EITF No. 96-18: "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and EITF No. 00-18 "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 June 30,		Six Months Ended June 30,		June 5, 1996 (Inception) to June 30, 2009
	2009	2008	2009	2008	
Employees included in research and development	\$ 7,009	\$ 10,295	\$ 13,941	\$ 22,946	\$ 2,675,826
Employees included in general and administrative	9,591	51,200	27,918	104,943	4,777,871
Subtotal employee stock option grants	16,600	61,495	41,859	127,889	7,453,697
Non-employee research and development		(4,242)		3,577	102,750
Non-employee general and administrative	91,842	(25,770)	84,503	88	9,924,901
Subtotal non-employee stock option grants	91,842	(30,012)	84,503	3,665	10,027,651
Total stock based compensation expense	\$ 108,442	\$ 31,483	\$ 126,362	\$ 131,554	\$ 17,481,348

The unrecognized compensation cost related to employee non-vested Callisto stock options outstanding at June 30, 2009, net of expected forfeitures, was \$42,602, to be recognized over a weighted average vesting period of approximately six months. The weighted-average remaining term of all options outstanding at June 30, 2009 was 4.7 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 six months ended June 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 June 30, 2009
Balance outstanding, December 31, 2008	7,938,538	\$0.08 - 6.75	\$ 1.72	\$
Granted		\$	\$	
Forfeitures	(35,000)	\$ 0.75	\$ 0.75	
Balance outstanding, June 30, 2009	7,903,538	\$0.08 - 6.75	\$ 1.72	\$

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10-Q

Exercisable as of June 30, 2009	5,995,205	\$0.47 - 6.75	\$ 1.64	\$
---------------------------------	-----------	---------------	---------	----

19

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") during the quarter ended September 30, 2008. Stock options granted under the Plan typically vest after three years of continuous service from the grant date and have a contractual term of ten years. Synergy did not issue stock options prior to the quarter ended September 30, 2008. Synergy granted no stock options during the quarter ended June 30, 2009.

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

	Three Months Ended June 30,		Six Months Ended June 30		November 15, 2005
	2009	2008	2009	2008	(inception) to June 30, 2009
Employees included in research and development	\$ 43,055	n/a	\$ 86,296	n/a	\$ 165,825
Employees included in general and administrative	56,695	n/a	112,769	n/a	225,496
Non-employees included in research and development	8,455	n/a	16,817	n/a	25,366
Non-employees included in general and administrative	69,585	n/a	138,404	n/a	317,482
Total stock-based compensation expense	\$ 177,790	n/a	\$ 354,286	n/a	\$ 734,169

The unrecognized compensation cost related to non-vested employee stock options outstanding at June 30, 2009, net of expected forfeitures, was \$1,029,223, to be recognized over a weighted-average remaining vesting period of approximately 2.0 years.

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 as of June 30, 2009
Balance outstanding, December 31, 2008	4,080,016	\$ 0.25 - 0.95	\$ 0.29	\$ 8,933,935
Granted				
Exercised				
Forfeited				
Balance outstanding, June 30, 2009	4,080,016	\$ 0.25 - 0.95	\$ 0.29	\$ 10,851,543
Exercisable at June 30, 2009	74,871	\$ 0.25	\$ 0.25	\$ 202,152

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 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 SFAS No. 123R 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. The total fair value is being expensed ratably by month over the 2 year service period.

On July 3, 2008, 874,760 restricted stock units were granted 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 June 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 \$49,069 and \$97,599 was recorded as stock-based compensation expense during the three and six months ended June 30, 2009. As of June 30, 2009 the unrecognized fair value of the 437,380 unvested stock units, net of expected forfeitures, was \$198,439 to be amortized over 12 months. The intrinsic value of the 874,760 outstanding restricted stock units was \$2,580,542 as of June 30, 2009, measured using the closing stock price of \$2.95 per share as of that date.

SFAS No. 123R 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

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, "Earnings per Share," for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per 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

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

5. Net Loss per Share (Continued)

following table sets forth the potentially dilutive effect of all outstanding derivative instruments which were not included in weighted average common shares outstanding as of:

	June 30, 2009	June 30, 2008
Common Shares outstanding	50,914,341	47,218,161
Potentially dilutive common shares issuable upon:		
Exercise of warrants	85,050,964	45,162,920
Exercise of stock options	7,903,538	7,927,038
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	167,212,163	127,347,619

6. Derivative Financial Instruments

Effective January 1, 2009, the Company adopted EITF Issue No. 07-05, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock" ("EITF 07-05"). EITF 07-05 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 SFAS 133.

Based upon the Company's analysis of the EITF 07-05 criteria, 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 EITF 07-05, the Company accounted for the Warrants as components of stockholders' equity under SFAS 133.

Consistent with EITF 07-05'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 EITF 07-05 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 EITF 07-05. (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 following

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

6. Derivative Financial Instruments (Continued)

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	23,219,105	\$ 181,732
01/01/2009	Cumulative effect adjustment upon adoption of EITF 07-05		\$ 1,903,900
01/01/2009	Fair value of New Warrants upon adoption of EITF 07-05	23,219,105	\$ 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	28,852,831	\$ 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	69,089,049	\$ 19,193,193

7. Fair Value Measurements

The Company estimates the fair value of the New Warrants using the Black-Scholes option pricing model. The assumptions used for the three and six months ended June 30, 2009 are noted in the following table:

	Three Months Ended June 30, 2009	Six Months Ended June 30, 2009
Expected option term	7.5 years	7.5 to 8 years
Risk-free interest rate	3.33%	2.27% to 3.33%
Expected volatility	150%	150% to 200%
Dividend yield	0%	0%

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

New Warrants. The risk free rate is based on the U.S. Treasury security rates consistent with the expected term of the New Warrants.

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

7. Fair Value Measurements (Continued)

The unrealized losses on the derivative liabilities are classified in other expenses as a change in derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company performs a detailed analysis of the assets and liabilities that are subject to SFAS 157. 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 June 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 June 30, 2009
Derivative liabilities related to Warrants	\$	\$	\$ 19,193,193	\$ 19,193,193

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

Description	Balance at December 31, 2008	Cumulative Effect of the Adoption of EITF 07-05 (See Note 4)	Unrealized Losses	Balance as of June 30, 2009
Derivative liabilities related to Warrants	\$	\$ 2,085,632	\$ 17,107,561	\$ 19,193,193

8. Stockholders' deficit

During the six months ended June 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 30, 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 69,089,049 common stock purchase

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

8. Stockholders' deficit (Continued)

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 \$65,215 and \$100,015 for the three and six months ended June 30, 2009, respectively. The following table summarizes the financial impact the 11% Notes payable and the related interest expense for the period from December 30, 2008 through June 30, 2009:

	11% Notes Payable	Interest expense
11% Notes issued during the year ended December 31, 2008	\$ 201,908	\$
Apportionment of net proceeds to 2008 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	51,374	
Accretion of 11% Note discount to interest expense	34,800	34,800
11% nominal interest expense	6,686	6,686
11% Notes balance March 31, 2009	\$ 113,036	\$ 41,486
11% Notes issued during the three months ended June 30, 2009	349,880	
Apportionment of net proceeds to 2008 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	\$ 115,018

Table of Contents

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

8. Stockholders' deficit (Continued)

During the six months ended June 30, 2009 Synergy sold 7,340,715 shares of unregistered common stock at \$0.70 per share to private investors, pursuant to a Securities Purchase Agreement, for aggregate proceeds of \$5,138,500. There were no warrants issued in connection with these transactions, although Synergy incurred \$147,927 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.

9. Subsequent events

On July 2, 2009, Synergy sold 1,870,000 shares of common stock, to certain investors at a per share price of \$0.70 for aggregate gross proceeds of \$1,309,000. On July 6, 2009, Synergy sold an additional 921,429 shares of common stock, to certain investors at a per share price of \$0.70 for aggregate gross proceeds of \$645,000. In July 2009 Synergy incurred fees to selling agents of \$87,073 in connection with its July 2009 private placements.

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 June 30, 2009, we have sustained cumulative net losses available to common stockholders of \$110,285,141. 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 June 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 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. We have 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.

Recent Developments

During the six months ended June 30, 2009 Synergy sold 7,340,715 shares of unregistered common stock at \$0.70 per share to private investors for aggregate proceeds of \$5,138,500. On July 2, 2009, Synergy sold 1,870,000 shares of common stock, to certain investors at a per share price of \$0.70 for aggregate gross proceeds of \$1,309,000. On July 6, 2009, Synergy sold an additional 921,429 shares of common stock, to certain investors at a per share price of \$0.70 for aggregate gross proceeds of \$645,000. During July 2009 Synergy paid an aggregate \$235,000 to selling agents in connection with certain of these 2009 private placements.

On January 27, 2009, we announced that we were focusing all further development of Atiprimod towards the treatment of RA. We recognized that although the ongoing Phase II clinical trial of Atiprimod in advanced carcinoid cancer gave encouraging results, the data were not sufficiently demonstrative to warrant further development of Atiprimod in this indication. We announced, instead, our intention that based on Atiprimod's demonstrated favorable clinical safety profile, robustly supported by earlier studies of Atiprimod in RA patients, as well as by the recent oncology trials in advanced carcinoid cancer patients, where the drug was dosed at levels and frequencies considerably higher than anticipated for use in RA, we believe that Atiprimod holds significant promise as a new class of orally-administered, disease-modifying agent in RA.

On December 30, 2008, we 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 30, 2009, pursuant to the Purchase Agreement, we issued

Table of Contents

\$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 which we own. Pursuant to the Purchase Agreement, we also issued 69,089,049 common stock purchase 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, we 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.

OFF-BALANCE SHEET ARRANGEMENTS

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

RESULTS OF OPERATIONS

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

We had no revenues during the three months ended June 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 \$80,518 or 8% to \$1,145,063 for the three months ended June 30, 2009 from \$1,064,545 for the three months ended June 30, 2008. This increase in research and development expense was attributable to a re-energized development program for Synergy's SP-304 candidate as Synergy was able to raise capital during the quarter. This was partially offset by a significant curtailment of all 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 \$326,000 or 48% to approximately \$1,007,000 for the three months ended June 30, 2009 from approximately \$681,000 during the three months ended June 30, 2008, principally due to the purchase of drug substance. Offsetting this were lower Atiprimod program expenses which decreased by approximately \$170,000 or 100% to \$0 for the three months ended June 30, 2009 from approximately \$170,000 during the three months ended June 30, 2008, and lower Annamycin program expenses which decreased by approximately \$75,000 or 77% to approximately \$22,000 for the three months ended June 30, 2009 from approximately \$97,000 during the three months ended June 30, 2008. Research and development in-house overhead, not allocated to specific programs, totaled approximately \$123,000 and \$130,000 during the three months ended June 30, 2009 and 2008, respectively. This decrease was attributable to lower compensation costs as a result of terminating in-house clinical monitors.

General and administrative expenses for the three months ended June 30, 2009 increased \$84,980 or 8%, to \$1,102,595 for the three months ended June 30, 2009 from \$1,017,615 for the three months ended June 30, 2008. This increase was primarily due to higher stock based compensation expense which increased by approximately \$200,000 or 795% to approximately \$227,000 during the three months ended June 30, 2009, attributable to new Synergy stock options. This non-cash increase during the three months ended June 30, 2009 was partially offset by a significant reduction of cash-based expenditures for (i) facilities and related overhead, lower by approximately \$91,000 or 52%, as well as (ii) legal and accounting fees which decreased by approximately \$32,000 or 20%, as compared to the three months ended June 30, 2008.

Net loss available to common stockholders for the three months ended June 30, 2009 increased \$15,959,705 or 781% to \$18,003,788 compared to a net loss of \$2,044,083 incurred for the three months ended June 30, 2008. The increased net loss is the result of higher research and development, and

Table of Contents

general and administrative expenses discussed above, plus (i) lower interest income (\$8,063) attributable to lower cash balances, (ii) higher interest expense (\$73,532) attributable to the newly issued 11% Notes and (iii) a \$16,519,465 non-cash charge incurred to increase the estimated fair value of the derivative liabilities during the three months ended June 30, 2009, partially offset by (iv) a credit of \$836,853 for the net losses attributable to the non-controlling (minority) interest in Synergy, our majority owned subsidiary.

SIX MONTHS ENDED JUNE 30, 2009 AND JUNE 30, 2008

We had no revenues during the six months ended June 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 \$1,538,443 or 50% to \$1,543,085 for the six months ended June 30, 2009 from \$3,081,528 for the six months ended June 30, 2008. This decrease in research and development expense was attributable to significant curtailment in all program expenses incurred with outside contract research organizations ("CROs"), including animal testing, drug formulation, hospital patient costs, monitoring, blood testing and FDA consultants. Our SP-304 program expenses decreased by approximately \$975,000 or 45% to approximately \$1,182,000 for the six months ended June 30, 2009 from approximately \$2,157,000 during the six months ended June 30, 2008. Also contributing to this reduction were lower Atiprimod program expenses which decreased by approximately \$179,000 or 90% to approximately \$20,000 for the six months ended June 30, 2009 from approximately \$199,000 during the six months ended June 30, 2008, and lower Annamycin program expenses which decreased by approximately \$144,000 or 68% to approximately \$68,000 for the six months ended June 30, 2009 from approximately \$212,000 during the six months ended June 30, 2008. Research and development in-house overhead, not allocated to specific programs, totaled approximately \$271,000 and \$512,000 during the six months ended June 30, 2009 and 2008, respectively, a decrease of approximately \$241,000, or 47%. This decrease was attributable to lower compensation costs as a result of terminating in-house clinical monitors.

General and administrative expenses for the six months ended June 30, 2009 increased \$21,000 or 1%, to \$2,059,171 for the six months ended June 30, 2009 from \$2,037,927 for the six months ended June 30, 2008. This increase was primarily due to higher stock based compensation expense which increased by approximately \$258,000 or 246% to approximately \$363,000 during the six months ended June 30, 2009, attributable to new Synergy stock options. This non-cash increase during the six months ended June 30, 2009 was partially offset by a significant reduction of cash-based expenditures for (i) facilities and related overhead, lower by approximately \$150,000 or 44%, (ii) legal and accounting fees, lower by approximately \$44,000 or 15%, as well as (iii) lower travel and entertainment expenses, which decreased by approximately \$43,000 or 35% as compared to the six months ended June 30, 2008.

Net loss available to common stockholders for the six months ended June 30, 2009 increased \$14.3 million or 283% to \$19.3 million compared to a net loss of \$5.0 million incurred for the six months ended June 30, 2008. The increased net loss is the result of lower research and development, and higher general and administrative expenses discussed above, plus (i) \$53,389 of lower interest and investment income attributable to lower cash balances, (ii) \$115,018 of higher interest expense attributable to the newly issued 11% Notes and (iii) a \$16,736,568 non-cash charge incurred to increase the estimated fair value of the derivative liabilities during the six months ended June 30, 2009, partially offset by (iv) a credit of \$1,155,743 for the net losses attributable to the non-controlling (minority) interest in Synergy, our majority owned subsidiary.

Table of Contents

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2009 we had \$3,709,014 in cash and cash equivalents, compared to \$301,323 as of December 31, 2008. We had a working capital deficit of \$1,997,036 as of June 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 \$2,176,045 during the six months ended June 30, 2009 as compared to \$5,318,725 for the six months ended June 30, 2008 and \$50,793,727 for the period from June 5, 1996 (inception) to June 30, 2009. To date, our sources of cash have been primarily limited to the sale of equity securities. Net cash provided by financing activities for the six months ended June 30, 2009 was \$5,583,736 as compared to \$0 for the six months ended June 30, 2008 and \$54,593,023 for the period from June 5, 1996 (inception) to June 30, 2009. Included in net cash provided by financing activities for the six months ended June 30, 2009 was primarily the Synergy private placement of 7,340,715 shares of unregistered common stock at \$0.70 per share to a private investors for aggregate proceeds of \$5,138,500. Fees to selling agents and other costs associated with this sale of common stock were \$157,927.

On December 30, 2008, we 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 our Series B Preferred Shares on August 2, 2007. During the period from December 30, 2008 to June 30, 2009, pursuant to the Purchase Agreement, we 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 we own and the intellectual property associated with Atiprimod. In connection with the issuance of \$349,880 of the \$603,163 11% Notes in June 2009, we 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.

On July 2, 2009, Synergy sold 1,870,000 shares of common stock, to certain investors at a per share price of \$0.70 for aggregate gross proceeds of \$1,309,000. On July 6, 2009, Synergy sold an additional 921,429 shares of common stock, to certain investors at a per share price of \$0.70 for aggregate gross proceeds of \$645,000. In July 2009 Synergy incurred fees to selling agents of \$87,073 in connection with its July 2009 private placements.

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;

Table of Contents

(ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Our consolidated financial statements as of June 30, 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.

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

Derivative Instruments Liability

Effective January 1, 2009, we adopted EITF Issue No. 07-05, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock" ("EITF 07-05"). EITF 07-05 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 SFAS 133.

Based upon our analysis of the EITF 07-05 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 EITF 07-05, we accounted for the Warrants as components of stockholders' equity under SFAS 133. 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 six months ended June 30, 2009 the change in estimated fair value of derivative financial instruments has resulted in an expense of \$16,736,568 or approximately 15% of our net loss available to common stockholders of \$110,285,141.

Table of Contents

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 June 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 short term investment accounts, commercial paper included in short term money market accounts. At June 30, 2009 we had no money market balances and no exposure to market risk.

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 June 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 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

Table of Contents

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 June 30, 2009 include all adjustments identified as a result of the evaluation performed.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As of June 30, 2009 we are planning to remediate the material weaknesses which existed at December 31, 2008 by adding financial staff resources to our accounting and finance department when funding becomes available. 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 June 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.

