GENTA INC DE/
Form 8-K
February 11, 2009

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): February 11, 2009

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**	**07922**
(Address of Principal Executive Offices)	(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 February 11, 2009, Genta Incorporated, (the Company), announced that it has submitted a proposal to the Food and Drug Administration for a randomized clinical trial of tesetaxel, an oral taxane chemotherapy compound, for Special Protocol Assessment (SPA). A SPA is intended to secure agreement on the design, size, and endpoints of clinical trials that are intended to form the primary basis of an efficacy claim in a New Drug Application (NDA). Genta also expects to seek Scientific Advice from the European Medicines Agency (EMEA) for this study to support a Marketing Authorization Application (MAA). The Company believes tesetaxel is the leading oral taxane currently in clinical development.

The proposed protocol will examine the safety and efficacy of tesetaxel in patients with advanced gastric cancer whose disease has progressed after receiving first-line chemotherapy. Further details of the study will be announced after final agreement is secured with both regulatory agencies. FDA has previously granted Orphan Drug designation to tesetaxel for treatment of patients with advanced gastric cancer

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company dated February 11, 2009

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: February 11, 2009

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

EXHIBIT INDEX

Exhibit Number	Description	Sequentially Numbered Page
99.1	Press Release of the Company dated February 11, 2009	