GENTA INC DE/
Form 8-K
June 03, 2011

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): June 3, 2011

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 June 3, 2011, Genta Incorporated announced updated interim results from a trial of tesetaxel used as 2nd-line treatment in patients with advanced gastric cancer. The ongoing trial is lead by the M.D. Anderson Cancer Center in Houston, TX. The data are presented in conjunction with the 2011 annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL.

The trial is evaluating 3 cohorts of patients, all of whom had failed one prior chemotherapy regimen that must have included a platinum-containing compound (cisplatin, oxaliplatin, or carboplatin) and a fluoropyrimidine compound (5-fluorouracil [5-FU] or capecitabine [Xeloda®; Hofmann LaRoche, Inc.]). Two patient cohorts were treated over a range of "fixed" (as opposed to "weight-based) doses starting at 40-45 mg (Cohort 1) and 50-60 mg (Cohort 2), whereas Cohort 3 is using conventional weight-based dosing at the previously identified maximally tolerable dose (MTD).

In Cohorts 1 and 2, wide variations in body weight were observed. By example, body surface area (BSA, a composite measure of weight and height), of an average adult male approximates 1.7 m2, whereas the median BSA for patients in the first 2 study cohorts was 1.9 and 2.0 m2, respectively. One major response was observed in each of 11 and 13 patients in the first 2 cohorts, respectively; however, no episodes of > Grade 3 neutropenia were observed in either fixed-dose cohort, suggesting that patients had been substantially under-dosed. Accordingly, Cohort 3 – which is currently open to accrual -- employs a starting dose of 27 mg/m2 with escalation to 35 mg/m2 as tolerated in subsequent cycles. Data from this cohort are too early to evaluate.

Since overall survival (OS) is the primary endpoint in planned Phase 3 studies, an analysis of OS was conducted across all 3 cohorts in which any patient's actual starting dose converted to a weight-based dose of –> 26 mg/m2. With early followup, median OS in this group of 11 patients has not been reached, but currently exceeds a median of 7.5+ months. For context, docetaxel (Taxotere®; Sanofi, Inc.), a standard taxane, is approved for 1st-line treatment of gastric cancer. Four publications have reported the use of docetaxel as 2nd-line therapy in gastric cancer that show response rates ranging from 5% to 19% and median OS ranging from 3.5 to 8.4 months.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company dated June 3, 2011

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: June 3, 2011

By: /s/ GARY SIEGEL

Name: Gary Siegel

Title: Vice President, Finance