CALLISTO PHARMACEUTICALS INC
Form 10-Q
November 19, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: SEPTEMBER 30, 2008

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

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

CALLISTO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**12-3894575**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

420 Lexington Avenue, Suite 1609, New York, New York 10170
(Address of principal executive offices) (Zip Code)

(212) 297-0010
(Registrant's telephone number)

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

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

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

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

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

The number of the registrant's shares of common stock outstanding was 48,056,661 as of November 19, 2008.

CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

FORM 10-Q

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INTRODUCTORY NOTE

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

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2007 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.

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2008 (Unaudited)	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,825,389	$ 3,269,341
Short term investments		2,967,690
Prepaid expenses and other	90,951	88,820
Total Current Assets	1,916,340	6,325,851
Property and equipment, net	22,683	15,108
Security deposits	73,716	73,716
Total Assets	$ 2,012,739	$ 6,414,675
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 3,136,290	$ 3,254,992
Accrued expenses	1,128,528	1,366,333
Total Current Liabilities	4,264,818	4,621,325
Minority interest in equity of majority owned subsidiary	125,041	
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Series A convertible preferred stock, par value $0.0001, 700,000 shares authorized, 214,925 shares outstanding at September 30, 2008 with a liquidation preference of $2,149,250 and 218,675 shares outstanding at December 31, 2007 with a liquidation preference of $2,186,750	21	22
Series B convertible preferred stock, par value $0.0001, 2,500,000 shares authorized, 1,137,050 shares outstanding at September 30, 2008 with a liquidation preference of $11,370,500 and 1,147,050 shares outstanding at December 31, 2007 with a liquidation preference of $11,470,500	114	115
Common stock, par value of $.0001 per share: Authorized 225,000,000 shares at September 30, 2008 and December 31, 2007; 47,218,161 and 46,943,161 shares outstanding at September 30, 2008 and December 31, 2007, respectively	4,722	4,694
Additional paid-in capital	85,734,013	83,120,315
Deficit accumulated during development stage	(88,115,990)	(81,331,796)
Total Stockholders' Equity (Deficit)	(2,377,120)	1,793,350

Total Liabilities and Stockholders' Equity (Deficit)	$ 2,012,739	$ 6,414,675

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

CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		June 5, 1996 (Inception) to September 30,
	2008	2007	2008	2007	2008
Revenues	$	$	$	$	$
Costs and Expenses:					
Research and development	1,048,228	1,420,886	4,129,756	3,498,604	32,778,300
Government grants		(93,000)	(30,000)	(196,069)	(1,135,318)
Purchased in-process research and development					6,944,553
General and administrative	1,253,268	1,364,965	3,291,196	3,295,245	37,958,034
Loss from Operations	(2,301,496)	(2,692,851)	(7,390,952)	(6,597,780)	(76,545,569)
Interest and investment income	14,420	18,682	68,034	47,396	856,344
Other income/(expense), net					(171,846)
Change in fair value of Series B Preferred investor warrants from date of issuance to expiration of put option		2,591,005		2,591,005	2,591,005
Minority interest in equity of majority owned subsidiary	538,724		538,724		538,724
Net Loss	(1,748,352)	(83,164)	(6,784,194)	(3,959,379)	(72,731,342)
Series A Preferred stock beneficial conversion feature accreted as a dividend		(2,384,790)		(2,504,475)	(4,888,960)
Series B Preferred stock beneficial conversion feature accreted as a dividend		(10,495,688)		(10,495,688)	(10,495,688)
Net loss available to common stockholders	$ (1,748,352)	$ (12,963,642)	$ (6,784,194)	$ (16,959,542)	$ (88,115,990)
Weighted Average Common Shares Outstanding					
Basic and Diluted	47,218,161	41,821,509	47,186,957	40,218,653	
Net Loss per Common Share					
Basic and Diluted	$ (0.04)	$ (0.31)	$ (0.14)	$ (0.42)	

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

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	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance at inception, June 5, 1996		$		$	$	$	$	$
Issuance of founder shares			2,642,500	264	528		(404,005)	(403,213)
Common stock issued			1,356,194	136	272			408
Common stock issued via private placement			1,366,667	137	1,024,863			1,025,000
Balance, December 31, 1996			5,365,361	537	1,025,663		(404,005)	622,195
Net loss for the year							(894,505)	(894,505)
Common stock issued via private placement			1,442,666	144	1,081,855			1,081,999
Balance, December 31, 1997			6,808,027	681	2,107,518		(1,298,510)	809,689
Net loss for the year							(1,484,438)	(1,484,438)
Amortization of stock-based compensation					52,778			52,778
Common stock issued via private placement			1,416,667	142	1,062,358			1,062,500
Common stock issued for services			788,889	79	591,588			591,667
Common stock repurchased and cancelled			(836,792)	(84)	(96,916)			(97,000)
Balance, December 31, 1998			8,176,791	818	3,717,326		(2,782,948)	935,196
Net loss for the year							(4,195,263)	(4,195,263)
Deferred compensation stock options					9,946	(9,946)		
Amortization of stock-based compensation						3,262		3,262
Common stock issued for services					3,168,832			3,168,832
Common stock issued via private placement			346,667	34	259,966			260,000
Balance, December 31, 1999			8,523,458	852	7,156,070	(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 issued			4,560,237	455	250,889			251,344
Other					432			432
Preferred shares issued	3,485,299	348			5,986,302			5,986,650
Preferred stock issued for services	750,000	75			1,124,925			1,125,000
Balance, December 31, 2000	4,235,299	$ 423	13,083,695	$ 1,307	$ 14,518,618	$ (2,487)	$ (9,594,472)	$ 4,923,389

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

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	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance, December 31, 2000	4,235,299	$ 423	13,083,695	$ 1,307	$ 14,518,618	$ (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	(20,000)		
Amortization of stock-based compensation						22,155		22,155
Balance, December 31, 2001	4,235,299	423	13,083,695	1,307	14,538,618	(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	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 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
Net loss for the year							(7,543,467)	(7,543,467)
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
					(816,865)			(816,865)

Variable account for stock options						
Amortization of stock-based compensation				3,084,473		3,084,473
Stock-based compensation			240,572	93,000		333,572
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.

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, Par Value	Common Shares	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, 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 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
Common stock issued via private placement August 2005			1,869,203	187	1,812,940			1,813,127
Finders fees and expenses					(176,249)			(176,249)
Exercise of common stock warrant			125,000	13	128,737			128,750
Common stock issued for services			34,000	3	47,177			47,180
Balance, December 31, 2005			33,233,096	3,323	46,387,875	(1,583,463)	(45,140,654)	(332,919)
Net loss for the year							(12,919,229)	(12,919,229)
Amortization of stock-based compensation					2,579,431			2,579,431
Reclassification of deferred unamortized stock-based compensation upon adoption of SFAS No. 123R					(1,583,463)	1,583,463		
Common stock issued via private placement February 2006			4,283,668	428	5,139,782			5,140,210
Common stock issued via private placement April 2006			666,667	67	799,933			800,000
Finders fees and expenses	11,775	1			(1,051,717)			(1,051,716)
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
Detachable warrants					2,384,485			2,384,485
Beneficial conversion feature accreted as a dividend							(2,384,485)	(2,384,485)
Balance, December 31, 2006	586,125	$ 58	39,194,996	$ 3,919	$61,290,509	$	$ (60,444,368)	$ 850,118

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

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, Par Value	Series B Convertible Preferred Shares	Series B Convertible Preferred Stock, Par Value	Common Shares	Common Stock Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance, December 31, 2006	586,125	$ 58		$	39,194,996	$ 3,919	$61,290,509	$ (60,444,368)	$ 850,118
Net loss for the year								(7,887,265)	(7,887,265)
Stock-based compensation expense							591,561		591,561
Common stock issued for services					80,000	8	36,792		36,800
Series A convertible preferred stock, issued via private placement	28,000	4					279,997		280,001
Finders fees and expenses, Series A private placement							(36,400)		(36,400)
Conversion of Series A preferred stock to common stock	(395,450)	(40)			7,668,165	767	(727)		
Beneficial conversion feature accreted as a dividend to Series A convertible preferred stock							2,504,475	(2,504,475)	
Series B convertible preferred stock, issued via private placement			1,147,050	115			11,470,385		11,470,500
Finders fees and expenses, Series B private placement							(920,960)		(920,960)
Beneficial conversion feature accreted as a dividend to Series B convertible 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
Recapitalization of majority owned subsidiary via private placements of common stock							2,951,913		2,951,913
Minority interest in equity of subsidiary acquired							(505,448)		(505,448)
Net loss for the period								(6,784,194)	(6,784,194)
Stock-based compensation expense							167,259		167,259
Conversion of Series A preferred stock to common stock	(3,750)	(1)			75,000	8	(7)		
			(10,000)	(1)	200,000	20	(19)		

Conversion of Series B preferred stock to common stock										
Balance, September 30, 2008	214,925	$ 21	1,137,050	$ 114	47,218,161	$ 4,722	$85,734,013	$ (88,115,990)	$ (2,377,120)	

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

CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,		Period from June 5, 1996 (Inception) to September 30, 2008
	2008	**2007**	
Cash Flows From Operating Activities:			
Net loss	$ (6,784,194)	$ (3,959,379)	$ (72,731,342)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	4,620	2,151	94,550
Stock-based compensation expense	304,038	263,309	17,449,844
Purchased in-process research and development			6,841,053
Purchase discount accreted as interest income on U.S. Treasury bills	(26,950)		(26,950)
Stock-based liquidated damages			579,696
Change in fair value of Series B preferred warrants from date of issuance to expiration of put options		(2,591,005)	(2,591,005)
Minority interest in net losses of majority owned subsidiary	(538,724)		(538,724)
Changes in operating assets and liabilities:			
Prepaid expenses	(2,131)	(27,381)	(90,951)
Security deposit			(73,716)
Accounts payable and accrued expenses	(334,968)	321,546	3,993,929
Total Adjustments	(594,115)	(2,031,380)	25,637,726
Net Cash Used in Operating Activities	(7,378,309)	(5,990,759)	(47,093,616)
Cash Flows From Investing Activities:			
Short-term investments purchased			(5,921,825)
Short-term investments liquidated	2,994,640		5,948,775
Additions to property and equipment	(12,196)		(117,233)
Net Cash Provided by Investing Activities	2,982,444		(90,283)
Cash Flows From Financing Activities:			
Issuance of common and preferred stock		11,750,500	48,719,673
Finders fees and expenses		(957,360)	(2,981,083)
Proceeds of private placement of majority owned subsidiary's common stock, net of fees and expenses	2,951,913		2,951,913
Exercise of common stock warrants			318,785
Proceeds from private placement to escrow		(8,480,000)	
Net Cash Provided by Financing Activities	2,951,913	2,313,140	49,009,288
Net (decrease) increase in cash and cash equivalents	(1,443,952)	(3,677,619)	1,825,389
Cash and cash equivalents at beginning of period	3,269,341	3,904,232	
Cash and cash equivalents at end of period	$ 1,825,389	$ 226,613	$ 1,825,389

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

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CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

(Unaudited)

	Nine months ended September 30, 2008	Nine months ended September 30, 2007	Period from June 5, 1996 (inception) to September 30, 2008
Supplementary disclosure of cash flow information:			
Cash paid for taxes	$ 31,816	$ 640	$ 142,532
Supplementary disclosure of non-cash investing and financing activities:			
Series A Preferred stock beneficial conversion feature accreted as a dividend	$	$ 2,504,475	$ 4,888,960
Series B Preferred stock beneficial conversion feature accreted as a dividend	$	$ 10,495,688	$ 10,495,688

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

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. Callisto was incorporated in the state of Delaware on June 5, 1996 (inception). Since inception, Callisto's efforts have been principally devoted to research and development, securing and protecting patents and raising capital.

From inception through September 30, 2008, Callisto has sustained cumulative net losses available to common stockholders of $88,115,990. Callisto's losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, stock based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees, as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception through September 30, 2008, 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.

On July 14, 2008, Callisto entered into an Exchange Agreement dated July 11, 2008 ("Exchange Agreement"), as amended and effective on July 14, 2008, with Pawfect Foods, Inc. ("Pawfect"), Synergy Pharmaceuticals, Inc. ("Synergy-DE"), a previously wholly owned subsidiary of Callisto, and the other holders of Synergy-DE common stock. According to the terms of the Exchange Agreement, Pawfect acquired 100% of the common stock of Synergy-DE, from Callisto and the other holders of Synergy-DE, in exchange for 45,464,760 shares of Pawfect's common stock representing approximately 70% of Pawfect's outstanding common stock (the "Exchange Transaction"). Callisto received 44,590,000 of the 45,464,760 shares of Pawfect's common stock exchanged for ownership of Synergy-DE, and Callisto is now the holder of 68% of Pawfect's outstanding common stock. The remaining 874,760 shares of Pawfect common stock exchanged for ownership of Synergy-DE were issued to certain executive officers of Synergy-DE who received their shares pursuant to a Repurchase Agreement with Synergy-DE dated July 3, 2008 and assumed by Pawfect. The fair value of each of the 874,760 shares was estimated on the grant date to be $0.60, which was based on the price paid by shareholders participating in Synergy's July 14, 2008 private placement. In connection with the Exchange Transaction Pawfect received $3,025,000 less transaction costs of $73,087, yielding net proceeds of $2,951,913 from two private placements, which the Company has recorded as an increase in additional paid-in capital. The Company is treating the Exchange Transaction as a recapitalization of its equity in Synergy and the minority interest in the net equity of subsidiary acquired of $505,448 has been recorded as a decrease in additional paid-in capital.

CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

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

1. Business Overview (Continued)

Pawfect was a development stage company developing a distribution channel in the pet food industry selling pet food products utilizing the World Wide Web, with immaterial operations to date. Pawfect's common stock is publicly traded on the Over The Counter Bulletin Board.

On July 21, 2008, Pawfect amended its articles of incorporation, in the state of Florida, to effect the actions necessary to complete the transactions contemplated by the Exchange Agreement and changed its name to Synergy Pharmaceuticals, Inc ("Synergy").

On July 14, 2008, Synergy discontinued its pet food business to focus all resources on continuing the development of drugs to treat gastrointestinal disorders and diseases acquired in connection with the Exchange Agreement. Amounts related to the discontinued pet food business in the condensed consolidated financial statements for all historical periods have not been restated to reflect these operations as discontinued due to being immaterial.

2. Basis of Presentation and Going Concern

The accompanying unaudited condensed consolidated financial statements are those of Callisto and subsidiaries: (1) Callisto Research Labs, LLC (including its wholly-owned subsidiary, Callisto Pharma, GmbH (Germany inactive)), and (2) Synergy (including Synergy's wholly-owned subsidiaries, Synergy DE, Synergy Advanced Pharmaceuticals, Inc. and IgX, Ltd (Ireland inactive)). In accordance with generally accepted accounting principles ("GAAP"), the results of operations of Synergy, a majority-owned subsidiary subsequent to the date of the Exchange Agreement continues to be consolidated with Callisto. All intercompany transactions and balances have been eliminated in consolidation.

The Company records adjustments to the minority interests in Synergy for the allocable portion of losses to which the minority interest holders are entitled. The Company will suspend allocation of losses to minority interest holders when the minority interest balance for a particular minority interest holder is reduced to zero. Any excess loss above the minority interest holder's balance is not charged to minority interests as the minority interest holders have no obligation to fund such losses.

Since Synergy has incurred losses during the period July 14, 2008 to September 30, 2008, Callisto reduced its minority interest for 32% of Synergy's losses, or $538,724, which excludes Synergy's charge for purchased in process research and development eliminated in consolidation. Accordingly, only Callisto's 68% share of net losses of Synergy is included in the accompanying consolidated statements of operations and the minority interest in equity of majority owned subsidiary is $125,041 on the accompanying balance sheet as of September 30, 2008.

These condensed consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission ("SEC") and GAAP for interim reporting. These statements should be read in conjunction with Callisto's audited financial statements and notes thereto for the year ended December 31, 2007, included in Form 10-K filed with the SEC on March 28, 2008. All intercompany balances and transactions have been eliminated. Callisto is responsible for the condensed consolidated financial statements included in this Form 10-Q. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, which include only normal recurring adjustments, necessary to present fairly the Callisto's

CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

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

2. Basis of Presentation and Going Concern (Continued)

interim financial information. The results of operations for the nine months ended September 30, 2008 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2008.

The accompanying condensed consolidated financial statements of Callisto as of September 30, 2008 and December 31, 2007 have been prepared under the assumption that Callisto will continue as a going concern for the twelve months ending December 31, 2008. 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 condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Callisto will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at its current cash expenditure levels.

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 license or otherwise dispose of rights to technologies, product candidates or products that Callisto would otherwise seek to develop or commercialize ourselves on unfavorable terms.

As of September 30, 2008, Callisto had an accumulated deficit of $88,115,990. Callisto expects to incur significant and increasing operating losses for the next several years as Callisto expands its research and development, continues clinical trials of SP-304 for the treatment of gastrointestinal ("GI") disorders, acquires or licenses technologies, advances other product candidates into clinical development, seeks regulatory approval and, if U.S. Food and Drug Administration ("FDA") approval is received, commercializes products. Because of the numerous risks and uncertainties associated with product development efforts, Callisto is unable to predict the extent of any future losses or when Callisto will become profitable, if at all. These losses have had and will continue to have an adverse effect on Callisto's stockholders' equity and working capital.

Net cash used in operating activities was approximately $7,378,309, $5,990,759 and $47,093,616, for the nine months ended September 30, 2008 and 2007 and for the period from June 5, 1996 (inception) to September 30, 2008, respectively. During the nine months ended September 30, 2008 and 2007 and for the period from June 5, 1996 (inception) to September 30, 2008, Callisto incurred net losses available to common stockholders of approximately $6,784,194, $16,959,542 and $88,115,990, respectively. To date, Callisto's sources of cash have been primarily limited to the sale of equity securities. Net cash provided by financing activities for the nine months ended September 30, 2008 and 2007 and for the period from June 5, 1996 (inception) to September 30, 2008, was approximately $2,951,913, $2,313,140 and $49,009,288, respectively. The cash provided by financing activities during

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

2. Basis of Presentation and Going Concern (Continued)

the nine month ended September 30, 2008 is the result of the Exchange Transaction and related private placements described above.

3. Recent Accounting Pronouncements

In October 2008, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position ("FSP") No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active,* ("FSP No. 157-3"). This FSP applies to financial assets within the scope of accounting pronouncements that require or permit fair value measurements in accordance with SFAS No. 157. This FSP clarifies the application of SFAS No. 157 in determining the fair values of assets or liabilities in a market that is not active. This FSP is effective upon issuance, including prior periods for which financial statements have not been issued. The adoption of this FSP did not have a material impact on the Company's consolidated financial statements.

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*. EITF No. 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. The Company is currently evaluating the impact of the pending adoption of EITF No. 07-05 on its consolidated financial statements.

In March 2008, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 161, *Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133*" ("SFAS No. 161"). SFAS No. 161 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. The guidance in SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. This Statement encourages, but does not require, comparative disclosures for earlier periods at initial adoption. The Company is currently assessing the impact of SFAS No. 161 on its consolidated financial statements.

In February 2008, the FASB issued FSP No. FAS 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 annually) to fiscal years beginning after November 15, 2008. The Company is currently evaluating the impact of SFAS No. 157 on nonfinancial assets and nonfinancial liabilities, but does not expect the adoption to have a material impact on its consolidated financial position, results of operations or cash flows.

CALLISTO PHARMACEUTICALS, INC.
(A development stage company)

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

4. Accounting for Shared-Based Payments

In December 2004, the FASB issued SFAS No. 123 (Revised 2004), *Share-Based Payments* ("SFAS 123R"). SFAS 123R requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005.

Stock options issued by Callisto typically vest after three years of continuous service from the grant date and have a contractual term of ten years. The fair values are amortized to stock-based compensation pro-rata over the vesting term.

Share-based payments have been recognized in operating results as follow:

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from June 5, 1996 (Inception) to September 30,
	2008	2007	2008	2007	2008
Employees included in research and development	$ 10,408	$ 19,443	$ 33,354	$ 51,987	$ 2,654,631
Employees included in general and administrative	28,741	64,636	133,684	266,596	4,721,375
Subtotal employee stock option grants	39,149	84,079	167,038	318,583	7,376,006
Non-employee included in research and development	(20,891)	1,004	(17,314)	1,004	102,750
Non-employee included in general and administrative	17,447	(53,401)	17,535	(56,278)	9,834,309
Subtotal non-employee stock option grants	(3,444)	(52,397)	221	(55,274)	9,937,059
Synergy options*	136,779		136,779		136,779
Total stock-based compensation expense	$ 172,484	$ 31,682	$ 304,038	$ 263,309	$ 17,449,844

* Synergy stock based compensation expense presented above reflects the Company's 68% ownership share of such expense.

The estimated fair value of each employee and non-employee stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the three and nine months ended September 30, 2008 and 2007.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Risk-free interest rate	N/A	4.7%	N/A	4.7%
Dividend yield	N/A		N/A	
Expected volatility	N/A	60%	N/A	60%
Expected term (in years)	N/A	5.0 yrs	N/A	5.0 - 6.0 yrs

There were no options granted during the nine months ended September 30, 2008. The weighted-average fair value of all options granted during the nine months ended September 30, 2007, estimated as of the grant date using the Black-Scholes option valuation model, was $0.42 per share.

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CALLISTO PHARMACEUTICALS, INC.
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited) (Continued)

4. Accounting for Shared-Based Payments (Continued)

The unrecognized compensation cost related to non-vested employee stock options outstanding at September 30, 2008 was $118,847, to be recognized over a weighted-average vesting period of approximately one year. The weighted-average remaining term of all options outstanding at September 30, 2008 was 5.4 years as compared to 5.9 years at December 31, 2007.

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

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value as of September 30, 2008
Balance outstanding, December 31, 2007	8,241,207	$0.66 - 6.75	$ 1.70	$
Granted				
Exercised				
Forfeited	(330,169)	$0.47 - 1,38	$ 0.84	
Balance outstanding, September 30, 2008	7,911,038	$0.66 - 6.75	$ 1.73	$
Exercisable, September 30, 2008	5,803,205	$0.66 - 6.75	$ 1.66	$

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

5. Commitments and Contingencies

Employment and Consulting Agreements:

Melvin K. Spigelman

On August 21, 2008, the Board of Directors ("the Board") of Synergy appointed Melvin K. Spigelman, M.D. as a Director of Synergy. In addition, the Board of Directors appointed Dr. Spigelman Chairman of Synergy's Clinical Oversight Committee as well as a member of the Synergy Compensation and Audit Committees ("the Committees"). In connection therewith, the Board approved the payment of an annual fee of $90,000 to Dr. Spigelman for his service on the Board and the Committees. Additionally, the Board approved a grant of 300,000 stock options to Dr. Spigelman, to purchase Synergy common stock, with an exercise price of $0.60 per share. Such options vest in 100,000 increments over a period of 3 years. The fair value of the 300,000 options on the date of grant was $135,655 of which $3,717 was recorded as stock-based compensation expense during the three and nine months ended September 30, 2008.

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

5. Commitments and Contingencies (Continued)

Kunwar Shailubhai, Ph.D

On April 6, 2004, Kunwar Shailubhai, Ph.D. entered into an employment agreement with Synergy in which he agreed to serve as Senior Vice President, Drug Discovery. Dr. Shailubhai's employment agreement was for a term of 12 months beginning April 6, 2004 and was automatically renewed for successive one year periods at the end of each term. On July 9, 2008, Dr. Shailubhai was appointed to the position of Chief Scientific Officer of Synergy, his base salary was increased to $190,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year.

Capebio, LLC

On September 25, 2007, Synergy Advanced Pharmaceuticals, Inc. entered into a Service Agreement with Capebio, LLC ("Capebio") to provide research and development services for the commercialization of non-oncology related gastrointestinal pharmaceutical products under the SP-304 patent (the "Service Agreement"). The Service Agreement was for a minimum term of eleven months starting October 1, 2007 during which period Synergy Advanced Pharmaceuticals, Inc. paid an initial fee of $55,000 and was obligated to pay $26,000 per month through August 31, 2008. This Service Agreement was terminated during the quarter ended September 30, 2008 and all amounts due there-under were paid.

License agreements:

On August 28, 2002, and as amended on May 23, 2003, Synergy entered into a worldwide license agreement (the "Original License") with AnorMED to research, develop, sell and commercially exploit the Atiprimod patent rights. The Original License provided for aggregate milestone payments of up to $14 million based upon achieving certain regulatory submissions and approvals for an initial indication, and additional payments of up to $16 million for each additional indication based on achieving certain regulatory submissions and approvals. Commencing on January 1, 2004 and on January 1 of each subsequent year Synergy was obligated to pay AnorMED a maintenance fee of $200,000 until the first commercial sale of the product. These annual maintenance fee payments under the Original License were made in January 2004, 2005, 2006 and 2007 and recorded as research and development expense.

On December 31, 2007, Callisto and Synergy entered into an Amended and Restated License Agreement with AnorMED Corporation ("AnorMED"), a wholly-owned subsidiary of Genzyme Corporation ("Genzyme"), pursuant to which Callisto and Genzyme amended the Original License agreement for Atiprimod to eliminate all future maintenance fees and milestone payments and reduce future royalties to single digits. In return for the reduced future payments to Genzyme, Callisto agreed to pay upfront fees which were recorded as a liability and expensed on December 31, 2007. These upfront fees were scheduled to be paid on January 31, 2008 and April 30, 2008. As of September 30, 2008 approximately $650,000 of these upfront fees remains due and payable. The Company is currently in discussions with AnorMED/Genzyme however there can be no assurance Callisto will retain its rights under the Amended and Restated License Agreement.

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

6. Net Loss Per Share

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, *Earnings per Share* ("SFAS No. 128"), 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. The Company has a net loss for all periods presented. Accordingly, the inclusion of common stock options, warrants and the conversion of preferred sock would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted earnings per share are the same.

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

	September 30, 2008	September 30, 2007
Common Shares Outstanding (included in weighted-average shares)	47,218,161	45,463,161
Potentially Dilutive Common Shares Issuable (excluded from weighted-average shares)		
Exercise of Warrants	43,852,920	45,162,920
Exercise of Stock Options	7,911,038	8,241,207
Conversion of Series A Convertible Preferred Stock	4,298,500	5,853,500
Conversion of Series B Convertible Preferred Stock	22,741,000	22,941,000
Common Shares Outstanding Fully Diluted	126,021,619	127,661,788

7. Stockholders' Equity (Deficit)

On April 7, 2008, Callisto received notice from the staff of the American Stock Exchange ("AMEX") of its intent to strike Callisto's common stock from the AMEX by filing a delisting application with the SEC for failure to regain compliance with Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide and falling out of compliance with Section 1003(a)(iii) of the Company Guide with shareholders' equity of less than $6,000,000 and losses from continuing operations and/or net losses in four of our five most recent fiscal years. On July 14, 2008, Callisto's common stock was delisted from the AMEX and currently trades on the Over The Counter Bulletin Board.

On January 31, 2008, the Board of Directors approved a reassignment, as well as, a decrease in the exercise price, of the 1,323,822 warrants, previously assigned from Trilogy Capital Partners LLC to two unaffiliated entities, from $1.03 per share to $0.70 per share. The decrease in the exercise price was effective immediately and the reassignment will be effective at management's discretion. Callisto has determined that the price modifications was compensatory in accordance with SFAS 123R and the associated stock based compensation expense of $45,086 was recorded during the quarter ended March 31, 2008. As of September 30, 2008, Callisto had not reassigned the warrants any further.

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, 2007 and other periodic reports filed with the United States Securities and Exchange Commission ("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 the Company's actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements.

OVERVIEW

We are a development stage biopharmaceutical company focused primarily on the development of drugs to treat neuroendocrine cancer (including advanced carcinoid cancer), acute leukemia and gastrointestinal ("GI") disorders and diseases. Our lead drug candidates are as follows:

(1) SP-304, a guanylyl cyclase C ("GC-C") receptor agonist, to treat gastrointestinal 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.

On April 2, 2008, we filed an investigational new drug ("IND") application with the United States Food and Drug Administration ("FDA"). On May 2, 2008, we received notice from the FDA that the proposed study was deemed safe to proceed and we initiated a Phase I clinical trial in volunteers on June 4, 2008. The purpose of the initial Phase I trial was to establish the safety of the drug. This first trial was a single-dose, dose-escalation, placebo-controlled trial in volunteers. Synergy plans to open a Phase Ib repeated-dose trial of SP-304 for CC patients during 2009.

SP-304 was developed by Synergy scientists based on structure-function studies performed in-house. A patent covering composition of matter and therapeutic applications of SP-304 was granted by the U.S. Patent and Trademark Office on May 9, 2006. SP-304 is an analog of uroguanylin, a natural GI hormone produced in the gut that is a key regulator of intestinal function. Uroguanylin works by activating the GC-C receptor on intestinal cells. The GC-C receptor, promotes fluid and ion transport

in the GI tract. Under normal conditions, the receptor is activated by the natural hormones uroguanylin and guanylin. Activation of the receptor leads to the transport of chloride and bicarbonate into the intestine, and water is carried with these ions into the lumen of the intestine, thereby softening stool, and producing other pharmacologic effects that could potentially benefit patients with chronic constipation and IBS-C.

A practical, efficient and cost effective method for producing SP-304 on a commercial scale is currently being developed by a contract research organization. At present we have multiple100 gram-scale lots of SP-304, produced under current good manufacturing practices ("cGMP") that are being used for non-clinical work to support further human studies.

SP-304 has also undergone pre-clinical animal studies as a treatment for GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of North Carolina, Chapel Hill, NC. Recent results from his laboratory also showed that SP-304 was efficacious in animal models of ulcerative colitis ("UC"). A second generation GC-C receptor SP-333 is now in pre-clinical development and Synergy plans to file an IND and initiate a Phase I clinical trial in UC patients in 2009.

On November 7, 2006, we announced the initiation of a multi-center open-label Phase II clinical trial of Atiprimod for low-to-intermediate grade neuroendocrine cancers, primarily in advanced carcinoid cancer patients. This trial is based on earlier encouraging clinical results from a Phase I trial of Atiprimod in advanced cancer patients that showed stable disease and disease-related symptom relief in patients with advanced carcinoid cancer. On September 20, 2007, we announced that we had completed enrollment of the 40-patient Phase II clinical trial, and that patients had been on drug as along as 11 months. In October 2007, we announced the opening of a Phase II extension trial to permit those patients who had successfully completed a full year in the Phase II advanced carcinoid cancer trial, which only permitted dosing for up to one year, to continue to receive Atiprimod therapy. We are no longer dosing patients in the Phase I clinical trial of Atiprimod in relapsed or refractory multiple myeloma and have no plans at present to continue evaluating the drug in this disease indication, instead focusing on the clinical development of Atiprimod to treat advanced carcinoid cancer.

L-Annamycin is presently in two clinical trials: 1) a Phase I/IIa clinical trial in adult relapsed acute myelogenous leukemia ("AML") or refractory acute lymphocytic leukemia ("ALL") patients at three clinical sites in the U.S.; and 2) a Phase I clinical trial in children and young adults with relapsed or refractory ALL or AML. We recently reached the maximum tolerated dose ("MTD") in the adult trial and are currently evaluating its potential at the fixed-dose portion of the trial. We have not yet established the MTD in children. We plan to review future development of this drug once data from the adult trial are available

RECENT DEVELOPMENTS

On July 14, 2008, we entered into an Exchange Agreement dated July 11, 2008, as amended and effective on July 14, 2008, with Pawfect Foods, Inc. ("Pawfect"), our then wholly-owned subsidiary, Synergy Pharmaceuticals, Inc. ("Synergy-DE") and certain other holders of Synergy-DE common stock. According to the terms of the Exchange Agreement, Pawfect acquired 100% of the common stock of Synergy-DE, from us and other unregistered holders of Synergy-DE, in exchange for 45,464,760 shares of Pawfect's common stock. The 45,464,760 shares represents approximately 70% of Pawfect's outstanding common stock ("Exchange Transaction").

We received 44,590,000 of the 45,464,760 shares of Pawfect's common stock exchanged for our ownership of Synergy-DE, and we are now the holder of 68% of Pawfect's outstanding common stock. The remaining 874,760 shares of Pawfect common stock exchanged for ownership of Synergy-DE were issued to certain executive officers of Synergy-DE who received their shares pursuant to a Repurchase Agreement with Synergy-DE dated July 3, 2008. The fair value of each of the 874,760 shares was

estimated on the grant date to be $0.60, which was based on the price paid by shareholders participating in Synergy's July 14, 2008 private placement. Pawfect was a development stage company developing a distribution channel in the pet food industry selling pet food products utilizing the World Wide Web with immaterial operations to date. Pawfect's common stock is publicly traded on the over the counter bulletin board. On July 21, 2008 Pawfect amended its articles of incorporation to effect the actions necessary to complete the transactions contemplated by the Exchange Agreement and changed its name to Synergy Pharmaceuticals, Inc. Pawfect received $3,025,000 less transaction costs of $73,087, yielding net proceeds of $2,951,913 on July 14, 2008 from two private placements, which we have recorded as additional paid-in capital.

On July 14, 2008, Synergy discontinued its pet food business to focus all resources on continuing the development of drugs to treat GI disorders and diseases acquired in connection with the Exchange Agreement. Amounts related to the discontinued pet food business in the condensed consolidated financial statements for all historical periods have not been restated to reflected these operations as discontinued due to being immaterial. Since Synergy incurred losses during the period July 14, 2008 to September 30, 2008, Callisto reduced its minority interest for 32% of Synergy's losses, or $538,724, which excludes Synergy's charge for purchased in-process research and development eliminated in consolidation. All intercompany transactions and balances have been eliminated in consolidation.

On April 7, 2008, we received notice from the staff of the American Stock Exchange ("AMEX") of its intent to strike our common stock from the AMEX by filing a delisting application with the SEC for failure to regain compliance with Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide and falling out of compliance with Section 1003(a)(iii) of the Company Guide with shareholders' equity of less than $6,000,000 and losses from continuing operations and/or net losses in four of our five most recent fiscal years. On July 14, 2008, our common stock was delisted from the AMEX and currently trades on the Over The Counter Bulletin Board.

FINANCIAL OPERATIONS OVERVIEW

Since inception in June of 1996, we have been a development stage company and our efforts have been principally devoted to research and development, securing and protecting patents and raising capital. From inception through September 30, 2008, we have sustained cumulative net losses available to common stockholders of $88,115,990. 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 advisory and financial consulting fees. From inception through September 30, 2008, we have not generated any revenue from operations and expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products. We do not expect to have such for several years, if at all.

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, the nature and timing of costs and competing technologies being developed by organizations with significantly greater resources.

Our research and development expenses consist primarily of costs associated with clinical development team salaries and staff costs, application and filing for regulatory approval of our proposed products, regulatory and scientific consulting fees, clinical and patient costs for product candidates in on-going trials, sponsored pre-clinical research, royalty payments as well as legal and professional fees associated with filing and maintaining our patent and license rights to our proposed

products. We expense all research and development costs as they are incurred. We expect our research and development expenses to increase significantly in the future as we develop our product candidates.

Our general and administrative expenses primarily include personnel and related costs, rent and professional accounting and corporate legal fees. We expect our general and administrative expenses to increase significantly over the next few years as we continue to build our operations to support our product candidates and as we incur costs associated with being a publicly traded company.

CRITICAL ACCOUNTING POLICIES

For a discussion of critical accounting policies, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Form 10-K for the year ended December 31, 2007.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

For a discussion of contractual obligations, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Form 10-K for the year ended December 31, 2007.

On December 31, 2007, Callisto and Synergy entered into an Amended and Restated License Agreement with AnorMED Corporation ("AnorMED"), a wholly-owned subsidiary of Genzyme Corporation ("Genzyme"), pursuant to which Callisto and Genzyme amended the Original License agreement for Atiprimod to eliminate all future maintenance fees and milestone payments and reduce future royalties to single digits. In return for the reduced future payments to Genzyme, Callisto agreed to pay upfront fees which were recorded as a liability and expensed on December 31, 2007. These upfront fees were payable on January 31, 2008 and April 30, 2008. As of September 30, 2008 approximately $650,000 of these upfront fees, remains due and payable. We are currently in discussions with AnorMED/Genzyme however if we fail to meet these obligations, the license agreement may be terminated and our business may be adversely affected.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2008.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

We had no revenues during the three months ended September 30, 2008 and 2007 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 $372,658 or 26%, to $1,048,228 for the three months ended September 30, 2008 from $1,420,886 for the three months ended September 30, 2007. This decrease in research and development expense was attributable to lower program costs associated with Atiprimod and Annamycin during 2008, partially offset by higher program expenses associated with SP-304. Program expenses are primarily incurred with outside contract research organizations ("CROs") and include pre-clinical animal testing, drug formulation, tableting, hospital patient costs, blood testing and FDA consultants. The SP-304 program expenses incurred by our majority-owned subsidiary increased to $519,000 for the three months ended September 30, 2008 from $425,000 during the three months ended September 30, 2007. Program expenses incurred on our Atiprimod program decreased to $304,000 for the three months ended September 30, 2008 from $416,000 during the three months ended September 30, 2007. Program expenses incurred on our Annamycin program decreased

to $36,000 for the three months ended September 30, 2008 from $212,000 during the three months ended September 30, 2007.

Research and Development overhead expenses not allocated to specific programs for the three months ended September 30, 2008 totaled $189,000, a decrease of approximately $173,000 or 48% from the $362,000 we incurred during the three months ended September 30, 2007. As we focused more of our research and development resources on established programs these non-program specific overhead expenses decreased to 18% from 25% of total research and development expenses during the three months ended September 30, 2008 and 2007, respectively.

General and administrative expenses for the three months ended September 30, 2008 decreased $111,697 or 8%, to $1,253,268 for the three months ended September 30, 2008 from $1,364,965 for the three months ended September 30, 2007. This decrease was primarily due to a decrease in legal and public relations expenses, partially offset by increased consulting, audit and stock-based compensation expense.

We record adjustments to the minority interests in Synergy for the allocable portion of losses to which the minority interest holders are entitled. We will suspend allocation of losses to minority interest holders when the minority interest balance for a particular minority interest holder is reduced to zero. Any excess loss above the minority interest holder's balance is not charged to minority interests as the minority interest holders have no obligation to fund such losses. Since Synergy has incurred losses during the period July 14, 2008 to September 30, 2008, we reduced our minority interest for 32% of Synergy's losses or $538,724, which excludes Synergy's charge for purchased in process research and development eliminated in consolidation.

Net loss available to common stockholders for the three months ended September 30, 2008 was $1,748,352 compared to a net loss of $12,963,642 incurred for the three months ended September 30, 2007. The decreased net loss is the result of (i) lower operating expenses discussed above, (ii) the beneficial conversion feature discounts related to the Series A and B preferred stock accreted as a dividend of $12,880,478 in the three months ended September 30, 2007 (iii) a benefit in the three months ended September 30, 2007 relating to a change in the fair value of the Series B warrants of $2,591,005. We had no such items (ii) and (iii) during 2008, however we did eliminate our 32% minority interest in the net losses of our majority owned subsidiary, Synergy, which totaled $538,724 during the three months ended September 30, 2008.

NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

We had no revenues during the nine months ended September 30, 2008 and 2007 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 $631,152 or 18%, to $4,129,756 for the nine months ended September 30, 2008 from $3,498,604 for the nine months ended September 30, 2007. This increase in research and development expense was attributable to an increase in SP-304 program expenses, partially offset by a decrease in Atiprimod and Annamycin program expenses. The SP-304 program expenses incurred by our majority-owned subsidiary increased to $2,676,000 for the nine months ended September 30, 2008 from $726,000 during the nine months ended September 30, 2007. Expenses incurred on our Atiprimod program decreased to $503,000 for the nine months ended September 30, 2008 from $1,293,000 during the nine months ended September 30, 2007. . Expenses incurred on our Annamycin program decreased to $248,000 for the nine months ended September 30, 2008 from $530,000 during the nine months ended September 30, 2007. All other program specific development expenses decreased approximately $12,000 for the nine months ended September 30, 2008 as compared to the same period in 2007.

Research and development in-house overhead, not allocated to specific programs, totaled $702,000 and $936,000 during the nine months ended September 30, 2008 and 2007, respectively, a decrease of $234,000 or 25%, as we focused more of all of our research and development resources on established programs. As a percent of our total research and development costs these non-program specific overhead expenses decreased to 17% from 27% of total research and development expenses during the nine months ended September 30, 2008 and 2007, respectively.

General and administrative expenses for the nine months ended September 30, 2008 were essentially unchanged at $3,291,196 for the nine months ended September 30, 2008 from $3,295,245 for the nine months ended September 30, 2007. Increased accounting, consulting and advisory expenses, were offset by a decrease in legal and public relations expenses.

We record adjustments to the minority interests in Synergy for the allocable portion of losses to which the minority interest holders are entitled. We will suspend allocation of losses to minority interest holders when the minority interest balance for a particular minority interest holder is reduced to zero. Any excess loss above the minority interest holder's balance is not charged to minority interests as the minority interest holders have no obligation to fund such losses. Since Synergy has incurred losses during the period July 14, 2008 to September 30, 2008, we reduced our minority interest for 32% of Synergy's losses, or $538,724, which excludes Synergy's charge for purchased in process research and development, eliminated in consolidation.

Net loss available to common stockholders for the nine months ended September 30, 2008 was $6,784,194 compared to a net loss of $16,959,542 incurred for the nine months ended September 30, 2007. The decreased net loss is the result of (i) lower operating expenses discussed above, (ii) the beneficial conversion feature discount related to the Series A and B preferred stock accreted as a dividend of $13,000,163 in the nine months ended September 30, 2007 and (iii) a benefit in the nine months ended September 30, 2007 relating to a change in the fair value of the Series B warrants of $2,591,005. We had no such items (ii) and (iii) during 2008, however we did eliminate our 32% minority interest in the net losses of our majority owned subsidiary, Synergy, which totaled $538,724 during the nine months ended September 30, 2008.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2008 we had $1,825,389 in cash and cash equivalents, compared to $3,269,341 as of December 31, 2007. Net cash used in operating activities was $7,378,309 and $5,990,759 for the nine months ended September 30, 2008 and 2007 respectively. As of December 31, 2007, we also had approximately $3,000,000 invested in U.S. Treasury bills classified as short term investments on our balance sheet. These investments were liquidated into cash during the nine months ended September 30, 2008.

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

available; or (iii) relinquish license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

On December 31, 2007, Callisto and Synergy entered into an Amended and Restated License Agreement with AnorMED, a wholly-owned subsidiary of Genzyme, pursuant to which Callisto and Genzyme amended the Original License agreement for Atiprimod to eliminate all future maintenance fees and milestone payments and reduce future royalties to single digits. In return for the reduced future payments to Genzyme, Callisto agreed to pay upfront fees which were recorded as a liability and expensed on December 31, 2007. These upfront fees were scheduled to be paid on January 31, 2008 and April 30, 2008. As of September 30, 2008 approximately $650,000 of these upfront fees remains due and payable. We are currently in discussions with AnorMED/Genzyme however if we fail to meet these obligations, the license agreement may be terminated and our business may be adversely affected.

Our consolidated financial statements as of September 30, 2008 and December 31, 2007 have been prepared under the assumption that we will continue as a going concern for the twelve months ending December 31, 2008. 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk on the fair values of certain assets is related to credit risk associated with securities held in money market accounts and the FDIC insurance limit on our bank balances. At September 30, 2008, our money market balances totaled approximately $1,700,000.

ITEM 4.T. CONTROLS AND PROCEDURES

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of September 30, 2008, 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 SEC'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, 2007. 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, 2007, 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, 2007, we did not maintain effective internal control over financial reporting. As defined by Regulation S-X, Rule 1-02(a)(4), a material weakness is a deficiency or a combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply

its judgment in evaluating the relationship between the benefit of desired controls and procedures and the cost of implementing new controls and procedures.

The condensed consolidated financial statements as of and for the period ended September 30, 2008 include all adjustments identified as a result of the evaluation performed.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As of September 30, 2008, we are in the process of remediating the material weaknesses which existed at December 31, 2007. We have added financial staff resources to our accounting and finance department and implemented certain other controls and procedures which management believes will prevent the recurrence of the material weakness described above. However, it will require a period of time to determine the operating effectiveness of these newly implement internal controls over financial reporting. We plan to be testing and re-evaluating our controls periodically during 2008.

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 quarter ended September 30, 2008.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

There have been no material changes from the legal proceedings reported in our Form 10-K for the year ended December 31, 2007.

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, 2007 except as follow:

IF OUR AGREEMENT WITH ANORMED CORPORATION TERMINATES, OUR BUSINESS WOULD BE ADVERSELY AFFECTED.

Our business is partially dependent on rights we have licensed from AnorMED Corporation (AnorMED"). On December 31, 2007, Callisto and Synergy entered into an Amended and Restated License Agreement with AnorMED, a wholly-owned subsidiary of Genzyme Corporation ("Genzyme"), pursuant to which Callisto and Genzyme amended the Original License agreement with AnorMED for Atiprimod to eliminate all future maintenance fees and milestone payments and reduce future royalties to single digits. In return for the reduced future payments to Genzyme, Callisto agreed to pay upfront fees which were recorded as a liability and expensed on December 31, 2007. These upfront fees were scheduled to be paid on January 31, 2008 and April 30, 2008. As of September 30, 2008 approximately $650,000 of these upfront fees remains due and payable. If we fail to meet these obligations or other material obligations, the license agreement may be terminated and our business would be adversely affected.

DOWNTURN IN THE GENERAL ECONOMY AND RECENT DISRUPTIONS IN THE EQUITY MARKETS MAY NEGATIVELY IMPACT OUR ACCESS TO FINANCING SOURCES.

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

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.

SIGNATURES

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

CALLISTO PHARMACEUTICALS, INC.
(Registrant)

Date: November 19, 2008 By: /s/ GARY S. JACOB

Gary S. Jacob
Chief Executive Officer

Date: November 19, 2008 By: /s/ BERNARD F. DENOYER

Bernard F. Denoyer
Senior Vice President, Finance

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