GENTA INC DE/
Form 8-K
December 04, 2008

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): December 2, 2008
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 December 2, 2008, Genta Incorporated, (the Company), announced that the Company has received a complete response letter from the Office of Oncology Drug Products (OODP) at the Food and Drug Administration (FDA) regarding the Company s amended New Drug Application (NDA) for the use of Genasense® plus chemotherapy in patients with chronic lymphocytic leukemia (CLL). In its letter, OODP indicated that the Division cannot approve the NDA in its present form and suggested the need for an additional clinical study.

On December 4, 2008, the Company announced that it has received notice from the FDA that tesetaxel, the Company s oral taxane in clinical development, has been granted designation as an Orphan Drug for treatment of patients with advanced melanoma. Orphan drug status provides for a period of marketing exclusivity, certain tax benefits, and an exemption from certain fees upon submission of a NDA.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company dated December 2, 2008
99.2	Press Release of the Company dated December 4, 2008

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: December 4, 2008

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 December 2, 2008	
99.2	Press Release of the Company dated December 4, 2008	