

IMMUNOGEN INC  
Form 8-K  
September 05, 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): **September 5, 2008**

**ImmunoGen, Inc.**

(Exact name of registrant as specified in its charter)

**Massachusetts**  
(State or other  
jurisdiction of  
incorporation)

**0-17999**  
(Commission File  
Number)

**04-2726691**  
(IRS Employer  
Identification No.)

**830 Winter Street, Waltham, MA 02451**

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(781) 895-0600**

## Edgar Filing: IMMUNOGEN INC - Form 8-K

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 (*see* General Instruction A.2. below):

- 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 7.01 REGULATION FD DISCLOSURE**

On September 5, 2008, Genentech reported trastuzumab-DM1 (T-DM1) Phase II clinical data at the American Society of Clinical Oncology (ASCO) Breast Cancer Symposium being held in Washington, DC. T-DM1 comprises ImmunoGen's DM1 cell-killing agent linked to Genentech's HER2-targeting antibody, trastuzumab, and is being developed by Genentech under a collaboration agreement with ImmunoGen.

The interim data reported were from the T-DM1 Phase II trial that began in July 2007. The trial is designed to evaluate T-DM1, administered at 3.6 mg/kg every 3 weeks, in approximately 100 efficacy-evaluable patients with HER2-positive metastatic breast cancer that progressed on treatment with HER2-directed therapy plus chemotherapy.

The study protocol included an interim analysis of activity in the first 30 efficacy-evaluable patients and it is these findings which were reported today.

Baseline demographic, disease characteristics and prior therapy information were reported for a total of 31 individuals, as there was one non-evaluable patient treated as well as the 30 evaluable patients. All of these patients had metastatic disease, with 19 (61%) having at least 3 distinct metastatic sites. They all had previously been treated with Herceptin (trastuzumab) plus chemotherapy, with a median time on Herceptin of 76.1 weeks (range: 12-379 weeks). Additionally, 13 (41.9%) of these patients also had received Tykerb (lapatinib) plus chemotherapy. The median duration of treatment with Tykerb among the patients who had received it was 25.3 weeks (range: 14-106 weeks).

The presentation conclusions focused on the findings relevant to the established interim analysis criteria. It was noted that 9 objective responses, as determined by an Independent Review Facility (IRF), were reported among the first 30 evaluable patients. This surpassed the activity criterion for study continuation, which was 5 IRF-assessed objective responses. It also was concluded that the safety profile seen with T-DM1 in this trial to date is similar to that observed in the Phase I study.

The findings section of the presentation included information on the activity of T-DM1 as assessed by a study investigator (the approach used in the T-DM1 Phase I study) as well as the IRF-assessment data. Based on investigator assessment, among the 30 evaluable patients, 1 had a complete response (CR), 12 had a partial response (PR), and 10 had stable disease (SD). The CR was ongoing through Cycle 10 when the patient discontinued treatment under the guidance of her physician due to her complete response. Eight (8) of the 12 PRs and 6 of the 10 SDs were ongoing at the time of data cut-off for presentation (May 6, 2008). The patient on T-DM1 the longest at that time had received 12 treatment cycles and had an ongoing PR.

**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.

**ImmunoGen, Inc.**  
(Registrant)

Date: September 5, 2008

/s/ Daniel M. Junius

Daniel M. Junius  
President and Chief Operating Officer