

CALLISTO PHARMACEUTICALS INC  
Form 10-Q  
November 20, 2006

**UNITED STATES OF AMERICA**  
**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, DC 20549

**FORM 10-Q**

(Mark  
One)

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

**FOR THE QUARTERLY PERIOD ENDED: SEPTEMBER 30, 2006**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-32325

**CALLISTO PHARMACEUTICALS, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**13-3894575**

(I.R.S. Employer  
identification No.)

**420 Lexington Avenue, Suite 1609, New York, New York**  
(Address of principal executive offices)

**10170**  
(Zip Code)

**(212) 297-0010**

(Registrant's telephone number)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

Large accelerated Filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The number of the registrant's shares of common stock outstanding was 39,111,596 as of November 13, 2006.

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CALLISTO PHARMACEUTICALS, INC.

FORM 10-Q

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**INTRODUCTORY NOTE**

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

**The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under Risk Factors in our Annual Report on Form 10-K/A for the year ended December 31, 2005 and other periodic reports filed with the SEC. Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of the Company, please be advised that Callisto's actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements.**

**PART I - FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements**

**CALLISTO PHARMACEUTICALS, INC.**  
**(A development stage company)**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

|   | <b>September 30,<br/>2006<br/>(Unaudited)</b> | <b>December 31,<br/>2005</b> |
|---|---|------------------------------|
| <b>Assets</b>   |   |                              |
| Current assets:   |   |                              |
| Cash and cash equivalents   | \$ 124,017                                    | \$ 1,420,510                 |
| Prepaid expenses  | 117,837                                       | 181,284                      |
|   | 241,854                                       | 1,601,794                    |
| Property and equipment net  | 7,168   |                              |
| Rent deposits   | 73,716  | 82,196                       |
|   | \$ 322,738                                    | \$ 1,683,990                 |
| <b>Liabilities and Stockholders Deficit</b>   |   |                              |
| Current liabilities:  |   |                              |
| Accounts payable  | \$ 1,737,415                                  | 1,424,612                    |
| Accrued expenses  | 969,045                                       | 592,297                      |
| Liquidated damages payable  | 185,159                                       |                              |
|   | 2,891,619                                     | 2,016,909                    |
| Stockholders deficit:   |   |                              |
| Common stock, par value \$.0001, 100,000,000 shares authorized, 38,454,931 and 33,233,096 outstanding at September 30, 2006 and December 31, 2005, respectively | 3,845   | 3,323                        |
| Additional paid-in capital  | 52,288,874                                    | 46,387,875                   |
| Unamortized deferred stock-based compensation   |   | (1,583,463 )                 |
| Deficit accumulated during development stage  | (54,861,600 )                                 | (45,140,654 )                |
|   | (2,568,881 )                                  | (332,919 )                   |
|   | \$ 322,738                                    | \$ 1,683,990                 |

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

**CALLISTO PHARMACEUTICALS, INC.**  
(A development stage company)

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited)

|   | Three Months Ended<br>September 30,<br>2006 |   | 2005           |   | Nine Months Ended<br>September 30,<br>2006 |   | 2005           |   | June 5, 1996<br>(Inception) to<br>September 30, 2006 |   |
|---|---|---|----------------|---|--|---|----------------|---|--|---|
|   | \$  |   | \$             |   | \$   |   | \$             |   | \$   |   |
| Revenues                                      |   |   |                |   |  |   |                |   |  |   |
| Costs and expenses:                           |   |   |                |   |  |   |                |   |  |   |
| Research and development                      | 1,139,094                                   |   | 1,787,956      |   | 4,898,524                                  |   | 4,946,525      |   | 20,904,386   |   |
| Government grants                             | (43,956)                                    | ) | (152,866)      | ) | (299,378)                                  | ) | (152,866)      | ) | (791,194)  | ) |
| Purchased in process research and development |   |   |                |   |  |   |                |   | 6,944,553  |   |
| General and administrative                    | 800,803                                     |   | 1,212,480      |   | 4,012,012                                  |   | 3,312,858      |   | 19,652,878   |   |
| Stock based compensation non employees        | (139,501)                                   | ) | 506,199        |   | 820,747                                    |   | 509,931        |   | 9,145,317  |   |
| Loss from operations                          | (1,756,440)                                 | ) | (3,353,769)    | ) | (9,431,905)                                | ) | (8,616,448)    | ) | (55,855,940)   | ) |
| Interest and investment income                | 3,304                                       |   | 33,200         |   | 45,405                                     |   | 91,071         |   | 700,390  |   |
| Other income (expense)                        | (177,010)                                   | ) |                |   | (334,446)                                  | ) |                |   | 293,950  |   |
| Net loss                                      | \$ (1,930,146)                              | ) | \$ (3,320,569) | ) | \$ (9,720,946)                             | ) | \$ (8,525,377) | ) | \$ (54,861,600)                                      | ) |
| Weighted average shares outstanding:          |   |   |                |   |  |   |                |   |  |   |
| basic and diluted                             | 38,454,931                                  |   | 31,867,103     |   | 37,558,910                                 |   | 30,954,422     |   |  |   |
| Net loss per common share:                    |   |   |                |   |  |   |                |   |  |   |
| basic and diluted                             | \$ (0.05)                                   | ) | \$ (0.10)      | ) | \$ (0.26)                                  | ) | \$ (0.28)      | ) |  |   |

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

**CALLISTO PHARMACEUTICALS, INC.****(A Development Stage Company)****CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)****(Unaudited)**

|   | <b>Preferred<br/>Shares</b> | <b>Preferred<br/>Stock,<br/>Par Value</b> | <b>Common<br/>Shares</b> | <b>Common<br/>Stock,<br/>Par Value</b> | <b>Additional<br/>Paid<br/>in Capital</b> |
|---|-----------------------------|---|--------------------------|--|---|
| Balance at inception, June 5, 1996        |                             | \$  |                          | \$                                     | \$  |
| Net loss for the period                   |                             |   |                          |  |   |
| Issuance of founder shares                |                             |   | 2,642,500                | 264                                    | 528                                       |
| Common stock issued                       |                             |   | 1,356,194                | 136                                    | 272                                       |
| Common stock issued via private placement |                             |   | 1,366,667                | 137                                    | 1,024,863                                 |
| Balance, December 31, 1996                |                             |   | 5,365,361                | 537                                    | 1,025,663                                 |
| Net loss for the year                     |                             |   |                          |  |   |
| Common stock issued via private placement |                             |   | 1,442,666                | 144                                    | 1,081,855                                 |
| Balance, December 31, 1997                |                             |   | 6,808,027                | 681                                    | 2,107,518                                 |
| Net loss for the year                     |                             |   |                          |  |   |
| Amortization of Stock based Compensation  |                             |   |                          |  | 52,778                                    |
| Common stock issued via private placement |                             |   | 1,416,667                | 142                                    | 1,062,358                                 |
| Common stock issued for services          |                             |   | 788,889                  | 79                                     | 591,588                                   |
| Common stock repurchased and cancelled    |                             |   | (836,792)                | (84)                                   | (96,916)                                  |
| Balance, December 31, 1998                |                             |   | 8,176,791                | 818                                    | 3,717,326                                 |
| Net loss for the year                     |                             |   |                          |  |   |
| Deferred Compensation - stock options     |                             |   |                          |  | 9,946                                     |
| Amortization of Stock based Compensation  |                             |   |                          |  |   |
| Common stock issued for services          |                             |   |                          |  | 3,168,832                                 |
| Common stock issued via private placement |                             |   | 346,667                  | 34                                     | 259,966                                   |
| Balance, December 31, 1999                |                             |   | 8,523,458                | 852                                    | 7,156,070                                 |
| Net loss for the year                     |                             |   |                          |  |   |
| Amortization of Stock based Compensation  |                             |   |                          |  |   |
| Common stock issued                       |                             |   | 4,560,237                | 455                                    | 250,889                                   |
| Other                                     |                             |   |                          |  | 432                                       |
| Preferred shares issued                   | 3,485,299                   | 348                                       |                          |  | 5,986,302                                 |
| Preferred stock issued for services       | 750,000                     | 75  |                          |  | 1,124,925                                 |
| Balance, December 31, 2000                | 4,235,299                   | 423                                       | 13,083,695               | 1,307                                  | 14,518,618                                |
| Net loss for the year                     |                             |   |                          |  |   |
| Deferred Compensation - stock Options     |                             |   |                          |  | 20,000                                    |
| Amortization of Stock based Compensation  |                             |   |                          |  |   |
| Balance, December 31, 2001                | 4,235,299                   | 423                                       | 13,083,695               | 1,307                                  | 14,538,618                                |
| Net loss for the year                     |                             |   |                          |  |   |
| Amortization of Stock based Compensation  |                             |   |                          |  |   |
| Balance, December 31, 2002                | 4,235,299                   | \$ 423                                    | 13,083,695               | \$ 1,307                               | \$ 14,538,618                             |

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

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|   | Unamortized<br>Deferred<br>Stock Based<br>Compensation | Deficit<br>Accumulated<br>during the<br>Development<br>Stage | Total<br>Stockholders<br>Equity |
|---|--|--|---------------------------------|
| Balance at inception, June 5, 1996        | \$   | \$   | \$                              |
| Net loss for the year                     |  | (404,005 )   | (404,005 )                      |
| Issuance of founder shares                |  |  | 792                             |
| Common stock issued                       |  |  | 408                             |
| Common stock issued via private placement |  |  | 1,025,000                       |
| Balance, December 31, 1996                |  | (404,005 )   | 622,195                         |
| Net loss for the year                     |  | (894,505 )   | (894,505 )                      |
| Common stock issued via private placement |  |  | 1,081,999                       |
| Balance, December 31, 1997                |  | (1,298,510 )   | 809,689                         |
| Net loss for the year                     |  | (1,484,438 )   | (1,484,438 )                    |
| Amortization of Stock based Compensation  |  |  | 52,778                          |
| Common stock issued                       |  |  | 1,062,500                       |
| Common stock issued for services          |  |  | 591,667                         |
| Common Stock repurchased and cancelled    |  |  | (97,000 )                       |
| Balance, December 31, 1998                |  | (2,782,948 )   | 935,196                         |
| Net loss for the year                     |  | (4,195,263 )   | (4,195,263 )                    |
| Deferred Compensation - stock options     | (9,946 )   |  |                                 |
| Amortization of Stock based Compensation  | 3,262  |  | 3,262                           |
| Common stock issued for services          |  |  | 3,168,832                       |
| Common stock issued via private placement |  |  | 260,000                         |
| Balance, December 31, 1999                | (6,684 )   | (6,978,211 )   | 172,027                         |
| Net loss for the year                     |  | (2,616,261 )   | (2,616,261 )                    |
| Amortization of Stock based Compensation  | 4,197  |  | 4,197                           |
| Common stock issue                        |  |  | 251,344                         |
| Other                                     |  |  | 432                             |
| Preferred shares issued                   |  |  | 5,986,650                       |
| Preferred stock issued for services       |  |  | 1,125,000                       |
| Balance, December 31, 2000                | (2,487 )   | (9,594,472 )   | 4,923,389                       |
| Net loss for the year                     |  | (1,432,046 )   | (1,432,046 )                    |
| Deferred Compensation - stock options     | (20,000 )  |  |                                 |
| Amortization of Stock based Compensation  | 22,155   |  | 22,155                          |
| Balance, December 31, 2001                | (332 )   | (11,026,518 )  | 3,513,498                       |
| Net loss for the year                     |  | (1,684,965 )   | (1,684,965 )                    |
| Amortization of Stock based Compensation  | 332  |  | 332                             |
| Balance, December 31, 2002                | \$   | \$ (12,711,483 )   | \$ 1,828,865                    |

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



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|   | Preferred<br>Stock | Preferred<br>Stock<br>Par<br>Value | Common<br>Stock | Common<br>Stock<br>Par<br>Value | Additional<br>Paid in<br>Capital | Unamortized<br>Deferred<br>Stock Based<br>Compensation | Deficit<br>Accumulated<br>during the<br>Development<br>Stage | Total<br>Stockholders<br>Equity |
|---|--------------------|------------------------------------|-----------------|---------------------------------|----------------------------------|--|--|---------------------------------|
| Balance December 31, 2002                                   | 4,235,299          | \$ 423                             | 13,083,695      | \$ 1,307                        | \$ 14,538,618                    | \$   | \$ (12,711,483)  | \$ 1,828,865                    |
| Net loss for the year                                       |                    |                                    |                 |                                 |                                  |  | (13,106,247)   | (13,106,247)                    |
| Conversion of preferred stock in connection with the Merger | (4,235,299)        | (423)                              | 4,235,299       | 423                             |                                  |  |  |                                 |
| Common stock issued to former Synergy stockholders          |                    |                                    | 4,329,927       | 432                             | 6,494,458                        |  |  | 6,494,890                       |
| Common stock issued in exchange for Webtronics common stock |                    |                                    | 1,503,173       | 150                             | (150)                            |  |  |                                 |
| Deferred Compensation - stock options                       |                    |                                    |                 |                                 | 9,313,953                        | (9,313,953)  |  |                                 |
| Amortization of deferred Stock based Compensation           |                    |                                    |                 |                                 |                                  | 3,833,946  |  | 3,833,946                       |
| Private placement of common stock, net                      |                    |                                    | 2,776,666       | 278                             | 3,803,096                        |  |  | 3,803,374                       |
| Balance, December 31, 2003                                  |                    | \$                                 | 25,928,760      | \$ 2,590                        | \$ 34,149,975                    | \$ (5,480,007)   | \$ (25,817,730)  | \$ 2,854,828                    |

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

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|   | Preferred<br>Stock | Preferred<br>Stock<br>Par<br>Value | Common<br>Stock | Common<br>Stock<br>Par<br>Value | Additional<br>Paid in<br>Capital | Unamortized<br>Deferred<br>Stock Based<br>Compensation | Deficit<br>Accumulated<br>during the<br>Development<br>Stage | Total<br>Stockholders<br>Equity |
|---|--------------------|------------------------------------|-----------------|---------------------------------|----------------------------------|--|--|---------------------------------|
| Balance, December 31, 2003  |                    | \$                                 | 25,928,760      | \$ 2,590                        | \$ 34,149,975                    | \$ (5,480,007)   | \$ (25,817,730)  | \$ 2,854,828                    |
| Net loss for the period   |                    |                                    |                 |                                 |                                  |  | (7,543,467)  | (7,543,467)                     |
| Amortization of deferred<br>Stock-based compensation<br>expense                       |                    |                                    |                 |                                 |                                  | 3,084,473  |  | 3,084,473                       |
| Variable accounting for<br>stock options  |                    |                                    |                 |                                 | (816,865)                        |  |  | (816,865)                       |
| Stock-based compensation<br>net of forfeitures  |                    |                                    |                 |                                 | 240,572                          | 93,000   |  | 333,572                         |
| Common stock issued via<br>private placements, net                                    |                    |                                    | 3,311,342       | 331                             | 6,098,681                        |  |  | 6,099,012                       |
| Warrant and stock-based<br>compensation for services in<br>connection with the Merger |                    |                                    |                 |                                 | 269,826                          |  |  | 269,826                         |
| Common stock returned<br>from former Synergy<br>stockholders                          |                    |                                    | (90,000)        | (9)                             | (159,083)                        |  |  | (159,092)                       |
| Stock issued for patent<br>rights   |                    |                                    | 25,000          | 3                               | 56,247                           |  |  | 56,250                          |
| Common stock issued for<br>services   |                    |                                    | 44,000          | 7                               | 70,833                           |  |  | 70,840                          |
| Balance, December 31, 2004  |                    | \$                                 | 29,219,102      | \$ 2,922                        | \$ 39,910,187                    | \$ (2,302,534)   | \$ (33,361,197)  | \$ 4,249,378                    |

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

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|  | Common<br>Stock | Common<br>Stock<br>Par<br>Value | Additional<br>Paid in<br>Capital | Unamortized<br>Deferred<br>Stock Based<br>Compensation | Deficit<br>Accumulated<br>during the<br>Development<br>Stage | Total<br>Stockholders<br>Equity (Deficit) |
|--|-----------------|---------------------------------|----------------------------------|--|--|---|
| Balance, December 31, 2004                           | 29,219,102      | \$ 2,922                        | \$ 39,910,187                    | \$ (2,302,534 )  | \$ (33,361,197 )   | \$ 4,249,378                              |
| Net loss for the year                                |                 |                                 |                                  |  | (11,779,457 )  | (11,779,457 )                             |
| Deferred stock-based<br>compensation - new grants    |                 |                                 | 1,571,772                        | (1,571,772 )   |  |   |
| Amortization of deferred<br>stock-based compensation |                 |                                 |                                  | 2,290,843  |  | 2,290,843                                 |
| Variable accounting for stock<br>options             |                 |                                 | 75,109                           |  |  | 75,109                                    |
| Common stock issued via<br>private placement:        |                 |                                 |                                  |  |  |   |
| March 2005   | 1,985,791       | 198                             | 3,018,203                        |  |  | 3,018,401                                 |
| August 2005  | 1,869,203       | 187                             | 1,812,940                        |  |  | 1,813,127                                 |
| Finders fees and expenses                            |                 |                                 | (176,250 )                       |  |  | (176,250 )                                |
| Exercise of common stock<br>warrant                  | 125,000         | 13                              | 128,737                          |  |  | 128,750                                   |
| Common stock issued for<br>services                  | 34,000          | 3                               | 47,177                           |  |  | 47,180                                    |
| Balance, December 31, 2005                           | 33,233,096      | \$ 3,323                        | \$ 46,387,875                    | \$ (1,583,463 )  | \$ (45,140,654 )   | \$ (332,919 )                             |

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

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|  | Common<br>Stock | Common<br>Stock<br>Par<br>Value | Additional<br>Paid in<br>Capital | Unamortized<br>Deferred<br>Stock Based<br>Compensation | Deficit<br>Accumulated<br>during the<br>Development<br>Stage | Total<br>Stockholders<br>Deficit |
|--|-----------------|---------------------------------|----------------------------------|--|--|----------------------------------|
| Balance, December 31, 2005   | 33,233,096      | \$ 3,323                        | \$ 46,387,875                    | \$ (1,583,463 )  | \$ (45,140,654 )   | \$ (332,919 )                    |
| Net loss for the nine months<br>ended September 30, 2006   |                 |                                 |                                  |  | (9,720,946 )   | (9,720,946 )                     |
| Reclassification of deferred<br>unamortized stock-based<br>compensation upon adoption of<br>FAS 123R |                 |                                 | (1,583,463 )                     | 1,583,463  |  |                                  |
| Stock based compensation<br>expense  |                 |                                 | 1,836,437                        |  |  | 1,836,437                        |
| Common stock issued via<br>private placement:  |                 |                                 |                                  |  |  |                                  |
| February 2006  | 4,283,668       | 428                             | 5,139,782                        |  |  | 5,140,210                        |
| Finders fees and expenses -<br>February 2006   |                 |                                 | (561,808 )                       |  |  | (561,808 )                       |
| April 2006   | 666,667         | 67                              | 799,933                          |  |  | 800,000                          |
| Finders fees and legal exp -<br>April 2006   |                 |                                 | (41,000 )                        |  |  | (41,000 )                        |
| Exercise of common stock<br>warrants   | 184,500         | 18                              | 190,017                          |  |  | 190,035                          |
| Common stock issued for<br>services  | 87,000          | 9                               | 121,101                          |  |  | 121,110                          |
| Balance, September 30, 2006  | 38,454,931      | \$ 3,845                        | \$ 52,288,874                    | \$   | \$ (54,861,600 )   | \$ (2,568,881 )                  |

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

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

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

|   | Nine months Ended September 30, |                 | Period from  |
|---|---------------------------------|-----------------|--|
|   | 2006                            | 2005            | June 5, 1996<br>(inception) to<br>September 30, 2006 |
| <b>Cash flows from operating activities:</b>                                |                                 |                 |  |
| Net loss  | \$ (9,720,946 )                 | \$ (8,525,377 ) | \$ (54,861,600 )                                     |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                 |                 |  |
| Depreciation  | 1,434                           | 15,217          | 86,071   |
| Stock based compensation expense  | 1,996,921                       | 1,657,743       | 15,767,889   |
| Purchased in-process research and development (non-cash portion)            |                                 |                 | 6,841,053  |
| Changes in operating assets and liabilities:                                |                                 |                 |  |
| Prepaid expenses  | 63,447                          | (44,241 )       | (117,837 )   |
| Rent deposits   | 8,480                           |                 | (73,716 )  |
| Accounts payable and accrued expenses                                       | 835,336                         | 459,261         | 2,605,753  |
| Total adjustments   | 2,905,618                       | 2,087,980       | 25,109,213   |
| Net cash used in operating activities                                       | (6,815,328 )                    | (6,437,397 )    | (29,752,387 )  |
| <b>Cash flows from investing activities:</b>                                |                                 |                 |  |
| Acquisition of equipment  | (8,602 )                        |                 | (93,239 )  |
| Net cash used in investing activities                                       | (8,602 )                        |                 | (93,239 )  |
| <b>Cash flows from financing activities:</b>                                |                                 |                 |  |
| Issuance of common and preferred stock, net of repurchases                  | 5,940,210                       | 4,831,528       | 31,225,673   |
| Finders fees and expenses   | (602,808 )                      | (176,250 )      | (1,574,815 )   |
| Exercise of common stock warrants   | 190,035                         |                 | 318,785  |
| Net cash provided by financing activities                                   | 5,527,437                       | 4,655,278       | 29,969,643   |
| Net (decrease) increase in cash and cash equivalents                        | (1,296,493 )                    | (1,782,119 )    | 124,017  |
| Cash and cash equivalents at beginning of period                            | 1,420,510                       | 5,323,384       |  |
| Cash and cash equivalents at end of period                                  | \$ 124,017                      | \$ 3,541,265    | \$ 124,017   |
| Supplementary disclosure of cash flow information:                          |                                 |                 |  |
| Cash paid for taxes   | \$ 6,409                        | \$ 43,043       | \$ 116,016   |
| Cash paid for interest  | \$                              | \$              | \$   |

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

CALLISTO PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(Unaudited)

1. Basis of presentation:

The accompanying unaudited condensed consolidated financial statements of Callisto Pharmaceuticals, Inc. ( Callisto ), which include its wholly owned subsidiaries: (1) Callisto Research Labs, LLC (including its wholly owned but inactive subsidiary, Callisto Pharma, GmbH (Germany)) and (2) Synergy Pharmaceuticals Inc. ( Synergy ), including its wholly owned but inactive subsidiary IgX, Ltd (Ireland)), have been prepared in accordance with (i) accounting principles generally accepted in the United States of America ( GAAP ) for interim financial information and (ii) the rules of the Securities and Exchange Commission (the SEC ) for quarterly reports on Form 10-Q. The results of operations of Synergy are included in the condensed consolidated financial statements since May 1, 2003. All intercompany balances and transactions have been eliminated and certain expense items in prior periods have been reclassified to conform to current financial statement presentation. 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, 2005, included in Form 10-K/A filed with the SEC on April 18, 2006. 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, 2006 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2006.

The audited financial statements and notes thereto for the year ended December 31, 2005, included in Form 10-K/A filed with the SEC on April 18, 2006, have been prepared under the assumption that Callisto will continue as a going concern for the twelve months ending December 31, 2006. Callisto's independent registered public accounting firm has issued a report dated March 29, 2006 that included an explanatory paragraph referring to recurring losses from operations and expressing substantial doubt in Callisto's ability to continue as a going concern without additional capital becoming available. The financial statements do not include any adjustments that might result from the unfavorable outcome of this ongoing uncertainty. Callisto will be required to raise additional capital to complete the development and commercialization of current product candidates and to continue to fund operations at our current cash expenditure levels. The assets and liability carrying amounts do not represent net realizable or settlement values.

To date, our sources of cash have been primarily limited to the sale of our equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. As of September 30, 2006 Callisto's cash balance was \$124,017. On October 23, 2006 Callisto closed on the sale of shares of Series A Preferred Stock and warrants to purchase common stock for net proceeds of \$1,010,000 (See Note 7 Subsequent events ). If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates.

2. Accounting for stock based compensation

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard ( SFAS ) No. 123 (Revised 2004), *Share-Based Payments* ( SFAS 123R ). SFAS 123R requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005 and accordingly Callisto adopted SFAS 123R on January 1, 2006.

SFAS 123R provides for two transition methods. The modified *prospective* method requires that share-based compensation expense be recorded for any employee options granted after the adoption date and for the unvested portion of any employee options outstanding as of the adoption date. The *modified retrospective* method requires that, beginning in the first quarter of 2006, all prior periods presented be restated to reflect the impact of share-based compensation expense consistent with the proforma disclosures previously required under SFAS 123. Callisto has elected to use the modified *prospective* in adopting this standard.

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Prior to January 1, 2006, Callisto had adopted SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ). As provided for by SFAS 123, Callisto had elected to continue to account for stock-based compensation according to the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ). Accordingly, compensation expense had been recognized to the extent of employee or director services rendered based on the intrinsic value of stock options granted under the plan. Callisto accounts for common stock, stock options, and warrants granted to non-employees based on the fair market value of the instrument, using the Black-Scholes option pricing model based on assumptions for expected stock price volatility, term of the option, risk-free interest rate and expected dividend yield at the grant date.

For all awards granted prior to January 1, 2006, the unearned deferred fair value of stock based compensation is being recognized as an expense on a straight line basis over the remaining requisite service period, ranging from nine months to three years. Our financial results for prior periods have not been restated. The adoption of SFAS 123R increased net loss for the three and nine months ended September 30, 2006 by \$225,401 and \$1,176,174, respectively, for stock based compensation cost related to employee stock options. The unrecognized compensation cost related to non-vested share-based compensation arrangements for all employee stock options outstanding at September 30, 2006, as measured at the date of grant, was approximately \$899,000

Effective with the adoption of SFAS 123R stock-based compensation expense related to Callisto's share-based compensation arrangements attributable to employees is being recorded as a component of general and administrative expense and research and development expense in accordance with the guidance of Staff Accounting Bulletin 107, Topic 14, paragraph F. *Classification of Compensation Expense Associated with Share-Based Payment Arrangements* ( SAB 107 ). Prior period financial statement accounts have been reclassified to conform to this presentation.

Stock based compensation expense related to employee and non-employee stock options recognized in operating results for the three and nine months ended September 30, 2006, September 30, 2005 and for the period from June 6, 1996 (inception), through September 30, 2006 were as follow:

| Stock based compensation expense                 | Three Months Ended September 30,<br>2006 | September 30,<br>2005 | Nine Months Ended September 30,<br>2006 | September 30,<br>2005 | June 5, 1996<br>(Inception) to<br>September 30,<br>2006 |
|--|--|-----------------------|---|-----------------------|---|
| Employees included in research and development   | \$ 74,059                                | \$ 69,063             | \$ 363,662                              | \$ 207,189            | \$ 2,495,523  |
| Employees included in general and administrative | 151,342                                  | 313,541               | 812,512                                 | 940,623               | 4,127,049   |
| Subtotal employee stock option grants            | 225,401                                  | 382,604               | 1,176,174                               | 1,147,812             | 6,622,572   |
| Non-employee research and development            |  |                       | 102,750                                 |                       | 102,750   |
| Non-employee general and administrative          | (139,501 )                               | 506,199               | 717,997                                 | 509,931               | 9,042,567   |
| Subtotal non-employee stock option grants        | (139,501 )                               | 506,199               | 820,747                                 | 509,931               | 9,145,317   |
| Total stock based compensation expense           | \$ 85,900                                | \$ 888,803            | \$ 1,996,921                            | \$ 1,657,743          | \$ 15,767,889   |

The estimated fair value of employee options granted was determined in accordance with SFAS 123R on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for options granted during the nine months and three months ended September 30, 2006: Risk free interest rate 4.25%; Dividend yield 0% and expected life of 3 to 7 years. The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of Callisto's employee stock options. Callisto has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future. The computation of the expected option term is based on expectations regarding future exercises of options which generally vest over 3 years and have a 10 year life. The expected volatility is based on the historical volatility of Callisto's stock and was 79% for all options granted through June 30, 2006 and 60% for options grant since July 1, 2006.





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SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Based on historical Company experience Callisto estimated future unvested option forfeitures at 20% as of January 1, 2006 and incorporated this rate in estimated fair value of employee option grants.

Callisto's determination of fair value is affected by Callisto's stock price as well as the assumptions discussed above that require judgment. The weighted-average fair value of all options granted during the nine months ended September 30, 2006, estimated as of the grant date using the Black-Scholes option valuation model, was \$1.17 per share. A summary of the status of Callisto's stock option plans as of September 30, 2006 and of changes in options outstanding under Callisto's plans during the nine months ended September 30, 2006 is as follows:

|   | Number of<br>Shares | Weighted Average<br>Price Per Share |
|---|---------------------|-------------------------------------|
| Outstanding at January 1, 2006            | 8,008,210           | \$ 1.79                             |
| Granted                                   | 925,000             | 1.52                                |
| Exercised                                 |                     |                                     |
| Terminated                                | (508,335 )          | 1.04                                |
| Outstanding at September 30, 2006         | 8,424,875           | \$ 1.79                             |
| Options exercisable at September 30, 2006 | 5,066,546           | \$ 1.63                             |

The weighted average remaining term of all options outstanding decreased from 7.4 years at December 31, 2005 to 7.2 years at September 30, 2006. At September 30, 2006 Callisto had 850,000 stock options outstanding under the 2005 Equity Plan, 52,500 stock options outstanding under the 2005 Director's Plan and 7,522,375 stock options outstanding under the 1996 Plan.

SFAS 123R requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to Callisto's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

Had compensation cost for stock options granted to employees and directors prior to January 1, 2006 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 for the three and nine months ended September 30, 2005 would have been as follows:

|   | Three Months<br>Ended<br>September 30,<br>2005 | Nine Months<br>Ended<br>September 30,<br>2005 |
|---|--|---|
| Net loss, as reported   | \$ (3,320,569 )                                | \$ (8,525,377 )                               |
| Add: Stock-based employee compensation expense recorded under APB No. 25 intrinsic value method | 382,604  | 1,147,812                                     |
| Deduct: Stock-based employee compensation expense determined under fair value method            | (672,488 )                                     | (1,857,890 )                                  |
| Pro forma net loss  | \$ (3,610,453 )                                | \$ (9,235,455 )                               |
| Net loss per share:   |  |   |
| Basic and diluted -as reported  | \$ (0.10 )                                     | \$ (0.28 )                                    |
| Basic and diluted -pro forma  | \$ (0.11 )                                     | \$ (0.30 )                                    |
| Black-Scholes Methodology Assumptions:  |  |   |
| Dividend yield  | 0  | % 0   |
| Risk free interest rate   | 4.25   | % 4.25  |
| Expected lives of options   | 7 to 10 years                                  | 7 to 10 years                                 |



Volatility of 0% was used until Callisto's common stock began to trade publicly on June 16, 2003. From June 13, 2003 through June 30, 2005 Callisto used 100% volatility to determine the fair value of options granted to employees. From July 1, 2005 to June 30, 2006 Callisto has used a volatility factor of 79%. Effective for all grants awarded subsequent to June 30, 2006 Callisto has used a volatility factor of 60%.

### 3. Net Loss per Share

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, Earnings per Share, for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares since the inclusion of issuable shares pursuant to the exercise of stock options and warrants, would have been antidilutive. As of September 30, 2006 there were 4,864,601 warrants and 8,424,875 stock options outstanding, and at September 30, 2005 there were 2,552,317 warrants and 8,675,710 stock options outstanding.

### 4. Government Grants

On April 1, 2005 Callisto was awarded a research grant for work on a biodefense program from the National Institute of Allergy and Infectious Diseases ( NIAID ) to develop a monoclonal antibody and vaccine against bacterial superantigen toxins under an exclusive license with Rockefeller University entered into on August 20, 1996. Callisto receives cash funding under approved grants and records the receipt as an offset to research and development expense only when the expense is incurred. Funds received as an offset to research and development expenses incurred totaled \$ 43,956 and \$299,378, during the three and nine months ended September 30, 2006, respectively and have been reported on our Condensed Consolidated Statements of Operations as a separate line item entitled Government Grant . In addition as of September 30, 2006 Callisto had received approximately \$78,000 of cash advances under the NIAID grant for which it had not yet incurred any expenses. During October 2006 Callisto advanced an additional amount of \$270,000 for research expenses not yet incurred and used some funds to pay operating expenses not specifically related to the work on the biodefense program.

### 5. Stockholders' equity:

On February 3, 2006, Callisto closed on a private placement of 4,283,668 shares of common stock and 1,070,917 common stock purchase warrants to certain accredited investors. The warrants are exercisable for 18 months from closing at an exercise price of \$1.60 per share. The securities were sold at a price of \$1.20 per share for aggregate gross proceeds of approximately \$5.14 million. Net proceeds, after fees and expenses, were \$4.58 million. As provided for by Emerging Issues Task Force Issue 00-19: *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* ( EITF 00-19 ) the warrants were classified as permanent equity. The fair value of the investor warrants on February 3, 2006, the date of grant was \$662,680 using Black Scholes assumptions of 79% volatility, a risk free interest rate of 4.25%, no dividend, an expected life of 18 months and a stock price on that date of \$1.59 per share. This fair value allocated to the investor warrants was recorded as additional paid in capital during the quarter ended March 31, 2006.

On April 7, 2006 Callisto had a second closing of the financing described above, in which we sold an additional 666,667 shares of common stock and issued 166,667 common stock purchase warrants at the same terms, for gross proceeds of \$800,000, bringing the total gross proceeds of the financing to \$5.94 million and net proceeds to \$5.34 million. Placement agent fees of \$41,000 were paid on this second closing and three year warrants to purchase a total of 66,667 common shares at a per share price of \$1.25 were issued to several selling agents.

In conjunction with this financing Callisto agreed to file, within 60 days after the first closing, a registration statement covering the resale of the shares of common stock and the shares underlying the warrants, and to use our commercially reasonable efforts to cause such registration statement to be declared effective within 120 days after closing or pay financial liquidated damages to the investors. Callisto has not yet filed a registration statement and is incurring liquidated damages at the rate of approximately \$59,400 for every 30-day period that a registration statement has not been filed, up to a maximum of 8% of the gross proceeds. As of September 30, 2006 Callisto has incurred \$334,446 in liquidated damages related to the registration rights agreement, or approximately 5.6%, which have been classified as other expense on our condensed consolidated statement of operations. \$149,287 of these damages was paid in cash during the nine months ended September 30, 2006 and \$185,159 was due and payable as of September 30, 2006.

### 6. Commitments and contingencies:

Licensing agreements:

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On January 10, 2006, Callisto entered into a Patent and Technology License Agreement with The University of Texas M.D. Anderson Cancer Center. Pursuant to the license agreement, Callisto was granted the exclusive right to manufacture, have manufactured, use, import, offer to sell and/or sell anti-cancer compounds called tyrphostins (renamed Degrasyns). In addition, at any time after two years from January 10, 2006, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if Callisto fails to provide evidence within 90 days of written notice that it has commercialized or is actively and effectively attempting to commercialize the licensed technology.

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Employment and consulting agreements:

On March 23, 2006, Callisto entered into a 2-year sponsored laboratory study agreement with the University of Texas M. D. Anderson Cancer Center whereby Dr. Nicholas Donato, as principal investigator, will analyze the anti-tumor activity and mechanism of action of Callisto's WP1130 Degrasyne compound and analogs. The agreement calls for payment of \$145,900 to M.D. Anderson in two installments of \$72,950 with the first payment due within 30 days of the effective date of the agreement, and the second payment due within six months of execution.

On March 27, 2006, Callisto entered into a 2-year sponsored laboratory study agreement with the University of Texas M. D. Anderson Cancer Center whereby Dr. William Bornmann, as principal investigator, will perform molecular modeling and synthesize a library of compounds based on Callisto's Degrasyne platform technology. The agreement calls for payment of \$127,145 to M.D. Anderson in two installments of \$63,572 with the first payment due within 30 days of the effective date of the agreement, and the second payment due within six months of execution.

7. Subsequent events

On October 3, 2006, Callisto received notice (the Deficiency Letter) from the staff of the American Stock Exchange (AMEX) indicating that it is not in compliance with certain continued listing standards, specifically, Section 1003(a)(i) of the Company Guide with shareholders' equity of less than \$2,000,000 and losses from continuing operations and/or net losses in two of its three most recent fiscal years and Section 1003(a)(iv) of the Company Guide in that it has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the Exchange, as to whether it will be able to continue operations and/or meet its obligations as they mature.

*On November 2, 2006 Callisto submitted a plan advising AMEX of the actions it has taken, or will take, that would bring it into compliance with Section 1003(a)(iv) of the Company Guide by April 3, 2007 and with Section 1003(a)(i) of the Company Guide by April 3, 2008. If AMEX accepts Callisto's plan, it may be able to continue its listing during the plan period of up to 18 months, during which time Callisto will be subject to periodic review to determine if it is making progress consistent with the plan. If it is not in compliance with the continued listing standards at the end of the plan period, or it does not make progress consistent with the plan during the plan period, AMEX staff may initiate delisting proceedings. There is no guarantee that the plan will be accepted by AMEX, or that Callisto will be able to make progress consistent with the plan if it is accepted. While the plan is under review by AMEX, Callisto expects that its common stock will continue to trade without interruption on AMEX. If the plan is not accepted by AMEX, it may be subject to delisting proceedings.*

*On October 23, 2006, Callisto closed a private placement of 105,000 shares of Series A Convertible Preferred Stock (the Series A Preferred Stock) and 1,400,000 warrants (the Warrants) to certain investors (the Investors) for aggregate gross proceeds of \$1,050,000. The Investors also are parties to a Registration Rights Agreement, dated as of October 23, 2006 pursuant to which Callisto agreed to file, within 60 days of closing, a registration statement covering the resale of the shares of common stock underlying the Series A Preferred Stock and the Warrants issued to the Investors. The Warrants are immediately exercisable at \$0.75 per share, will expire five years from the date of issuance, and have certain antidilution rights for the twelve month period beginning on the effective date of the registration statement registering the shares of common stock underlying the Warrants. Callisto paid an aggregate \$40,000 and issued an aggregate 53,334 warrants to purchase common stock to certain selling agents. The warrants are immediately exercisable at \$0.75 per share, will expire five years after issuance and have the same antidilution rights as the Investor Warrants. Callisto's Certificate of Incorporation has been amended to provide for the issuance of 400,000 shares of Series A Preferred Stock pursuant to the Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Convertible Preferred Stock filed with the State of Delaware on October 24, 2006.*

*Callisto is currently evaluating whether the Warrants will be treated as permanent equity in accordance with Emerging Issues Task Force Issue 00-19: Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock (EITF 00-19). The fair value of the Warrants on October 23, 2006, the date of grant, was \$725,000 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.25%, no dividend, an expected life of five years and a stock price on that date of \$0.88 per share. In addition Callisto is currently evaluating the Series A Preferred Stock conversion feature in accordance with Emerging Issues Task Force Issue 00-27: Application of Issue No. 98-5 to Certain Convertible Instruments, (EITF 00-27) to determine whether the embedded beneficial conversion*

feature should be measured, during the quarter ended December 31, 2006, using the fair value or intrinsic method. The fair value of *the Series A Preferred Stock conversion feature* on October 23, 2006 was approximately \$725,000 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.25%, no dividend, an expected life of 5 years and a stock price on that date of \$0.88 per share and the intrinsic value was approximately \$182,000.

On September 8, 2006 Callisto entered into a Letter Agreement with certain investors (the Investors ) who participated in a private placement of our common stock and warrants in February and April 2006 (the Prior Placement ). Pursuant to this Letter Agreement, the Investors agreed to amend (the Amendment ) the securities purchase agreement (the Securities Purchase Agreement ), entered into in connection with the Prior Placement, to (i) delete the mandatory registration rights set forth in the Securities Purchase Agreement and add piggyback

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registration rights and (ii) waive any unpaid penalties pursuant to the liquidated damages provisions contained in the Securities Purchase Agreement. In addition, the Investors agreed to enter into a lock-up agreement (the Lock-up Agreement ) pursuant to which they agreed not to sell or transfer the shares of common stock and warrants acquired in the Prior Placement for a period of nine months beginning September 1, 2006. In exchange for the Investors entering into the Amendment and the Lock-Up Agreement, Callisto agreed to issue to each Investor one share of common stock and 2.35 five year warrants exercisable at \$1.00 per share (the New Warrants ) for every five shares of common stock they purchased in the Prior Placement. In addition, Callisto agreed in the Letter Agreement to amend the warrants (the Old Warrants ) issued in the Prior Placement to the Investors to (i) extend the expiration date of the Old Warrants by 42 months thereby making them 5 year warrants and (ii) eliminate the provision in the Old Warrants by which Callisto can force exercise of the unexercised warrants. During October and November 2006 Callisto entered into the Amendment and Lock-up Agreements with each Investor pursuant to which Callisto issued 740,067 shares of common stock and 1,739,157 New Warrants. Approximately \$150,000 in cash liquidated damages, payable to these Investors as of September 30, 2006, was concurrently waived.

The fair value of the New Warrants when issued was approximately \$700,000 using Black Scholes assumptions of 60% volatility, a risk free interest rate of 4.25%, no dividend, an expected life of 5 years and a stock price on that date of \$0.82 per share. The fair value of the shares issued to the Investors in October and November 2006 was approximately \$600,000 using a volume weighted average price for October and November of \$0.82 per share. Callisto is currently evaluating the appropriate basis for allocating a portion, or all, of this fair value to liquidated damages expense during the quarter ended December 31, 2006.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our condensed consolidated financial statements and other financial information appearing elsewhere in this Quarterly Report. In addition to historical information, the following discussion and other parts of this quarterly report contain forward-looking information that involves risks and uncertainties.

### OVERVIEW

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, 2006, we have sustained cumulative net losses of \$54,861,600. Our losses have resulted primarily from expenditures incurred in connection with clinical development of licensed products, 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, 2006 we have not generated any revenue from operations. We expect to incur substantial and increasing losses for the next several years as we develop our product candidates, expand our clinical development team and prepare for the commercial launch of our product candidates. We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all.

*On October 23, 2006, we closed a private placement of 105,000 shares of Series A Convertible Preferred Stock (the Series A Preferred Stock ) and 1,400,000 warrants (the Warrants ) to certain investors (the Investors ) for aggregate gross proceeds of \$1,050,000. The Investors also are parties to a Registration Rights Agreement, dated as of October 23, 2006 pursuant to which we agreed to file, within 60 days of closing, a registration statement covering the resale of the shares of common stock underlying the Series A Preferred Stock and the Warrants issued to the Investors. The Warrants are immediately exercisable at \$0.75 per share, will expire five years from the date of issuance, and have certain antidilution rights for the twelve month period beginning on the effective date of the registration statement registering the shares of common stock underlying the Warrants. We paid an aggregate \$40,000 and issued an aggregate 53,334 warrants to purchase common stock to certain selling agents. The warrants are immediately exercisable at \$0.75 per share, will expire five years after issuance and have the same antidilution rights as the Investor Warrants*

### HISTORY

In March 2002, Callisto Pharmaceuticals, Inc. ( Old Callisto ), a non-public company, 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 at 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. In 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. Old Callisto changed its name to Callisto Research Labs, LLC ( Callisto Research ) and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware. Subsequently, 171,818 shares of common stock issued to former Synergy shareholders were returned to us under the terms of certain indemnification agreements.



## PLAN OF OPERATIONS

Our plan of operations for the next twelve months is to focus primarily on the clinical development of our two drugs, Atiprimod and L-Annamycin, to treat advanced carcinoid cancer, adult and pediatric acute leukemia (a disease of the white blood cells) and multiple myeloma (an incurable blood cancer that invades and proliferates in bone marrow).

Our lead drug candidate, Atiprimod, is an orally administered drug with antiproliferative and antiangiogenic activity. Atiprimod is presently in three clinical trials in advanced carcinoid cancer, relapsed or refractory multiple myeloma and advanced cancer patients at a number of clinical sites in the U.S. On November 7, 2006, we announced the initiation of a multi-center open-label Phase II clinical trial of Atiprimod in advanced carcinoid cancer patients. This trial is based on earlier encouraging clinical results from an ongoing trial of Atiprimod in advanced cancer patients that showed a clear response in a patient with advanced carcinoid cancer plus additional encouraging clinical data on other carcinoid patients. Atiprimod is also in a multi-center, dose-escalation Phase I/IIa clinical trial in relapsed or refractory multiple myeloma patients. In December 2005, we announced interim results from this trial on 15 patients treated with Atiprimod, including 3 patients at the highest dose level of 180 mg/day. Two patients exhibited stable disease, with one patient having a 34% decrease in M protein (measure of tumor burden) over 3 months of treatment. In 2006, we amended the protocol to continue the trial at higher dose levels and currently have this trial underway at 4 clinical sites in the U.S.

Our second lead drug candidate, L-Annamycin, earlier completed an initial Phase I/IIa clinical trial in relapsed or refractory leukemia patients with a prior sponsor. L-Annamycin is a novel compound from the anthracycline family of proven anti-cancer drugs, which has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart. L-Annamycin was in-licensed by Callisto in October, 2004 and is presently in a Phase I/IIa clinical trial in adult relapsed or refractory acute lymphocytic leukemia (ALL) patients at three clinical sites in the U.S. We are also planning to evaluate the drug in pediatric patients with relapsed or refractory ALL and relapsed or refractory acute myelocytic leukemia (AML).

## ATIPRIMOD TO TREAT MULTIPLE MYELOMA AND ADVANCED CARCINOID CANCER PATIENTS

On August 28, 2002, Synergy entered into a worldwide license agreement with AnorMED to research, develop, sell and commercially exploit the Atiprimod patent rights. The license agreement provides for aggregate milestone payments of up to \$14 million based upon achieving certain regulatory submissions and approvals for an initial indication, and additional payments of up to \$16 million for each additional indication based on achieving certain regulatory submissions and approvals. In addition the agreement requires Synergy to pay AnorMED 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 until the first commercial sale of the product. The first of these annual maintenance fee payments under this agreement was made on January 22, 2004. Pursuant to the license agreement, failure to pay the maintenance fee is a material breach of the license agreement. The license agreement will terminate in 2018.

## DEVELOPMENT STRATEGY FOR ATIPRIMOD

Advanced Cancer and Advanced Carcinoid Cancer:

On March 15, 2005 we announced the initiation of a Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The trial is entitled: An Open Label Study of the Safety and Efficacy of Atiprimod Treatment for Patients with Advanced Cancer. The primary objective is to assess the safety and determine the maximum tolerated dose (MTD) of Atiprimod in advanced cancer patients. The secondary objectives are to measure the pharmacokinetics of Atiprimod and evaluate the response in a variety of relapsed solid tumors and hematologic malignancies. The trial protocol received IRB approval on February 22, 2005 at The University of Texas M.D. Anderson Cancer Center with Dr. Razelle Kurzrock acting as the Principal Investigator. Site initiation was completed on March 3, 2005, and patient screening and dosing began in April, 2005. On June 2, 2006 at the American Society of Clinical Oncology (ASCO) annual meeting abstract number 13050, titled Phase I Study of the Safety and Efficacy of Atiprimod, a Novel Azaspirane, for Patients with Advanced Cancer described data from the Phase I/IIa clinical trial of Atiprimod in advanced cancer patients. The abstract stated that 14 patients had been treated at that date with 60 mg tablets (n=3), 60 mg capsules (n=3), 90 mg capsules (n=3) and 120 mg capsules (n=5). Of the 14 patients, 4 had carcinoid tumors and 3 of these patients had shown responses with one patient being on drug for 7 cycles of therapy (7 months). Due to encouraging results in the carcinoid patients from the Phase I trial in advanced cancer, on June 27, 2006 we announced plans to begin a Phase II trial in advanced carcinoid patients to include approximately 30 patients.



On November 7, 2006, we announced the commencement of the multi-center, open-label Phase II clinical trial of Atiprimod to treat low to intermediate grade neuroendocrine carcinomas including advanced carcinoid cancers. The first study site to enter this trial was the Hematology Oncology Services of Arkansas in Little Rock, Arkansas. The primary objective of the Phase II clinical trial is to evaluate efficacy of Atiprimod in patients with low to intermediate grade neuroendocrine carcinoma who have metastatic or unresectable cancer and who have either symptoms, despite standard therapy (octreotide), or progression of neuroendocrine tumors. Patients, after signing an informed consent, are required to complete two weeks of a symptoms diary to establish their symptoms baseline before commencing Atiprimod dosing. A maximum of 40 evaluable patients will be enrolled in this trial. Efficacy evaluations will include the measure of target lesions (per RECIST), and the quantization of multiple myeloma symptom relief:

Atiprimod commenced a Phase I/IIa clinical trial in relapsed or refractory multiple myeloma patients on May 26, 2004. These are patients that have a re-occurrence of active disease, and no longer respond to approved therapies. The Phase I/IIa clinical trial presently includes four sites, The University of Texas M.D. Anderson Cancer Center (Houston, TX), the University of Michigan Medical Center (Ann Arbor, MI), Fred Hutchinson Cancer Research Center (Seattle, WA), and the Roswell Park Cancer Institute (Buffalo, NY). The clinical trial is an open label study, with the primary objective of assessing the safety of the drug and identifying the maximum tolerated dose. The secondary objectives are to measure the pharmacokinetics, evaluate the response in patients with refractory disease and to identify possible surrogate responses to drug to better determine the mechanism of drug action. In December 2005, we announced interim results from this trial on 15 patients treated with Atiprimod, including 3 patients at the highest dose level of 180 mg/day. Two patients exhibited stable disease, with one patient having a 34% decrease in M protein (measure of tumor burden) over 3 months of treatment. In early 2006, we amended the protocol to continue the trial at higher dose levels and to include the use of an FDA approved liver-protecting drug, Ursodiol, in combination with Atiprimod to enable dosing of Atiprimod at higher levels. We currently have this trial underway at 4 clinical sites in the U.S. and plan to continue this study until a maximum tolerated dose has been established for Atiprimod, and it has been determined what level of efficacy is observed with Atiprimod in relapsed or refractory multiple myeloma patients.

#### **L-ANNAMYCIN TO TREAT RELAPSED OR REPRACTORY ACUTE LEUKEMIA**

On August 12, 2004, we entered into a world-wide license agreement with The University of Texas M.D. Anderson Cancer Center to research, develop, sell and commercially exploit the patent rights for L-Annamycin, an anthracycline 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 L-Annamycin patent rights and a \$100,000 initial license fee. We also agreed to pay The University of Texas M.D. Anderson Cancer Center 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 from August 12, 2004 until November 2, 2019. Under the terms of the license agreement, we are required to make certain good faith expenditures towards the clinical development of at least one licensed product within the one year period after March 2006. In addition, at any time after five years from August 12, 2004, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or we are actively and effectively attempting to commercialize L-Annamycin.

L-Annamycin was discovered by scientists at The University of Texas M.D. Anderson Cancer Center and initially evaluated in a Phase I clinical trial in 36 patients with relapsed solid tumors, a Phase II clinical trial in 13 patients with doxorubicin-resistant breast cancer, and a Phase I/IIa trial in 20 patients with relapsed or refractory AML or ALL.

#### **DEVELOPMENT STRATEGY FOR L-ANNAMYCIN**

We began a clinical trial at The University of Texas M.D. Anderson Cancer Center in adult relapsed or refractory ALL patients on December 1, 2005. This single-arm, open-label Phase I/IIa clinical trial was designed to enroll up to 12 patients in a dose-escalation portion, to obtain the maximum tolerated dose, followed by 10 patients at this final fixed dose. As many as 34 patients can be treated under this protocol.

Additionally, we plan to commence in late 2006 a single-arm, open label, dose escalation Phase I/IIa clinical trial of L-Annamycin in pediatric relapsed or refractory ALL and AML patients.

#### **GUANYLATE CYCLASE RECEPTOR AGONIST TECHNOLOGY**

Our guanylate cyclase receptor agonist (GCRA) program is based on control of cyclic guanosine monophosphate ( cyclic GMP ), an important second messenger involved in key cellular processes that are essential for maintaining the balance between proliferation and cellular death (apoptosis). Uroguanylin, a hormone produced by and secreted by specialized cells in the human GI tract, helps to maintain this balance by activating synthesis of cyclic GMP through activation of guanylate cyclase receptor. Recent findings suggest a role of cyclic GMP in gastrointestinal (GI) inflammatory diseases.



We have successfully developed a potent analog (synthetic molecule) of uroguanylin called Guanilib (also called SP304). Guanilib has been demonstrated to be superior to uroguanylin in its biological activity, protease stability and pH characteristics. Guanilib was evaluated in a pre-clinical animal model of ulcerative colitis, an inflammatory bowel disease, in a collaboration involving clinical gastroenterologist Dr. Scott Plevy of the University of North Carolina. Those data, along with independent animal data obtained by Callisto, showed that Guanilib significantly reduced inflammation in mouse models of experimental ulcerative colitis. Callisto presently has Guanilib in pre-clinical development. On May 9, 2006 the U.S. Patent and Trademark Office (USPTO) notified Callisto that its patent issued covering a novel drug candidate, Guanilib, developed by Callisto scientists to treat and prevent a variety of inflammatory diseases of the bowel. The drug candidate is first-in-class of a new category of compounds with the potential to treat gastro-intestinal diseases such as ulcerative colitis.

On January 10, 2006, we entered into a license agreement with the University of Texas M.D. Anderson Cancer Center whereby we were granted the exclusive right to manufacture, have manufactured, use, import, offer to sell and/or sell anti-cancer compounds called tyrphostins (renamed Degrasyns). Degrasyns are a second-generation class of tyrphostins developed by scientists at the University of Texas M.D. Anderson Cancer Center that have a novel anti-cancer mechanism-of-action that centers on their ability to promote selective degradation of key proteins that are involved in tumor cell proliferation and survival. We have been working closely with scientists at the University of Texas M.D. Anderson Cancer Center during 2006 to bring forward a pre-clinical candidate for development in the clinic.

On March 23, 2006, we entered into a 2-year sponsored laboratory study agreement with the University of Texas M.D. Anderson Cancer Center whereby Dr. Nicholas Donato, as principal investigator, will analyze the anti-tumor activity and mechanism of action of our WP1130 Degrasyn compound and analogs. The agreement calls for payment of \$145,900 to M.D. Anderson in two installments of \$72,950, with the first payment due within 30 days and the second payment due within six months. On March 27, 2006, we entered into a 2-year sponsored laboratory study agreement with the University of Texas M.D. Anderson Cancer Center whereby Dr. William Bornmann, as principal investigator, will perform molecular modeling and synthesize a library of compounds based on our Degrasyn platform technology. The agreement calls for payment of \$127,145 to M.D. Anderson in two installments of \$63,572, with the first payment due within 30 days and the second payment due within six months.

## **MANUFACTURING**

An improved manufacturing method for Annamycin has been developed at Antibioticos S.p.A., our commercial supplier of Good Manufacturing Practice, or GMP, drug substance. GMP material is currently being produced in sufficient quantity for all three anticipated Phase I/II trials. Currently, Antibioticos S.p.A. is our sole supplier of Annamycin for our clinical trials. Our agreement with Antibioticos provides that Antibioticos S.p.A. will provide 400 grams of GMP drug substance (Annamycin) for our L-Annamycin clinical trials. Upon the conclusion of our Phase IIb clinical trials, the agreement provides that the parties will negotiate in good faith towards a commercial supply agreement for Annamycin. If our relationship with this contract manufacturer, or any other contract manufacturer we might use, terminates or if any of their facilities are damaged for any reason, including fire, flood, earthquake or other similar event, we may be unable to obtain supply of Annamycin. If any of these events were to occur, we may need to find alternative manufacturers or manufacturing facilities. The number of contract manufacturers with the expertise, required regulatory approvals and facilities to manufacture Annamycin on a commercial scale is extremely limited, and it would take a significant amount of time to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must approve these manufacturers facilities and processes prior to our use, which would require new testing and compliance inspections. In addition, we may not have the intellectual property rights, or may have to share intellectual property rights, to any improvements in the current manufacturing processes or any new manufacturing processes for Annamycin. Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of L-Annamycin, entail higher costs, and could result in our being unable to commercialize L-Annamycin successfully. One large-scale GMP production run of Atiprimod dimaleate led to the successful release of 10 Kg of material available for future Phase II clinical studies. We plan to enter into a supply contract for Atiprimod with a commercial supplier by the end of 2007 or after confirming activity of the drug candidate in our current human clinical trials.

## **EMPLOYEES**

Our plan is to use contract research organizations for most of our development efforts thus minimizing the need to hire full time employees. As of November 14, 2006, we had 8 full-time and 3 part-time employees. We believe our employee relations are satisfactory.

## **OFF-BALANCE SHEET ARRANGEMENTS**

We had no off-balance sheet arrangements as of September 30, 2006.



## RESULTS OF OPERATIONS

### THREE MONTHS ENDED SEPTEMBER 30, 2006 AND SEPTEMBER 30, 2005

We had no revenues during the three months ended September 30, 2006 and 2005 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses decreased by \$648,862, or 36%, to \$1,139,094 for the three months ended September 30, 2006 from \$1,787,956 for the three months ended September 30, 2005. The factors contributing to the decreased research and development expense during the quarter ended September 30, 2006 were the scale back of certain clinical development activities and the curtailment of non-essential in-house overhead while we continued to seek additional funding. Overall outside spending on product candidates, primarily with contract research organizations ( CRO ) was down \$150,666 or 13%, to \$1,016,670 during the three months ended September 30, 2006 from \$1,167,336 during the same period in 2005. CRO spending for Atiprimod was down by \$242,715 or 35% and L-Annamycin costs were down by \$52,138 or 14% from the quarter ended September 30, 2005, partially offset by an increase in spending for non-clinical products, principally, Degrasyns and Guanilib. Additionally our in-house research overhead was cut by \$498,196 or 80% to \$122,424 for the three months ended September 30, 2006 from \$620,621 in the three months ended September 30, 2005. This in-house overhead reduction reflects cost containment, including approximately \$87,000 or 40% in lower salaries and wages, \$84,000 or 54% less in patent legal, \$67,000 in license fees recovered on inactive patents, \$42,000 or 24% in lower sponsored laboratory studies and a clinical trial insurance rebate of \$37,000.

On April 1, 2005 we received an \$885,641 biodefense partnership grant from the National Institute of Allergy and Infectious Diseases ( NIAID ) to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over the next two years. Government grant funding for the three months ended September 30, 2006 was \$43,956 as compared to \$152,866 for the three months ended September 30, 2005. We request grant funding to reimburse research and development expenses as incurred.

General and administrative expenses for the three months ended September 30, 2006 decreased \$411,677 or 34%, to \$800,803, from \$1,212,480 for the three months ended September 30, 2005. Consistent with our scaled back research and development activities we also decreased certain non-essential in-house general and administrative expenses while we continued to seek additional funding. Approximately (i) \$75,000 of this decreased spending was on lower investor relations, a decrease of 55% from investor relations expense for the prior period, (ii) \$102,000 of this decrease was in lower accounting fees, primarily for Sarbanes-Oxley compliance testing under Section 404 which has now been deferred until 2007 and (iii) \$162,000 of lower stock based compensation cost for employees and directors.

Stock-based compensation for non employees decreased \$645,700 or 128% from \$506,199 for the three months ended September 30, 2005 to a credit of (\$139,501) for the three months ended September 30, 2006 primarily attributable to (i) the warrants granted to Trilogy Capital Partners in July 2005 which expense was being amortized until June 30, 2006 and (ii) a decline in our stock price during 2006, which caused the reversal of expense recorded in prior periods on certain option requiring variable accounting treatment. (See Note 2 Stock-based Compensation to our Condensed Consolidated Financial Statements included in this report).

Interest income for the three months ended September 30, 2006 decreased \$29,897 or 90% to \$3,304 from \$33,200 in the three months ended September 30, 2005 due to decreased average cash balances.

Other expense for the three months ended September 30, 2006 consisted of \$177,010 of liquidated damages accruing to investors for failure to register shares of our common stock sold in a private placement in February and April 2006. We had no such payments during the three months ended September 30, 2005.

Net loss for the three months ended September 30, 2006 was \$1,930,146 compared to a net loss of \$3,320,569 incurred for the three months ended September 30, 2005, a 42% decrease for the reasons discussed above.

**NINE MONTHS ENDED SEPTEMBER 30, 2006 AND SEPTEMBER 30, 2005**

We had no revenues during the nine months ended September 30, 2006 and 2005 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses decreased by \$48,001 or 1%, to \$4,898,524 for the nine months ended September 30, 2006 from the \$4,946,525 we incurred for the nine months ended September 30, 2005. Spending on product candidates, primarily with outside CROs was up by \$60,076 or 2% to \$3,581,810 during the nine months ended September 30, 2006 from \$3,521,734 during the same period in 2005. Spending on our Atiprimod drug candidate was down \$186,343 or 12% and L-Annamycin CRO costs were down \$668,759 or 36% from the nine months ended September 30, 2005, more than offset by an increase in spending for our non-clinical products, principally, Degrasyns and Guanilib. Offsetting this increase in outside CRO costs during the nine months ended September 30, 2006 was the curtailment of in-house research and development overhead.

On April 1, 2005 we received an \$885,641 biodefense partnership grant from the National Institute of Allergy and Infectious Diseases ( NIAID ) to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over the next two years. Government grant funding for the nine months ended September 30, 2006 was \$299,378 from our NIAID grant versus \$152,866 for the nine months ended September 30, 2005.

General and administrative expenses increased by \$699,154 or 21%, to \$4,012,012 for the nine months ended September 30, 2006 from \$3,312,858 for the nine months ended September 30, 2005. During the nine months ended September 30, 2006 cash-based general and administrative expenses were \$3,199,501 versus \$2,372,236 for the nine months ended September 30, 2005, an increase of \$827,266 or 35%. Non-cash employee stock based compensation expense was \$812,511 for the nine months ended September 30, 2006 as compared to \$940,623 for the nine months ended September 30, 2005, a decrease of \$128,112 or 14%. The increase in cash-based general and administrative expenses was due primarily to approximately (i) \$660,000 of increased investor relations costs including the fees paid to Trilogy Capital Partners and affiliates, (ii) \$139,000 of additional staff cost attributable to higher headcount and salary increases, and (iii) \$113,000 in higher bonuses.

Stock-based compensation related to non-employee options recorded during the nine months ended September 30, 2006 totaled \$820,747 as compared to \$509,931 recorded during the nine months ended September 30, 2005 attributable to the warrants granted to Trilogy Capital Partners in July 2005. See Note 2 to our condensed consolidated financial statements for more detailed discussion of employee and non-employee stock based compensation.

Interest income for the nine months ended September 30, 2006 decreased \$45,666 or 50% to \$45,405 from \$91,071 for the nine months ended September 30, 2005 due to lower cash balances.

Other expense for the nine months ended September 30, 2006 was \$334,446 recorded for liquidated damages due to investors for failure to register shares of our common stock sold in a private placement in February and April 2006. We had no such expense during the nine months ended September 30, 2005.

Net loss for the nine months ended September 30, 2006 was \$9,720,946 compared to a net loss of \$8,525,377 incurred for the nine months ended September 30, 2005. The increased net loss is primarily the result of higher research and development, general and administrative expenses, and higher stock based compensation expense, as discussed above.



**LIQUIDITY AND CAPITAL RESOURCES**

As of September 30, 2006 we had \$124,017 in cash and cash equivalents, compared to \$1,420,510 as of December 31, 2005. The decrease in cash of \$1,296,493 for the nine months ended September 30, 2006 was \$485,626 less than the decrease of \$1,782,119 during the nine months ended September 30, 2005. Cash used in operating activities of \$6,815,328 for the nine months ended September 30, 2006 was partially offset by a private placement of common stock yielding net proceeds of \$5,337,402 and warrant exercise proceeds of \$190,035. Cash used in operating activities of \$6,437,397 for the nine months ended September 30, 2005 was partially offset by a private placement of common stock yielding net proceeds of \$4,655,278.

On February 3, 2006, we closed on a private placement of 4,283,668 shares of common stock and 1,070,917 common stock purchase warrants to certain accredited investors. The warrants are exercisable for 18 months from closing at an exercise price of \$1.60 per share. The securities were sold at a price of \$1.20 per share for aggregate gross proceeds of approximately \$5.14 million. The net proceeds, after fees and expenses, were \$4.58 million.

On April 7, 2006 we had a second closing of the financing described above, in which we sold an additional 666,667 shares of common stock and issued 166,667 common stock purchase warrants at the same terms, for gross proceeds of \$800,000, bringing the total gross proceeds of the financing to \$5.94 million and net proceeds to \$5.34 million. Placement agent fees of \$41,000 were incurred on this second closing and three year warrants to purchase a total of 66,667 common shares at a per share price of \$1.25 were issued to several selling agents.

In conjunction with this financing we agreed to file, within 60 days after the first closing, a registration statement covering the resale of the shares of common stock and the shares underlying the warrants, and to use our commercially reasonable efforts to cause such registration statement to be declared effective within 120 days after closing or pay financial liquidated damages to the investors. We have not yet filed a registration statement and we are incurring liquidated damages at the rate of approximately \$59,400 for every 30-day period that a registration statement has not been filed, up to a maximum of 8% of the gross proceeds. As of September 30, 2006 we have incurred \$334,446 in liquidated damages related to the registration rights agreement, or approximately 5.6%, which have been classified as other expense on our condensed consolidated statement of operations. \$149,287 of these damages was paid in cash during the nine months ended September 30, 2006 and \$185,159 was due and payable as of September 30, 2006.

On September 8, 2006 Callisto entered into a Letter Agreement with certain investors (the *Investors*) who participated in a private placement of our common stock and warrants in February and April 2006 (the *Prior Placement*). Pursuant to this Letter Agreement, the Investors agreed to amend (the *Amendment*) the securities purchase agreement (the *Securities Purchase Agreement*), entered into in connection with the Prior Placement, to (i) delete the mandatory registration rights set forth in the Securities Purchase Agreement and add piggyback registration rights and (ii) waive any and all penalties pursuant to the liquidated damages provisions contained in the Securities Purchase Agreement. In addition, the Investors agreed to enter into a lock-up agreement (the *Lock-up Agreement*) pursuant to which they agreed not to sell or transfer the shares of common stock and warrants acquired in the Prior Placement for a period of six months beginning September 1, 2006. In exchange for the Investors entering into the Amendment and the Lock-Up Agreement, Callisto agreed to issue to each Investor one share of common stock and 2.35 five year warrants exercisable at \$1.00 per share (the *New Warrants*) for every five shares of common stock they purchased in the Prior Placement. In addition, Callisto agreed in the Letter Agreement to amend the warrants (the *Old Warrants*) issued in the Prior Placement to the Investors to (i) extend the expiration date of the Old Warrants by 42 months thereby making them 5 year warrants and (ii) eliminate the provision in the Old Warrants by which Callisto can force exercise of the unexercised warrants. During October and November 2006 Callisto entered into the Amendment and Lock-up Agreements with each Investor pursuant to which Callisto issued 740,067 shares of common stock and 1,739,157 New Warrants. Approximately \$150,000 in cash liquidated damages, payable to these Investors as of September 30, 2006, was concurrently waived.

*On October 23, 2006, we closed a private placement of 105,000 shares of Series A Convertible Preferred Stock (the Series A Preferred Stock) and 1,400,000 warrants (the Warrants) to certain investors (the Investors) for aggregate gross proceeds of \$1,050,000. The Investors also are parties to a Registration Rights Agreement, dated as of October 23, 2006 pursuant to which we agreed to file, within 60 days of closing, a registration statement covering the resale of the shares of common stock underlying the Series A Preferred Stock and the Warrants issued to the Investors. The Warrants are immediately exercisable at \$0.75 per share, will expire five years from the date of issuance, and have certain antidilution rights for the twelve month period beginning on the effective date of the registration statement registering the shares of common stock underlying the Warrants. We paid an aggregate \$40,000 and issued an aggregate 53,334 warrants to purchase common stock to certain selling agents. The warrants are immediately exercisable at \$0.75 per share, will expire five years after issuance and have the same antidilution rights as the Investor Warrants. Our Certificate of Incorporation has been amended to provide for the issuance of 400,000 shares of Series A Preferred Stock pursuant to the Certificate of Designations, Number, Voting Powers,*

Preferences and Rights of Series A Convertible Preferred Stock filed with the State of Delaware on October 24, 2006.

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On April 1, 2005 we were awarded a research grant for work on a biodefense program from the National Institute of Allergy and Infectious Diseases ( NIAID ) to develop a monoclonal antibody and vaccine against bacterial superantigen toxins under an exclusive license with Rockefeller University entered into on August 20, 1996. We receive cash funding under approved grants and record the receipt as an offset to research and development expense only when the expense is incurred. Funds received as an offset to research and development expenses incurred totaled \$ 43,956 and \$299,378, during the three and nine months ended September 30, 2006, respectively and have been reported on our Condensed Consolidated Statements of Operations as a separate line item entitled Government Grant . In addition as of September 30, 2006 we had received approximately \$78,000 of cash advances under the NIAID grant for which we had not yet incurred any expenses. During October 2006 we advanced an additional amount of \$270,000 for research expenses not yet incurred and used some funds to pay operating expenses not specifically related to work on the biodefense program.

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. Our existing capital resources will not be sufficient to fund our operations and we will be required to raise additional capital to complete the development and commercialization of our current product candidates.

Our consolidated financial statements as of December 31, 2005 have been prepared under the assumption that we will continue as a going concern for the twelve months ending December 31, 2006. Our independent registered public accounting firm has issued a report dated March 29, 2006 that included an explanatory paragraph referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at our current cash expenditure levels.

To date, our sources of cash have been primarily limited to the sale of our equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to further delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of financial condition and results of operations are based upon our condensed consolidated financial statements, which have been prepared by us without audit in accordance with the rules and regulations of the Securities and Exchange Commission. The preparation of our financial statements requires us to make estimates that affect the reported amounts of assets, liabilities, revenue and expense, and related disclosure of contingent assets and liabilities. We base our accounting estimates on historical experience and other factors that are believed to be reasonable under the circumstances. However, actual results may vary from these estimates under different assumptions or conditions. The following is a summary of our critical significant accounting policies and estimates.

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in Note 3 of the notes to our consolidated financial statements included in our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2005. The financial statements are prepared in accordance with accounting principles generally accepted in the United States of America, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard ( SFAS ) No. 123 (Revised 2004), *Share-Based Payments* ( SFAS 123R ). SFAS 123R requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. SFAS 123R is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005 and accordingly we adopted this standard on January 1, 2006. For all awards granted prior to January 1, 2006, the unearned deferred fair value of stock based compensation, on the date of adoption, will be recognized as an expense on a straight line basis over the remaining requisite service period. Our financial results for prior periods have not been restated. See Note 2 to our condensed consolidated financial statements for more detailed discussion of stock based compensation.

Prior to January 1, 2006 we accounted for stock-based compensation expense in accordance with Statement of Financial Accounting Standard No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ). As provided for by SFAS 123, we had elected to account for our 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 had been recognized based on the intrinsic value of stock issued or options granted to employees and directors for services rendered. We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options is designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage. Since inception through September 30, 2006 stock based compensation expense totaled \$15,767,889 or approximately 29% of our accumulated deficit. We account for stock options and warrants granted to non-employees based on the fair value of the stock option or warrant using the Black-Scholes option pricing model based on assumptions for expected stock price volatility, expected term of the option, risk-free interest rate and expected dividend yield at the grant date.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk on the fair values of certain assets is related to credit risk associated with short term investment grade commercial paper included in short term money market accounts and the FDIC insurance limit on our balances. At September 30, 2006 our money market balances totaled approximately \$124,000.

**ITEM 4. CONTROLS AND PROCEDURES**

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of September 30, 2006, our Chief Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms. Our Chief Executive Officer and Principal Financial Officer also concluded that, as of September 30, 2006, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, to allow timely decisions regarding required disclosure.

During the three months ended September 30, 2006, 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 1A. RISK FACTORS**

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K/A for the year ended December 31, 2005, which could materially affect our business, financial condition or future results.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

At our Annual Meeting of Stockholders held on October 12, 2006, three matters were voted upon. A description of each matter and a tabulation of the votes for each of the matters follow:

1. Proposal to elect seven directors to our Board of Directors to serve for the ensuing year or until their successors are duly elected and qualified or until their resignation or removal:

| Nominee               | Votes      |         |
|-----------------------|------------|---------|
|                       | For        | Abstain |
| Gabriele M. Cerrone   | 26,960,560 | 455,721 |
| Gary S. Jacob         | 27,249,794 | 166,037 |
| Christoph Bruening    | 27,233,894 | 181,937 |
| John P. Brancaccio    | 27,233,960 | 181,871 |
| Stephen K. Carter     | 27,233,460 | 182,371 |
| Randall K. Johnson    | 27,233,794 | 182,037 |
| Riccardo Dalla-Favera | 27,233,460 | 182,371 |

2. Proposal to approve an amendment to our 2005 Directors Stock Option Plan allowing the grant of options to non-employee directors as compensation for service on Board committees

| Votes      |         |         |
|------------|---------|---------|
| For        | Against | Abstain |
| 18,878,728 | 630,294 | 14,287  |

3. Proposal to ratify the appointment of BDO Seidman, LLP as our independent registered public accountants for the year ending December 31, 2006.

| Votes |         |         |
|-------|---------|---------|
| For   | Against | Abstain |

27,293,591

102,285

19,954

26

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**ITEM 6. EXHIBITS**

(a) Exhibits

- 31.1 Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
- 31.2 Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.



**SIGNATURES**

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

**CALLISTO PHARMACEUTICALS, INC.**  
(Registrant)

Date: November 20, 2006

By: /s/ GARY S. JACOB

Gary S. Jacob  
Chief Executive Officer

Date: November 20, 2006

By: /s/ BERNARD F. DENOYER

Bernard F. Denoyer  
Vice President, Finance