GENTA INC DE/
Form 8-K
June 29, 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 29, 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 29, 2011, Genta Incorporated provided a comprehensive update of its clinical trials programs with tesetaxel, the Company's lead investigational drug. The information was presented by Genta's Chairman and Chief Executive Officer, Dr. Raymond P. Warrell, Jr., at the 2011 BIO International Business Forum in Washington, D.C.

Tesetaxel is the leading oral taxane in clinical development. Updates in 7 ongoing or planned clinical trials include the following:

- Breast Cancer: To date, with accrual of 21 patients, the major response rate in evaluable patients continues to exceed 50%. Safety results are consistent with prior studies. Based on these favorable data, two actions are anticipated: (1) expansion of the initial cohort treated on the once-every-3-weeks dosing schedule from 25 to 40 patients; and (2) a protocol amendment to evaluate dosing on an alternate schedule (i.e., once weekly for 3 consecutive weeks) after the dose has been identified from an ongoing study (see below).

- Gastric Cancer: The Company intends to submit a request for Special Protocol Assessment (SPA) of its planned Phase 3 trial of tesetaxel as 2nd-line therapy in patients with advanced gastric cancer to the U.S. Food and Drug Administration (FDA) in Q3 2011. The protocol has completed the "Scientific Advice" process at the European Medicines Agency (EMA) and is currently under review at other global regulatory authorities.

- The confirmatory Phase 2b study of tesetaxel as 2nd-line treatment for patients with advanced gastric cancer, which is currently open in the U.S., will be expanded into Asia with opening of a leading Korean cancer center in Q3 2011.

- Accrual to a study in 1st-line gastric cancer (i.e., escalating doses of tesetaxel in combination with full fixed doses of cisplatin and capecitabine [Xeloda®]) has been completed at the initial dose level. To date, safety results are consistent with prior reports for the drugs used alone. The trial is currently accruing patients at the second dose level (of a planned maximum of four). This dose-finding phase is expected to enroll 12-15 patients. Upon completion of the first phase, the study will expand to an extended multinational trial in approximately 48 patients. This trial is expected to be a "run-in" study for a planned Phase 3 trial in previously untreated patients with advanced gastric cancer.

- A second, U.S.-based, confirmatory safety study of tesetaxel plus capecitabine in patients with advanced cancer has completed accrual. Results, which will be submitted to FDA as part of the SPA request previously noted, are consistent with data from a recently published trial: http://www.ncbi.nlm.nih.gov/pubmed/21547572.

- Dose-Ranging Studies: A study of escalating doses of tesetaxel in Japanese subjects has completed accrual at its initial dose level. The trial is currently accruing patients at a level previously established as the maximally tolerable dose (MTD) in Western subjects.

- Having completed accrual to all lower dose levels, patients are currently being accrued to the weekly dosing schedule at 15 mg/m2 once per week for 3 weeks, followed by one week off. Preliminary data suggests that this new schedule may enable approximately a 30% increase in the amount of drug that can be safely delivered compared with the once every 3 weeks schedule. Upon determination of the MTD, the Company will evaluate the activity and safety of this schedule in patients with breast cancer.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company dated June 29, 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 29, 2011

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

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