GENTA INC DE/
Form 8-K
June 04, 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): **May 29, 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 May 29, 2008, Genta Incorporated, (the Company), announced the results of long-term followup from a Phase 3 trial of the Company s lead oncology product, Genasense® (oblimersen sodium) Injection, in patients with chronic lymphocytic leukemia (CLL). With 5 years of followup, new data show that patients who achieved either a complete response (CR the trial s primary endpoint) or a partial response (PR) have also achieved a statistically significant increase in overall survival. The data was featured in an oral presentation at the annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago on June 2, 2008.

In the Phase 3 trial, 241 patients with relapsed or refractory CLL were randomly assigned to receive chemotherapy with fludarabine plus cyclophosphamide (Flu/Cy) with or without Genasense. This study achieved its primary endpoint, which was a statistically significant increase in the proportion of patients who achieved a complete or nodular partial response (CR) with the addition of Genasense to the Flu/Cy regimen. (17% vs. 7%; P=0.025). In addition, the median duration of CR was also significantly longer for patients treated with Genasense (median not reached but estimated to exceed 36 months vs. 22 months).

Previous analyses showed a significant benefit in overall survival accrued to patients who attained CR. Extended followup has shown that all major responses (CR+PR) achieved with Genasense have now been associated with significantly increased overall survival compared with all major responses achieved with chemotherapy alone (median = 56 months vs. 38 months, respectively). At 5 years, 22 of 49 (45%) responders in the Genasense group remain alive compared with 13 of 54 (24%) responders in the chemotherapy-only group (HR = 0.6; P = 0.038).

On May 30, 2008, the Company announced preliminary results that have shown a high objective response rate in a pilot study that incorporates Genasense in a chemotherapy program for patients with advanced melanoma. In this study, Genasense was used to potentially enhance the clinical activity of temozolomide (Temodar®; Schering Plough, Inc.), the most commonly used anticancer drug for melanoma, combined with Abraxane® (paclitaxel protein-bound particles for injectable suspension; Abraxis Bioscience, Inc.). The data was featured in a presentation at the annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago on June 1, 2008.

All 14 of the first cohort of patients accrued to this study had non-resectable stage 4 melanoma. None had previously received chemotherapy, and their baseline LDH did not exceed 1.1 times the upper limit of normal. (LDH is a tumor-derived blood marker that was shown to affect the response to Genasense plus chemotherapy in a recent randomized trial.) To date, 6 patients (43%) have achieved major objective responses: one with complete response (CR) after 6 cycles of treatment, and 5 with at least a partial response after only one treatment cycle. Three additional patients have maintained stable disease (SD) after at least three treatment cycles, for an overall clinical benefit response (CR+PR+SD) of 64%.

On June 2, 2008, the Company announced the release of final results from a Phase 1 clinical trial of G4544, a proprietary small molecule that is intended as a treatment for diseases associated with accelerated bone loss. Results showed that the drug was very well-tolerated, and that blood levels were achieved in a range that is known to be clinically bioactive. The data were featured in a poster session at the annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago on Saturday May 31, 2008.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| **Exhibit Number** | **Description** |
| --- | --- |
| 99.1 | Press Release of the Company dated May 29, 2008 |
| 99.2 | Press Release of the Company dated May 30, 2008 |
| 99.3 | Press Release of the Company dated June 2, 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: June 4, 2008

By:

/s/ GARY SIEGEL

Name: Gary Siegel
Title: Vice President, Finance

**EXHIBIT INDEX**

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