

GENTA INC DE/
Form 8-K
June 08, 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 8, 2011

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)

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)

- 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 8, 2011, Genta Incorporated announced updated results from multiple dose-ranging trials of tesetaxel, the leading oral taxane in clinical development. Together, the trials show a consistent and predictable safety profile along with clinical activity used alone or combination with capecitabine (Xeloda®; Hoffman LaRoche, Inc.), the leading oral fluoropyrimidine used in patients with breast cancer and gastric cancer. Updated results, published in conjunction with the 2011 annual meeting of the American Society of Clinical Oncology (ASCO), are summarized as follows:

Three Phase 1 studies of tesetaxel administered as a single agent have been completed. Together, these trials show that 27 mg/m² is a safe starting dose, and that subsequent doses can be escalated to 35 mg/m² depending upon individual patient tolerance. The principal adverse reaction has been neutropenia. Hypersensitivity reactions have not been observed.

Two studies (one completed, one ongoing) have examined the safety, dosing and pharmacokinetics of tesetaxel administered in combination with capecitabine. The completed study, which showed no adverse drug interactions or difference in pharmacokinetics when the drugs were co-administered, was recently published. An abstract of this new report is available here: <http://www.ncbi.nlm.nih.gov/pubmed/21547572>.

Ongoing dose-ranging studies include:

A trial of tesetaxel plus capecitabine administered at the maximally tolerated dose of both agents. The use of this combination is envisioned for future clinical trials, and completion of accrual is expected in June 2011.

A study of tesetaxel in combination with cisplatin and capecitabine as initial therapy for patients with gastric cancer.

A dose-ranging study of tesetaxel (24 to 31 mg/m² every 3 weeks) in Japanese subjects.

A study of tesetaxel administered weekly for 3 consecutive weeks – currently open to accrual at a total dose of 45 mg/m².

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company dated June 8, 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 8, 2011

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