

GENTA INC DE/  
Form 8-K  
May 31, 2012

---

---

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 31, 2012

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 May 31, 2012, Genta Incorporated announced that the first patient has been accrued to a new randomized trial of tesetaxel as initial chemotherapy for women with advanced or recurrent breast cancer. The trial -- a randomized, three-arm, Phase 2b study that is expected to accrue approximately 220 patients -- will be conducted at approximately 15 sites in the U.S. and Western Europe. Accrual is projected to take approximately 12 months, with approximately 12 months of followup. Tesetaxel is the leading oral taxane in clinical development.

The trial will enroll women who have not previously received chemotherapy for metastatic or recurrent disease. Eligible patients who are HER2-negative (including so-called "triple negative" patients) may have received adjuvant chemotherapy and hormonal therapy. In this study, which compares two oral chemotherapy agents, patients will be randomized to one of three treatment groups: tesetaxel administered once every 3 weeks; tesetaxel administered once weekly for 3 consecutive weeks; or capecitabine (Xeloda®; Hoffmann La Roche, Inc.) administered twice per day for 14 consecutive days. The primary endpoint of the trial is overall response rate; secondary endpoints include progression-free survival and safety.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

| Number | Description                                     |
|--------|---|
| 99.1   | Press Release of the Company dated May 31, 2012 |

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: May 31, 2012

By: /s/ GARY SIEGEL  
Name: Gary Siegel  
Title: Vice President, Finance