

GENTA INC DE/
Form 8-K
March 09, 2009

**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 6, 2009**

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:

- ☐ 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 6, 2009, 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 December 2008, CDER concluded that new information submitted by the Company in its amended New Drug Application (NDA) was insufficient, and the Agency has recommended conducting a confirmatory clinical trial.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company dated March 6, 2009

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 6, 2009

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 6, 2009	