

GENTA INC DE/
Form 8-K
October 06, 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): October 6, 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:

- ☐ 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))

Item 8.01 Other Events.

On October 6, 2008, Genta Incorporated, (the Company), announced the presentation of a progress update from the Company's ongoing Phase 3 trial of Genasense® (oblimersen sodium) Injection, Genta's lead oncology product, in patients with advanced melanoma. A pooled analysis of data from this study, which remains blinded, was compared with the Company's previous data from a similarly designed randomized trial. The comparative analysis shows that to date AGENDA has enrolled patients with similar demographics, and also that the aggregate incidence of serious adverse events is comparable. The data were presented this past weekend by Dr. Agop Bedikian at an international symposium entitled *Perspectives in Melanoma XII* in The Hague, The Netherlands.

AGENDA is a Phase 3, randomized, double-blind, placebo-controlled trial that is intended to support global registration of Genasense for patients with advanced melanoma. The study is designed to confirm certain safety and efficacy results from Genta's prior randomized trial of Genasense combined with dacarbazine (DTIC) in patients identified by a biomarker who have not previously received chemotherapy. The co-primary endpoints of AGENDA are progression-free survival and overall survival.

To date, approximately 60% of the planned 300 patients have been accrued. Target accrual of 300 patients is expected to complete in the first quarter of 2009. Clinical characteristics of the first 150 patients accrued to AGENDA (not identified by treatment group) were shown to be similar to the biomarker-defined population that was accrued in the previous Phase 3 trial of Genasense, known as GM301. Moreover, the overall incidence of serious adverse events in AGENDA has been comparable to this population in the preceding trial.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

**Exhibit
Number**

Description

99.1	Press Release of the Company dated October 6, 2008
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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: October 6, 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 October 6, 2008	