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CALLISTO PHARMACEUTICALS INC

Form 10-Q

November 14, 2003

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, 2003

( ) 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 November 13, 2003 |
|----------------------------------|----------------------------------|
| -----                            | -----                            |
| Common Stock, par value \$0.0001 | 23,404,821 shares                |

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

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 Report on Form 8-K 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.

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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, 2003  
(Unaudited)

ASSETS

|   |            |
|---|------------|
| Current assets:   |            |
| Cash and cash equivalents                                 | \$ 703,903 |
| Prepaid insurance (\$107,387) and other current assets    | 112,484    |
|   | -----      |
|   | 816,387    |
|   | -----      |
| Fixed assets, net of accumulated depreciation of \$26,388 | 59,537     |
|   | -----      |
| Other assets:   |            |
| Rent deposit  | 47,246     |
|   | -----      |
|   | 47,246     |
|   | -----      |
|   | \$ 923,170 |
|   | =====      |

LIABILITIES AND SHAREHOLDERS' DEFICIT

|   |              |
|---|--------------|
| Accounts payable, accruals and other current liabilities                                | \$ 1,050,952 |
|   | -----        |
| Shareholders' deficit:  |              |
| Common stock \$.0001 par value, 60,000,000 authorized shares and issued and outstanding | 23,204,851   |
| Additional paid-in-capital  | 27,505,551   |
| Unamortized deferred stock based compensation   | (6,239,033)  |
| Accumulated deficit during the development stage  | (21,396,619) |
|   | -----        |
|   | (127,782)    |
|   | -----        |
|   | \$ 923,170   |

=====

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

CALLISTO PHAMACEUTICALS, INC.  
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS  
(Unaudited)

|                                      | Three Months Ended    |                       | Nine Months Ended     |                       |
|--------------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|                                      | September 30,<br>2003 | September 30,<br>2002 | September 30,<br>2003 | September 30,<br>2002 |
| Revenues                             | \$ -                  | \$ -                  | \$ -                  | \$ -                  |
| Costs and expenses:                  |                       |                       |                       |                       |
| Research and development             | 576,266               | 141,717               | 885,252               | 4,000,000             |
| General and administrative           | 340,912               | 187,001               | 831,474               | 8,000,000             |
| Purchased in-process R&D             | (19,091)              | -                     | 6,814,363             | -                     |
| Stock based compensation             | 468,437               | 81,027                | 3,774,987             | 2,000,000             |
| Net loss                             | \$ (1,366,524)        | \$ (409,745)          | \$ (12,306,076)       | \$ (1,400,000)        |
| Weighted average shares outstanding: |                       |                       |                       |                       |
| basic and diluted                    | 23,209,139            | 17,318,994            | 20,621,950            | 17,000,000            |
| Net loss per common share:           |                       |                       |                       |                       |
| basic and diluted                    | (\$0.06)              | (\$0.02)              | (\$0.60)              | (\$0.08)              |

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

CALLISTO PHAMACEUTICALS, INC.  
(A Development Stage Company)

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CONDENSED CONSOLIDATED STATEMENT OF CASHFLOWS  
(Unaudited)

|   | Nine Months<br>Months Ended<br>September 30, 2003<br>----- | Nine Months<br>Months Ended<br>September 30, 2002<br>----- | (Se<br>----- |
|---|--|--|--------------|
| Cash flows from operating activities:                                       |  |  |              |
| Net loss  | (\$12,306,076)   | (\$ 1,495,057)   | (            |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |  |              |
| Purchased in process research and development                               | 6,814,363  | -  |              |
| Stock based compensation  | 3,774,987  | 248,981  |              |
| Depreciation and amortization   | 14,261   | 5,084  |              |
| Unrealized loss on investment   | -  | -  |              |
| Common and preferred stock issued for services                              | -  | -  |              |
| Cancellation in note receivable   | -  | -  |              |
| Increase in note receivable   | -  | -  |              |
| Changes in operating assets and liabilities:                                |  |  |              |
| Increase in prepaid and other current assets                                | (84,028)   | 8,204  |              |
| Increase in accounts payable, accruals and other liabilities                | 369,930  | 42,941   |              |
| Total adjustments   | 10,889,513   | 305,210  |              |
| Net cash used in operating activities                                       | (1,416,563)  | (1,189,847)  |              |
| Cash flows from investing activities:                                       |  |  |              |
| Acquisition of furniture & equipment  | (55,750)   | (22,029)   |              |
| Rent deposit  | (47,246)   | -  |              |
| Proceeds (loss) on sale of marketable securities                            | -  | -  |              |
| Net cash (used in) provided by investing activities                         | (102,996)  | (22,029)   |              |
| Cash flows from financing activities:                                       |  |  |              |

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|  |             |              |
|--|-------------|--------------|
| Issuance of common and preferred stock<br>(net of repurchases) | -           | -            |
|  | -----       | -----        |
| Net cash (used in) provided by financing<br>activities         | -           | -            |
| Net (decrease) increase in cash and cash<br>equivalents        | (1,519,559) | (1,211,876)  |
| Cash and cash equivalent at beginning of period                | 2,223,462   | 3,627,479    |
|  | -----       | -----        |
| Cash and cash equivalent at end of period                      | \$ 703,903  | \$ 2,415,603 |
| Supplementary disclosures of cash flows<br>information:        |             |              |
| Cash paid for taxes  | \$ 23,091   | \$ 13,487    |

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

CALLISTO PHAMACEUTICALS, INC.  
(A Development Stage Company)

### NOTES TO SEPTEMBER 30, 2003 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") acquired April 30, 2003 (collectively "Callisto" a development stage company), have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and the rules of the Securities and Exchange Commission (the "SEC") for quarterly reports on Form 10-QSB and do not include all of the information and footnote disclosures required by GAAP for complete financial statements. Certain prior year expenses in our Condensed Consolidated Statement of Operations have been reclassified to conform to our current year results. These statements should be read in conjunction with the Callisto's audited financial statements and notes thereto for the year ended December 31, 2002, included in Form 8K filed with the SEC on May 15, 2003.

During the quarter ended September 30, 2003 Callisto made certain adjustments to correct its financial statements for the three and six months ended June 30, 2003, filed on Form 10-QSB. The effect of these adjustments has been included in the balances as of and for the nine months ended September 30, 2003. Callisto intends to file an amended Form 10-QSB for the quarter ended June 30, 2003 shortly. The following is a summary of the impact of these adjustments:

|   |                |
|---|----------------|
| Net loss for the six months ended June 30, 2003 - as reported | (\$10,083,910) |
| Net loss for the six months ended June 30, 2003 - restated    | (\$10,939,552) |

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|   |                |
|---|----------------|
| Accumulated Deficit June 30, 2003 - as reported | (\$19,695,989) |
| Accumulated Deficit June 30, 2003 - restated    | (\$20,030,095) |

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, primarily consisting of normal adjustments, necessary for the fair presentation of the balance sheet and results of operations for the interim periods. The results of operations for the three and nine months ended September 30, 2003 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2003.

The accompanying unaudited condensed consolidated financial statements have been prepared assuming that Callisto will continue as a going concern. Management believes that current resources will be sufficient to support its planned operations through the fourth quarter 2003. Callisto does not have commercial biopharmaceutical products, and does not expect to have such for several years, if at all. In addition, the merger of Callisto with Synergy in April 2003 has required additional cash to integrate the combined companies. Callisto believes that it will need additional funds to complete the development of its biomedical products and pursue FDA approval. These circumstances raise substantial doubt about Callisto's ability to continue as a going concern beyond December 31, 2003. Management's plans with regard to these matters include continued development of its products as well as seeking additional research support funds and financial arrangements. We are also in the process of raising additional capital through a private placement of common stock which began in July 2003. Although management continues to pursue these plans, there is no assurance that Callisto will be successful in obtaining sufficient financing on terms acceptable to Callisto. In the event that Callisto is unable to raise additional funds, planned operations will need to be scaled back or discontinued. The financial statements do not include any adjustments that might result from the outcome of these uncertainties. In November 2003, Callisto closed on a sufficient amount of funds in a private placement of common stock such that it no longer had a working capital deficiency.

### 2. Significant Accounting Policies

#### Business Combinations

Callisto accounts for business combinations in accordance with the provisions of Statement of Financial Accounting Standards No. 141 "Business Combinations" ("SFAS 141"). SFAS 141 requires business combinations completed after June 30, 2001 to be accounted for using the purchase method of accounting. It also specifies the types of acquired intangible assets required to be recognized and reported separately from goodwill.

#### Long-lived assets

Callisto accounts for long-lived assets in accordance with the provisions of Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"). SFAS 144 requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Callisto compares the carrying amount of the asset to the estimated undiscounted future cash flows expected to result from the use of the asset. If the carrying amount of the asset exceeds estimated expected undiscounted future cash flows, Callisto records an impairment charge for the difference between the carrying amount of the asset and its fair value. Changes in events or

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circumstances impacting long-lived assets include, but are not limited to, cancellations or terminations of research contracts or pending government research grants.

### Income taxes

Income taxes are accounted for under the asset and liability method prescribed by Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes." Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or the entire deferred tax asset will not be realized.

### 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 compensatory 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<br>September 30, |              | Nine Mon<br>Septem |
|--|-------------------------------------|--------------|--------------------|
|  | 2003                                | 2002         | 2003               |
| Net loss, as reported  | (\$1,366,524)                       | (\$ 409,745) | (\$12,306,076)     |
|  | =====                               |              |                    |
| Add: Stock-based compensation expense recorded for compensatory stock options                          | 468,437                             | 81,027       | 3,774,987          |
| Deduct: Total stock-based compensation expense determined under fair value based method for all awards | (562,507)                           | (82,918)     | (4,070,015)        |
|  | -----                               |              |                    |
| Pro forma net loss   | (\$1,460,594)                       | (\$ 411,636) | (\$12,601,104)     |
|  | =====                               |              |                    |
| Net loss per share:  |                                     |              |                    |
| Basic and diluted -as reported   | ( \$0.06)                           | (\$ 0.02)    | (\$ 0.60)          |
|  | =====                               |              |                    |
| Basic and diluted -pro forma   | (\$ 0.06)                           | (\$ 0.02)    | (\$ 0.61)          |
|  | =====                               |              |                    |

=====

The fair value of the options granted to employees during 2003 and 2002 ranged from \$1.26 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 2003 and 2002: 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 rates of 2.87%-4.50% and an expected term of 7 to 10 years.

Cash and cash equivalents:

For purposes of the statements of cash flows, Callisto considers all highly liquid investment instruments with an original maturity of three months or less to be cash equivalents.

Research and development:

Callisto is engaged in various pharmaceutical patent and research and development projects under arrangements with various research facilities and universities whereby certain minimum annual fees and royalty payments are required to be paid. Research and development costs are expensed as incurred and include mainly expenditures made to research facilities and universities, as well as legal and professional fees associated with filing and maintaining Callisto's patent and license rights to its proposed products.

Loss per share:

The assumed exercise of all Callisto's outstanding options was excluded from the computation of net loss per share due to their anti-dilutive effect as a result of the net losses reported for the three and nine months ended September 30, 2003 and 2002.

3. Merger and consolidation:

On April 30, 2003 Webtronics, Inc. ("Webtronics") entered into a merger agreement with Callisto Research Labs, LLC ("Callisto Research", formerly known as Callisto Pharmaceuticals, Inc.) and Synergy, an unaffiliated company also in the development stage, under which agreement Callisto Research and Synergy agreed to merge in a stock for stock transaction and each become subsidiaries of Webtronics. Webtronics subsequently changed its name to Callisto Pharmaceuticals, Inc. Pursuant to the merger agreement 17,318,994 shares of Webtronics common stock were issued to holders of Callisto Research common stock; and 4,395,684 shares of Webtronics common stock were issued to holders of Synergy common stock in exchange for outstanding Callisto Research and Synergy common stock.

The 4,395,684 shares issued to the former shareholders of Synergy were valued at \$6,593,526. In addition net assumed liabilities in excess of Synergy assets acquired at April 30, 2003 were as follows:

|                     |          |
|---------------------|----------|
| Cash                | \$ 9,501 |
| Accounts receivable | 258,928  |
| Rent deposit        | 44,746   |
| Fixed assets        | 38,343   |
|                     | -----    |

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|  |           |
|--|-----------|
| Total assets acquired                                | 351,518   |
| Accounts payable and other liabilities assumed       | 591,446   |
|  | -----     |
| Net liabilities assumed in excess of assets acquired | \$239,928 |
|  | =====     |

The merged companies are considered to be in the development stage. No revenues have been realized and all activities have been concentrated in research and development of biopharmaceutical products yet to be approved by the Food and Drug Administration. The value of the shares issued to former Synergy shareholders in the merger plus the net liabilities assumed in excess of assets acquired totaled \$6,833,454. During the quarter ended September 30, 2003 certain former Synergy shareholders returned 12,727 shares to Callisto under an indemnification agreement, reducing purchased in-process research and development expense by \$19,091. This net amount was allocated in full to the Synergy research and development projects which had not yet reached technological possibility and having no alternative use was charged to purchased in-process research and development expense.

The results of operations of Synergy for the period May 1, 2003 through September 30, 2003 are included in the consolidated statement of operations for the quarter and nine months ended September 30, 2003, as well as the consolidated balance sheet as of September 30, 2003.

The following (unaudited) combined proforma results of operations for the nine months ended September 30, 2003 and 2002 have been prepared as if the merger of the companies had occurred at January 1, 2003, and 2002

|                            | 2003         | 2002        |
|----------------------------|--------------|-------------|
|                            | ----         | ----        |
| Revenues                   | \$ -         | \$ -        |
| Net loss                   | (12,754,343) | (2,384,062) |
| Net loss per common share  |              |             |
| (23,204,851 common shares) | (\$0.55)     | (\$0.10)    |

#### 4. Stock option plan:

In 1996, Callisto adopted an incentive and non-qualified stock option plan (the "Plan") for employees, consultants and outside directors to purchase up to 2,000,000 shares of common stock. The Plan was amended in December 2002 to increase the number of shares authorized under the Plan to 10,000,000. The option term for options granted under the Plan is ten years from date of grant. Additionally Callisto has granted stock options not subject to the Plan.

The following represent options outstanding for the nine months ended September 30, 2003 and for the years ended December 31, 2002 and 2001:

Total  
-----

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|                                      |             |
|--------------------------------------|-------------|
| Balance, January 1, 2001             | 1,931,505   |
| Year 2001:                           |             |
| Granted                              | 400,000     |
| Exercised                            | -           |
|                                      | -----       |
| Balance, December 31, 2001           | 2,331,505   |
| Year 2002:                           |             |
| Granted                              | 330,000     |
| Cancelled                            |             |
| Exercised                            | -           |
|                                      | -----       |
| Balance, December 31, 2002           | 2,661,505   |
| Nine month ended September 30, 2003: |             |
| Granted                              | 3,731,055   |
| Exercised                            | -           |
| Cancelled                            | (1,717,333) |
|                                      | -----       |
| Balance, September 30, 2003          | 4,675,227   |
|                                      | =====       |

Included in the above balance at September 30, 2003 were 2,446,338 non-Plan options.

Options are exercisable at various prices as follows at September 30, 2003:

| Exercise<br>Price<br>----- | Total<br>----- |
|----------------------------|----------------|
| \$0.75                     | 615,839        |
| 1.10                       | 500,000        |
| 1.25                       | 400,000        |
| 1.30                       | 383,055        |
| 1.50                       | 1,968,000      |
| 1.75                       | 27,500         |
| 1.95                       | 266,667        |
| 2.25                       | 90,000         |
| 2.85                       | 262,500        |
| 4.90                       | 125,000        |
| 6.75                       | 36,666         |
|                            | -----          |
|                            | 4,675,227      |
|                            | =====          |

### 5. Income taxes:

At December 31, 2002, Callisto had available net operating tax loss carry forwards of approximately \$8,000,000 for income tax purposes expiring through 2022 to offset future taxable income. The net deferred tax asset has been fully offset by a valuation allowance due to uncertainties regarding realization of benefits from these future tax deductions. As a result of the change in control provisions of Internal Revenue Code Section 382, a significant portion of these

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net operating loss carryforwards may be subject to limitation on future utilization.

### 6. Contractual obligations:

On August 28, 2002, Callisto's wholly-owned subsidiary, Synergy Pharmaceuticals Inc. entered into a license agreement with AnorMED Inc. to license Atiprimod from AnorMED. The license agreement provides for milestone payments and royalties on net sales. 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.

On June 13, 2003, Callisto entered into employment agreements with Gary S. Jacob, Ph.D., Chief Executive Officer and Chief Scientific Officer and Kunwar Shailubhai, Ph.D., Executive Vice President and Head of Research and Development. Each of their employment agreements is 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. Jacob's salary is \$225,000 per year and he is eligible to receive a cash bonus of up to 15% of his salary per year. Dr. Jacob received a grant of 500,000 stock options which vest over a three year period and are exercisable at \$1.50 per share. 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. 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 September 23, 2003, Callisto entered into an employment agreement with Donald H. Picker, Ph.D., our Vice President, Drug Development. The employment agreement is for a term of 18 months beginning September 23, 2003 and is automatically renewable for successive one year periods at the end of the term. Dr. Picker's salary is \$175,000 per year and he is eligible to receive a cash bonus of up to \$45,000 per year upon the achievement of certain performance milestones. Dr. Picker received a grant of 325,000 stock options which vest over a three year period and are exercisable at \$1.50 per share.

On August 20, 2003 Callisto entered into a five year lease for its corporate headquarters in New York City comprising 2,722 square feet with an approximate fixed rent of \$100,000 annually through 2008.

### 7. Subsequent Events:

In November 2003, Callisto closed on a sufficient amount of funds in a private placement of common stock such that it no longer had a working capital deficiency.

## 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.

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### Overview

We are a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. Since inception in September 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, 2003, we have sustained cumulative net losses of \$21,396,619. Our losses have resulted primarily from expenditures incurred in connection with the purchase of in-process research and development, stock compensation expense, patent filing and maintenance, outside accounting and legal services and regulatory consulting fees.

From inception through September 30, 2003 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. Our lead drug candidate, Atiprimod, is a small molecule, orally available drug, with antiproliferative and antiangiogenic activity. Atiprimod successfully completed Phase I/IIa clinical trials in rheumatoid arthritis patients and we plan to enter Atiprimod in a safety and proof of principle clinical trial in multiple myeloma patients. The IND application (Investigational New Drug) for Phase I/IIa of these clinical trials was filed with the FDA on September 23, 2003.

Our product development efforts are thus 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. We could however receive grants, contracts or technology licenses in the short-term. The amount and timing of these inflows, if any, is not known. We are also in the process of raising additional capital through a private placement of common stock which began in July 2003. There can be no assurance we will be successful in these fund raising efforts. In November 2003, we closed on a sufficient number of funds in a private placement of common stock such that we no longer have a working capital deficiency.

The accompanying unaudited condensed consolidated financial statements have been prepared assuming that we will continue as a going concern. We believe that current resources will be sufficient to support planned operations through the fourth quarter 2003. These circumstances raise substantial doubt about our ability to continue as a going concern. Our plan is to continue product development beyond December 31, 2003 and seek additional research support and investment capital. There is no assurance that we will be successful in obtaining sufficient financing on terms acceptable to us. In the event that we are unable to raise additional funds, planned operations will need to be scaled back or discontinued. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., our wholly-owned subsidiary, merged into Synergy Pharmaceuticals Inc. and Callisto Acquisition Corp., our wholly-owned subsidiary, merged into the predecessor of Callisto Research Labs, LLC. As a result of the merger Callisto Research and Synergy are our wholly owned subsidiaries. We issued 17,318,994 shares of our common stock in exchange for all outstanding Callisto Research, LLC common stock and an additional 4,395,684 shares in exchange for outstanding Synergy common stock. During the quarter ended September 30, 2003 certain former Synergy shareholders returned 12,727 shares to Callisto under an indemnification agreement.

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### Significant Accounting Policies

Financial Reporting Release No. 60, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Note 2 of the notes to our condensed consolidated financial statements includes a summary of all significant accounting policies and methods used in the preparation of our financial statements, the most critical of which are:

#### 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 compensatory options or shares granted under the Plan. 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."

#### Research and development:

Callisto is engaged in various pharmaceutical patent and research and development projects under arrangements with various research facilities and universities whereby certain minimum annual fees and royalty payments are required to be paid. Research and development costs are expensed as incurred and include mainly expenditures made to research facilities and universities, as well as legal and professional fees associated with filing and maintaining Callisto's patent and license rights to its proposed products.

#### Results of Operations

Three Months Ended September 30, 2003 and September 30, 2002

We had no revenues during the three months ended September 30, 2003 and September 30, 2002 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 \$434,549 or 307% to \$576,266 for the three months ended September 30, 2003 from \$141,717 for the same period in 2002. The results of operations of Synergy for the period July 1, 2003 through September 30, 2003 are included in the consolidated statement of operations for the quarter ended September 30, 2003, as well as the consolidated balance sheet as of September 30, 2003, and are not included in the results of the same periods of 2002. Of this increase in research and development expense, \$347,619 was attributable to costs associated with preparing and filing our IND application for Atiprimod. These IND related costs included quantitative analysis and synthesis, as well as pre-clinical management consulting fees paid to contract research organizations to develop and advise on IND requirements, proposed clinical trial protocols, site selection and principal investigator contracting. Our IND was filed on September 23, 2003. Also contributing to this increase in research and development expense were higher patent costs and payroll as we retained three Synergy executive staff scientists subsequent to the Synergy merger. Annual compensation and other benefits associated with the

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employment of Drs. Jacob, Picker and Shailubhai is discussed in detail elsewhere in this quarterly report.

General and administrative expenses for the three months ended September 30, 2003 increased \$153,911 or 82% to \$340,912, from \$187,001 for the three months ended September 30, 2002. The increase was primarily due to higher legal, accounting and professional fees related to regulatory filing and fund raising efforts. In addition facilities and related office overhead increased as we opened our New York City headquarters during the quarter ended September 30, 2003.

Net loss for the three months ended September 30, 2003 was \$1,366,524 compared to a net loss of \$409,745 incurred for the three months ended September 30, 2002. The increase in the net loss is the result of higher research, development, general and administrative expenses discussed above, plus \$468,437 of stock based compensation expense during the three months ended September 30, 2003, as compared to \$81,027 of stock based compensation expense recorded during the three months ended September 30, 2002.

Nine Months ended September 30, 2003 and September 30, 2002.

We had no revenues during the nine months ended September 30, 2003 and September 30, 2002 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 \$445,008 or 101% to \$885,252 for the nine months ended September 30, 2003 from \$440,244 for the same period in 2002. The increase in research and development expense was primarily attributable to higher costs associated with preparing and filing our IND application for Atiprimod, discussed above in the quarter ended September 30, 2003, plus higher patent costs and higher payroll as we retained three Synergy executive staff scientists subsequent to the Synergy merger.

General and administrative expenses for the nine months ended September 30, 2003 of \$831,474 were approximately the same as \$805,832 for the nine months ended September 30, 2002. These expenses primarily comprise legal, accounting and professional fees related to the Synergy merger and our regulatory filing, insurance and fund raising efforts. During the quarter ended June 30, 2002 we incurred a charge of \$400,000 associated with the purchase of Webtronics, Inc., a non-operating public company. In addition facilities and related office overhead increased slightly as we opened our New York City headquarters during the quarter ended September 30, 2003.

Net loss for the nine months ended September 30, 2003 was \$12,306,076 compared to a net loss of \$1,495,057 incurred for the nine months ended September 30, 2002. The increase in our net loss is the result of higher research and development expenses and general and administrative expenses discussed above, plus \$3,774,987 of stock based compensation expense recorded during the nine months ended September 30, 2003, as compared to \$248,981 recorded during the nine months ended September 30, 2002. The remaining balance of unamortized deferred stock based compensation expense, presented in the shareholder's equity section of our September 30, 2003 balance sheet, totaled \$6,239,033 .

During the nine months ended September 30, 2003 we also incurred \$6,814,363 of net purchased in-process research and development expense related to the Synergy merger. There was no such expense during the same period ended September 30, 2002.

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### Liquidity and Capital Resources

As of September 30, 2003 we had \$703,903 in cash and cash equivalents, compared to \$2,223,462 as of December 31, 2002. This decrease in cash of \$1,519,559 during the nine months ended September 30, 2003 was principally the result of cash used in operating activities. Our working capital as of September 30, 2003 was deficient by \$234,565.

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 Atiprimod for multiple myeloma and bone resorption disease, a major complication associated with multiple myeloma disease. We plan to enter Atiprimod in a safety and proof of principle clinical trial in multiple myeloma patients. The IND application for Phase I/IIa of these trials was filed with the FDA on September 23, 2003.

Our product development efforts are thus 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 make take several years to achieve. We could however receive grants, contracts or technology licenses in the short-term. The amount and timing of these inflows, if any, is not known.

We are also in the process of raising additional capital through a private placement of common stock which began in July 2003. There can be no assurance we will be successful in these fund raising efforts. In November 2003, we closed on a sufficient amount of funds in a private placement of common stock such that we no longer have a working capital deficiency.

### Contractual Obligations

On August 28, 2002, our wholly-owned subsidiary, Synergy Pharmaceuticals Inc. entered into a license agreement with AnorMED Inc. to license Atiprimod from AnorMED. The license agreement provides for milestone payments and royalties on net sales. 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.

On September 23, 2003, we entered into an employment agreement with Donald H. Picker, Ph.D., our Vice President, Drug Development. The employment agreement is for a term of 18 months beginning September 23, 2003 and is automatically renewable for successive one year periods at the end of the term. Dr. Picker's salary is \$175,000 per year and he is eligible to receive a cash bonus of up to \$45,000 per year upon the achievement of certain performance milestones. Dr. Picker received a grant of 325,000 stock options which vest over a three year period and are exercisable at \$1.50 per share.

On August 20, 2003 we entered into a five year lease for our corporate headquarters in New York City comprising 2,722 square feet with an approximate fixed rent of \$100,000 annually through 2008.

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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 September 30, 2003, 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

- 10.3 Employment Agreement dated September 23, 2003 by and between Callisto Pharmaceuticals, Inc. and Donald Picker.
- 10.4 License Agreement dated as of August 28, 2002 between AnorMED Inc. and Synergy Pharmaceuticals Inc.\*
- 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.
- 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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\*Confidential treatment requested

##### (b) Reports on Form 8-K.

On July 1, 2003, we filed a Form 8-K announcing the appointment of new members to Callisto's Board of Directors and certain management changes in connection with the merger agreement with Synergy Pharmaceuticals Inc.

On August 6, 2003, we filed a Form 8-K disclosing that Baum & Company, PA had resigned as the independent accountants for Callisto Pharmaceuticals, Inc. and BDO Seidman LLP had been hired as the new independent accountants.

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: November 14, 2003

By: /s/ Gary S. Jacob

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Gary S. Jacob

Acting Chief Executive Officer

Date: November 14, 2003

By: /s/ Bernard Denoyer

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Bernard Denoyer

Principal Financial Officer