GENTA INC DE/
Form 8-K
March 17, 2008

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 17, 2008**

GENTA INCORPORATED

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

0-19635
(Commission File Number) **33-0326866**
(IRS Employer Identification No.) **200 Connell Drive**
Berkeley Heights, NJ
(Address of Principal Executive Offices) **07922**
(Zip Code)

(908) 286-9800
(Registrant s Telephone Number, Including Area Code)

(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:

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

Item 8.01 Other Events.

On March 17, 2008, Genta Incorporated, (the Company), announced that the Food and Drug Administration s (FDA) Center for Drug Evaluation and Research (CDER) has decided that available data are not adequate to support approval of Genasense® (oblimersen sodium) Injection for treatment of patients with relapsed or refractory chronic lymphocytic leukemia (CLL). In a decision issued in response to an appeal filed by Genta in October 2007, CDER acknowledged that complete response, which was the primary endpoint in the pivotal trial, was an appropriate endpoint for assessing efficacy. FDA also agreed that this endpoint was achieved, and that those results supported the efficacy of the drug. However, CDER concluded that at present there was insufficient confirmatory evidence in the New Drug Application (NDA) to approve the drug.

CDER recommended two alternatives for exploring the efficacy of Genasense that could provide such confirmatory evidence. One option is to conduct an additional clinical trial. The other option is to collect additional information regarding the clinical course and progression of disease in patients from the previous pivotal trial in order to ascertain whether those data contain sufficient confirmatory evidence. The Company currently plans to pursue both of these options.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Description**
99.1	Press Release of the Company dated March 17, 2008

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.

GENTA INCORPORATED

Date: March 17, 2008

By:

/s/ GARY SIEGEL

Name: Gary Siegel

Title: Vice President Finance

EXHIBIT INDEX

Exhibit Number	**Description**	**Sequentially Numbered Page**
99.1	Press Release of the Company dated March 17, 2008	