

GENTA INC DE/
Form 8-K
April 30, 2007

**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): April 27, 2007

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:

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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 April 27, 2007, Genta Incorporated, (the Company), issued a press release announcing that it has received notice from the European Medicines Agency (EMA) that the Committee for Medicinal Products for Human Use (CHMP) has adopted a negative opinion for the Company's marketing authorization application (MAA) for Genasense® (oblimersen). The MAA proposes the use of Genasense plus dacarbazine for treatment of patients with advanced melanoma. The Company had previously announced its anticipation of this negative opinion on March 23, 2007.

In a separate action, the Company will file a formal complaint and request for correction of information with the U.S. Food and Drug Administration (FDA) under the Federal Data Quality Act. The complaint will challenge as erroneous a key statistical analysis of the Company's data on Genasense for melanoma used by FDA at the Oncology Drug Advisory Committee meeting on May 3, 2004. That analysis sought to discredit the finding that Genasense yielded a statistically significant increase in progression-free survival (PFS). At that meeting, ODAC voted unanimously that PFS was an endpoint that would support full approval in the absence of a survival improvement in patients with advanced melanoma. The Company will seek a formal public acknowledgement of the error, removal of the analysis from the FDA website (with a note that the previous analysis was in error), and revision of the transcript.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit Number | Description |
|---------------------------|---|
| 99.1 | Press Release of the Company dated April 27, 2007 |

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: April 27, 2007

By: /s/ RICHARD J. MORAN

Name: Richard J. Moran

Title: Senior Vice President, Chief
Financial Officer and
Corporate Secretary

EXHIBIT INDEX

| Exhibit Number | Description | Sequentially Numbered Page |
|---------------------------|---|---------------------------------------|
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