

GENTA INC DE/
Form 8-K
May 08, 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 8, 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)

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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))
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Item 8.01 Other Events.

On May 8, 2012, Genta Incorporated announced that the first patient has been accrued to a new randomized clinical trial of its lead compound, tesetaxel, in patients with advanced gastric cancer. The trial, known as TESEGAST, is a randomized, double-blind, placebo-controlled study that is expected to accrue approximately 260 patients. The trial will be conducted at approximately 40 sites worldwide, including the U.S., Western Europe, and Asia. Accrual is projected to take approximately 12-15 months, with approximately 9 months of followup after the last patient is randomized.

The trial will enroll patients with advanced gastric cancer who have measurable disease that has progressed after initial chemotherapy. Prior treatment must have included a platinum-containing drug and a fluoropyrimidine. Testing for HER2 expression is required; HER2+ patients must have received and progressed on trastuzumab (Herceptin®; Hoffmann La Roche, Inc.). In this “all-oral” chemotherapy program, eligible patients will receive capecitabine (Xeloda®; Hoffmann La Roche, Inc.) and will be randomly assigned to receive capsules of tesetaxel or placebo. The primary endpoint of the trial is overall survival; secondary endpoints include overall response, 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 8, 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

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|-------|-------------|--------|-------------------------|
| Date: | May 8, 2012 | By: | /s/ GARY SIEGEL |
| | | Name: | Gary Siegel |
| | | Title: | Vice President, Finance |