

CALLISTO PHARMACEUTICALS INC

Form 8-K

December 12, 2005

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

**FORM 8-K**

**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 11, 2005

**Callisto Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

Delaware	001-32325	13-3894575
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(IRS Employer Identification No.)

420 Lexington Avenue, Suite 1609  
New York, New York 10170  
(Address of principal executive offices)

Registrant's telephone number, including area code: (212) 297-0010

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
- 
- 
-

**Item 7.01 Regulation FD Disclosure.**

In accordance with General Instruction B.2. of Form 8-K, the following information shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended. Callisto Pharmaceuticals, Inc. disclaims any intention or obligation to update or revise this information.

Callisto Pharmaceuticals, Inc. intends to continue the current Phase I/II trial of Atiprimod at higher dose levels to define the MTD (Maximum Tolerated Dose) and to enroll 10 additional patients at this dose. All future patients will receive concomitant treatment with Ursodiol, a FDA approved bile acid, that has been shown to mitigate against liver toxicity. Callisto is encouraged by the initial activity observed and believes greater efficacy can be demonstrated at the higher doses planned in the extension of this clinical trial.

---

**SIGNATURE**

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

Dated: December 12, 2005

CALLISTO PHARMACEUTICALS, INC.

By: /s/ Gary S. Jacob

---

Gary S. Jacob, Ph.D.  
Chief Executive Officer