GENTA INC DE/
Form 8-K
May 22, 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 22, 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 May 22, 2012, Genta Incorporated announced results from the Company's Phase 2 clinical trial using tesetaxel as initial, single-agent chemotherapy in women with advanced breast cancer. The data will be formally presented at the upcoming annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL. Tesetaxel is the leading oral taxane in clinical development. The trial is lead by Memorial Sloan-Kettering Cancer Center, New York, NY, in collaboration with three other U.S. centers.

Women were eligible if they had not received chemotherapy for locally advanced or metastatic HER2-negative breast cancer. Prior adjuvant chemotherapy was allowed if the recurrence was at least 12 months from the last dose. Forty-six patients were accrued to the trial, and 44 are currently evaluable for response. Seventy percent of patients had received adjuvant chemotherapy; more than 80% of those regimens had included an injectable taxane. More than 50% of patients had received local radiotherapy, and approximately two-thirds had progressed on one or more hormonal therapies.

Major objective responses were observed in 20 of 44 patients (45%), including 1 complete response and 19 partial responses. Seven of the major responders cleared more than 75% of their measurable disease. The disease-control/clinical-benefit rate, which includes major responders and patients with stable disease, was 82%.

Exploratory analyses showed that 17 of 35 patients (49%) whose disease was estrogen receptor positive (ER+) had major responses. Median progression-free survival in the ER+ population was 7.3 months. In women with "triple-negative" disease, which is relatively insensitive to chemotherapy, 3 of 9 patients responded (33%).

Tesetaxel was generally well-tolerated. Neutropenia was the most common Grade 3-4 adverse event. The incidence of Grade 4 neutropenia was sharply reduced (from 32% to 11%) after dose escalation (from the starting level of 27 mg/m2 to 35 mg/m2) was discontinued – a change that has now been incorporated into all protocols. Consistent with prior studies, no hypersensitivity reactions were observed.

"These data confirm results from our prior study, both of which show substantial activity for tesetaxel in patients with advanced, HER2-negative breast cancer", said Dr. Loretta M. Itri, Genta's President, Pharmaceutical Development, and Chief Medical Officer. "Genta is also exploring an alternate dosing schedule in this population using weekly treatment. Based on this favorable experience, and after conferring with regulatory authorities in the U.S. and EU, Genta plans to proceed with a new randomized trial of tesetaxel as initial, single-agent chemotherapy for patients with recurrent breast cancer."

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company dated May 22, 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 22, 2012	By:	/s/ GARY SIEGEL
			Name: Gary Siegel
			Title: Vice President, Finance