CALLISTO PHARMACEUTICALS INC
Form 424B3
November 16, 2004

Prospectus Supplement filed under Rule 424(b)(3)
Registration Number 333-115471

Prospectus Supplement No. 2, dated November 15, 2004

(To Prospectus dated August 12, 2004)

6,056,041 SHARES

CALLISTO PHARMACEUTICALS, INC.

COMMON STOCK

This prospectus supplement to the prospectus dated August 12, 2004 relates to the public offering, which is not being underwritten, of 6,056,041 shares of our common stock that are held by the selling shareholders identified in the prospectus.

This prospectus supplement should be read in conjunction with the prospectus dated August 12, 2004 and Prospectus Supplement No. 1 dated September 8, 2004, each of which is to be delivered with this prospectus supplement. The information in this prospectus supplement updates and supercedes certain information contained in the prospectus dated August 12, 2004 as amended by Prospectus Supplement No. 1 dated September 8, 2004.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS PASSED UPON THE ACCURACY OR ADEQUACY OF THE PROSPECTUS OR THIS PROSPECTUS SUPPLEMENT OR THE INVESTMENT MERITS OF OUR COMMON STOCK. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

On November 12, 2004, Callisto Pharmaceuticals, Inc. filed with the Securities and Exchange Commission the attached QUARTERLY REPORT on Form 10-QSB for the fiscal quarter ended September 30, 2004.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-QSB

(Mark One)
(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED: SEPTEMBER 30, 2004

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number: 001-32325

CALLISTO PHARMACEUTICALS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	13-3894575
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

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

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 past 90 days.

|X| Yes |_| No

APPLICABLE ONLY TO CORPORATE ISSUERS:

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date:

Class	Outstanding at November 12, 2004
Common Stock, par value $0.0001	29,219,102 shares

Transitional Small Business Disclosure Format (check one): Yes No |X|

CALLISTO PHARMACEUTICALS, INC.
FORM 10-QSB
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PART I -- FINANCIAL INFORMATION

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INTRODUCTORY NOTE

This Report on Form 10-QSB for Callisto Pharmaceuticals, Inc. (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-KSB for the year ended December 31, 2003 and

other periodic reports filed with the SEC. Accordingly, to the extent that this Report contains forward-looking statements regarding the acquisitions, 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.

PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEET AS OF SEPTEMBER 30, 2004
(Unaudited)

ASSETS

Current assets:	
Cash and cash equivalents	$ 6,340,066
Prepaid expenses	72,561
	6,412,627
Property and equipment, net of accumulated depreciation of $58,873	25,764
Rent deposits	82,196
	$ 6,520,587

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:	
Accounts payable	$646,848
Accrued expenses	274,955
	921,803
Stockholders' equity:	
Preferred stock, $.0001 par value, authorized 20,000,000 shares, none outstanding	--
Common stock, $.0001 par value, authorized 75,000,000 shares, 29,175,102 outstanding	2,915
Additional paid-in-capital	40,634,767
Unamortized deferred stock-based compensation	(3,877,772)
Deficit accumulated during the development stage	(31,161,126)

	5,598,784
	$ 6,520,587

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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2004	2003	2004	2003
Revenues	$ --	$ --	$ --	$
Costs and expenses:				
Research and development	1,777,062	885,252	851,410	576,2
Government grant	(188,100)	--	(87,880)	
General and administrative	1,646,673	839,775	572,440	342,1
Purchased in process R&D	209,735	6,814,363	--	(19,0
Stock based compensation	1,952,945	2,938,734	287,351	475,7
Loss from operations	(5,398,315)	(11,478,124)	(1,623,321)	(1,375,0
Interest income	54,919	8,301	17,635	1,2
Other income	--	--	--	
Net loss	$ (5,343,396)	$(11,469,823)	$ (1,605,686)	$ (1,373,8
Weighted average shares outstanding: basic and diluted	28,239,940	20,621,950	29,175,102	23,209,1

Net loss per common share:				
basic and diluted	$ (0.19)	$ (0.56)	$ (0.06)	$ (0.

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

	Preferred Shares	Preferred Stock Par Value	Common Shares	
Balance at inception, June 5, 1996	--	$ --		$
Net loss for the period	--	--	--	
Issuance of founder shares	--	--	2,642,500	
Common stock issued	--	--	1,356,194	
Common stock issued via private placement	--	--	1,366,667	
Balance, December 31, 1996	--	--	5,365,361	
Net loss for the year	--	--	--	
Common stock issued via private placement	--	--	1,442,666	
Balance, December 31, 1997	--	--	6,808,027	
Net loss for the year	--	--	--	

Amortization of stock based compensation	--	--	--	
Common stock issued via private placement	--	--	1,416,667	
Common stock issued for services	--	--	788,889	
Common stock repurchased and cancelled	--	--	(836,792)	
Balance, December 31, 1998	--	--	8,176,791	
Net loss for the year	--	--	--	
Deferred compensation - stock options	--	--	--	
Amortization of stock based compensation	--	--	--	
Common stock issued for services	--	--	--	
Common stock issued via private placement	--	--	346,667	
Balance, December 31, 1999	--	--	8,523,458	
Net loss for the year	--	--	--	
Amortization of stock based compensation	--	--	--	
Common stock issued	--	--	4,560,237	
Other	--	--	--	
Preferred stock issued	3,485,299	348	--	
Preferred stock issued for services	750,000	75	--	
Balance, December 31, 2000	4,235,299	423	13,083,695	
Net loss for the year	--	--	--	
Deferred compensation - stock options	--	--	--	
Amortization of stock based compensation	--	--	--	
Balance, December 31, 2001	4,235,299	423	13,083,695	
Net loss for the year	--	--	--	
Amortization of stock based compensation	--	--	--	
Balance, December 31, 2002	4,235,299	$ 423	13,083,695	$

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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

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

	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholde Equity
Balance at inception, June 5, 1996	$ --	$ --	$
Net loss for the year	--	(404,005)	(404,0
Issuance of founder shares	--	--	7
Common stock issued	--	--	4
Common stock issued via private placement	--	--	1,025,0
Balance, December 31, 1996	--	(404,005)	622,1
Net loss for the year	--	(894,505)	(894,5
Common stock issued via private placement	--	--	1,081,9
Balance, December 31, 1997	--	(1,298,510)	809,6
Net loss for the year	--	(1,484,438)	(1,484,4
Amortization of stock based compensation	--	--	52,7
Common stock issued	--	--	1,062,5
Common stock issued for services	--	--	591,6
Common stock repurchased and cancelled	--	--	(97,0
Balance, December 31, 1998	--	(2,782,948)	935,1
Net loss for the year	--	(4,195,263)	(4,195,2
Deferred compensation - stock options	(9,946)	--	
Amortization of stock based compensation	3,262	--	3,2
Common stock issued for services	--	--	3,168,8
Common stock issued via private placement	--	--	260,0
Balance, December 31, 1999	(6,684)	(6,978,211)	172,0
Net loss for the year	--	(2,616,261)	(2,616,2
Amortization of stock based compensation	4,197	--	4,1
Common stock issued	--	--	251,3
Other	--	--	4
Preferred stock issued	--	--	5,986,6
Preferred stock issued for services	--	--	1,125,0
Balance, December 31, 2000	(2,487)	(9,594,472)	4,923,3
Net loss for the year	--	(1,432,046)	(1,432,0

Deferred compensation - stock options	(20,000)	--	
Amortization of stock based compensation	22,155	--	22,1
Balance, December 31, 2001	(332)	(11,026,518)	3,513,4
Net loss for the year	--	(1,684,965)	(1,684,9
Amortization of stock based compensation	332	--	3
Balance, December 31, 2002	$ --	$(12,711,483)	$ 1,828,8

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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (CONTINUED)

	Preferred Stock	Preferred Stock Par Value	Common Stock	Common Stock Par Value
Balance, December 31, 2002	4,235,299	423	13,083,695	1,307
Net loss for the year	--	--	--	--
Conversion of preferred stock in connection with the Merger	(4,235,2)9	(423)	4,235,299	423
Common stock issued to former Synergy stockholders	--		4,329,927	432
Common stock issued in exchange for Webtronics common stock	--		1,503,173	150
Deferred compensation - stock options	--	--	--	

Amortization of stock based compensation	--	--	--	--
Private placement of common stock, net	--	--	2,776,666	278
Balance, December 31, 2003	--	--	25,928,760	2,590
Net loss for the period (unaudited)	--	--	--	--
Amortization of deferred stock based compensation expense (unaudited)	--	--	--	--
Stock-based compensation expense (unaudited)	--	--	--	--
Common stock issued via private placements (unaudited)	--	--	3,311,342	331
Warrant and stock-based compensation for services in connection with the Merger (unaudited)	--	--	--	--
Common stock issued for patent rights (unaudited)	--	--	25,000	3
Common stock returned from former Synergy stockholders (unaudited)	--	--	(90,000)	(9)
Balance September 30, 2004 (Unaudited)	--	$ --	29,175,102	$ 2,915

	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
Balance, December 31, 2002	(12,711,483)	$ 1,828,865
Net loss for the year	(13,106,2)	(13,106,247)
Conversion of preferred stock in connection with the Merger	--	--
Common stock issued to		

former Synergy stockholders	--	6,494,890
Common stock issued in exchange for Webtronics common stock	--	--
Deferred compensation - stock options	--	--
Amortization of stock based compensation		3,833,946
Private placement of common stock, net	--	3,803,374
Balance, December 31, 2003	(25,817,730)	2,854,828
Net loss for the period (unaudited)	(5,343,396)	(5,343,396)
Amortization of deferred stock based compensation expense (unaudited)	--	1,534,438
Stock-based compensation expense (unaudited)	--	286,918
Common stock issued via private placements (unaudited)	--	6,099,012
Warrant and stock-based compensation for services in connection with the Merger (unaudited)	--	269,826
Common stock issued for patent rights (unaudited)	--	56,250
Common stock returned from former Synergy stockholders (unaudited)	--	(159,092)
Balance September 30, 2004 (Unaudited)	$(31,161,126)	$ 5,598,784

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

CALLISTO PHARMACEUTICALS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine months ended September 3	
	2004	2003
Cash flows from operating activities:		
Net loss	$ (5,343,396)	$(11,469,
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	20,724	14,
Stock-based compensation expense	1,952,945	2,938,
Purchased in-process research and development-non cash	106,235	6,814,
Changes in operating assets and liabilities:		
Prepaid expenses	(19,917)	(84,
Rent deposits	(19,216)	(47,
Accounts payable and accrued expenses	(412,807)	369,
Total adjustments	1,627,964	10,006,
Net cash used in operating activities	(3,715,432)	(1,463,
Cash flows from investing activities:		
Acquisition of property and equipment	--	(55,
Net cash used in investing activities	--	(55,
Cash flows from financing activities:		
Net proceeds from issuance of common and preferred stock, net of repurchases	6,099,012	
Net cash provided by financing activities	6,099,012	
Net increase (decrease) in cash and cash equivalents	2,383,580	(1,519,
Cash and cash equivalents at beginning of the period	3,956,486	2,223,

Cash and cash equivalents at end of the period	$ 6,340,066	$ 703,
Supplementary disclosure of cash flows information:		
Cash paid for taxes	$ 2,921	$ 23,

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

CALLISTO PHAMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO SEPTEMBER 30, 2004 CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Basis of presentation:

The accompanying unaudited condensed consolidated financial statements of Callisto Pharmaceuticals, Inc., and its wholly owned subsidiaries Callisto Research Labs, LLC., Synergy Pharmaceuticals Inc. ("Synergy") and Callisto Pharmaceuticals, GmbH ("GmbH"), (collectively, "Callisto" a development stage company), have been prepared in accordance with (i) accounting principles generally accepted in the United States ("GAAP") for interim financial information and (ii) the rules of the Securities and Exchange Commission (the "SEC") for quarterly reports on Form 10-QSB. The results of operations of Synergy are included in the condensed consolidated statement of operations for the nine months ended September 30, 2004 and since May 1, 2003 in the period from June 5, 1996 (inception) to September 30, 2004 and for the nine months ended September 30, 2003. (See note 3.) These condensed consolidated financial statements do not include all of the information and footnote disclosures required by GAAP for complete financial statements. These statements should be read in conjunction with Callisto's audited financial statements and notes thereto for the year ended December 31, 2003, included in Form 10-KSB filed with the SEC on April 14, 2004.

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 nine months ended September 30, 2004 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2004.

2. Accounting for stock based compensation:

Callisto has adopted Statement of Financial Accounting Standard No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). As provided for by SFAS 123, Callisto has also elected to continue to account for its stock-based compensation programs according to the provisions of Accounting Principles Board

Opinion No. 25, "Accounting for Stock Issued to Employees ("APB 25")." Accordingly, compensation expense has been recognized to the extent of employee or director services rendered based on the intrinsic value of options or shares granted under the plans. Callisto has also adopted the disclosure provisions required by SFAS 123, as amended by SFAS 148, "Accounting for Stock-Based Compensation - Transition and Disclosure, an amendment to FASB Statement No. 123."

Had compensation cost for stock options granted been determined based upon the fair value at the grant date for awards, consistent with the methodology prescribed under SFAS 123, Callisto's net loss and net loss per share would have been as follows:

	Nine Months Ended September 30,		Three Mo
	2004	2003	
Net loss, as reported	$ (5,343,396)	$(11,469,823)	$ (1
Add: Stock-based employee compensation expense recorded under APB No. 25	1,666,936	1,525,178	
Deduct: stock-based employee compensation expense determined under fair value method	(2,656,870)	(1,893,512)	
Pro forma net loss	$ (6,333,330)	$(11,838,157)	$ (1
Net loss per share:			
Basic and diluted -as reported	$ (0.19)	$ (0.56)	$
Basic and diluted -pro forma	$ (0.22)	$ (0.57)	$

The fair value of the options granted to employees during 2004 and 2003 ranged from $0.26 to $5.53 on the date of the respective grant using the Black-Scholes option-pricing model. The following weighted average assumptions were used for 2004 and 2003: no dividend yield, expected volatility of 0% to April 30, 2003 and 100% since Callisto's common stock began to trade publicly on June 16, 2003, risk free interest rate ranged from 4.50% to 2.87% and an expected term of 7 to 10 years.

3. Merger and consolidation:

In March 2002, Callisto Pharmaceuticals, Inc. ("Old Callisto") purchased 99.7% of the outstanding common shares of Webtronics, Inc., ("Webtronics") a public company for $400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations during the year ended December 31, 2002. The purchase price of Webtronics was treated as a cost of becoming a public company, however

because there was no capital raised at the time, the amount was charged to general and administrative expense during the year ended December 31, 2002.

On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Synergy and Callisto Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Old Callisto (collectively, the "Merger"). As a result of the Merger, Old Callisto and Synergy became wholly-owned subsidiaries of Webtronics. In connection with the Merger, Webtronics issued 17,318,994 shares of its common stock in exchange for outstanding Old Callisto common stock and an additional 4,395,684 shares in exchange for outstanding Synergy common stock. Subsequently, 171,818 shares of common stock issued to former Synergy shareholders were returned to Callisto under the terms of certain indemnification agreements through September 30, 2004. The merged companies are considered to be in the development stage. No revenues have been realized since inception and all activities have been concentrated in research and development of biopharmaceutical products not yet approved by the Food and Drug Administration. The fair value of the net shares issued to former Synergy shareholders in the Merger totaled $6,335,798 through September 30, 2004. The fair value per share of $1.50, used to determine this amount, was the value per share Callisto sold common stock in a private placement consummated in January 2004. The total consideration was allocated in full to the Synergy research and development projects which had not yet reached technological feasibility and having no alternative use was charged to purchased in-process research and development expense.

4. Net loss per share:

The assumed exercise of all of Callisto's outstanding stock options was excluded from the computation of net loss per share due to their anti-dilutive effect because of the net losses reported for the three and nine months ended September 30, 2004 and 2003. As of September 30, 2004 and 2003, Callisto had 6,783,560 and 4,675,227 stock options outstanding, respectively. In addition Callisto had 758,995 common stock warrants outstanding as of September 30, 2004 and none as of September 30, 2003.

5. Government Research Grant:

On October 7, 2003, Callisto was awarded a $265,697 Small Business Technology Transfer Research Grant from the National Institutes of Health for studies on Atiprimod. No funding was received during 2003. During the three and nine months ended September 30, 2004, Callisto received $87,880 and $188,100 of grant funding, respectively, as reimbursement of expenses and recorded the receipt as an offset to research and development expense. As of September 30, 2004 Callisto had unused grant funding available of $77,597.

6. Stockholders' equity:

During the three months ended March 31, 2004:

In January 2004, Callisto completed a private placement begun in late 2003 and issued 1,128,766 shares of common stock at an issue price of $1.50 for aggregate proceeds of $1,693,149, less $139,891 in fees to various selling agents. In addition, Callisto incurred and issued 31,467 shares of common stock and an aggregate 370,543 warrants to purchase common stock to such selling agents. The warrants are immediately exercisable at $1.90 per share and will expire five years after issuance.

a.) Callisto issued to Houston Pharmaceuticals, Inc. ("HPI") 25,000 shares of common stock at a fair value of $56,250 in connection with the acquisition of certain patent rights, which cost was charged to purchased in-process research and development expense (see note 7);

b.) 90,000 shares of common stock issued to former Synergy shareholders were returned to Callisto and purchased in process research and development expense was decreased by $159,092;

c.) Callisto recorded $209,076 of purchased in process research and development as a result of the issuance of 263,741 warrants to two Callisto shareholders, which warrants are immediately exercisable at $1.50 per share and will expire ten years after issuance; and $60,750 of stock-based compensation expense associated with shares of common stock issued to a shareholder for services performed.

During the three months ended June 30, 2004:

On April 19, 2004, Callisto sold and issued 2,151,109 shares of common stock at an issue price of $2.25 per share for aggregate gross proceeds of $4,839,995 and incurred fees and expenses aggregating $294,241 to various selling agents. In addition, Callisto issued an aggregate 124,711 warrants to purchase common stock to such selling agents. The warrants are immediately exercisable at $2.48 per share and will expire five years after issuance.

On April 26, 2004, Callisto's Board of Directors granted 100,000 stock options to Gabriele M. Cerrone, Chairman of the Board, in recognition of his efforts during the past year on behalf of the company. The stock options are immediately exercisable at $3.20 per share and stock-based compensation expense of $286,918 was recorded in connection with the grants, based on a Black-Scholes fair value of $2.87 per share.

On June 29, 2004, Callisto's Compensation Committee recommended and the Board of Directors approved the grant of 275,000 stock options to Gary Jacob, Chief Executive Officer, as additional compensation. The stock options are exercisable at $3.00 per share. 25,000 options vest on each of June 1, 2005 and June 1, 2006 and 50,000 options vest on June 1, 2007. The remaining 175,000 options vest upon the achievement of performance milestones associated with the successful in-licensing, advancement and development of certain drug candidates. If the milestones are achieved Callisto will record stock-based compensation expense based on the intrinsic value of the options at that time.

On June 29, 2004, Callisto's Compensation Committee recommended and the Board of Directors approved the grant of 400,000 stock options to Donald Picker, Executive Vice President, R&D as additional compensation. The stock options are exercisable at $3.00 per share. 50,000 options vest on each of June 1, 2005 and June 1, 2006 and 75,000 options vest on June 1, 2007. The remaining 225,000 options vest upon the achievement of performance milestones associated with the successful advancement and development of our drug candidates through various stages of clinical trials. If the milestones are achieved Callisto will record stock-based compensation expense based on the intrinsic value of the options at that time.

During the three months ended September 30, 2004:

On August 12, 2004, in connection with the Annamycin license (see Note 7), Callisto entered into a consulting agreement with Roman Perez-Soler, M.D., for a term concurrent with the Annamycin license agreement. In connection therewith Dr. Perez-Soler agreed to be appointed to the Company's Scientific Advisory

Board. As consideration for consulting and advisory services Dr. Perez-Soler shall receive a $30,000 per year consulting fee and, 44,000 shares of restricted common stock. These shares had not yet been issued as of September 30, 2004, however we accrued stock based compensation expense totaling $70,840 based on the closing stock price of $1.61 on August 12, 2004, the date on which the Company became obligated to issue the stock. In addition, Callisto will grant Dr. Perez-Soler an option to purchase 468,500 shares of common stock at an exercise price of $3.00 per share. The option shares vest upon achievement of specific milestones related to future development of Annamycin, at which time stock-based compensation expense will be recorded based upon the fair value of the options at that time.

7. Commitments and contingencies:

License agreements:

On August 28, 2002, Synergy entered into a worldwide license agreement with AnorMED, Inc. ("AnorMED") to research, develop, sell and commercially exploit the Atiprimod patent rights. The license agreement provides for aggregate milestone payments by Synergy of up to $14 million based on achieving regulatory submissions and approvals for an initial indication and additional payments of $16 million for each additional indication based on achieving regulatory submissions and approvals. In addition, the license agreement requires Synergy to pay royalties based on net sales to AnorMED. Commencing on January 1, 2004 and on January 1 of each subsequent year Synergy is obligated to pay AnorMED a maintenance fee of $200,000 until the first commercial sale of the product. The first of these annual maintenance fee payments made on January 22, 2004 was reported as research and development expense in the nine months ended September 30, 2004. The agreement will terminate upon expiration of the last to expire of any patents included in the licensed patents as defined in the agreement.

On February 24, 2004, Callisto entered into an agreement with HPI, a privately held company, to acquire the rights to two key patents covering a novel cancer platform technology. Callisto issued to HPI 25,000 shares of common stock at a fair value of $56,250 and reimbursed HPI approximately $103,500 for various costs and expenses. The total consideration of $159,750 was allocated in full to the HPI patent rights, which have not yet reached technological feasibility, and having no alternative use, was accounted for as purchased in-process research and development expense during the quarter ended March 31, 2004. The fair value of the common stock issued to HPI was $2.25, based on the price per share paid in the April 2004 private placement, which closed on April 19, 2004. (See note 6)

In addition, Callisto granted to HPI 1,170,000 performance based stock options, exercisable at $3.50 per share, which vest upon the achievement of certain milestones. If the milestones are achieved, Callisto will record additional purchased in-process research and development expense based upon the fair value of the options at that time. Callisto also agreed to pay HPI a royalty of 2% of net sales from any products resulting from commercializing the patents.

On August 12, 2004, Callisto entered into a world-wide license agreement with The University of Texas M. D. Anderson Cancer Center ("UTMDACC") to research, develop, sell and commercially exploit the patent rights for Annamycin, an anthacycline cancer drug for leukemia therapy. Consideration paid for this license amounted to $31,497 for reimbursement of out-of-pocket costs for filing, enforcing and maintaining the Annamycin patent rights and a $100,000 initial license fee. Annamycin has not yet reached technological feasibility, and having no alternative use, these costs were recorded as research and development expense in the quarter ended September 30, 2004. Callisto also agreed to pay UTMDACC royalties based on net sales from any licensed products, plus aggregate milestone payments of up to $750,000 based upon achieving certain regulatory

submissions and approvals. The term of the agreement is the life of the underlying patent rights.

Employment Agreements:

On June 13, 2003, Callisto entered into an employment agreement with Kunwar Shailubhai, Ph.D. to serve as Executive Vice President and Head of Research and Development for a term of 18 months beginning June 13, 2003 and is automatically renewable for successive one year periods at the end of the term. Dr. Shailubhai's salary is $170,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. In connection with his employment agreement, Dr. Shailubhai received a grant of 25,000 stock options which are fully vested and have an exercise price of $1.50 per share. Dr. Shailubhai also received a grant of 325,000 stock options which vest over a three year period and are exercisable at $1.50 per share.

On April 6, 2004, Dr. Shailubhai's employment agreement was terminated and he entered into an employment agreement with Synergy in which he agreed to serve as Senior Vice President, Drug Discovery. Dr. Shailubhai's employment agreement is for a term of 12 months beginning April 6, 2004 and is automatically renewable for successive one year periods at the end of the term. Dr. Shailubhai's salary is $150,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. His unvested options for 325,000 shares granted June 13, 2003 were cancelled and Dr. Shailubhai received a new grant of 100,000 stock options which are exercisable at $1.50 per share. 50,000 of such stock options vested in June 2004 and the remainder in December 2004.

The unamortized balance of deferred stock based compensation expense associated with the 225,000 cancelled options, amounting to $706,813 as of the date of cancellation, was charged to stock-based compensation expense during the quarter ended June 30, 2004. The deferred balance of stock-based compensation expense associated with the remaining 100,000 options of $314,139, will be expensed over the vesting period of the new grant (e.g. April 7, 2004 through December 31, 2004). During the quarter ended September 30, 2004 this expense amounted to $108,203.

On July 22, 2004 the employment agreement of Donald H. Picker, Callisto's Executive Vice President, R&D was amended. Dr, Picker's salary was increased from $175,000 to $200,000 per year and certain milestones were added upon achievement of which cash bonuses of up to $92,500 over a 12 month period may be paid. During the quarter ended September 30, 2004 no milestones were achieved and no expense was recorded.

Lease agreements:

On June 7, 2004 Callisto extended its lease for its corporate headquarters in New York City two additional years through August 2010, and increased its space by approximately 60%. This increases average annual rent by approximately $50,000 to $150,000. Laboratory space in New Jersey, principally to support combined Callisto and Synergy research efforts, with an approximate rent of $50,000 annually through November 2005 was unchanged in the nine months ended September 30, 2004.

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 notes to those statements. In addition to historical information, the following discussion and other parts of this quarterly report contain forward-looking information that involves risks and uncertainties.

OVERVIEW

We are a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. Since inception in June 1996, our efforts have been principally devoted to research and development, securing patent protection, obtaining corporate relationships and raising capital. Since inception, through September 30, 2004, we have sustained cumulative net losses of $31,161,126. Our losses have resulted primarily from expenditures incurred in connection with the purchase of in-process research and development, stock-based compensation expense, patent filing and maintenance, outside accounting and legal services and regulatory consulting fees. From inception through September 30, 2004 we have not generated any revenue from operations. We expect to incur additional losses to perform further research and development activities. We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all.

HISTORY

In March 2002, Callisto Pharmaceuticals, Inc. ("Old Callisto") purchased 99.7% of the outstanding common shares of Webtronics, Inc., a public company ("Webtronics"), for $400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations during the year ended December 31, 2002. On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Synergy Pharmaceuticals Inc. ("Synergy") and Callisto Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Old Callisto (collectively, the "Merger"). As a result of the Merger, Old Callisto and Synergy became wholly-owned subsidiaries of Webtronics. Old Callisto changed its name to Callisto Research Labs, LLC and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2004 AND SEPTEMBER 30, 2003.

The results of operations of Synergy are included in the consolidated statement of operations for the full quarter ended September 30, 2004 and September 30, 2003.

We had no revenues during the three months ended September 30, 2004 and 2003 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 approximately $275,144, or 48%, to $851,410 for the three months ended September 30, 2004 from $576,266 for the same period in 2003. Of this increase in research and development expense, approximately $95,000 was associated with the patient cost of our Phase I/IIa clinical trials of Atiprimod currently underway. Also contributing to higher research and development expenses in the quarter ended September 30, 2004 was approximately $75,000 in higher license fees attributable to Annamycin and approximately $95,000 of higher expenses incurred under our NIH research grant. During the three months ended September 30, 2004, a portion of our research and development expenses consisted of costs incurred developing commercial production capacity for future trials of Atiprimod as compared to the three month period ended September 30, 2003 during which a portion of our research and development expenses were pre-clinical costs associated with preparing our Atiprimod IND application.

Government grant funding for the three months ended September 30, 2004 was $87,880 as compared to $0 for the three months ended September 30, 2003. We request grant funding for research and development expenses as incurred.

General and administrative expenses for the three months ended September 30, 2004 increased $230,283, or 67%, to $572,440, from $342,157 for the three months ended September 30, 2003. The increase was due in part to approximately $80,000 in higher salaries and wages as a result of our CEO devoting more of his time to administrative and fund raising activities and the hiring of permanent financial staff. During the three months ended September 30, 2003 our CEO's salary was recorded as research and development expense because of his heavy involvement in the IND application process and other patent and research grant related efforts. Also contributing to this increase in general and administrative expenses were approximately $90,000 of higher travel and registration fees related to investor and technical conferences, approximately $30,000 in higher facilities overhead, $24,000 in higher outside directors fees and $16,000 in higher transfer agent costs during the quarter ended September 30, 2004.

Net loss for the three months ended September 30, 2004 was $1,605,686 compared to a net loss of $1,373,814 incurred for the three months ended September 30, 2003. This increase of $231,872, or 17%, in our net loss is primarily the result of the operating expense increases discussed above, partially offset by a decrease of $188,376 or 40% in stock-based compensation expense. This decrease is the result of substantially fewer options being granted (resulting in lower amortization of deferred stock based compensation) during the three months ended September 30, 2004 as compared to 2003, as well as a decline in the market price of our common stock from $4.05 as of September 30, 2003 to $1.49 per share on September 30, 2004.

NINE MONTHS ENDED SEPTEMBER 30, 2004 AND SEPTEMBER 30, 2003.

The results of operations of Synergy are included in the consolidated statement of operations for the full nine months ended September 30, 2004 but only five months of the nine months ended September 30, 2003.

We had no revenues during the nine months ended September 30, 2004 and 2003 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 approximately $891,810, or 101%, to $1,777,062 for the nine months ended September 30, 2004 from $885,252 for the same period in 2003. Of this increase in research and development expense, $300,000 was attributable to our payments of the first annual $200,000 maintenance fee to AnorMED, Inc. for the Atiprimod license and $100,000 to the University of Texas MD Anderson Cancer Center for the Annamycin license. Also contributing to this increase in research and development expense was approximately $152,000 associated with the patient cost (including insurance) of our Phase I/IIa clinical trials of Atiprimod currently underway. In addition personnel costs increased approximately $106,000 as we retained two Synergy executive staff scientists, Drs. Picker and Shailubhai, subsequent to the Merger. The remainder of the increase was primarily associated with higher expenses incurred under our NIH research grant. During the nine months ended September 30, 2004, a portion of our research and development expenses consisted of costs incurred developing commercial production capacity for future trials of Atiprimod as compared to the nine month period ended September 30, 2003 during which a portion of our research and development expenses were pre-clinical costs associated with preparing our Atiprimod IND application.

Government grant funding for the nine months ended September 30, 2004 was $188,100 as compared to $0 for the nine months ended September 30, 2003. We request grant funding to reimburse research and development expenses as incurred.

General and administrative expenses for the nine months ended September 30, 2004 were $1,646,673, an increase of $806,898, or 96%, from $839,775 for the nine months ended September 30, 2003. The increase was due primarily to approximately (i) $200,000 of increased personnel costs as a result of the Merger and the hiring of a senior financial officer in January 2004, (ii) $118,000 in higher facilities and office overhead related to the move into our new corporate headquarters in New York City late in the quarter ended September 30, 2003, (iii) $110,000 in higher legal and accounting fees related to certain regulatory filings and corporate business development activities, (iv) $199,000 in higher outside services associated with being a public company including outside directors, transfer agent fees and investor relations and (v) $155,000 in higher business travel principally attending investor, professional and medical conferences in the United States, England, Italy and Germany.

Purchased in-process research and development was $209,735 for the nine months ended September 30, 2004, primarily in connection with the acquisition of rights to two key patents covering a novel cancer platform technology from Houston Pharmaceuticals, Inc.. During the nine months ended September 30, 2003 we recorded $6,814,363 of purchased in-process research and development expense in connection with the Merger.

Net loss for the nine months ended September 30, 2004 was $5,343,396 compared to a net loss of $11,469,823 incurred for the nine months ended September 30, 2003. The decreased net loss is primarily the result of the lower purchased in-process research and development expenses, partially offset by higher research, development, general and administrative expenses discussed above. In addition we recorded lower stock based compensation expense of $1,952,945 during the nine months ended September 30, 2004, as compared to $2,938,734 recorded during the same period ended September 30, 2003, due to (i) substantially fewer options being granted (resulting in lower amortization of deferred stock based compensation) during the nine months ended September 30, 2004 as compared to 2003 (ii) more immediately vested options granted during the nine months ended September 30, 2003, with exercise prices below market value and (iii) a decline in the market price of our common stock from $4.05 as of September 30, 2003 to $1.49 per share on September 30, 2004.

LIQUIDITY AND CAPITAL RESOURCES:

As of September 30, 2004 we had $6,340,066 in cash and cash equivalents, compared to $3,956,486 as of December 31, 2003. This increase in cash of $2,383,580 during the nine months ended September 30, 2004 was principally the result of completing two private placements of common stock yielding net proceeds of $6,099,012. This was partially offset by cash used in operating activities of $3,715,432 during the nine months ended September 30, 2004. Cash used in operating activities was primarily for research & development and general & administrative expenses discussed above totaling $3,423,735, plus $341,625 used to reduce December 31, 2003 accrued finders fees payable on that portion of our private placement closed during 2003.

In January 2004, we completed a private placement begun in late 2003 and issued 1,128,766 shares of common stock at an issue price of $1.50 for aggregate proceeds of $1,693,149, less $139,891 in fees to various selling agents. In addition, we incurred and issued 31,467 shares of common stock and an aggregate 370,543 warrants to purchase common stock to such selling agents. The warrants are immediately exercisable at $1.90 per share and will expire five years after issuance.

On April 19, 2004, we sold and issued in a private placement to accredited investors an aggregate 2,151,109 shares of common stock at an issue price of $2.25 per share for aggregate gross proceeds of $4,839,995. We incurred fees and expenses aggregating $294,241 to various selling agents. In addition, we issued an aggregate 124,711 warrants to purchase common stock to such selling agents. The warrants are immediately exercisable at $2.48 per share and will expire five years after issuance.

CONTRACTUAL OBLIGATIONS:

On July 22, 2004 the employment agreement of Donald H. Picker, Callisto's Executive Vice President, R&D was amended. Dr, Picker's salary was increased from $175,000 to $200,000 per year and certain milestones were added upon which cash bonuses of up to $92,500 may be paid over a 12 month period.

On August 12, 2004, We entered into a world-wide license agreement with The University of Texas M. D. Anderson Cancer Center ("UTMDACC") to research, develop, sell and commercially exploit the patent rights for Annamycin, an anthacycline cancer drug for leukemia therapy. Consideration paid for this license amounted to $31,497 for reimbursement of out-of-pocket costs for filing, enforcing and maintaining the Annamycin patent rights and a $100,000 initial license fee. We also agreed to pay UTMDACC royalties based on net sales from any licensed products, plus aggregate milestone payments of up to $750,000 based upon achieving certain regulatory submissions and approvals. The term of the agreement is the life of the underlying patent rights.

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; pre-clinical and clinical testing; obtaining regulatory approvals; technological advances and our ability to establish collaborative arrangements with research organizations and individuals needed to commercialize our products. Our capital resources will be focused primarily on the clinical development and regulatory approval of our current product candidates, and the acquisition of licenses and rights to certain other cancer related drug technologies. We expect that our existing capital resources will be sufficient to fund our operations for at least the next 12 months. We will be required to raise additional capital to complete the development and commercialization of our current product candidates.

ITEM 3. Controls and Procedures

Our Chief Executive Officer and Principal Financial Officer, based on the 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 the end of the period covered by this report, have concluded that our disclosure controls and procedures were effective to ensure the timely collection, evaluation and disclosure of information relating to our company that would potentially be subject to disclosure under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated there under.

During the three months ended September 30, 2004, there were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(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

(b) Reports on Form 8-K.

On September 7, 2004 we filed a Form 8-K announcing we had entered into a license agreement with the University of Texas M.D. Anderson Cancer Center.

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 12, 2004

By: /s/ Gary S. Jacob

Gary S. Jacob
Chief Executive Officer

Date: November 12, 2004

By: /s/ Bernard F. Denoyer

Bernard F. Denoyer
Vice President, Finance