GENTA INC DE/
Form 8-K
July 14, 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): July 14, 2008
GENTA INCORPORATED
(Exact Name of Registrant
as Specified in Its Charter)
Delaware
(State or Other Jurisdiction of Incorporation)

0-19635	**33-0326866**
(Commission File Number)	(IRS Employer Identification No.)
200 Connell Drive **Berkeley Heights, NJ**	**07922**
(Address of Principal Executive Offices)	(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 July 14, 2008, Genta Incorporated, (the Company), announced that the Food and Drug Administration (FDA) has accepted the Company s amendment to its New Drug Application (NDA) for Genasense® (oblimersen sodium) Injection as a complete response . The NDA proposed the use of Genasense plus chemotherapy for patients with relapsed or refractory chronic lymphocytic leukemia (CLL). The recent submission was based on new information from the Company s completed, randomized Phase 3 trial that showed, among other findings, a significant increase in overall survival for patients who achieved a complete or partial response when treated with Genasense plus chemotherapy compared with patients treated with chemotherapy alone.

The amendment responds to a communication received in March 2008 from FDA s Center for Drug Evaluation and Research (CDER) that denied Genta s appeal of a prior non-approvable decision of the Genasense NDA in December 2006. That communication described a regulatory path forward that included but was not limited to determination of long-term survival in patients who entered the study. FDA has informed the Company that it considers Genta s complete response as a Class 2 resubmission with a Prescription Drug User Fee Act (PDUFA) goal date of December 3, 2008.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company dated July 14, 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: July 14, 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 July 14, 2008	