

Edgar Filing: CYTODYN INC - Form 8-K

CYTODYN INC
Form 8-K
September 29, 2009

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) September 28, 2009

CytoDyn, Inc.

(Exact name of registrant as specified in its charter)

Colorado

000-49908

75-3056237

(State or other jurisdiction
incorporation)

(Commission File Number)

(IRS Employer of
identification No.)

1511 Third Street, Santa Fe, NM 87505

(Address of Principal Executive Offices) (Zip Code)

(505) 988-5520

(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)
227 E. Palace Ave, Suite M, Santa Fe, NM 87501

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

- Written communications 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))

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Item 8.01 Other Event

CytoDyn has entered into an agreement to provide financial support and free GMP product to Massachusetts General Hospital for the purpose of conducting an ex-vivo study of Cytolin(R), the Company's lead drug. The study will enroll 10 adults with early HIV infection and 10 healthy controls, each of whom will be required to participate for six months. This study, which is intended as a prelude to an in vivo study, will take advantage of the state-of-the-art laboratories available at Massachusetts General Hospital to confirm, and perhaps sharpen, the previously demonstrated role of killer T cells in causing the wholesale loss of CD4 T cells in humans infected with HIV, as well as the mechanisms of action responsible for the clinical benefits seen in patients treated with Cytolin(R).

The Principal Investigator for the study is Eric S. Rosenberg, MD, an Associate Professor of Medicine in the Infectious Diseases Division of Massachusetts General Hospital and a prominent researcher specializing in HIV/AIDS. The study is being initiated by the Principal Investigator, who designed the study protocol, and is being sponsored by Massachusetts General Hospital.

The costs associated with this study are estimated to be approximately \$316,000 of which 50% or \$158,000 has already been paid to Massachusetts General Hospital by CytoDyn, along with a \$2,500 fee for the Institutional Review Board (IRB). The company has raised all the capital required for this study through a company offering of preferred shares.

This agreement with Massachusetts General Hospital is a departure from the Company's previously announced strategy for developing Cytolin(R) and from the traditional model of drug development under which clinical studies are conducted strictly for the purpose of demonstrating the safety and efficacy of a new drug. However, management believes that because of new economic and regulatory realities, it is in the interests of CytoDyn to support this study sponsored by Massachusetts General Hospital, which is intended to confirm, and perhaps sharpen, the scientific breakthrough underlying Cytolin(R).

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
10.1	Clinical Trial Agreement between CytoDyn, Inc. and The General Hospital Corporation

SIGNATURE

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

CytoDyn, Inc.

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Date: September 29, 2009

/s/ Allen D. Allen

Allen D. Allen