

Edgar Filing: CALLISTO PHARMACEUTICALS INC - Form 10QSB

CALLISTO PHARMACEUTICALS INC  
Form 10QSB  
May 17, 2004

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-QSB

(Mark One)

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

For the quarterly period ended: March 31, 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: 33-63474

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 2500, 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)

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 May 12, 2004 -----
Common Stock, par value \$0.0001	29,175,102 shares

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

CALLISTO PHARMACEUTICALS, INC.  
FORM 10-QSB  
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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

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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 March 31, 2004  
(Unaudited)

#### ASSETS

##### Current assets:

Cash and cash equivalents

Prepaid expenses

Property and equipment, net of

accumulated depreciation of \$41,328

Rent deposits

#### LIABILITIES AND STOCKHOLDERS' EQUITY

##### Current liabilities:

Accounts payable

Accrued expenses

##### Stockholders' equity:

Preferred stock, \$.0001 par value, authorized 20,000,000  
shares, none outstanding

Common stock, \$.0001 par value, authorized 75,000,000  
shares, 27,023,993 outstanding

Additional paid-in-capital

Unamortized deferred stock-based compensation

Deficit accumulated during the development stage

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

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## CALLISTO PHARMACEUTICALS, INC. (A Development Stage Company)

### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three months ended March 31,	
	2004	2003
Revenues	\$ -	\$ -
Costs and Expenses:		
Research and development	601,290	77,454
Government grant	(52,259)	-
Purchased in-process research and development	209,735	-
General and administrative	518,371	91,640
Stock-based compensation	563,376	356,370
	(1,840,513)	(525,464)
Loss from operations		
Interest income	12,600	4,243
Other income	-	-
	(1,827,913)	(521,221)
Net loss		
Weighted average shares outstanding:		
Basic and diluted	26,784,833	17,318,994
Net loss per common share: Basic and diluted	\$ (0.07)	\$ (0.03)

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

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CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

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

	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

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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.

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CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENT OF CHANGES  
IN STOCKHOLDERS' EQUITY (Continued)

	Unamortized Deferred Stock Based Compensation -----	Deficit Accumulated during the Development Stage -----	Total Stockholders' Equity -----
Balance at inception, June 5, 1996	\$-	\$-	\$-
Net loss for the year	-	(404,005)	(404,005)
Issuance of founder shares	-	-	792
Common stock issued	-	-	408
Common stock issued via private placement	-	-	1,025,000
	-----	-----	-----
Balance, December 31, 1996	-	(404,005)	622,195
Net loss for the year	-	(894,505)	(894,505)
Common stock issued via private placement	-	-	1,081,999
	-----	-----	-----
Balance, December 31, 1997	-	(1,298,510)	809,689
Net loss for the year	-	(1,484,438)	(1,484,438)
Amortization of stock based compensation	-	-	52,778
Common stock issued	-	-	1,062,500
Common stock issued for services	-	-	591,667
Common stock repurchased and cancelled	-	-	(97,000)
	-----	-----	-----
Balance, December 31, 1998	-	(2,782,948)	935,196
Net loss for the year	-	(4,195,263)	(4,195,263)
Deferred compensation - stock options	(9,946)	-	-
Amortization of stock based compensation	3,262	-	3,262
Common stock issued for services	-	-	3,168,832
Common stock issued via private placement	-	-	260,000
	-----	-----	-----
Balance, December 31, 1999	(6,684)	(6,978,211)	172,027
Net loss for the year	-	(2,616,261)	(2,616,261)
Amortization of stock based compensation	4,197	-	4,197

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Common stock issued	-	-	251,344
Other	-	-	432
Preferred stock issued	-	-	5,986,650
Preferred stock issued for services	-	-	1,125,000
	-----	-----	-----
Balance, December 31, 2000	(2,487)	(9,594,472)	4,923,389
Net loss for the year	-	(1,432,046)	(1,432,046)
Deferred compensation - stock options	(20,000)	-	-
Amortization of stock based compensation	22,155	-	22,155
	-----	-----	-----
Balance, December 31, 2001	(332)	(11,026,518)	3,513,498
Net loss for the year	-	(1,684,965)	(1,684,965)
Amortization of stock based compensation	332	-	332
	-----	-----	-----
Balance, December 31, 2002	\$-	(\$12,711,483)	\$ 1,828,865

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

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CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENT 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,
Net loss for the year	-	-	-	
Conversion of preferred stock in connection with the Merger	(4,235,299)	(423)	4,235,299	
Common stock issued to former Synergy stockholders	-	-	4,329,927	
Common stock issued in exchange for Webtronics common stock	-	-	1,503,173	
Deferred compensation - stock options	-	-	-	

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Amortization of stock based compensation	-	-	-	
Private placement of common stock, net	-	-	2,776,666	
Balance, December 31, 2003	-	-	25,928,760	2,
Net loss for the quarter	-	-	-	
Amortization of stock based compensation	-	-	-	
Private placement of common stock, net	-	-	1,160,233	
Warrants and common stock issued for services	-	-	-	
Common stock issued for patent rights	-	-	25,000	
Common stock returned from former Synergy stockholders	-	-	(90,000)	
Balance March 31, 2004	-	\$ -	27,023,993	\$ 2,

	Unamortized Deferred Stock Based Compensation	Deficit Accumulated during the Development Stage	Total Stockholders' Equity
	-----	-----	-----
Balance, December 31, 2002	-	(\$12,711,483)	\$ 1,828,865
Net loss for the year	-	(13,106,247)	(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	(9,313,953)	-	-
Amortization of stock based compensation	3,833,946	-	3,833,946
Private placement of common stock, net	-	-	3,803,374



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Balance, December 31, 2003	(5,480,007)	(25,817,730)	2,854,828
Net loss for the quarter	-	(1,827,913)	(1,827,913)
Amortization of stock based compensation	502,626	-	502,626
Private placement of common stock, net	-	-	1,553,258
Warrants and common stock issued for services	-	-	269,826
Common stock issued for patent rights	-	-	56,250
Common stock returned from former Synergy stockholders	-	-	(159,092)
	-----	-----	-----
Balance March 31, 2004	(\$ 4,977,381)	(\$27,645,643)	\$ 3,249,784
	=====	=====	=====

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

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CALLISTO PHARMACEUTICALS, INC.  
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)

	Three months
	-----
	2004
	----
Cash flows from operating activities:	
Net loss	\$ (1,827,913)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation and amortization	3,179
Stock-based compensation expense	563,376
Purchased in-process research and development-non cash	106,235
Changes in operating assets and liabilities:	
Prepaid expenses	35,763
Rent deposit	-
Accounts payable and accrued expenses	(578,174)
	-----
Total adjustments	130,379
	-----
Net cash used in operating activities	(1,697,534)
	-----

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Cash flows from investing activities:	
Acquisition of property and equipment	-
	-----
Net cash used in investing activities	-
	-----
Cash flows from financing activities:	
Net proceeds from issuance of common and preferred stock, net of repurchases	1,553,258
	-----
Net cash provided by financing activities	1,553,258
	-----
Net increase (decrease) in cash and cash equivalents	(144,276)
Cash and cash equivalents at beginning of year	3,956,486
	-----
Cash and cash equivalents at end of year	\$ 3,812,210
	=====
Supplementary disclosure of cash flows information:	
Cash paid for taxes	\$ 2,921
	=====

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

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CALLISTO PHAMACEUTICALS, INC.  
(A Development Stage Company)

### NOTES TO MARCH 31, 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 subsidiary Synergy Pharmaceuticals Inc. ("Synergy"), (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 three months ended March 31, 2004 and since May 1, 2003 in the period from June 5, 1996 (inception) to March 31, 2004, but are not included in the results of operations for the three months ended March 31, 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 the 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 three months ended March 31, 2004 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2004.

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### 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:

	Three Months Ended March 31,	
	2004 ----	2003 ----
Net loss, as reported	(\$1,827,913)	(\$ 521,221)
Add: Stock-based employee compensation expense recorded under APB No. 25	313,762	-
Deduct: stock-based employee compensation expense determined under fair value method	(484,385)	-
	(\$1,998,536)	(\$ 521,221)
Pro forma net loss		
Net loss per share:		
Basic and diluted -as reported	(\$ 0.07)	(\$ 0.03)
Basic and diluted -pro forma	(\$ 0.07)	(\$ 0.03)

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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

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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 March 31, 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 \$6,335,799 through March 31, 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 months ended March 31, 2004 and 2003. As of March 31, 2004 and 2003, Callisto had 6,123,560 and 2,781,505 stock options outstanding, respectively. In addition Callisto had 634,284 common stock warrants outstanding as of March 31, 2004 and none as of March 31, 2003.

#### 5. License agreements:

On January 22, 2004, Callisto made the first annual maintenance fee payment of \$200,000 under the worldwide license agreement with AnorMED, Inc. for the Atiprimod patent rights. This payment was recorded as research and development expense in the quarter ended March 31, 2004.

On February 24, 2004, Callisto entered into an agreement with Houston Pharmaceuticals, Inc., ("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 8 Subsequent Event).

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 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

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products resulting from commercializing the patents.

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### 6. 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 months ended March 31, 2004 Callisto received \$52,259 of grant funding as reimbursement of expenses incurred during the first quarter of 2004 and recorded the receipt as an offset to research and development expense. As of March 31, 2004 Callisto had unused funding of \$213,438 available.

### 7. Stockholders' equity:

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.

In addition, during the three months ended March 31 2004;

a.) Callisto issued to 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;

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.

### 8. Subsequent Event:

On April 19, 2004, Callisto sold and issued 2,151,109 shares of common stock (the "April 2004 Private Placement"), at an issue price of \$2.25 per share for aggregate gross proceeds of approximately \$4,840,000 and incurred fees aggregating \$280,600 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.

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### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our condensed consolidated financial statements and 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 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 March 31, 2004, we have sustained cumulative net losses of \$27,645,643. 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 March 31, 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 March 31, 2004 and March 31, 2003

The results of operations of Synergy are included in the consolidated statement of operations for the quarter ended March 31, 2004 but are not included in the results for the same period in 2003.

We had no revenues during the three months ended March 31, 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 \$523,836 to \$601,290 for the three months ended March 31, 2004 from \$77,454 for the same period in 2003. Of this increase in research and development expense, \$200,000 was attributable to our payment of the first annual maintenance fee to AnorMED for the Atiprimod license. In addition, \$121,930 was incurred in preparing for the clinical trials of Atiprimod during the three months ended March 31, 2004, where none was incurred during the same period of 2003. These pre-clinical costs included management consulting fees paid to contract research organizations to develop and advise on clinical trial protocols, site selection and principal

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investigator contracting, plus procurement of drugs and clinical trial liability insurance. Also contributing to this increase in research and development expense were higher patent legal costs and payroll as we retained two Synergy executive staff scientists, Drs. Picker and Shailubhai, subsequent to the Merger. We expect research and development expenses to increase in 2004, compared to 2003, as our product candidates move into the more expensive later stages of development.

Government grant funding for the three months ended March 31, 2004 were \$52,259 as compared to \$0 for the three months ended March 31, 2003. We request grant funding to reimburse expenses as incurred and record the receipt as an offset to research and development expense.

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General and administrative expenses for the three months ended March 31, 2004 increased \$426,731 to \$518,371, from \$91,640 for the three months ended March 31, 2003. The increase was primarily due to \$135,684 in higher legal, accounting, auditing and legal fees related to regulatory filings. In addition, payroll cost increased \$93,613 as we retained one Synergy executive, Dr. Jacob, as CEO subsequent to the Merger and hired a financial officer in January 2004. We had no salaried executive officers during the three months ended March 31, 2003. Also contributing to this increase in general and administrative expense were higher facilities and related office overhead, travel associated with fund raising and directors and officers liability insurance.

Purchased in-process research and development was \$209,735 for the three months ended March 31, 2004 where we had no such expenses during the same period of 2003. These expenses were primarily the result of \$159,750 consideration paid in connection with the acquisition of patent rights from Houston Pharmaceuticals, Inc.

Net loss for the three months ended March 31, 2004 was \$1,827,913 compared to a net loss of \$521,221 incurred for the three months ended March 31, 2003. The increase in the net loss is the result of higher research, development, general and administrative expenses discussed above, and \$563,376 of stock-based compensation expense recorded during the three months ended March 31, 2004, as compared to \$356,370 of stock-based compensation expense recorded during the three months ended March 31, 2003.

### Liquidity and Capital Resources

As of March 31, 2004 we had \$3,812,210 in cash and cash equivalents, compared to \$3,956,486 as of December 31, 2003. This decrease in cash of \$144,276 during the three months ended March 31, 2004 was principally the result of cash used in operating activities of \$1,697,534; partially offset by the completion of our private placement on January 21, 2004 which yielded a net proceeds of \$1,553,258. Our working capital as of March 31, 2004 increased by approximately \$398,135 to \$3,143,495, from \$2,745,360 as of December 31, 2003.

On April 19, 2004, we sold and issued in a private placement an additional 2,151,109 shares of common stock at an issue price of \$2.25 per share for aggregate gross proceeds of approximately \$4,840,000 and incurred fees aggregating \$280,600 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.

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of: pharmaceutical research and

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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 Atiprimod, 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.

Our product development efforts are in their early stages and we cannot make estimates of the costs or the time it will take to complete. The risk of completion of any program is high because of the long duration of clinical testing, extended regulatory approval and review cycles and uncertainty of the costs. Net cash inflows from any products developed may take several years to achieve. In addition, during the next few years, we may have to meet the substantially new challenge of developing the capability to manufacture and market products. Accordingly, our activities to date are not as broad in depth or scope as the activities we must undertake in the future, and our historical operations and financial information are not indicative of the future operating results or financial condition or ability to operate profitably as a commercial enterprise if and when we succeed in bringing any drug candidate to market.

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### 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 March 31, 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.

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## PART II. OTHER INFORMATION

### Item 2. Changes in Securities and Use of Proceeds

From November 2003 through January 2004, we sold and issued 3,905,432 shares of common stock at an issue price of \$1.50 for aggregate gross proceeds of \$5,858,148 to accredited investors. The issuance of shares was done in accordance with Regulation D under the Securities Act of 1933, as amended. In connection therewith, a filing on Form D with the Securities and Exchange Commission was made on November 21, 2003. We intend to use the net proceeds from



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the sale of these shares for working capital and to further the clinical development of our lead drug candidate, Atiprimod. We incurred fees aggregating \$508,615 to various selling agents. In addition, we 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 January 21, 2004, we issued 263,741 warrants to purchase common stock to two persons. This issuance was done in accordance with Section 4(2) of the Securities Act of 1933. The warrants are exercisable at \$1.50 per share and expire ten years after issuance.

On February 24, 2004, we entered into an agreement with Houston Pharmaceuticals, Inc., ("HPI") a privately held company, to acquire the rights to two key patents covering a novel cancer platform technology. As part of the consideration paid to HPI, we issued to HPI 25,000 shares of common stock. This issuance was done in accordance with Section 4(2) of the Securities Act of 1933. In addition, we granted to HPI 1,170,000 performance based stock options, exercisable at \$3.50 per share, which vest upon the achievement of certain milestones.

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### Item 6. Exhibits and Reports on Form 8-K

#### (a) Exhibits

- 4.1 Form of Warrant to purchase shares of Common Stock issued in connection with the sale of the Common Stock (incorporated by reference to Exhibit 4.1 on Form 8-K filed on January 28, 2004).
- 10.1 Form of Registration Rights Agreement, dated as of January 21, 2004 by and among the Registrant and the purchasers set forth on the signature page thereto (incorporated by reference to Exhibit 10.1 on Form 8-K filed on January 28, 2004).
- 10.2 Asset Purchase Agreement dated as of February 24, 2004 between the Registrant and Houston Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 on Form 8-K filed on February 27, 2004).
- 10.3 Sublicense Agreement dated as of February 24, 2004 between the Registrant and Houston Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 on Form 8-K filed on February 27, 2004).
- 10.4 Common stock purchase agreement dated as of April 19, 2004 by and among the Registrant and the purchasers set forth on Exhibit A thereto (incorporated by reference to Exhibit 10.1 on Form 8-K filed on April 19, 2004)
- 31.1 Certification of Chief Executive Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.
- 31.2 Certification of Principal Financial Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.

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- 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.

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(b) Reports on Form 8-K.

On January 28, 2004, we filed a Form 8-K announcing the completion of a private placement of 3,905,432 shares of our common stock at an issue price of \$1.50 per share for aggregate proceeds of \$5,858,148.

On January 30, 2004, we filed an amendment to the Form 8-K filed on January 28, 2004, to revise the cash amount paid and the number of warrants issued to certain selling agents in connection with the private placement.

On February 27, 2004, we filed a Form 8-K announcing our entering into an Asset Purchase Agreement and Sublicense Agreement with Houston Pharmaceuticals, Inc. pursuant to which we acquired the rights to two key patents pertinent to a novel cancer technology platform developed by Dr. Waldemar Priebe, Professor of Medicinal Chemistry at the University of Texas M. D. Anderson Cancer Center, Houston, and his associates.

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SIGNATURES

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

CALLISTO PHARMACEUTICALS, INC.

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(Registrant)

Date: May 17, 2004

By: /s/ Gary S. Jacob  
Gary S. Jacob

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Chief Executive Officer

Date: May 17, 2004

By: /s/ Bernard F. Denoyer

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Bernard Denoyer  
Vice President, Finance

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