

CALLISTO PHARMACEUTICALS INC

Form 10-Q

May 15, 2012

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 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: MARCH 31, 2012**

or

**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 10170**

(Address of principal executive offices) (Zip Code)

**(212) 297-0010**

(Registrant's telephone number)

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

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

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

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The number of the registrant's shares of common stock outstanding was 158,516,071 as of May 14, 2012.

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CALLISTO PHARMACEUTICALS, INC.

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

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under **Risk Factors** in our Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the Securities Exchange Commission on March 30, 2012. 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. All drug candidates to treat GI disorders and diseases, currently plecanatide and SP-333, are being developed exclusively by Synergy Pharmaceuticals, Inc., our controlled subsidiary ( **Synergy** ). Use of the terms **we, our** or **us** in connection with GI drug candidates discussed herein refer to research and development activities and plans of Synergy.

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****CALLISTO PHARMACEUTICALS, INC.****(A Development Stage Company)****CONDENSED CONSOLIDATED BALANCE SHEETS**

|  | March 31, 2012<br>(Unaudited) | December 31, 2011    |
|--|-------------------------------|----------------------|
| <b>ASSETS</b>  |                               |                      |
| Current Assets:  |                               |                      |
| Cash and cash equivalents  | \$ 6,123,418                  | \$ 13,244,961        |
| Prepaid expenses and other   | 1,268,642                     | 796,028              |
| Tax credits receivable   | 377,865                       | 377,865              |
| <b>Total Current Assets</b>  | <b>7,769,925</b>              | <b>14,418,854</b>    |
| Property and equipment, net  | 5,282                         | 5,774                |
| Security deposits  | 87,740                        | 87,740               |
| <b>Total Assets</b>  | <b>\$ 7,862,947</b>           | <b>\$ 14,512,368</b> |
| <b>LIABILITIES AND STOCKHOLDERS (DEFICIT)/EQUITY</b>   |                               |                      |
| Current Liabilities:   |                               |                      |
| Accounts payable   | \$ 3,806,085                  | \$ 3,206,827         |
| Accrued expenses   | 1,047,883                     | 1,457,427            |
| <b>Total Current Liabilities</b>   | <b>4,853,968</b>              | <b>4,664,254</b>     |
| Derivative financial instruments, at estimated fair value warrants   | 3,317,168                     | 3,325,114            |
| <b>Total Liabilities</b>   | <b>8,171,136</b>              | <b>7,989,368</b>     |
| Stockholders (Deficit)/Equity:   |                               |                      |
| Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized,<br>8,000 shares outstanding at March 31, 2012 and December 31, 2011 | 1                             | 1                    |
| Common stock, par value of \$.0001 per share: 225,000,000 shares authorized;<br>158,516,071 shares outstanding at March 31, 2012 and December 31, 2011   | 15,852                        | 15,852               |
| Additional paid-in capital   | 168,982,120                   | 168,531,201          |
| Deficit accumulated during development stage   | (145,508,572)                 | (142,366,313)        |
| <b>Total Callisto Stockholders Equity</b>  | <b>23,489,401</b>             | <b>26,180,741</b>    |
| Non-controlling interest   | (23,797,590)                  | (19,657,741)         |
| <b>Total Stockholders (Deficit)/Equity</b>   | <b>(308,189)</b>              | <b>6,523,000</b>     |
| <b>Total Liabilities and Stockholders (Deficit)/Equity</b>   | <b>\$ 7,862,947</b>           | <b>\$ 14,512,368</b> |

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

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## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

|  | Three Months<br>Ended<br>March 31, 2012 | Three Months<br>Ended<br>March 31, 2011 | For the period<br>June 5, 1996<br>(inception) to<br>March 31, 2012 |
|--|---|---|--|
| Revenues   | \$                                      | \$                                      | \$   |
| Costs and Expenses:  |   |   |  |
| Research and development   | 5,338,140                               | 1,371,928                               | 64,432,657   |
| Government grants  | 3,508                                   |   | (1,131,810)  |
| Purchased in-process research and development  |   |   | 6,944,553  |
| General and administrative   | 1,953,309                               | 1,959,844                               | 62,325,966   |
| Loss from Operations   | (7,294,957)                             | (3,331,772)                             | (132,571,366)  |
| Interest and investment income   | 4,903                                   | 51                                      | 921,480  |
| Tax credit   |   |   | 1,393,219  |
| Other income   |   | (12,414)                                | (943,124)  |
| Loss on debt extinguishment  |   |   | (2,099,892)  |
| Change in fair value of derivative instruments   | 7,946                                   | (338,715)                               | (16,902,339)   |
| Net Loss   | (7,282,108)                             | (3,682,850)                             | (150,202,022)  |
| Net Loss attributable to noncontrolling interest   | 4,139,849                               | 1,921,483                               | 23,797,590   |
| Net loss attributable to Callisto  | (3,142,259)                             | (1,761,367)                             | (126,404,432)  |
| Series A Preferred stock conversion rate change and beneficial conversion feature accreted as a dividend |   |   | (5,025,849)  |
| Series B Preferred stock conversion rate change and beneficial conversion feature accreted as a dividend |   |   | (12,174,391)   |
| Cumulative effect of adopting ASC Topic 815 January 1, 2009  |   |   | (1,903,900)  |
| Net loss attributable to Callisto common stockholders  | \$ (3,142,259)                          | \$ (1,761,367)                          | \$ (145,508,572)   |
| <i>Weighted Average Common Shares Outstanding</i>  |   |   |  |
| Basic and Diluted  | 158,516,071                             | 157,645,404                             |  |
| <i>Net Loss per Common Share</i>   |   |   |  |
| Basic and Diluted  | \$ (0.02)                               | \$ (0.01)                               |  |

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





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## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN  
STOCKHOLDERS EQUITY (DEFICIT)

(Unaudited)

|   | Preferred<br>Shares | Preferred<br>Stock,<br>Par Value | Common<br>Shares | Common<br>Stock,<br>Par Value | Additional<br>Paid in Capital |
|---|---------------------|----------------------------------|------------------|-------------------------------|-------------------------------|
| Balance at inception, June 5, 1996        |                     | \$                               |                  | \$                            | \$                            |
| Net loss for the year                     |                     |                                  |                  |                               |                               |
| 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  |                     |                                  |                  |                               |                               |

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|  |              |     |               |          |            |
|--|--------------|-----|---------------|----------|------------|
| 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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## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

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

|   | Unamortized Deferred<br>Stock Based<br>Compensation | Deficit Accumulated<br>during the Development<br>Stage | Total 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                          |

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|                            |    |    |                 |           |
|----------------------------|----|----|-----------------|-----------|
| 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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## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

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

|  | Preferred<br>Stock | Preferred<br>Stock 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<br>preferred stock in<br>connection with the<br>Merger | (4,235,299)        | (423)                           | 4,235,299       | 423                             |                                  |  |  |                                 |
| Common stock<br>issued to former<br>Synergy<br>stockholders          |                    |                                 | 4,329,927       | 432                             | 6,494,458                        |  |  | 6,494,890                       |
| Common stock<br>issued in exchange<br>for Webtronics<br>common stock |                    |                                 | 1,503,173       | 150                             | (150)                            |  |  |                                 |
| Deferred<br>Compensation stock<br>options                            |                    |                                 |                 |                                 | 9,313,953                        | (9,313,953)  |  |                                 |
| Amortization of<br>deferred Stock<br>based<br>Compensation           |                    |                                 |                 |                                 |                                  | 3,833,946  |  | 3,833,946                       |
| Private placement<br>of common stock,<br>net                         |                    |                                 | 2,776,666       | 278                             | 3,803,096                        |  |  | 3,803,374                       |
| Balance,<br>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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## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

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

|  | Common<br>Stock | Common<br>Stock<br>Par 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,<br>2003  | 25,928,760      | \$ 2,590                     | \$ 34,149,975                    | \$ (5,480,007)   | \$ (25,817,730)  | \$ 2,854,828                    |
| Net loss for the year  |                 |                              |                                  |  | (7,543,467)  | (7,543,467)                     |
| 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<br>via private placements, net                                       | 3,311,342       | 331                          | 6,098,681                        |  |  | 6,099,012                       |
| Warrant and stock-based<br>compensation for services<br>in connection with the<br>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,<br>2004  | 29,219,102      | \$ 2,922                     | \$ 39,910,186                    | \$ (2,302,534)   | \$ (33,361,197)  | \$ 4,249,377                    |

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

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## CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

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

|   | Common<br>Stock | Common<br>Stock<br>Par 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<br>(Deficit) |
|---|-----------------|------------------------------|----------------------------------|--|--|--|
| Balance, December 31,<br>2004                           | 29,219,102      | \$ 2,922                     | \$ 39,910,186                    | \$ (2,302,534)   | \$ (33,361,197)  | \$ 4,249,377                                 |
| Net loss for the year                                   |                 |                              |                                  |  | (11,779,457)   | (11,779,457)                                 |
| Deferred stock-based<br>compensation new<br>grants      |                 |                              | 1,571,772                        | (1,571,772)  |  |  |
| Amortization of<br>deferred stock-based<br>compensation |                 |                              |                                  | 2,290,843  |  | 2,290,843                                    |
| Variable accounting for<br>stock options                |                 |                              | 75,109                           |  |  | 75,109                                       |
| Common stock issued<br>via 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<br>expenses                            |                 |                              | 176,249                          |  |  | 176,249                                      |
| Exercise of common<br>stock warrant                     | 125,000         | 13                           | 128,737                          |  |  | 128,750                                      |
| Common stock issued<br>for services                     | 34,000          | 3                            | 47,177                           |  |  | 47,180                                       |
| Balance, December 31,<br>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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**CALLISTO PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN  
STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

|   | Series A<br>Convertible<br>Preferred<br>Shares | Series A<br>Convertible<br>Preferred<br>Stock | 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<br>(Deficit) |
|---|--|---|-----------------|---------------------------------|----------------------------------|--|--|--|
| Balance, December 31,<br>2005   |  | \$  | 33,233,096      | \$ 3,323                        | \$ 46,387,875                    | \$ (1,583,463)   | \$ (45,140,654)  | \$ (332,919)                                 |
| Net loss for the year   |  |   |                 |                                 |                                  |  | (12,919,229)   | (12,919,229)                                 |
| Reclassification of<br>deferred unamortized<br>stock-based<br>compensation upon<br>adoption of FAS 123R |  |   |                 |                                 | (1,583,463)                      | 1,583,463  |  |  |
| Stock based<br>compensation expense   |  |   |                 |                                 | 2,579,431                        |  |  | 2,579,431                                    |
| Common stock issued<br>via private placement:<br>February 2006  |  |   | 4,283,668       | 428                             | 5,139,782                        |  |  | 5,140,210                                    |
| Finders fees and<br>expenses<br>April 2006  |  |   | 666,667         | 67                              | 799,933                          |  |  | 800,000                                      |
| Finders fees and<br>expenses  |  |   |                 |                                 | (41,000)                         |  |  | (41,000)                                     |
| Waiver and Lock-up<br>Agreement   |  |   | 740,065         | 74                              | 579,622                          |  |  | 579,696                                      |
| Common stock issued<br>for services   |  |   | 87,000          | 9                               | 121,101                          |  |  | 121,110                                      |
| Exercise of common<br>stock warrants  |  |   | 184,500         | 18                              | 190,017                          |  |  | 190,035                                      |
| Series A convertible<br>preferred stock issued<br>via private placement:                                | 574,350  | 57  |                 |                                 | 5,743,443                        |  |  | 5,743,500                                    |
| Finders fees and<br>expenses  | 11,775   | 1   |                 |                                 | (448,909)                        |  |  | (448,908)                                    |
| Detachable warrants   |  |   |                 |                                 | 2,384,485                        |  |  | 2,384,485                                    |
| Beneficial conversion<br>feature accreted as a<br>dividend  |  |   |                 |                                 |                                  |  | (2,384,485)  | (2,384,485)                                  |
| Balance, December 31,<br>2006   | 586,125  | \$ 58   | 39,194,996      | \$ 3,919                        | \$ 61,290,509                    | \$   | \$ (60,444,368)  | \$ 850,118                                   |

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

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

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN  
STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

|  | Series A<br>Convertible<br>Preferred<br>Shares | Series A<br>Convertible<br>Preferred<br>Stock,<br>Par Value | Series B<br>Convertible<br>Preferred<br>Shares | Series B<br>Convertible<br>Preferred<br>Stock,<br>Par Value | Common<br>Shares | Common<br>Stock,<br>Par<br>Value | Additional<br>Paid in<br>Capital | Deficit<br>Accumulated<br>during the<br>Development<br>Stage | Total<br>Stockholders<br>Equity |
|--|--|---|--|---|------------------|----------------------------------|----------------------------------|--|---------------------------------|
| Balance,<br>December 31, 2006  | 586,125  | \$ 58   |  | \$  | 39,194,996       | \$ 3,919                         | \$ 61,290,509                    | \$ (60,444,368)  | \$ 850,118                      |
| Net loss for the year  |  |   |  |   |                  |                                  |                                  | (7,887,265)  | (7,887,265)                     |
| Stock-based<br>compensation<br>expense   |  |   |  |   |                  |                                  | 591,561                          |  | 591,561                         |
| Common stock<br>issued for services  |  |   |  |   | 80,000           | 8                                | 36,792                           |  | 36,800                          |
| Series A convertible<br>preferred stock,<br>issued via private<br>placement                                | 28,000   | 4   |  |   |                  |                                  | 279,997                          |  | 280,001                         |
| Finders fees and<br>expenses, Series A<br>private placement  |  |   |  |   |                  |                                  | (36,400)                         |  | (36,400)                        |
| Conversion of<br>Series A preferred<br>stock to common<br>stock  | (395,450)                                      | (40)  |  |   | 7,668,165        | 767                              | (727)                            |  |                                 |
| Beneficial<br>conversion feature<br>accreted as a<br>dividend to Series A<br>preferred stock               |  |   |  |   |                  |                                  | 2,504,475                        | (2,504,475)  |                                 |
| Series B convertible<br>preferred stock,<br>issued via private<br>placement                                |  |   | 1,147,050                                      | 115   |                  |                                  | 11,470,385                       |  | 11,470,500                      |
| Finders fees and<br>expenses, Series B<br>private placement  |  |   |  |   |                  |                                  | (920,960)                        |  | (920,960)                       |
| Beneficial<br>conversion feature<br>accreted as a<br>dividend to Series B<br>preferred stock               |  |   |  |   |                  |                                  | 10,495,688                       | (10,495,688)   |                                 |
| Change in fair value<br>of Series B warrants<br>from date of<br>issuance to<br>expiration of put<br>option |  |   |  |   |                  |                                  | (2,591,005)                      |  | (2,591,005)                     |
| Balance,<br>December 31, 2007  | 218,675  | 22  | 1,147,050                                      | 115   | 46,943,161       | 4,694                            | 83,120,315                       | (81,331,796)   | 1,793,350                       |
| Net loss for the year  |  |   |  |   |                  |                                  |                                  | (9,655,471)  | (9,655,471)                     |

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|  |           |      |              |           |               |           |               |                 |  |             |
|--|-----------|------|--------------|-----------|---------------|-----------|---------------|-----------------|--|-------------|
| Recapitalization of majority owned subsidiary via private placements of common stock |           |      |              |           |               | 2,951,913 |               |                 |  | 2,951,913   |
| Minority interest in equity of subsidiary acquired                                   |           |      |              |           |               | (42,824)  |               |                 |  | (42,824)    |
| Stock-based compensation expense   |           |      |              |           |               | 589,063   |               |                 |  | 589,063     |
| Proceeds from issuance of 11% Notes attributable to detachable warrants              |           |      |              |           |               | 181,732   |               |                 |  | 181,732     |
| Conversion of Series A preferred stock to common stock                               | (120,675) | (12) |              | 2,413,500 | 241           | (229)     |               |                 |  |             |
| Conversion of Series B preferred stock to common stock                               |           |      | (10,000)     | (1)       | 200,000       | 20        | (19)          |                 |  |             |
| Balance, December 31, 2008   | 98,000 \$ | 10   | 1,137,050 \$ | 114       | 49,556,661 \$ | 4,955 \$  | 86,799,951 \$ | (90,987,267) \$ |  | (4,182,237) |

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

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

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN  
STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

(Unaudited)

|   | Series A<br>Convertible<br>Preferred<br>Shares | Series A<br>Convertible<br>Preferred<br>Stock | Series B<br>Convertible<br>Preferred<br>Shares | Series B<br>Convertible<br>Preferred<br>Stock | Common<br>Shares | Common<br>Stock<br>Par Value | Additional<br>Paid in<br>Capital | Deficit<br>Accumulated<br>during the<br>Development<br>Stage | Non-<br>Controlling<br>Interest | Total<br>Stockholders<br>Equity<br>(Deficit) |
|---|--|---|--|---|------------------|------------------------------|----------------------------------|--|---------------------------------|--|
| Balance,<br>December 31,<br>2008  | 98,000   | \$ 10   | 1,137,050                                      | \$ 114  | 49,556,661       | 4,955                        | \$ 86,799,951                    | \$ (90,987,267)  |                                 | \$ (4,182,237)                               |
| Cumulative effect<br>of adoption of<br>ASC Topic 815  |  |   |  |   |                  |                              | (181,732)                        | (1,903,900)  |                                 | (2,085,632)                                  |
| Net Loss  |  |   |  |   |                  |                              |                                  | (15,073,021)   | (3,282,393)                     | (18,355,414)                                 |
| Stock based<br>compensation<br>expense  |  |   |  |   |                  |                              | 1,119,856                        |  |                                 | 1,119,856                                    |
| Conversion of<br>Series A<br>preferred stock to<br>common stock   | (35,000)                                       | (4)   |  |   | 894,445          | 89                           | (85)                             |  |                                 |  |
| Conversion of<br>Series B<br>preferred stock to<br>common stock   |  |   | (122,884)                                      | (12)  | 2,963,236        | 296                          | (284)                            |  |                                 |  |
| Private<br>placements of<br>common stock of<br>majority owned<br>subsidiary   |  |   |  |   |                  |                              | 15,970,100                       |  |                                 | 15,970,100                                   |
| Fees and<br>expenses<br>associated with<br>private<br>placements of<br>majority owned<br>subsidiary   |  |   |  |   |                  |                              | (260,002)                        |  |                                 | (260,002)                                    |
| Preferred Stock<br>dividend<br>attributable to<br>reset of<br>conversion price<br>in conjunction<br>with waiver of<br>liquidation<br>preference |  |   |  |   |                  |                              | 1,815,592                        | (1,815,592)  |                                 |  |
| Cashless<br>Conversion of   |  |   |  |   | 193,769          | 19                           | (19)                             |  |                                 |  |

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|  |          |    |     |             |    |       |             |    |        |    |             |    |               |    |              |    |              |
|--|----------|----|-----|-------------|----|-------|-------------|----|--------|----|-------------|----|---------------|----|--------------|----|--------------|
| Warrants to<br>Common Stock  |          |    |     |             |    |       |             |    |        |    |             |    |               |    |              |    |              |
| Balance  |          |    |     |             |    |       |             |    |        |    |             |    |               |    |              |    |              |
| December 31,<br>2009   | 63,000   | \$ | 6   | 1,014,166   | \$ | 102   | 53,608,111  | \$ | 5,359  | \$ | 105,263,377 | \$ | (109,779,780) | \$ | (3,282,393)  | \$ | (7,793,329)  |
| Net Loss   |          |    |     |             |    |       |             |    |        |    |             |    | (25,793,488)  |    | (7,854,264)  |    | (33,647,752) |
| Stock based<br>compensation<br>expense   |          |    |     |             |    |       |             |    |        |    |             |    | 854,651       |    |              |    | 854,651      |
| Conversion of<br>Series A<br>preferred stock to<br>common stock  | (55,000) |    | (5) |             |    |       | 1,527,777   |    | 153    |    |             |    | (148)         |    |              |    |              |
| Conversion of<br>Series B<br>preferred stock to<br>common stock  |          |    |     | (1,014,166) |    | (102) | 28,171,278  |    | 2,817  |    |             |    | (2,715)       |    |              |    |              |
| Common shares<br>in exchange for<br>modification of<br>convertible notes   |          |    |     |             |    |       | 265,770     |    | 27     |    |             |    | 100,169       |    |              |    | 100,196      |
| Extinguishment<br>on debt  |          |    |     |             |    |       |             |    |        |    |             |    | 2,809,531     |    |              |    | 2,809,531    |
| Cashless<br>conversion of<br>Warrants to<br>common stock<br>upon<br>extinguishment<br>of convertible<br>notes  |          |    |     |             |    |       | 72,355,769  |    | 7,236  |    |             |    | (7,236)       |    |              |    |              |
| Warrants<br>exchanged  |          |    |     |             |    |       | 1,505,699   |    | 151    |    |             |    | (151)         |    |              |    |              |
| Direct offering of<br>common stock of<br>controlled<br>subsidiary  |          |    |     |             |    |       |             |    |        |    |             |    | 7,179,000     |    |              |    | 7,179,000    |
| Fair value of<br>warrants issued in<br>connection with<br>controlled<br>subsidiary<br>registered direct<br>offerings<br>reclassified to<br>derivative<br>liability |          |    |     |             |    |       |             |    |        |    |             |    | (3,784,743)   |    |              |    | (3,784,743)  |
| Fees and<br>expenses<br>associated with<br>direct offering of<br>controlled<br>subsidiary  |          |    |     |             |    |       |             |    |        |    |             |    | (468,130)     |    |              |    | (468,130)    |
| Reclassification<br>of derivative<br>liability to equity<br>upon termination<br>of price<br>protection   |          |    |     |             |    |       |             |    |        |    |             |    | 27,511,730    |    |              |    | 27,511,730   |
| Common stock<br>issued as<br>settlement for<br>director s fees   |          |    |     |             |    |       | 75,000      |    | 8      |    |             |    | 41,117        |    |              |    | 41,125       |
| Balance  |          |    |     |             |    |       |             |    |        |    |             |    |               |    |              |    |              |
| December 31,<br>2010   | 8,000    | \$ | 1   |             | \$ |       | 157,509,404 | \$ | 15,751 | \$ | 139,496,452 | \$ | (135,573,268) | \$ | (11,136,657) | \$ | (7,197,721)  |

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

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

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN  
STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

(Unaudited)

|   | Series A<br>Convertible<br>Preferred<br>Shares | Series A<br>Preferred<br>Stock | Series B<br>Convertible<br>Preferred<br>Shares | Series B<br>Convertible<br>Preferred<br>Stock | Common<br>Shares | Common<br>Stock<br>Par Value | Additional<br>Paid in<br>Capital | Deficit<br>Accumulated<br>during the<br>Development<br>Stage | Non-<br>Controlling<br>Interest | Total<br>Stockholders<br>Equity<br>(Deficit) |
|---|--|--------------------------------|--|---|------------------|------------------------------|----------------------------------|--|---------------------------------|--|
| Net Loss  |  |                                |  |   |                  |                              |                                  | (6,793,045)  | (8,521,084)                     | (15,314,129)                                 |
| Stock based<br>compensation expense   |  |                                |  |   |                  |                              | 424,168                          |  |                                 | 424,168                                      |
| Common stock issued<br>for services   |  |                                |  |   | 850,000          | 85                           | 532,915                          |  |                                 | 533,000                                      |
| Value of common stock<br>issued by controlled<br>subsidiary for consulting<br>services provided   |  |                                |  |   |                  |                              | 341,295                          |  |                                 | 341,295                                      |
| Placement of common<br>stock of controlled<br>subsidiary  |  |                                |  |   |                  |                              | 34,369,064                       |  |                                 | 34,369,064                                   |
| Fees and expenses<br>associated with direct<br>offering of controlled<br>subsidiary   |  |                                |  |   |                  |                              | (2,148,384)                      |  |                                 | (2,148,384)                                  |
| Warrant exercise  |  |                                |  |   | 106,667          | 11                           | 53,323                           |  |                                 | 53,334                                       |
| Warrants issued in<br>connection with<br>controlled subsidiary<br>registered direct offering<br>reclassified to derivative<br>liability-net |  |                                |  |   |                  |                              | (5,094,186)                      |  |                                 | (5,094,186)                                  |
| Exercise of<br>warrants-controlled<br>subsidiary  |  |                                |  |   |                  |                              | 415,309                          |  |                                 | 415,309                                      |
| Common stocks issued<br>for settlement of<br>directors fee  |  |                                |  |   | 50,000           | 5                            | 41,245                           |  |                                 | 41,250                                       |
| Sale of option to<br>purchase shares of<br>controlled subsidiary  |  |                                |  |   |                  |                              | 100,000                          |  |                                 | 100,000                                      |
| Balance December 31,<br>2011  | 8,000  | 1                              |  |   | 158,516,071      | 15,852                       | 168,531,201                      | (142,366,313)  | (19,657,741)                    | 6,523,000                                    |
| Net loss for the period   |  |                                |  |   |                  |                              |                                  | (3,142,259)  | (4,139,849)                     | (7,282,108)                                  |
| Stock based<br>compensation expense   |  |                                |  |   |                  |                              | 358,256                          |  |                                 | 358,256                                      |
| Common stock issued<br>by controlled subsidiary<br>for services rendered  |  |                                |  |   |                  |                              | 92,663                           |  |                                 | 92,663                                       |

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|                        |       |    |   |    |             |    |        |    |             |    |               |    |              |    |           |
|------------------------|-------|----|---|----|-------------|----|--------|----|-------------|----|---------------|----|--------------|----|-----------|
| Balance March 31, 2012 | 8,000 | \$ | 1 | \$ | 158,516,071 | \$ | 15,852 | \$ | 168,982,120 | \$ | (145,508,572) | \$ | (23,797,590) | \$ | (308,189) |
|------------------------|-------|----|---|----|-------------|----|--------|----|-------------|----|---------------|----|--------------|----|-----------|

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



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**CALLISTO PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

|   | Three months<br>ended<br>March 31, 2012 | Three months<br>ended<br>March 31, 2011 | Period from<br>June 5, 1996<br>(inception) to<br>March 31, 2012 |
|---|---|---|---|
| <b>Cash flows from operating activities:</b>                                |   |   |   |
| Net loss  | \$ (7,282,108)                          | \$ (3,682,850)                          | \$ (150,202,022)  |
| Adjustments to reconcile net loss to net cash used in operating activities: |   |   |   |
| Depreciation  | 492                                     | 1,317                                   | 111,950   |
| Purchase discount accreted as interest income on U.S.Treasury bills         |   |   | (26,950)  |
| Stock-based compensation expense  | 525,919                                 | 124,653                                 | 21,458,758  |
| Purchased in-process research and development                               |   |   | 6,841,053   |
| Interest expense on notes   |   | 11,877                                  | 759,400   |
| Stock-based liquidated damages  |   |   | 579,696   |
| Change in fair value of derivative instruments warrants                     | (7,946)                                 | 338,715                                 | 16,902,339  |
| Loss on debt extinguishment   |   |   | 2,099,892   |
| Net liabilities assumed in excess of assets acquired in merger              |   |   | (282,752)   |
| Changes in operating assets and liabilities:                                |   |   |   |
| Prepaid expenses  | (547,614)                               | 267,898                                 | (1,268,642)   |
| Tax credit receivable   |   | 205,727                                 | (377,865)   |
| Security deposit  |   |   | (87,740)  |
| Accounts payable and accrued expenses                                       | 189,714                                 | (205,878)                               | 4,883,842   |
| Total Adjustments   | 160,565                                 | 744,309                                 | 51,592,981  |
| Net cash used in operating activities                                       | (7,121,543)                             | (2,938,541)                             | (98,609,041)  |
| <b>Cash flows from investing activities:</b>                                |   |   |   |
| Short term investments purchased  |   |   | (5,921,825)   |
| Short term investments liquidated   |   |   | 5,948,775   |
| Acquisition of equipment  |   |   | (117,233)   |
| Net cash used in investing activities                                       |   |   | (90,283)  |
| <b>Cash flows from financing activities:</b>                                |   |   |   |
| Issuance of common and preferred stock                                      |   |   | 48,719,673  |
| Issuance of common stock of controlled subsidiary                           |   | 1,800,000                               | 60,543,162  |
| Selling Agent fees and expenses-combined                                    |   | (185,000)                               | (5,930,684)   |
| Proceeds from sale of 11% Notes   |   | 500,000                                 | 603,163   |
| Proceed from exercise of warrants of controlled subsidiary                  |   |   | 415,309   |
| Exercise of common stock warrants   |   |   | 372,119   |
| Proceeds from sale of option  |   | 53,334                                  | 100,000   |
| Net cash provided by financing activities                                   |   | 2,168,334                               | 104,822,742   |
| Net (decrease) increase in cash and cash equivalents                        | (7,121,543)                             | (770,207)                               | 6,123,418   |

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|  |    |            |    |           |              |
|--|----|------------|----|-----------|--------------|
| Cash and cash equivalents at beginning of period |    | 13,244,961 |    | 1,708,982 |              |
| Cash and cash equivalents at end of period       | \$ | 6,123,418  | \$ | 938,775   | \$ 6,123,418 |

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

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

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

(Unaudited)

|   | Three months<br>ended<br>March 31, 2012 | Three months<br>ended<br>March 31, 2011 | Period from<br>June 5, 1996<br>(inception) to<br>March 31, 2012 |
|---|---|---|---|
| Supplementary disclosure of cash flow information:                            |   |   |   |
| Cash paid for taxes   | \$ 35,776                               | \$ 12,009                               | \$ 360,660  |
| Supplementary disclosure of non-cash investing and financing activities:      |   |   |   |
| Series A Preferred stock beneficial conversion feature accreted as a dividend | \$                                      | \$                                      | \$ (4,888,960)  |
| Series B Preferred stock beneficial conversion feature accreted as a dividend | \$                                      | \$                                      | \$ (10,495,688)   |
| Series A Preferred stock conversion rate change accreted as a dividend        | \$                                      | \$                                      | \$ (136,889)  |
| Series B Preferred stock conversion rate change accreted as a dividend        | \$                                      | \$                                      | \$ (1,678,703)  |
| Common stock issued to extend notes payable                                   | \$                                      | \$                                      | \$ 100,196  |
| Value of warrants classified as derivative liability-net                      | \$                                      | \$ 1,312,673                            | \$ 20,331,912   |
| Value of shares issued for services   | \$                                      | \$ 533,000                              | \$ 625,663  |
| Director s fees settled for shares of common stock                            | \$                                      | \$                                      | \$ 82,375   |

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

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Business overview:**

Callisto Pharmaceuticals, Inc. (which may be referred to as "Callisto", the Company) is a development stage biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal (GI) disorders and diseases and was incorporated under the laws of the State of Delaware on June 5, 1996 (inception). Since inception, Callisto's efforts have been principally devoted to research and development, securing and protecting patents and raising capital.

All drug candidates, currently plecanatide and SP-333 to treat GI disorders and diseases, are being developed exclusively by Synergy. Use of the terms "the Company" in connection with the GI drug candidates discussed herein refer to research and development activities and plans of Synergy.

Synergy's lead drug candidates are as follows:

(1) Plecanatide, a guanylyl cyclase C (GC-C) receptor agonist, to treat GI disorders, primarily chronic constipation (CC) and constipation-predominant irritable bowel syndrome (IBS-C).

(2) SP-333, a second generation GC-C receptor agonist, SP-333, now in pre-clinical development to treat gastrointestinal inflammatory diseases.

From inception through March 31, 2012, Callisto has sustained cumulative net losses attributable to common stockholders of \$145,508,572. Callisto's losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, stock-based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees, as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception through March 31, 2012, Callisto has not generated any revenue from operations. The Company expects to incur additional losses to perform further research and development activities and does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all.

Callisto's product development efforts are thus in their early stages and Callisto cannot make estimates of the costs or the time they will take to complete. The risk of not completing any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, the nature and timing of costs and competing technologies being developed by organizations with significantly greater resources.

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**2. Basis of presentation and going concern:**

These condensed consolidated financial statements include Callisto and subsidiaries: (1) Callisto Research Labs, LLC (including its wholly-owned subsidiary, Callisto Pharma, GmbH (Germany inactive)), and (2) Synergy Pharmaceuticals, Inc. (including Synergy's wholly-owned subsidiaries, Synergy Advanced Pharmaceuticals, Inc. and IgX, Ltd (Ireland inactive)). All intercompany balances and transactions have been eliminated. 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, 2011, included in Form 10-K filed with the SEC on March 30, 2012. Certain items in the prior year's financial statements have been reclassified to conform to the current year's presentation.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, primarily consisting of normal adjustments, necessary for the fair presentation of the balance sheet and results of operations for the interim periods. The results of operations for the three months ended March 31, 2012 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2012. The condensed consolidated balance sheet as of December 31, 2011 presented above was derived from the audited consolidated financial statements as of that date.

The condensed consolidated financial statements as of March 31, 2012 and December 31, 2011 have been prepared under the assumption that Callisto will continue as a going concern for the twelve months ending December 31, 2012. Callisto's ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Net cash used in operating activities was \$7,121,543 during the three months ended March 31, 2012 as compared to \$2,938,541 for the three months ended March 31, 2011 and \$98,609,041 during the period from June 5, 1996 (inception) to March 31, 2012. During the three months ended March 31, 2012 and 2011, Callisto incurred net losses attributable to common stockholders of \$3,142,259 and \$1,761,367, respectively and \$145,508,572 during the period from June 5, 1996 (inception) to March 31, 2012. To date, Callisto's sources of cash have been primarily limited to the sale of common stocks, warrants, and issuance of debt instruments. There were no financing activities for the three months ended March 31, 2012. As of March 31, 2012 Callisto had working capital of \$2,915,957 as compared to working capital of \$9,754,600 as of December 31, 2011.

On May 9, 2012, Synergy closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of \$4.50 per share. The gross proceeds from this offering are \$45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of approximately \$3 million. Synergy also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of \$4.50 per share to cover over-allotments, if any.

Callisto may be required to raise additional capital within this year to complete the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Callisto cannot be certain that additional funding will be available on acceptable terms, or at all. Recently worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain difficult for the foreseeable future. These developments may make it more difficult to obtain additional equity or credit financing, when needed. To the extent that Callisto raises additional funds by issuing equity securities, Callisto's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Callisto's ability to conduct business. If Callisto is unable to raise additional capital when required or on acceptable terms, Callisto may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product

candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that Callisto would otherwise seek to develop or commercialize ourselves on unfavorable terms.

### 3. Recent Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income* ( ASU 2011-05 ) which is intended to facilitate the convergence of U.S. GAAP and International Financial Reporting Standards ( IFRS ) as well as to increase the transparency of items reported in other comprehensive income. As a result of ASU 2011-05, all nonowner changes in stockholders' equity are required to be presented in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present other comprehensive income in the statement of changes in equity has been eliminated. ASU 2011-05 is effective for fiscal years beginning after December 15, 2011 and should be applied retrospectively. The Company adopted this standard on January 1, 2012 and the adoption did not have a material impact on the Company's consolidated financial statements.

In May 2011, FASB issued ASU No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. ASU 2011-04 amends Topic 820 to provide common fair value measurement and disclosure requirements in U.S. Generally Accepted Accounting Principles ( U.S. GAAP ) and International Financial Reporting Standards. Consequently, the amendments change the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements, as well as providing guidance on how fair value should be applied where its use is already required or permitted by other standards within U.S. GAAP. ASU No. 2011-04 is to be applied prospectively, and early adoption is not permitted. For public entities, the amendments are effective during interim and annual periods beginning after

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December 15, 2011. The adoption of ASU No. 2011-04 on January 1, 2012 did not have a material impact on the Company's consolidated financial statements.

In December 2011, the FASB issued ASU 2011-11, *Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities*. ASU 2011-11 provides for additional disclosures of both gross information and net information about both instruments and transactions eligible for offset in the statement of financial position and instruments and transactions subject to an agreement similar to a master netting arrangement. This scope would include derivatives, sale and repurchase agreements and reverse sale and repurchase agreements, and securities borrowing and securities lending arrangements. The amendments in this Update are effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods, and disclosures required by these amendments should be provided retrospectively for all comparative periods presented. The adoption of ASU No. 2011-11 is not expected to have a material impact on the Company's consolidated financial statements.

In December 2011, the FASB issued ASU 2011-12, *Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*. ASU 2011-12 defers the specific requirement to present items that are reclassified from accumulated other comprehensive income to net income separately with their respective components of net income and other comprehensive income. ASU 2011-12 did not defer the requirement to report comprehensive income either in a single continuous statement or in two separate but consecutive financial statements. The amendments are effective at the same time as the amendments in ASU 2011-05.

#### **4. Accounting for share-based payments**

ASC Topic 718 *Compensation - Stock Compensation* requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award.

ASC Topic 718 did not change the way Callisto accounts for non-employee stock-based compensation. Callisto continues to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 *Equity-Based Payment to Non-Employees* whereas the value of the stock compensation is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly the fair value of these options is being marked to market quarterly until the measurement date is determined.

ASC Topic 718 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.

Callisto accounts for common stock, stock options, and warrants granted to employees and 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.

*Callisto options*

Stock based compensation expense, related to Callisto employee and non-employee share based payments, has been recognized in operating results as follow:

|  | Three Months Ended<br>March 31, |      | June 5, 1996<br>(Inception) to<br>March 31, 2012 |
|--|---------------------------------|------|--|
|  | 2012                            | 2011 |  |
| Employees included in research and development   | \$                              | \$   | \$ 2,692,157                                     |
| Employees included in general and administrative |                                 |      | 4,863,996  |
| Subtotal employee stock option grants            |                                 |      | 7,556,153  |
| Non-employee research and development            |                                 |      | 102,750  |
| Non-employee general and administrative          |                                 |      | 10,393,135                                       |
| Subtotal non-employee stock option grants        |                                 |      | 10,495,885                                       |
| Total stock based compensation expense           | \$                              | \$   | \$ 18,052,038                                    |

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The unrecognized compensation cost related to employee non-vested Callisto stock options outstanding at March 31, 2012, net of expected forfeitures, was \$21,020 to be recognized over a weighted average vesting period of approximately a year.

The estimated fair value of each Callisto stock option award was determined on the date of grant using the Black-Scholes option valuation model. No options were granted during the quarter ended March 31, 2012 and March 31, 2011.

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

|   | Number of<br>options | Exercise<br>Price<br>Per Share | Weighted<br>Average<br>Exercise<br>Price<br>Per Share | Aggregate<br>Intrinsic<br>Value | Weighted<br>Average<br>Remaining<br>Contractual<br>Term |
|---|----------------------|--------------------------------|---|---------------------------------|---|
| Balance outstanding,<br>December 31, 2011 | 7,435,372            | \$ 0.08 - 3.60                 | \$ 1.49   | \$ 7,200                        | 3.39  |
| Granted                                   |                      | \$                             | \$  |                                 |   |
| Forfeitures                               |                      | \$                             | \$  |                                 |   |
| Balance outstanding, March 31,<br>2012    | 7,435,372            | \$ 0.08 - 3.60                 | \$ 1.49   | \$ 180,860                      | 3.14  |
| Exercisable as of March 31, 2012          | 5,903,372            | \$ 0.08 - 3.60                 | \$ 1.37   | \$ 125,710                      | 2.92  |

*Stock Options*

ASC Topic 718 *Compensation Stock Compensation* requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. ASC Topic 718 did not change the way Synergy accounts for non-employee stock-based compensation. Synergy continues to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 *Equity-Based Payment to Non-Employees* and accordingly the value of the stock compensation to non-employees is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly the fair value of these options is being marked to market quarterly until the measurement date is determined.

ASC Topic 718 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 Synergy's accumulated deficit position, no excess tax benefits have been recognized. Synergy accounts for common stock, stock options, and warrants granted to employees and 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.



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Synergy adopted the 2008 Equity Compensation Incentive Plan (the Plan) during the quarter ended September 30, 2008. Stock options granted under the Plan typically vest after three years of continuous service from the grant date and have a contractual term of ten years. Synergy did not issue stock options prior to the quarter ended September 30, 2008.

Stock-based compensation has been recognized in operating results as follow:

|  |            | Three Months Ended<br>March 31, |    | November 15, 2005<br>(inception) to<br>March 31, 2012 |
|--|------------|---------------------------------|----|---|
|  | 2012       | 2011                            |    |   |
| Employees included in research and development       | \$ 115,770 | \$ 36,749                       | \$ | 742,552   |
| Employees included in general and administrative     | 93,649     | 44,618                          |    | 868,060   |
| Subtotal employee stock based compensation           | 209,419    | 81,367                          |    | 1,610,612   |
| Non-employees included in research and development   |            | 8,362                           |    | 168,096   |
| Non-employees included in general and administrative | 228,652    | 57,731                          |    | 1,628,012   |
| Subtotal non-employee stock based compensation       | 228,652    | 66,093                          |    | 1,796,108   |
| Total stock-based compensation expense               | \$ 438,071 | \$ 147,460                      | \$ | 3,406,720   |

The unrecognized compensation cost related to non-vested stock options outstanding at March 31, 2012, net of expected forfeitures, was \$3,498,455 to be recognized over a weighted-average remaining vesting period of approximately 2.5 years. This unrecognized compensation cost does not include amounts related to 4,364,000 stock options which vest upon a change of control.

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the periods indicated.

|                          | Three Months<br>Ended<br>March 31, 2011 | Three Months<br>Ended<br>March 31, 2010 |
|--------------------------|---|---|
| Risk-free interest rate  | 1.05%-1.50%                             | (*)                                     |
| Dividend yield           |   | (*)                                     |
| Expected volatility      | 60%                                     | (*)                                     |
| Expected term (in years) | 6 years                                 | (*)                                     |

(\*) No stock options granted during this period.

On March 1, 2010, a majority of Synergy's shareholders acting by written consent approved an amendment to the Plan increasing the number of shares reserved under the Plan to 7,500,000 shares, after a retroactive change of a one for two (1:2) reverse stock split effective on November 30, 2011. A summary of stock option activity and of changes in stock options outstanding under the Plan is presented below:

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|   | Number of<br>Options | Exercise Price<br>Per Share | Weighted Average<br>Exercise Price<br>Per Share | Intrinsic<br>Value | Weighted Average<br>Remaining<br>Contractual Term |            |
|---|----------------------|-----------------------------|---|--------------------|---|------------|
| Balance outstanding, December 31,<br>2011 | 5,964,039            | \$ 0.50                     | 4.30 \$   | 1.77 \$            | 10,631,388  | 8.18 years |
| Granted                                   | 772,000              | \$ 3.40                     | 4.38 \$   | 3.54               |   |            |
| Exercised                                 |                      | \$                          | \$  |                    |   |            |
| Forfeited                                 |                      | \$                          | \$  |                    |   |            |
| Balance outstanding, March 31,<br>2012    | 6,736,039            | \$ 0.50                     | 4.38 \$   | 1.97 \$            | 14,107,539  | 8.06 years |
| Exercisable at March 31, 2012             | 2,076,539            | \$ 0.50                     | 4.30 \$   | 0.75 \$            | 6,857,989   | 6.45 years |

Table of Contents**5. Research and Development Expense**

Research and development costs include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, regulatory and scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring, insurance and FDA consultants.

In accordance with FASB ASC Topic 730-10-55, Research and Development, Callisto recorded prepaid research and development costs of \$1,064,136 and \$577,745 as of March 31, 2012 and December 31, 2011, respectively, for nonrefundable pre-payments for production of drug substance and analytical testing services for its drug candidates. In accordance with this guidance, Synergy expenses deferred research and development costs when drug compound is delivered and services are performed.

**6. Income Taxes**

During the year ended December 31, 2011, our controlled subsidiary recorded refundable tax credit in prepaid and other current assets for its (i) 2010 New York State QETC credit, totaling \$248,486 and (ii) its New York City Biotechnology Tax Credit for the tax year of 2011 totaling \$118,437. On April 25, 2012, the Company received \$246,402 for 2010 New York State QETC credit.

**7. Net Loss per Share**

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, Earnings per Share, for all periods presented. In accordance with ASC Topic 260, basic and diluted net loss per common share was determined by dividing net loss attributable 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, and the conversion of preferred stock would have been antidilutive.

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

|  | March 31, 2012 | March 31, 2011 |
|--|----------------|----------------|
| Common Shares outstanding                          | 158,516,071    | 158,466,071    |
| Potentially dilutive common shares issuable upon:  |                |                |
| Exercise of warrants                               | 988,741        | 10,265,332     |
| Exercise of Callisto stock options                 | 7,435,372      | 7,414,872      |
| Conversion of Series A Convertible Preferred Stock | 222,222        | 222,222        |
| Conversion of Series B Convertible Preferred Stock |                |                |

|                     |             |             |
|---------------------|-------------|-------------|
| Total fully diluted | 167,162,406 | 176,368,497 |
|---------------------|-------------|-------------|

**8. Derivative Financial Instruments**

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, Derivatives and Hedging: Contracts in Entity's Own Equity (ASC Topic 815-40). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity's own stock, which would qualify as a scope exception under ASC Topic 815-10.

Table of Contents**8. Derivative Financial Instruments (Continued)***Synergy Derivative Financial Instruments*

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, Derivatives and Hedging: Contracts in Entity's Own Equity (ASC Topic 815-40). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity's own stock, which would qualify as a scope exception under ASC Topic 815-10.

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that certain warrants issued in connection with sale of its common stock must be classified as derivative instruments. In accordance with ASC Topic 815-40, these warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company's statement of operations. The Company estimates the fair value of certain warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability and change in fair value described above. The range of assumptions used to determine the fair value of the warrants at each period end during the three months ended March 31, 2012 and March 31, 2011 were:

|  | <b>Three Months Ended<br/>March 31, 2012</b> | <b>Three Months Ended<br/>March 31, 2011</b> |
|--|--|--|
| Estimated fair value of Synergy common stock | \$3.51 - \$4.05                              | \$4.86 - \$6.26                              |
| Expected warrant term                        | 5.0 - 7.0 years                              | 4.0 - 7.0 years                              |
| Risk-free interest rate                      | 0.51%-1.33%                                  | 1.80% - 2.9%                                 |
| Expected volatility                          | 60%  | 90%  |
| Dividend yield                               |  |  |

Estimated fair value of stock is the closing market price of the Company's common stock on the date of warrant issuance and at the end of each reporting period when the derivative instruments are marked to market. Expected volatility is a management estimate of future volatility, over the expected warrant term, based on historical volatility of Synergy's common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants and the date of grant or quarterly revaluation.

As of March 31, 2012, certain of Synergy's outstanding warrants contained a price protection clause which variable exercise price required the Company to use a binomial model to determine fair value. There were no price protected warrants outstanding and therefore no binomial model calculation was required during the three months ended March 31, 2011. The range of assumptions used to determine the fair value of the warrants at March 31, 2012 was as follows:

|  | <b>Three months ended,<br/>March 31, 2012</b> |
|--|---|
| Estimated fair value of Synergy common stock | \$ 3.28                                       |
| Expected warrant term                        | 4.63 years                                    |
| Risk-free interest rate                      | 1.04%   |



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|                     |     |
|---------------------|-----|
| Expected volatility | 60% |
| Dividend yield      | 0%  |

In the Binomial model, the assumption for estimated fair value of the stock is based on a Black-Scholes based apportionment of the unit price paid for the shares and warrants issued in Synergy's most recent registered direct offerings, which resulting stock prices were deemed to be arms-length negotiated prices. Expected volatility is a management estimate of future volatility over the expected warrant term, based on historical volatility of Synergy's common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants.

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The following table sets forth the components of changes in the Synergy's outstanding warrants which were deemed derivative financial instruments and the associated liability balance for the periods indicated:

| Date       | Description  | Warrants    | Derivative Instrument Liability |
|------------|--|-------------|---------------------------------|
| 12/31/2010 | Balance  | 728,469     | \$ 3,487,959                    |
| 3/31/2011  | Fair value of new warrants issued during the quarter   | 210,000     | \$ 1,312,673                    |
| 3/31/2011  | Change in fair value of warrants during the quarter recognized as other expense in the statement of operations |             | \$ 338,715                      |
| 3/31/2011  | Balance  | 938,469     | \$ 5,139,347                    |
| 6/30/2011  | Fair value of new warrants issued during the quarter   | 611,207     | \$ 2,607,827                    |
| 6/30/2011  | Exercise of warrants during the quarter  | (80,000)    | \$ (486,328)                    |
| 6/30/2011  | Change in fair value of warrants during the quarter recognized as other expense in the statement of operations |             | \$ 697,660                      |
| 6/30/2011  | Balance  | 1,469,676   | \$ 7,958,506                    |
| 9/30/2011  | Fair value of new warrants issued during the quarter   | 40,458      | \$ 285,128                      |
| 9/30/2011  | Change in fair value of warrants during the quarter recognized as other income in the statement of operations  |             | \$ (4,382,796)                  |
| 9/30/2011  | Balance  | 1,510,134   | \$ 3,860,838                    |
| 12/31/2011 | Fair value of new warrants issued during the quarter   | 1,810,294   | \$ 3,082,203                    |
| 12/31/2011 | Reclass of derivative liability to equity during the quarter   | (1,055,268) | \$ (1,707,317)                  |
| 12/31/2011 | Change in fair value of warrants during the quarter recognized as other income in the statement of operations  |             | \$ (1,910,610)                  |
| 12/31/2011 | Balance  | 2,265,160   | \$ 3,325,114                    |
| 3/31/2012  | Change in fair value of warrants during the quarter recognized as other income in the statement of operations  |             | (7,946)                         |
| 3/31/2012  | Balance  | 2,265,160   | \$ 3,317,168                    |

*Synergy Fair Value Measurements*

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2011 and March 31, 2012:

| Description                                | Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1) |    |    | Significant Unobservable Inputs (Level 3) | Balance as of December 31, 2011 | Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1) |    |    | Significant Unobservable Inputs (Level 3) | Balance as of March 31, 2012 |           |
|--|--|----|----|---|---------------------------------|--|----|----|---|------------------------------|-----------|
|  | Significant Other Observable Inputs (Level 2)                                  |    |    |   |                                 | Significant Other Observable Inputs (Level 2)                                  |    |    |   |                              |           |
| Derivative liabilities related to Warrants | \$   | \$ | \$ | 3,325,114                                 | \$                              | 3,325,114  | \$ | \$ | 3,317,168                                 | \$                           | 3,317,168 |

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The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the three months ended March 31, 2012:

| Description                                | Balance at<br>December 31,<br>2011 | Fair Value of<br>warrants upon<br>issuance | Unrealized<br>(gains) or<br>losses | Balance as of<br>March 31,<br>2012 |
|--|------------------------------------|--|------------------------------------|------------------------------------|
| Derivative liabilities related to Warrants | \$ 3,325,114                       | \$   | \$ (7,946)                         | \$ 3,317,168                       |

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The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

**9. Stockholders' Equity**

On January 30, 2012 Synergy issued 26,250 unregistered shares of common stock to its corporate counsel for professional services rendered. The shares had a fair value on the date of issuance of \$3.53 per share and \$92,663 was recorded as legal expense during the quarter ended March 31, 2012.

On February 14, 2012, Synergy Pharmaceuticals, Inc., (the "Company") entered into an agreement and plan of merger (the "Agreement") with its wholly-owned subsidiary, Synergy Pharmaceuticals Inc., a Delaware corporation ("Synergy-DE") for the purpose of changing the state of incorporation of the Company to Delaware from Florida. Pursuant to the Agreement, the Company merged with and into Synergy-DE with Synergy-DE continuing as the surviving corporation. The directors and officers in office of the Company upon the effective date of the merger shall be the directors and officers of Synergy-DE, all of whom shall hold their directorships and offices until the election and qualification of their respective successors or until their tenure is otherwise terminated in accordance with the by-laws of Synergy-DE. The effective date of the merger shall be the date on which the Certificate of Merger is filed with the Secretary of State of Delaware and the Secretary of State of Florida. The Certificate of Merger was filed with the Secretary of State of Florida on February 15, 2012 and with the Secretary of State of Delaware of February 16, 2012.

**10. Subsequent Events**

On May 9, 2012, Synergy closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of \$4.50 per share. The gross proceeds from this offering are \$45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of approximately \$3 million. Synergy also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of \$4.50 per share to cover over-allotments, if any.

During the year ended December 31, 2011 the Company recorded refundable tax credit in prepaid and other current assets for its (i) 2010 New York State QETC credit, totaling \$248,486 and (ii) its New York City Biotechnology Tax Credit for the tax year of 2011 totaling \$118,437. On April 25, 2012, Synergy received \$246,402 for 2010 New York State QETC credit and Synergy will expense the difference of \$2,084 in the quarter ended June 30, 2012.

On October 20, 2010 Callisto entered into an option agreement (the "Agreement") with a third party ("Optionee") granting the Optionee the right to purchase up to 2,000,000 shares of the common stock of Synergy Pharmaceuticals, Inc., currently owned by Callisto (the "Shares") at a purchase price of \$2.45 per share. On June 3, 2011, the Optionee paid Callisto \$100,000 in cash for this option which may be exercised at any time during the period from the date of the Agreement until (i) October 20, 2012 with respect to 1,000,000 Shares and (ii) October 20, 2015 with respect to 1,000,000 Shares. On April 25, 2012, Callisto amended the Agreement (the "Amended Agreement") to reflect Synergy's (1:2) reverse stock split

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and also simplified the option term. This Amended Agreement granted the Optionee the right to purchase up to 1,000,000 shares of the common stock of Synergy Pharmaceuticals, Inc. currently owned by Callisto, at a purchase price of \$4.90 per share, at any time during the period from April 25, 2012 until April 20, 2014.

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**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion should be read in conjunction with our condensed consolidated financial statements and other financial information appearing elsewhere in this quarterly report. In addition to historical information, the following discussion and other parts of this quarterly report contain forward-looking statements. You can identify these statements by forward-looking words such as may, will, expect, intend, anticipate, believe, estimate and continue or similar words. Forward-looking statements include information concerning possible or assumed future business success or financial results. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Accordingly, we do not undertake any obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2011 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. All drug candidates to treat GI disorders and diseases, currently plecanatide and SP-333, are being developed exclusively by Synergy Pharmaceuticals, Inc., our controlled subsidiary ( Synergy ). Use of the terms we , our or us in connection with GI drug candidates discussed herein refer to research and development activities and plans of Synergy.

**BUSINESS OVERVIEW**

Callisto Pharmaceuticals, Inc. (which may be referred to as Callisto , the Company , we , our or us ) is a development stage biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal ( GI ) disorders and diseases and was incorporated under the laws of the State of Delaware on June 5, 1996 (inception). Since inception, our efforts have been principally devoted to research and development, securing and protecting patents and raising capital. We operate as a holding company through two controlled subsidiaries: Synergy Pharmaceuticals, Inc. ( Synergy ) (41% owned) and Callisto Research Labs, LLC (100% owned). Synergy owns one inactive subsidiary, IgX, Ltd (Ireland).

All of our drug candidates, currently plecanatide and SP-333 to treat GI disorders and diseases, are being developed exclusively by Synergy. Use of the terms we , our or us in connection with the GI drug candidates discussed herein refer to research and development activities and plans of Synergy.

Synergy's lead drug candidates are as follows:

- (1) Plecanatide, a guanylyl cyclase C ( GC-C ) receptor agonist, to treat GI disorders, primarily chronic constipation ( CC ) and constipation-predominant irritable bowel syndrome ( IBS-C ).

(2) SP-333, a second generation GC-C receptor agonist, SP-333, now in pre-clinical development to treat gastrointestinal inflammatory diseases.

Callisto's product development efforts are thus in their early stages and Callisto cannot make estimates of the costs or the time they will take to complete. The risk of not completing of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, the nature and timing of costs and competing technologies being developed by organizations with significantly greater resources.

#### **RECENT DEVELOPMENTS**

On May 9, 2012, Synergy closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of \$4.50 per share. The gross proceeds from this offering are \$45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of approximately \$3 million. Synergy also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of \$4.50 per share to cover over-allotments, if any.

As of April 9, 2012, our controlled subsidiary Synergy has successfully achieved the halfway mark for total enrollment in our ongoing plecanatide Phase II/III clinical trial in chronic idiopathic constipation (CIC) patients. Over 800 patients have been screened at present, resulting in a total of 440 randomized, enrolled patients as of April 9, 2012. The trial, designed to enroll 880 patients to achieve 800 evaluable

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patients, was initiated on October 24, 2011. We anticipate completing enrollment of the trial in the third quarter of this year and reporting top line data in the fourth quarter.

**FINANCIAL OPERATIONS OVERVIEW**

From inception through March 31, 2012, we have sustained cumulative net losses attributable to common stockholders of \$145,508,572. Our losses have resulted primarily from expenditures incurred in connection with research and development activities related to the application and filing for regulatory approval of proposed products, stock-based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees, as well as deemed dividends attributable to the beneficial conversion rights of convertible preferred stock at issuance. From inception through March 31, 2012, we have not generated any revenue from operations, expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all.

Net cash used in operating activities was \$7,121,543 during the three months ended March 31, 2012 as compared to \$2,938,541 for the three months ended March 31, 2011 and \$98,609,041 during the period from June 5, 1996 (inception) to March 31, 2012. During the three months ended March 31, 2012 and 2011 Callisto incurred net losses attributable to common stockholders of \$3,142,259 and \$1,761,367, respectively and \$145,508,572 during the period from June 5, 1996 (inception) to March 31, 2012. To date, Callisto's sources of cash have been primarily limited to the sale of equity securities, issuance of debt instruments and warrants. There were no financing transactions for the three months ended March 31, 2012, and \$2,168,334 was provided by financing activities for the three months ended March 31, 2011. As of March 31, 2012, we had working capital of \$2,915,957, as compared to working capital of \$9,754,600 on December 31, 2011.

Callisto may be required to raise additional capital within this year to complete the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Callisto cannot be certain that additional funding will be available on acceptable terms, or at all. Recently worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain difficult for the foreseeable future. These developments will make it more difficult to obtain additional equity or credit financing, when needed. To the extent that Callisto raises additional funds by issuing equity securities, Callisto's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Callisto's ability to conduct business. If Callisto is unable to raise additional capital when required or on acceptable terms, Callisto may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that Callisto would otherwise seek to develop or commercialize ourselves on unfavorable terms.

**OFF-BALANCE SHEET ARRANGEMENTS**

We had no off-balance sheet arrangements as of March 31, 2012.

**RESULTS OF OPERATIONS**



**THREE MONTHS ENDED MARCH 31, 2012 AND MARCH 31, 2011**

We had no revenues during the three months ended March 31, 2012 and 2011 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses increased \$3,966,212 or 289% to \$5,338,140 for the three months ended March 31, 2012 from \$1,371,928 for the three months ended March 31, 2011. This increase in research and development expenses was entirely attributable to continuing the development of our plecanatide product candidate. These expenses included (i) higher program expenses for ongoing plecanatide Phase II/III clinical trial in CIC patients which totaled approximately \$3,249,000, as compared to approximately \$258,000 during the three months ended March 31, 2011, (ii) higher chemistry, manufacturing, and controls (CMC) costs of drug substance and product, which totaled approximately \$1,327,000, as compared to approximately \$900,000 during the three months ended March 31, 2011, (ii) higher compensation and employee benefits of approximately \$ 469,000, as compared to \$260,000 during the three months ended March 31, 2011, as a result of increased staffing levels required to support our Phase II/III trial which was initiated in October 2011 and (iii) higher scientific and regulatory advisory fees and expenses of approximately \$129,000, as compared to \$56,000 during the three months ended March 31, 2011.

General and administrative expenses for the three months ended March 31, 2011 decreased \$6,535, to \$1,953,309 for the three months ended March 31, 2012 from \$1,959,844 for the three months ended March 31, 2011. These decreased expenses were primarily the result of (i) lower compensation and related employee benefits of approximately \$558,000, as compared to \$707,000 during the three months ended March 31, 2011, (ii) lower consultants and financial advisors fees of approximately \$445,000, as compared to \$736,000 during the three months ended March 31, 2011, partially offset by (iii) higher facilities cost of approximately \$342,000 as compared to \$224,000 during the three months ended March 31, 2011 and (iv) higher corporate legal services of approximately \$574,000 for the three months ended

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March 31, 2012, as compared to \$248,000 for the three months ended March 31, 2011 as a result of increased intellectual property related costs.

Net loss attributable to common stockholders for the three months ended March 31, 2012 decreased \$1,380,892 to \$3,142,259 compared to a net loss of \$1,761,367 incurred for the three months ended March 31, 2011. This increase in our net loss was a result of the higher in research and development expenses partially offset by lower general and administrative expenses discussed above, plus the following non-operating expenses for the periods indicated.

|   | Quarter Ended<br>03/31/2012 | Quarter Ended<br>03/31/2011 | Change (\$)    |
|---|-----------------------------|-----------------------------|----------------|
| Loss from Operations                                  | \$ (7,294,957)              | \$ (3,331,772)              | \$ (3,963,185) |
| Interest and investment income                        | 4,903                       | 51                          | 4,852          |
| Interest income/(expense) and other income/(expenses) |                             | (12,414)                    | 12,414         |
| Change in FV of financial instruments                 | 7,946                       | (338,715)                   | 346,661        |
| Net loss attributable to noncontrolling interest      | 4,139,849                   | 1,921,483                   | 2,218,366      |
| Net loss attributable to common stockholders          | \$ (3,142,259)              | \$ (1,761,367)              | \$ (1,380,892) |

**LIQUIDITY AND CAPITAL RESOURCES**

As of March 31, 2012 we had \$ 6,123,418 in cash and cash equivalents, compared to \$13,244,961 as of December 31, 2011. Net cash used in operating activities was \$7,121,543 during the three months ended March 31, 2012 as compared to \$2,938,541 for the three months ended March 31, 2012. There were no financing transactions for the three months ended March 31, 2012, and \$2,168,334 was provided by financing activities for the three months ended March 31, 2011. As of March 31, 2012, we had working capital of \$2,915,957, as compared to working capital of \$9,754,600 on December 31, 2011.

On May 9, 2012, Synergy closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of \$4.50 per share. The gross proceeds from this offering are \$45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of approximately \$3 million. Synergy also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of \$4.50 per share to cover over-allotments, if any.

Our condensed consolidated financial statements as of March 31, 2012 and December 31, 2011 have been prepared under the assumption that we will continue as a going concern for the next twelve months. 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 negative outcome of this uncertainty.

**CRITICAL ACCOUNTING POLICIES**

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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 ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA of our Annual Report on Form 10-K as of and for year ended December 31, 2011, filed with the SEC on March 30, 2012. There have been no changes to our critical accounting policies since December 31, 2011.

### CONTRACTUAL OBLIGATIONS AND COMMITMENTS

For a discussion of our contractual obligations see (i) our Financial Statements and Notes To Consolidated Financial Statements Note 7. *Commitments and Contingencies*, and (ii) Item 7 Management Discussion and Analysis of Financial Condition and Results of Operations *Contractual Obligations and Commitment*, included in our Annual Report on Form 10-K as of December 31, 2011. There have been changes in our contractual obligations and commitments during the three months ended March 31, 2012 as follows:

Our corporate headquarters totals approximately 4,300 rentable square feet located at 420 Lexington Avenue, New York, and was subject to a lease which has a monthly rate of \$16,414 and expired on March 31, 2012. On March 30, 2012 we extended this lease through March 31, 2014, at a monthly rate of \$18,833 on a straight line basis. We also occupy a small laboratory and several offices, totaling approximately 1,300

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square feet, in the Bucks County Biotechnology Center in Doylestown, Pennsylvania under a lease which expired August 31, 2011. On February 1, 2012 we extended this lease through December 31, 2013, at a monthly rate of \$2,254.

In addition during the quarter ended March 31, 2012 Synergy has entered into new drug substance purchase commitments to support our clinical and non-clinical development of plecanatide and SP-333.

The following table is a summary of contractual cash obligations for the periods indicated that existed as of March 31, 2012, and is based on information appearing in the notes to Consolidated Financial Statements included in our Annual Report on Form 10-K as of December 31, 2011, filed with the SEC on March 30, 2012; as well as the notes to Condensed Consolidated Financial Statements included in elsewhere in this Quarterly Report on Form 10-Q.

|   | Total        | Less than<br>1 Year | 1-2 Years    | 3-5<br>Years | More<br>than<br>5 Years |
|---|--------------|---------------------|--------------|--------------|-------------------------|
| Operating leases  | \$ 472,294   | \$ 242,950          | \$ 229,344   | \$           | \$                      |
| Purchase obligations principally employment and consulting services (1) | 2,859,140    | 1,153,865           | 1,705,275    |              |                         |
| Purchase Obligations Major Vendors (2)                                  | 3,506,589    | 3,506,589           |              |              |                         |
| Total obligations   | \$ 6,838,023 | \$ 4,903,404        | \$ 1,934,619 | \$           | \$                      |

(1) Represents salary and bonus for remaining term of employment agreements with Gary S. Jacob, CEO, Bernard F Denoyer, Senior Vice President, Finance and consulting fees and bonus for remaining term of consulting agreement with Gabriele M. Cerrone, Chairman.

(2) Represents amounts that will become due upon future delivery of supplies, drug substance and test results from various suppliers, under open purchase orders as of March 31, 2012.

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

Our exposure to market risk on the fair values of certain assets is related to credit risk associated with securities held in short term investment accounts, commercial paper included in short term money market accounts and the FDIC insurance limit on our bank balances. At March 31, 2012 we had \$5,262,000 balances in money market balances.

**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 March 31, 2012, our Chief Executive Officer and Principal Financial Officer have concluded that as of March 31, 2012, our disclosure controls and procedures were not effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms.

In connection with the preparation of our annual financial statements, our management performed an assessment of the effectiveness of internal control over financial reporting as of December 31, 2011. Management's assessment included an evaluation of the design of our internal control over financial reporting and the operational effectiveness of those controls. Based on this evaluation, management determined that, as of December 31, 2011, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management's assessment were (i) an effective whistle-blower program or other comparable mechanism and (ii) an ongoing program to manage identified fraud risks. As of December 31, 2012, we did not maintain effective internal control over financial reporting. As defined by Regulation S-X, Rule 1-02(a)(4), a material weakness is a deficiency or a combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the relationship between the benefit of desired controls and procedures and the cost of implementing new controls and procedures.

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**CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING**

As of March 31, 2012, we are in the process of remediating the material weakness which existed at December 31, 2011. If these remedial measures are insufficient to address any of the identified material weaknesses or are not implemented effectively, or additional deficiencies arise in the future, material misstatements in our interim or annual financial statements may occur in the future.

There were no changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that could significantly affect internal controls over financial reporting during the quarter ended March 31, 2012.

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**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

There have been no material changes from the legal proceedings disclosed in our Form 10-K for the year ended December 31, 2011.

**ITEM 1A. RISK FACTORS**

There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2011.

**ITEM 2. PROPERTIES.**

Our corporate headquarters total approximately 4,300 rentable square feet located at 420 Lexington Avenue, New York, and is subject to a lease which has a monthly rate of \$16,414 and expired on March 31, 2012. On March 30, 2012, we extended this lease through March 31, 2014, at a monthly rate of \$ 18,833 on a straight line basis. We also occupy a small laboratory and several offices, totaling approximately 1, 300 square feet, in the Bucks County Biotechnology Center in Doylestown, Pennsylvania under a lease which expired August 31, 2011. On February 1, 2012 we extended this lease through December 31, 2013, at a monthly rate of \$2,254.

**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

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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.

- 101 Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2012, filed on May 15, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows (iv) the Condensed Consolidated Statement of Stockholders Equity (Deficit) and (v) the Notes to Consolidated Financial Statements tagged as blocks of text.



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**SIGNATURES**

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

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

Date: May 15, 2012

By:

*/s/ GARY S. JACOB*  
Gary S. Jacob  
*Chief Executive Officer*

Date: May 15, 2012

By:

*/s/ BERNARD F. DENOYER*  
Bernard F. Denoyer  
*Senior Vice President, Finance*