GENTA INC DE/
Form 8-K
January 19, 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): January 19, 2012

GENTA INCORPORATED
(Exact Name of Registrant
as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

0-19635	33-0326866
(Commission File Number)	(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 January 19, 2012, Genta Incorporated ("the Company") announced results from the Company's Phase 2b, confirmatory clinical trial of tesetaxel in patients with advanced gastric cancer. The trial is lead by investigators from M.D. Anderson Cancer Center, Houston, TX, in collaboration with Northwestern University, Chicago, IL, University of Pennsylvania, Philadelphia, PA, and the Severance Hospital, Seoul, Korea. The data are being presented this week at the GI Cancer Symposium in San Francisco, CA, sponsored by the American Society of Clinical Oncology (ASCO).

The study has enrolled 41 patients who progressed on at least one prior chemotherapy regimen that included a platinum compound (cisplatin, oxaliplatin, or carboplatin) and a fluoropyrimidine compound (5-fluorouracil [5-FU] or capecitabine [Xeloda®; Hoffman-La Roche, Inc.]). Two patient cohorts were treated over a range of "flat" (as opposed to "weight-based") doses starting at 40-45 mg (Cohort 1) and 50-60 mg (Cohort 2), whereas Cohort 3 used weight-based dosing at the maximally tolerable dose (MTD) of 27 mg/m2. Doses were repeated every 3 weeks, and overall response rate (ORR) was the trial's primary endpoint.

The ORR in Cohort 3, which remains open to accrual, was 20% in patients treated with tesetaxel as 2nd-line therapy. Body weight variation resulted in under-dosing relative to the MTD in Cohorts 1 and 2, which yielded ORRs of 8% and 15%, respectively. Median survival has not been reached in Cohort 3, whereas median survival in Cohorts 1 and 2 was 7.6 and 7.5 months, respectively. Overall survival (OS) is the primary endpoint in planned Phase 3 studies of tesetaxel in gastric cancer.

The standard taxane docetaxel (Taxotere®; Sanofi, Inc.), is approved for 1st-line treatment of advanced gastric cancer. However, four studies have shown that docetaxel, when used as 2nd-line therapy in patients with advanced gastric cancer, achieved an ORR ranging from 5% to 19% and median OS ranging from 3.5 to 8.4 months.

Tesetaxel has been generally well-tolerated. The most common Grade 3-4 adverse events have been fatigue and anemia (17%), followed by neutropenia (15%) and nausea (10%). Consistent with prior studies, no hypersensitivity reactions were observed.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company dated January 19, 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: January 19, 2012

By: /s/ GARY SIEGEL

Name: Gary Siegel

Title: Vice President, Finance