

GENTA INC DE/  
Form 8-K  
June 18, 2012

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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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 18, 2012

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)

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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:

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- 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))
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Item 8.01 Other Events.

On June 18, 2012, Genta Incorporated (the “Company”) announced that it has reached agreement with the U.S. Food and Drug Administration (“FDA”) under its Special Protocol Assessment (“SPA”) process for the Company’s proposed Phase 3 trial of oral tesetaxel as initial chemotherapy for women with metastatic breast cancer. The SPA provides FDA agreement that the study design and planned analysis of this Phase 3 trial adequately address objectives necessary to support a regulatory submission. The Company also announced review completion and positive Scientific Advice on the same trial design from the European Medicines Agency (“EMA”).

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit<br>Number | Description                                      |
|-------------------|--|
| 99.1              | Press Release of the Company dated June 18, 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: June 18, 2012

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