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CYTOGEN CORP
Form 8-K
March 03, 2005

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 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): March 3, 2005

CYTOGEN CORPORATION

(Exact Name of Registrant as Specified in Charter)

| | | |
|--|-----------------------------------|--|
| Delaware | 000-14879 | 22-2322400 |
| ----- (State or Other Jurisdiction of Incorporation) | ----- (Commission File Number) | ----- (I.R.S. Employer Identification No.) |
| 650 College Road East, CN 5308, Suite 3100, Princeton, NJ | | 08540 |
| ----- (Address of Principal Executive Offices) | | ----- (Zip Code) |

Registrant's telephone number, including area code: (609) 750-8200

(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 (see General Instruction A.2. below):

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 EVENTS.

On March 3, 2005, Advanced Magnetics, Inc. and Cytogen Corporation announced that the U.S. Food and Drug Administration's Oncologic Drugs Advisory Committee (ODAC) voted 15 to 4 to not recommend approval of the proposed indication for Combidex(R), Advanced Magnetics' investigational functional molecular imaging agent. In making its recommendation, the committee cited insufficient clinical data to support a broad indication for use of Combidex to differentiate metastatic from non-metastatic lymph nodes across all cancer types.

Combidex (ferumoxtran-10) consists of iron oxide nanoparticles for use in conjunction with magnetic resonance imaging (MRI) to aid in the differentiation of cancerous from non-cancerous lymph nodes.

Combidex received an approvable letter, subject to certain conditions, from the FDA in June 2000. In September 2004, Advanced Magnetics submitted a complete response to the approvable letter. A decision by the FDA on Combidex is expected by the FDA-designated user fee goal date of March 30, 2005.

The full text of the March 3, 2005 press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference. The foregoing description is qualified in its entirety by reference to such Exhibit.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(c) Exhibits.

| Exhibit No. ----- | Description ----- |
|----------------------|---|
| 99.1 | Press Release of Advanced Magnetics and Cytogen dated March 3, 2005 |

SIGNATURES

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

CYTOGEN CORPORATION

By: /s/ William J. Thomas

William J. Thomas
Senior Vice President and General Counsel

Dated: March 3, 2005

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EXHIBIT INDEX

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