

CALLISTO PHARMACEUTICALS INC  
Form 10-Q  
May 20, 2009

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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, 2009**

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

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Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a 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

The number of the registrant's shares of common stock outstanding was 50,914,341 as of May 18, 2009.

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CALLISTO PHARMACEUTICALS, INC.

FORM 10-Q

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**INTRODUCTORY NOTE**

**This Report on Form 10-Q for Callisto Pharmaceuticals, Inc. ("Callisto" or the "Company") may contain forward-looking statements. You can identify these statements by forward-looking words such as "may," "will," "expect," "intend," "anticipate," "believe," "estimate" and "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, 2008 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.**

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

|  | March 31,<br>2009 | December 31,<br>2008 |
|--|-------------------|----------------------|
|  | (Unaudited)       |                      |
| <b>ASSETS</b>  |                   |                      |
| Current Assets:  |                   |                      |
| Cash and cash equivalents  | \$ 44,876         | \$ 301,323           |
| Cash in escrow   | 199,042           | 201,908              |
| Prepaid expenses and other   | 28,572            | 59,756               |
| <br>Total Current Assets   | <br>272,490       | <br>562,987          |
| Property and equipment, net  | 18,615            | 20,649               |
| Security deposits  | 78,116            | 78,116               |
| <br>Total Assets   | <br>\$ 369,221    | <br>\$ 661,752       |
| <b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>   |                   |                      |
| Current Liabilities:   |                   |                      |
| Accounts payable   | \$ 3,944,471      | \$ 3,687,549         |
| Accrued expenses   | 1,304,407         | 1,136,264            |
| <br>Total Current Liabilities  | <br>5,248,878     | <br>4,823,813        |
| Notes payable  | 113,036           | 20,176               |
| Derivative financial instruments, at estimated fair value warrants   | 2,302,735         |                      |
| <br>Total Liabilities  | <br>7,664,649     | <br>4,843,989        |
| Commitments and contingencies  |                   |                      |
| Stockholders' Deficit:   |                   |                      |
| Series A convertible preferred stock, par value \$0.0001, 700,000 shares authorized, 88,000 and 98,000 shares outstanding with a liquidation preference of \$880,000 and \$980,000 at March 31, 2009 and December 31, 2008, respectively               | 9                 | 10                   |
| Series B convertible preferred stock, par value \$0.0001, 2,500,000 shares authorized, 1,087,500 and 1,137,050 shares outstanding with a liquidation preference of \$10,875,000 and \$11,370,500 at March 31, 2009 and December 31, 2008, respectively | 109               | 114                  |
| Common stock, par value of \$.0001 per share: Authorized 225,000,000 shares at December 31, 2008 and 2007; 50,747,661 and 49,556,661 shares outstanding at March 31, 2009 and December 31, 2008, respectively  | 5,074             | 4,955                |
| Additional paid-in capital   | 87,203,523        | 86,799,951           |

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|  |                    |                    |
|--|--------------------|--------------------|
| Deficit accumulated during development stage | (94,185,253)       | (90,987,267)       |
| <b>Total Stockholders' Deficit</b>           | <b>(6,976,538)</b> | <b>(4,182,237)</b> |
| Non-controlling interest                     | (318,890)          |                    |
| <b>Total Deficit</b>                         | <b>(7,295,428)</b> | <b>(4,182,237)</b> |
| <br>   |                    |                    |
| Total Liabilities and Stockholders' Deficit  | \$ 369,221         | \$ 661,752         |

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, 2009 | Three Months<br>Ended<br>March 31, 2008 | For the period<br>From<br>June 5, 1996<br>(Inception) to<br>March 31, 2009 |
|---|---|---|--|
| Revenues  | \$                                      | \$                                      | \$   |
| Costs and expenses:   |   |   |  |
| Research and development  | 398,022                                 | 2,016,983                               | 34,496,286   |
| Government grant  |   |   | (1,135,318)  |
| Purchased in process research and development                                 |   |   | 6,944,553  |
| General and administrative  | 956,576                                 | 1,020,312                               | 39,935,181   |
| Loss from operations  | (1,354,598)                             | (3,037,295)                             | (80,240,702)   |
| Interest and investment income  | 211                                     | 45,537                                  | 864,538  |
| Other income (expense), net   | (41,486)                                |   | (213,333)  |
| Change in fair value of derivative instruments warrants                       | (217,103)                               |   | 2,373,902  |
| Net loss  | (1,612,976)                             | (2,991,758)                             | (77,215,595)   |
| Net loss attributable to non-controlling interest                             | 318,890                                 |   | 318,890  |
| Net loss attributable to controlling interest                                 | (1,294,086)                             | (2,991,758)                             | (76,896,705)   |
| 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)   |
| Net loss available to common stockholders                                     | \$ (1,294,086)                          | \$ (2,991,758)                          | \$ (92,281,353)  |
| Weighted average shares outstanding:  |   |   |  |
| basic and diluted   | 50,627,450                              | 47,124,205                              |  |
| Net loss per common share:  |   |   |  |
| basic and diluted   | \$ (0.03)                               | \$ (0.06)                               |  |

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<br>Value | Common<br>Shares | Common<br>Stock,<br>Par<br>Value | Additional<br>Paid in<br>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<br>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)**

(Unaudited)

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

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|   |       |                 |              |
|---|-------|-----------------|--------------|
| 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<br>Compensation | 332   |                 | 332          |
| Balance, December 31, 2002                  | \$    | \$ (12,711,483) | \$ 1,828,865 |

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

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

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

(Unaudited)

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

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

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

(Unaudited)

|  | Common<br>Stock | Common<br>Stock<br>Par<br>Value | Additional<br>Paid in<br>Capital | Unamortized<br>Deferred Stock<br>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 via<br>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)**

(Unaudited)

|  | 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>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 grants      |                 |                                 | 1,571,772                        | (1,571,772)  |  |   |
| Amortization of deferred<br>stock-based compensation |                 |                                 |                                  | 2,290,843  |  | 2,290,843                                     |
| Variable accounting for<br>stock options             |                 |                                 | 75,109                           |  |  | 75,109  |
| Common stock issued via<br>private placement:        |                 |                                 |                                  |  |  |   |
| March 2005   | 1,985,791       | 198                             | 3,018,203                        |  |  | 3,018,401                                     |
| August 2005  | 1,869,203       | 187                             | 1,812,940                        |  |  | 1,813,127                                     |
| Finders fees and expenses                            |                 |                                 | (176,250)                        |  |  | (176,250)                                     |
| Exercise of common stock<br>warrant                  | 125,000         | 13                              | 128,737                          |  |  | 128,750                                       |
| Common stock issued for<br>services                  | 34,000          | 3                               | 47,177                           |  |  | 47,180  |
| Balance, December 31,<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)**

(Unaudited)

|  | 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 deferred<br>unamortized stock-based<br>compensation upon<br>adoption of FAS 123R |  |   |                 |                                 | (1,583,463)                      | 1,583,463  |  |   |
| Stock based compensation<br>expense  |  |   |                 |                                 | 2,579,431                        |  |  | 2,579,431                                     |
| Common stock issued via<br>private placement:  |  |   |                 |                                 |                                  |  |  |   |
| February 2006  |  |   | 4,283,668       | 428                             | 5,139,782                        |  |  | 5,140,210                                     |
| Finders fees and<br>expenses   |  |   |                 |                                 | (561,808)                        |  |  | (561,808)                                     |
| 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 for<br>services  |  |   | 87,000          | 9                               | 121,101                          |  |  | 121,110                                       |
| Exercise of common stock<br>warrants   |  |   | 184,500         | 18                              | 190,017                          |  |  | 190,035                                       |
| Series A convertible<br>preferred stock issued via<br>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                        |  |  |   |
| Beneficial conversion<br>feature accreted as a<br>dividend   |  |   |                 |                                 |                                  |  | (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)**

|   | 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, 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 compensation expense  |  |   |  |   |                  |                                  | 591,561                          |  | 591,561                          |
| Common stock issued for services  |  |   |  |   | 80,000           | 8                                | 36,792                           |  | 36,800                           |
| Series A convertible preferred stock, issued via private placement                          | 28,000   | 4   |  |   |                  |                                  | 279,997                          |  | 280,001                          |
| Finders fees and expenses, Series A private placement                                       |  |   |  |   |                  |                                  | (36,400)                         |  | (36,400)                         |
| Conversion of Series A preferred stock to common stock                                      | (395,450)                                      | (40)  |  |   | 7,668,165        | 767                              | (727)                            |  |                                  |
| Beneficial conversion feature accreted as a dividend to Series A preferred stock            |  |   |  |   |                  |                                  | 2,504,475                        | (2,504,475)  |                                  |
| Series B convertible preferred stock, issued via private placement                          |  |   | 1,147,050                                      | 115   |                  |                                  | 11,470,385                       |  | 11,470,500                       |
| Finders fees and expenses, Series B private placement                                       |  |   |  |   |                  |                                  | (920,960)                        |  | (920,960)                        |
| Beneficial conversion feature accreted as a dividend to Series B preferred stock            |  |   |  |   |                  |                                  | 10,495,688                       | (10,495,688)   |                                  |
| Change in fair value of Series B warrants from date of issuance to expiration of put option |  |   |  |   |                  |                                  | (2,591,005)                      |  | (2,591,005)                      |
| Balance, 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)                      |
| 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)**

|  | 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<br>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, 2008  | 98,000   | \$ 10   | 1,137,050                                      | \$ 114  | 49,556,661       | \$ 4,955                        | \$86,799,951                     | \$ (90,987,267)  |                                 | \$ (4,182,237)                                |
| Cumulative effect of<br>adoption of EITF<br>Issue 07-05                  |  |   |  |   |                  |                                 | (181,732)                        | (1,903,900)  |                                 | (2,085,632)                                   |
| Net loss for the period  |  |   |  |   |                  |                                 |                                  | (1,294,086)  | (318,890)                       | (1,612,976)                                   |
| Stock based<br>compensation expense                                      |  |   |  |   |                  |                                 | 194,417                          |  |                                 | 194,417                                       |
| Conversion of<br>Series A preferred<br>stock to common<br>stock          | (10,000)                                       | (1)   |  |   | 200,000          | 20                              | (19)                             |  |                                 |   |
| Conversion of<br>Series B preferred<br>stock to common<br>stock          |  |   | (49,550)                                       | (5)   | 991,000          | 99                              | (94)                             |  |                                 |   |
| Private placements of<br>common stock of<br>majority owned<br>subsidiary |  |   |  |   |                  |                                 | 391,000                          |  |                                 | 391,000                                       |
| Balance March 31,<br>2009  | 88,000   | \$ 9  | 1,087,500                                      | \$ 109  | 50,747,661       | \$ 5,074                        | \$87,203,523                     | \$ (94,185,253)  | \$ (318,890)                    | (7,295,428)                                   |

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, 2009 | Three months<br>ended<br>March 31, 2008 | Period from<br>June 5, 1996<br>(inception) to<br>March 31, 2009 |
|---|---|---|---|
| <b>Cash flows from operating activities:</b>  |   |   |   |
| Net loss  | \$ (1,612,976)                          | \$ (2,991,758)                          | \$ (77,215,595)   |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b>                  |   |   |   |
| Depreciation  | 2,034                                   | 1,540                                   | 98,618  |
| Purchase discount accreted as interest income on U.S.Treasury bills                                 |   | (26,950)                                | (26,950)  |
| Stock-based compensation expense  | 194,417                                 | 100,071                                 | 17,929,286  |
| Purchased in-process research and development (non-cash portion)                                    |   |   | 6,841,053   |
| Interest expense on long term notes   | 41,486                                  |   | 41,486  |
| Stock-based liquidated damages  |   |   | 579,696   |
| Change in fair value of derivative instruments warrants   | 217,103                                 |   | (2,373,902)   |
| Minority interest in net losses of majority owned subsidiary  |   |   | (335,254)   |
| <b>Changes in operating assets and liabilities:</b>   |   |   |   |
| Prepaid expenses  | 31,184                                  | 59,302                                  | (28,572)  |
| Security deposit  |   |   | (78,116)  |
| Accounts payable and accrued expenses   | 425,065                                 | (175,047)                               | 5,248,881   |
| Total adjustments   | 911,289                                 | (41,084)                                | 27,896,226  |
| Net cash used in operating activities   | (701,687)                               | (3,032,842)                             | (49,319,369)  |
| <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  |
| Finders fees and expenses   |   |   | (2,981,083)   |
| Proceeds from sale of 11% Notes   | 245,240                                 |   | 245,240   |
| Proceeds of private placement of majority owned subsidiary's common stock, net of fees and expenses | 200,000                                 |   | 3,151,913   |
| Exercise of common stock warrants   |   |   | 318,785   |
| Net cash provided by financing activities   | 445,240                                 |   | 49,454,528  |
| Net (decrease) increase in cash and cash equivalents  | (256,447)                               | (3,032,842)                             | 44,876  |

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|  |           |            |           |  |
|--|-----------|------------|-----------|--|
| Cash and cash equivalents at beginning of period | 301,323   | 3,269,341  |           |  |
| Cash and cash equivalents at end of period       | \$ 44,876 | \$ 236,499 | \$ 44,876 |  |

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, 2009 | Three months<br>ended<br>March 31, 2008 | Period from<br>June 5, 1996<br>(inception) to<br>March 31, 2009 |
|--|---|---|---|
| Supplementary disclosure of cash flow information:   |   |   |   |
| Cash paid for taxes  | \$ 6,141                                | \$ 11,481                               | \$ 167,866  |
| 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   |
| Cash received in escrow for private placement of majority-owned subsidiary common stock and sale of Callisto 11% Notes | \$ 199,042                              | \$                                      | \$ 199,042  |

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. ("Callisto" or the "Company") is a development stage biopharmaceutical company, whose primary focus is on biopharmaceutical product development. Since inception in June of 1996, Callisto's efforts have been principally devoted to research and development, securing and protecting patents and raising capital. From inception through March 31, 2009, Callisto has sustained cumulative net losses available to common stockholders of \$92,281,353. 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, 2009, Callisto has not generated any revenue from operations, 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 completion 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.

**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-DE, 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, 2008, included in Form 10-K filed with the SEC on April 15, 2009. 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, 2009 are not necessarily indicative of the results of operations to be expected for the full year ending December 31, 2009. The condensed consolidated balance sheet as of December 31, 2008 was derived from the audited consolidated financial statements as of that date.

The condensed consolidated financial statements as of March 31, 2009 and December 31, 2008 have been prepared under the assumption that Callisto will continue as a going concern for the twelve month ending December 31, 2009. 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,

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

**2. Basis of presentation and going concern: (Continued)**

ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Callisto will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at its current cash expenditure levels.

Net cash used in operating activities was \$701,687 during the three months ended March 31, 2009 as compared to \$3,032,842 for the three months ended March 31, 2008. During the three months ended March 31, 2009 and 2008 Callisto incurred net losses available to common stockholders of \$1,294,086 and \$2,991,758, respectively. To date, Callisto's sources of cash have been primarily limited to the sale of equity securities. Net cash provided by financing activities for the three months ended March 31, 2009 and 2008 and for the period from June 5, 1996 (inception) to March 31, 2009, was \$445,240, \$0 and \$49,454,528, respectively. On April 15, 2009, Synergy sold 1,045,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$732,000.

Worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult for us to obtain additional equity or credit financing, when needed. Callisto has accordingly taken steps to conserve our cash which include extending payment terms to our vendors and suppliers as well as staff salary cuts and deferrals. These actions may not be sufficient to allow the Company time to raise additional capital.

Callisto will be required to raise additional capital within the next 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. 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**

Effective January 1, 2009, the Company adopted SFAS No. 160, "*Non-controlling Interests in Consolidated Financial Statements.*" This statement amends Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to establish accounting and reporting standards for a non-controlling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. This statement clarifies that a non-controlling interest in a subsidiary is an ownership in the consolidated entity that should be reported as equity in the consolidated financial statements. The adoption of SFAS 160 impacted the presentation and disclosure of noncontrolling (minority) interests in the Company's condensed consolidated financial statements. SFAS 160 is to be applied prospectively. The

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

**3. Recent Accounting Pronouncements (Continued)**

noncontrolling (minority) interest relates to third party shareholders of Synergy who own 32% of Synergy since July 14, 2008.

The net loss attributable to the non-controlling interest totaled \$318,890 during the three months ended March 31, 2009 and this was recorded as such in the condensed consolidated financial statements prospectively upon adoption of SFAS No. 160 on January 1, 2009. The net loss attributable to the non-controlling interest of \$1,139,746 for the period from July 14, 2008 (inception of non-controlling interest) to December 31, 2008 was not retrospectively adjusted in Callisto's Consolidated Financial Statements for the period ended and as of December 31, 2008 because the non-controlling interest had been reduced to zero. If this amount had been recorded, Callisto's net loss available to common stockholders would have been \$89,847,521 from inception through December 31, 2008.

In April 2009, the FASB issued FSP 107-1 and Accounting Principles Board ("APB") 28-1, *Interim Disclosures about Fair Value of Financial Instruments* ("FSP 107-1"). FSP 107-1 amends SFAS No. 107, *Disclosures About Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FSP 107-1 also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods. FSP 107-1 is effective for interim reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. FSP 107-1 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP 107-1 requires comparative disclosures only for periods ending after initial adoption. We are currently evaluating the potential impact of the provisions of FSP FAS 107-1 and APB 28-1.

In April 2009, the FASB issued FSP 115-2 and 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments* ("FSP 115-2 and 124-2"). FSP 115-2 and 124-2 amends the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. FSP 115-2 and 124-2 does not amend existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. FSP 115-2 and 124-2 is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. FSP 115-2 and 124-2 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP 115-2 and 124-2 requires comparative disclosures only for periods ending after initial adoption. We are currently evaluating the potential impact of the provisions of FSP FAS 115-2 and FAS 124-2.

In April 2009, the FASB issued FSP 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* (FSP 157-4"). FSP 157-4 provides additional guidance for estimating fair value in accordance with SFAS 157 when the volume and level of activity for the asset or liability have significantly decreased. FSP 157-4 also includes guidance on identifying circumstances that indicate a transaction is not orderly. FSP 157-4 is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. FSP 157-4 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after



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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

**3. Recent Accounting Pronouncements (Continued)**

initial adoption, FSP 157-4 requires comparative disclosures only for periods ending after initial adoption. We are currently evaluating the potential impact of the provisions of FSP FAS 157-4.

In June 2008, the FASB ratified the consensus reached on Emerging Issues Task Force ("EITF") Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* ("EITF No. 07-05"). EITF No. 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. The Company adopted of EITF No. 07-05 on January 1, 2009. See Note 6 below.

In February 2008, the FASB issued FSP No. 157-2, *Partial Deferral of the Effective Date of Statement 157*, ("FSP No. 157-2"). FSP No. 157-2 delays the effective date of SFAS No. 157, *Fair Value Measurements* ("SFAS No. 157") for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually) to fiscal years beginning after November 15, 2008. The Company adopted SFAS No. 157 for nonfinancial assets and nonfinancial liabilities on January 1, 2009 and the adoption did not have a material impact on its consolidated financial position, results of operations or cash flows.

In December 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, ("EITF No. 07-1"), which provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure requirements. EITF No. 07-1 is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company adopted the provisions of EITF No. 07-1 on January 1, 2009 and the adoption did not have a material impact on its consolidated financial position, results of operations or cash flows.

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

The Company periodically issues stock options and warrants to employees and non-employees in capital raising transactions, for services and for financing costs. The Company adopted SFAS No. 123R for employee awards effective January 1, 2006, and is using the modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of APB No. 25 for all awards granted to employees prior to the effective date of SFAS No. 123R that remained unvested on the effective date.

The Company accounts for stock option and warrant grants issued and vesting to non-employees in accordance with EITF No. 96-18: "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and EITF No. 00-18 "Accounting Recognition for Certain Transactions involving Equity Instruments Granted to Other Than 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

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

**4. Accounting for share-based payments (Continued)**

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.

***Callisto options***

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

|  | <b>Three Months Ended<br/>March 31,</b> |                   | <b>June 5, 1996<br/>(Inception) to<br/>March 31,<br/>2009</b> |
|--|---|-------------------|---|
|  | <b>2009</b>                             | <b>2008</b>       |   |
| Employees included in research and development   | \$ 6,932                                | \$ 12,651         | \$ 2,668,817  |
| Employees included in general and administrative | 18,328                                  | 53,743            | 4,768,281   |
| Subtotal employee stock option grants            | 25,260                                  | 66,394            | 7,437,098   |
| Non-employee research and development            |   | 7,820             | 102,750   |
| Non-employee general and administrative          | (7,339)                                 | 25,858            | 9,833,059   |
| Subtotal non-employee stock option grants        | (7,339)                                 | 33,678            | 9,935,809   |
| <b>Total stock based compensation expense</b>    | <b>\$ 17,921</b>                        | <b>\$ 100,071</b> | <b>\$ 17,372,907</b>  |

The unrecognized compensation cost related to employee non-vested Callisto stock options outstanding at March 31, 2009, net of expected forfeitures, was \$59,202, to be recognized over a weighted average vesting period of approximately six months. The weighted-average remaining term of all options outstanding at March 31, 2009 was 4.9 years as compared to 5.1 years at December 31, 2008.

On January 31, 2008, the Board of Directors approved a reassignment, as well as, a decrease in the exercise price, of the 1,323,822 warrants, previously assigned from Trilogy Capital Partners LLC to two unaffiliated entities, from \$1.03 per share to \$0.70 per share. The decrease in the exercise price was effective immediately and the reassignment will be effective at management's discretion. Callisto has determined that the price modifications was compensatory in accordance with SFAS 123R and the associated stock based compensation expense of \$45,086 was recorded during the quarter ended March 31, 2008. As of March 31, 2009 Callisto had not reassigned the warrants.

Callisto granted no stock options during the quarter ended March 31, 2009. The estimated fair value of each Callisto employee stock option award was determined on the date of grant using the

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

**4. Accounting for share-based payments (Continued)**

Black-Scholes option valuation model with the following weighted-average assumptions during the three months ended March 31, 2009 and 2008.

|                         | Three months<br>ended<br>March 31, |         |
|-------------------------|------------------------------------|---------|
|                         | 2009                               | 2008    |
| Risk free interest rate | n/a                                | 4.68%   |
| Dividend yield          | n/a                                | 0.0%    |
| Expected volatility     | n/a                                | 60%     |
| Expected term           | n/a                                | 6 years |

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<br>Share | Intrinsic<br>Value<br>Per<br>Share |
|--|----------------------|--------------------------------|--|------------------------------------|
| Balance outstanding, December 31, 2008 | 7,938,538            | \$0.08 - 6.75                  | \$ 1.72  | \$                                 |
| Granted                                |                      | \$                             | \$   |                                    |
| Forfeitures                            |                      | \$                             | \$   |                                    |
| Balance outstanding, March 31, 2009    | 7,938,538            | \$0.08 - 6.75                  | \$ 1.72  | \$                                 |
| Exercisable as of March 31, 2009       | 6,030,205            | \$0.47 - 6.75                  | \$ 1.64  | \$                                 |

***Synergy Options***

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. Synergy granted no stock options during the quarter ended March 31, 2009.

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(Unaudited)

**4. Accounting for share-based payments (Continued)**

Stock-based compensation expense related to Synergy options and restricted stock units have been recognized in operating results as follow:

|  | Three months<br>ended<br>March 31 |            | November 15,<br>2005             |
|--|-----------------------------------|------------|----------------------------------|
|  | 2009                              | 2008       | (inception) to<br>March 31, 2009 |
| Employees included in research and development       | \$ 43,241                         | n/a        | \$ 122,771                       |
| Employees included in general and administrative     | 56,073                            | n/a        | 168,801                          |
| Non-employees included in research and development   | 8,362                             | n/a        | 16,910                           |
| Non-employees included in general and administrative | 68,820                            | n/a        | 247,897                          |
| <b>Total stock-based compensation expense</b>        | <b>\$ 176,496</b>                 | <b>n/a</b> | <b>\$ 556,379</b>                |

The unrecognized compensation cost related to non-vested Synergy employee stock options outstanding at March 31, 2009, net of expected forfeitures, was \$1,162,156, to be recognized over a weighted-average remaining vesting period of approximately 2.3 years.

**Synergy Restricted Stock Units**

Restricted Stock Units, which entitle the holder to receive, at the end of a vesting term, a specified number of shares of Synergy common stock are accounted for as stock based compensation in accordance with SFAS No. 123R in the same manner as stock options using fair value at the date of grant. Subject to a repurchase agreement assumed by Synergy pursuant to the Exchange Transaction, 50% of the units vest after 1 year of continuous service and the remaining 50% vest after 2 years of continuous service from the grant date. The total fair value is being expensed ratably by month over the 2 year service period.

On July 3, 2008, 874,760 restricted stock units were granted by Synergy-DE and assumed by Synergy as part of the Exchange Transaction and are subject to a repurchase agreement, as defined. These restricted stock units were issued to certain officers and a consultant of Synergy. The fair value of each Synergy restricted stock unit is estimated on the grant date based on the price paid by shareholders participating in Synergy's July 14, 2008 private placement. As of March 31, 2009 there were 874,760 Synergy restricted stock units outstanding. The fair value of the 874,760 Synergy restricted stock units on the date of grant was \$524,856 of which \$48,530 was recorded as stock-based compensation expense during the three months ended March 31, 2009.

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

**5. Net Loss per Share**

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, "Earnings per Share," for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

**5. Net Loss per Share (Continued)**

common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares since the inclusion of issuable shares pursuant to the exercise of stock options and warrants, 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,<br>2009  | March 31,<br>2008  |
|--|--------------------|--------------------|
| Common Shares outstanding                          | 50,747,661         | 47,218,161         |
| Potentially dilutive common shares issuable upon:  |                    |                    |
| Exercise of warrants                               | 57,771,750         | 45,162,920         |
| Exercise of stock options                          | 7,938,538          | 8,191,207          |
| Conversion of Series A Convertible Preferred Stock | 1,760,000          | 4,298,500          |
| Conversion of Series B Convertible Preferred Stock | 21,750,000         | 22,741,000         |
| <b>Total fully diluted</b>                         | <b>139,967,949</b> | <b>127,611,788</b> |

**6. Derivative Financial Instruments**

Effective January 1, 2009, the Company adopted EITF Issue No. 07-05, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock" ("EITF 07-05"). EITF 07-05 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 SFAS 133.

Based upon the Company's analysis of the EITF 07-05 criteria, certain warrants (the "New Warrants") issued in connection with the issuance of the 11% Notes (see Note 8 below) must now be treated as derivative liabilities in the Company's statement of financial position. Prior to the adoption of EITF 07-05, the Company accounted for the Warrants as components of stockholders' equity under SFAS 133.

Consistent with EITF 07-05's requirements, the Company recognized the cumulative effect of the change in accounting principle to reduce the opening balance of the deficit accumulated during the development stage for fiscal year 2009. The cumulative effect adjustment of \$1,903,900 represents the difference between the amounts recognized in the statement financial position before initial application of EITF 07-05 on January 1, 2009 and the initial fair value of the warrants. Additionally, the initial relative fair value of the Warrants, aggregating \$181,732, which were initially recorded as additional paid-in capital upon issuance, was reclassified to long-term liabilities upon adoption of EITF 07-05. (See Note 8.) The total amount recognized at initial issuance of \$2,085,632 was determined based on the estimated fair value of the Warrants using a Black-Scholes option pricing model. Prospectively, the New Warrants will be re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value will be recorded as non-cash valuation adjustments within other income (expense) in the Company's statement of operations. During the three months ended March 31, 2009, the Company recorded other expense of \$217,103 relating to the net change in fair value of the New

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

**6. Derivative Financial Instruments (Continued)**

Warrants during this period based on an estimated fair value of \$2,302,735 for the New Warrants as of March 31, 2009.

The net change in the fair value of the New Warrants of \$217,103 during the three months ended March 31, 2009 is comprised of: (i) a \$232,505 decrease in the fair value of the 23,219,105 New Warrants which were the basis for the cumulative effect adjustment on January 1, 2009 of \$2,085,632, (ii) a \$562,270 increase the derivative liabilities balance attributable to the fair value of an additional 5,633,726 New Warrants issued January 31, 2009 in connection with the second tranche of \$51,374 of 11% Notes and (iii) a \$112,662 decrease in the fair value of the 5,633,726 New Warrants for the period from February 1, 2009 to March 31, 2009.

The Company estimates the fair value of the New Warrants using the Black-Scholes option pricing model. The assumptions used for the three months ended March 31, 2009 are noted in the following table:

|                         | <b>Three Months<br/>Ended<br/>March 31, 2009</b> |
|-------------------------|--|
| Expected option term    | 8 years  |
| Risk-free interest rate | 2.01% - 2.28%                                    |
| Expected volatility     | 200%   |
| Dividend yield          | 0%   |

Expected volatility is based on historical volatility of the Company's common stock. The New Warrants have a transferability provision and based on guidance provided in SAB 107 for options issued with such a provision, we used the full contractual term as the expected term of the New Warrants. The risk free rate is based on the U.S. Treasury security rates consistent with the expected term of the New Warrants.

**7. 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 March 31, 2009:

| <b>Description</b>                         | <b>Quoted<br/>Prices in<br/>Active<br/>Markets<br/>for<br/>Identical<br/>Assets and<br/>Liabilities<br/>(Level 1)</b> | <b>Significant<br/>Other<br/>Observable<br/>Inputs<br/>(Level 2)</b> | <b>Significant<br/>Unobservable<br/>Inputs<br/>(Level 3)</b> | <b>Balance as<br/>of<br/>March 31,<br/>2009</b> |
|--|---|--|--|---|
| Derivative liabilities related to Warrants | \$  | \$   | \$ 2,302,735   | \$ 2,302,735                                    |

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(Unaudited)

**7. Fair Value Measurements (Continued)**

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, 2009:

| Description                                | Balance at<br>December 31,<br>2008 | Cumulative<br>Effect of the<br>Adoption of<br>EITF 07-05<br>(See Note 4) | Unrealized<br>Losses | Balance as<br>of<br>March 31,<br>2009 |
|--|------------------------------------|--|----------------------|---------------------------------------|
| Derivative liabilities related to Warrants | \$                                 | \$2,085,632  | \$ 217,103           | \$2,302,735                           |

The unrealized losses on the derivative liabilities are classified in other expenses as a change in derivative liabilities in the Company's statement of operations. Fair value is determined based on Black-Scholes option pricing model calculation. (See Note 6).

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 performs a detailed analysis of the assets and liabilities that are subject to SFAS 157. 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.

**8. Stockholders' deficit**

During the three months ended March 31, 2009, 10,000 shares of Series A Convertible Preferred Stock were converted to 200,000 shares of common stock and 49,550 shares of Series B Convertible Preferred Stock were converted to 991,000 shares of common stock, at conversion price of \$0.50 per share.

On December 30, 2008, Callisto entered into a securities purchase and exchange agreement ("Purchase Agreement") with several investors, each of whom were holders of record as of November 4, 2008 of outstanding warrants to purchase shares of the Company's common stock, exercisable at \$0.50 or \$0.70 per share until August 2, 2010 ("Series B Warrants"). The Series B Warrants were issued in connection with the private placement of the Company's Series B Preferred Shares on August 2, 2007. Pursuant to the Purchase Agreements Callisto issued \$201,908 of an authorized \$500,000 11% Secured Notes due April 15, 2010 ("11% Notes") with no discount. Interest on the 11% Notes is due at maturity and repayment of the 11% Notes is secured by a pledge of up to 1,900,000 shares (if all \$500,000 principal amount of the 11% Notes is sold) of the common stock of Synergy owned by us. On February 3, 2009, Callisto issued an additional \$51,374 of the 11% Notes bringing the aggregate proceeds from issuance of 11% Notes since inception to \$253,282. Of these proceeds \$8,042 remained in escrow as of March 31, 2009.

Pursuant to the Purchase Agreement, Callisto issued, to the December 30, 2008 purchasers of the 11% Notes, 23,219,105 common stock purchase warrants ("2008 New Warrants") in exchange for the surrender and cancellation of 11,298,123 outstanding Series B Warrants. The 2008 New Warrants have an exercise price, subject to certain anti-dilution adjustments, of \$0.02 per share and are exercisable at any time on or prior to December 31, 2016.

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

**8. Stockholders' deficit (Continued)**

The proceeds from the issuance of these instruments were allocated to the notes and warrants based upon the relative fair value amounts of the fair value of the notes and the estimated fair value of the warrants. The 2008 New Warrants had a fair value of \$1,853,616 upon issuance, measured utilizing the Black Scholes fair value methodology using assumptions of 8 years for expected term, volatility of 200%, no dividends and a risk free interest rate of 1.76%. This resulted in a debt discount of \$181,732 apportioned to the 2008 New Warrants recorded as additional paid in capital and the balance of \$20,176 was reflected on the Company's balance sheet as long term notes as of December 31, 2008. The debt discount of \$181,732 will be accreted to the 11% Notes as interest expense over the life of the 11% Notes and such accretion totaled \$34,800 for the three months ended March 31, 2009. The following table summarizes activity in the 11% Notes payable and the related interest expense for the three months ended March 31, 2009:

|   | 11% Notes  | Interest<br>expense |
|---|------------|---------------------|
| 11% Notes issued during the year ended<br>December 31, 2008   | \$ 201,908 | \$                  |
| Apportionment of net proceeds to 2008 New<br>Warrants recorded as additional paid in capital<br>(11% Note discount) | (181,732)  |                     |
| 11% Notes balance at December 31, 2008  | 20,176     |                     |
| 11% Notes issued during the three months ended<br>March 31, 2009  | 51,374     |                     |
| Accretion of 11% Note discount to interest expense  | 34,800     | 34,800              |
| 11% nominal interest expense  | 6,686      | 6,686               |
| 11% Notes balance March 31, 2009  | \$ 113,036 | \$ 41,486           |

On February 13, 2009, Synergy sold 285,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$200,000. On March 31, 2009 Synergy sold 280,000 shares of unregistered common stock at \$0.70 per share to two private investors for aggregate proceeds of \$196,000. There were no warrants issued or finder's fees associated with these transactions, although the Company incurred \$5,000 in legal fees. Net proceeds during the three month ended March 31, 2009 was \$391,000. The \$191,000 net proceeds from the 280,000 shares sold on March 31, 2009 were included in cash in escrow at March 31, 2009 and were deposited into the Company's cash account April 2 and 13, 2009.

**9. Subsequent events**

On April 15, 2009 Synergy sold 1,045,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$732,000.



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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, 2008 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.

Callisto Pharmaceuticals, Inc. (which may be referred to as "Callisto", "the Company", "we" or "us") was incorporated under the laws of the State of Delaware in May 2003. Our principal offices are located at 420 Lexington Avenue, Suite 1609, New York, NY 10170. We are a development stage biopharmaceutical company focused primarily on the development of drugs to treat neuroendocrine cancer (including advanced carcinoid cancer), rheumatoid arthritis ("RA"), acute leukemia and gastrointestinal ("GI") disorders and diseases. Our lead drug candidates are as follows:

1. SP-304, a guanylyl cyclase C ("GC-C") receptor agonist, to treat GI disorders, primarily chronic constipation ("CC") and constipation-predominant irritable bowel syndrome ("IBS-C"), currently being developed by our majority-owned subsidiary, Synergy Pharmaceuticals, Inc. ("Synergy").
2. Atiprimod, an orally administered drug with antiproliferative and antiangiogenic activity.
3. L-Annamycin, a novel compound from the anthracycline family of proven anti-cancer drugs, which has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart.

From inception through March 31, 2009, we have sustained cumulative net losses available to common stockholders of \$92,281,353. Our 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, 2009, 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.

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Our product development efforts are thus in their early stages and we cannot make estimates of the costs or the time they will take to complete. The risk of completion 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, our ability to raise additional capital, the nature and timing of research and development expenses and competing technologies being developed by organizations with significantly greater resources.

Net cash used in operating activities was \$701,687 during the three months ended March 31, 2009 as compared to \$3,032,842 for the three months ended March 31, 2008. During the three months ended March 31, 2009 and 2008 we incurred net losses available to common stockholders of \$1,294,086 and \$2,991,758, respectively. To date our sources of cash have been primarily limited to the sale of equity securities. Net cash provided by financing activities for the three months ended March 31, 2009 and 2008 and for the period from June 5, 1996 (inception) to March 31, 2009, was \$445,240, \$0 and \$49,454,528, respectively. On April 15, 2009 Synergy sold 1,045,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$732,000.

**Recent Developments**

On February 13, 2009, we sold 285,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$200,000. On March 31, 2009 we sold 280,000 shares of unregistered common stock at \$0.70 per share to two private investors for aggregate proceeds of \$196,000. There were no warrants issued or finder's fees associated with these transactions, although we incurred \$5,000 in legal fees. Net proceeds during the three month ended March 31, 2009 was \$391,000. The \$191,000 net proceeds from the 280,000 shares sold on March 31, 2009 were included in cash in escrow at March 31, 2009 and were deposited into into our cash account April 2 and 13, 2009.

On January 27, 2009, we announced that we were focusing all further development of Atiprimod towards the treatment of RA. We recognized that although the ongoing Phase II clinical trial of Atiprimod in advanced carcinoid cancer gave encouraging results, the data were not sufficiently demonstrative to warrant further development of Atiprimod in this indication. We announced, instead, our intention that based on Atiprimod's demonstrated favorable clinical safety profile, robustly supported by earlier studies of Atiprimod in RA patients, as well as by the recent oncology trials in advanced carcinoid cancer patients, where the drug was dosed at levels and frequencies considerably higher than anticipated for use in RA, we believe that Atiprimod holds significant promise as a new class of orally-administered, disease-modifying agent in RA.

On December 30, 2008, Callisto entered into a securities purchase and exchange agreement ("Purchase Agreement") with several investors, each of whom were holders of record as of November 4, 2008 of outstanding warrants to purchase shares of the Company's common stock, exercisable at \$0.50 or \$0.70 per share until August 2, 2010 ("Series B Warrants"). The Series B Warrants were issued in connection with the private placement of the Company's Series B Preferred Shares on August 2, 2007. Pursuant to the Purchase Agreements Callisto issued \$201,908 of an authorized \$500,000 11% Secured Notes due April 15, 2010 ("11% Notes") with no discount. Interest on the 11% Notes is due at maturity and repayment of the 11% Notes is secured by a pledge of up to 1,900,000 shares (if all \$500,000 principal amount of the 11% Notes is sold) of the common stock of Synergy owned by us. On February 3, 2009 Callisto issued an additional \$51,374 of the 11% Notes bringing the aggregate proceeds from issuance of 11% Notes since inception to \$253,282.

**OFF-BALANCE SHEET ARRANGEMENTS**

We had no off-balance sheet arrangements as of March 31, 2009.

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**RESULTS OF OPERATIONS**

**THREE MONTHS ENDED MARCH 31, 2009 AND MARCH 31, 2008**

We had no revenues during the three months ended March 31, 2009 and 2008 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses decreased \$1,618,961 or 80% to \$398,022 for the three months ended March 31, 2009 from \$2,016,983 for the three months ended March 31, 2008. This decrease in research and development expense was attributable to significant curtailment in all program expenses incurred with outside contract research organizations ("CROs"), including pre-clinical animal testing, drug formulation, tableting, hospital patient costs, blood testing and FDA consultants. Our SP-304 program expenses decreased by \$1,301,046 or 88% to \$174,901 for the three months ended March 31, 2009 from \$1,475,947 during the three months ended March 31, 2008. Also contributing to this reduction were lower Annamycin program expenses which decreased by \$67,621 or 59% to \$46,498 for the three months ended March 31, 2009 from \$114,119 during the three months ended March 31, 2008.

Research and development in-house overhead, not allocated to specific programs, totaled approximately \$148,000 and \$382,000 during the three months ended March 31, 2009 and 2008, respectively, a decrease of approximately \$234,000, or 61%. This decrease was attributable to lower compensation costs as a result of terminating in-house clinical monitors.

General and administrative expenses for the three months ended March 31, 2009 decreased \$63,736 or 6%, to \$956,576 for the three months ended March 31, 2009 from \$1,020,312 for the three months ended March 31, 2008. This decrease was primarily due to lower corporate legal (down \$25,119 or 62%), and lower investor relations costs (reduced \$48,625 or 57%).

Net loss available to common stockholders for the three months ended March 31, 2009 decreased \$1,697,671 or 57% to \$1,294,086 compared to a net loss of \$2,991,758 incurred for the three months ended March 31, 2008. The decreased net loss is the result of lower research and development, and general and administrative expenses discussed above, plus (i) lower interest income (\$45,326) attributable to lower cash balances, (ii) higher interest expense (\$41,486) attributable to the 11% Notes, (iii) a \$217,103 charge incurred to increase the estimated fair value of the derivative liabilities during the three months ended March 31, 2009 and (iv) \$318,890 of net losses attributable to the non-controlling interest in Synergy, our majority owned subsidiary.

**LIQUIDITY AND CAPITAL RESOURCES**

As of March 31, 2009 we had \$44,876 in cash and cash equivalents, compared to \$301,323 as of December 31, 2008. We had a working capital deficit of \$4,976,391 as of March 31, 2009.

Net cash used in operating activities was \$701,687 during the three months ended March 31, 2009 as compared to \$3,032,842 for the three months ended March 31, 2008. To date our sources of cash have been primarily limited to the sale of equity securities. Net cash provided by financing activities for the three months ended March 31, 2009 and 2008 and for the period from June 5, 1996 (inception) to March 31, 2009, was \$445,240, \$0 and \$49,454,528, respectively.

On February 13, 2009, we sold 285,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$200,000. On March 31, 2009 we sold 280,000 shares of unregistered common stock at \$0.70 per share to two private investors for aggregate proceeds of \$196,000. There were no warrants issued or finder's fees associated with these transactions, although we incurred \$5,000 in legal fees. Net proceeds during the three month ended March 31, 2009 was

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\$391,000. The \$191,000 net proceeds from the 280,000 shares sold on March 31, 2009 were included in cash in escrow at March 31, 2009 and were deposited into into our cash account April 2 and 13, 2009.

On April 15, 2009 Synergy sold 1,045,714 shares of unregistered common stock at \$0.70 per share to a private investor for aggregate proceeds of \$732,000.

Worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain depressed for the foreseeable future. These developments will make it more difficult for us to obtain additional equity or credit financing, when needed. We have accordingly taken steps to conserve our cash which include extending payment terms to our vendors and suppliers as well as management and staff cuts and salary deferrals. These actions may not be sufficient to allow the Company time to raise additional capital.

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of pharmaceutical research and development programs. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates, to fund the existing working capital deficit and to continue to fund operations at our current cash expenditure levels. To date, our sources of cash have been primarily limited to the sale of equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more of 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 license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Our consolidated financial statements as of March 31, 2009 and December 31, 2008 have been prepared under the assumption that we will continue as a going concern for the twelve months ending December 31, 2009. Our independent registered public accounting firm has issued a report dated April 15, 2009 that included an explanatory paragraph referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## **CRITICAL ACCOUNTING POLICIES**

We prepare our financial statements in conformity with accounting principles generally accepted in the U.S. The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and contingent liabilities, at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Because of the uncertainty of factors surrounding the estimates or assumptions used in the preparation of the consolidated financial statements, actual results may vary from these estimates.

## **Share-Based Payments**

We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options is designed to provide long-term incentives, develop and maintain an ownership stake and

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conserve cash during our development stage. Since inception through December 31, 2008 stock-based compensation expense has totaled \$17,929,286 or 19% of our net loss available to common stockholders of \$92,281,353.

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard ("SFAS") No. 123 (Revised 2004), *Share-Based Payments* ("SFAS No. 123R"). SFAS No. 123R requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award.

SFAS No. 123R did not change the way we account for non-employee stock-based compensation. We continue 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. Stock-based compensation expense associated with these non-employee option grants is being recorded in accordance with EITF 96-18 and accordingly (i) the measurement date will be when "performance commitment is completed" and accordingly the fair value of these options is being "marked to market" quarterly until the measurement date is determined.

Upon adoption of SFAS No. 123R, we selected the Black-Scholes option pricing model as the most appropriate model for determining the estimated fair value for stock-based awards. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Expected volatility was calculated based on our historical volatility. Our stock price has fluctuated from \$3.95 per share as of December 31, 2003 to \$0.08 per share as of March 31, 2009. The expected term was determined based on the simplified method provided in Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment*, ("SAB No. 107"). The risk-free interest rate is based on observed interest rate appropriate for the expected term of our stock options. Forfeitures are estimated, based on our historical experience, at the time of grant.

#### **Research and Development**

We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all and therefore our research and development costs are expensed as incurred. These include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of our proposed products, purchase of in-process research and development, regulatory and scientific consulting fees, contract research and royalty payments to outside suppliers, facilities and universities as well as legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products. While certain of our research and development costs may have future benefits, our policy of expensing all research and development expenditures is predicated on the fact that we have no history of successful commercialization of biopharmaceutical products to base any estimate of the number of future periods that would be benefitted.

#### **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, 2009 we had no money market balances and no exposure to market risk.

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**ITEM 4T. 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, 2009, our Chief Executive Officer and Principal Financial Officer have concluded that 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, 2008. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls. Based on this evaluation, management determined that, as of December 31, 2008, there were material weaknesses in our internal control over financial reporting. The material weaknesses identified during management's assessment were (i) a lack of sufficient internal accounting expertise to provide reasonable assurance that our financial statements and notes thereto, are prepared in accordance with generally accepted accounting principles (GAAP) and (ii) a lack of segregation of duties to ensure adequate review of financial statement preparation. In light of these material weaknesses, management concluded that, as of December 31, 2008, we did not maintain effective internal control over financial reporting. As defined by the Public Company Accounting Oversight Board Auditing Standard No. 5, 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.

The condensed consolidated financial statements as of and for the period ended March 31, 2009 include all adjustments identified as a result of the evaluation performed.

**CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING**

As of March 31, 2009 we are in the process of remediating the material weaknesses which existed at December 31, 2008. We plan to add financial staff resources to our accounting and finance department when funding becomes available and implement certain other controls and procedures which management believes will prevent the recurrence of the material weakness described above. However, it will require a period of time to determine the operating effectiveness of these newly implemented internal controls over financial reporting. We plan to be testing and re-evaluating our controls periodically during 2009.

Other than described above there were no changes in our internal controls over financial reporting that could significantly affect internal controls over financial reporting during the quarter ended March 31, 2009.

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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, 2008.

**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, 2008.

**ITEM 6. EXHIBITS**

(a)

Exhibits

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

