CALLISTO PHARMACEUTICALS INC
Form 8-K
February 03, 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): February 3, 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 8.01 OTHER EVENTS.

Callisto Pharmaceuticals, Inc. (the "Company") hereby discloses a

description of complete responses in a Phase I study of Annamycin in patients with relapsed/ refractory acute myeloid ("AML") and lymphoid leukemias ("ALL").

Twenty-one patients with relapsed/refractory AML (n=18) or ALL (n=3) were enrolled in this Phase I trial which commenced in April 1999 at The University of Texas M.D. Anderson Cancer Center with Dr. Michael Andreeff as the Principal Investigator. The study enrolled 21 patients, of which 20 were evaluable. An abstract on the outcome of this trial was presented at the 2001 ASCO Annual Meeting, Abstract No. 1211. Of the 21 registered patients, one patient (AML) was enrolled but not treated. The median age of patients in the trial was 58. The maximum tolerated dose ("MTD") in the leukemia trial was determined to be 280 mg/m2 daily x 3 days with grade 3/4 hepatoxicity and mucositis observed at the higher dose level. Two patients achieved complete responses ("CR"), one AML and one ALL patient. The AML patient achieved a CR at 280 mg/m2/day X 3 days, taking 5 weeks to achieve CR with two consolidations. The CR duration was 13 weeks, and the patient failed further salvage. Survival post treatment was 30 weeks. The ALL patient achieved a CR at 350 mg/m2/day X 3 days, taking 6 weeks to achieve CR with one consolidation, with clearance of CNS leukemia. The CR duration was 5+ weeks, and the patient expired in CR. Survival post treatment was 11 weeks.

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: February 3, 2005

CALLISTO PHARMACEUTICALS, INC.

By: /s/ Gary S. Jacob

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