IMMUNOGEN INC
Form 8-K
December 12, 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 12, 2008**

# ImmunoGen, Inc.

(Exact name of registrant as specified in its charter)

| **Massachusetts** | **0-17999** | **04-2726691** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (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**

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))

**ITEM 7.01 REGULATION FD DISCLOSURE**

On December 12, 2008, interim clinical data from a trastuzumab-DM1 (T-DM1) Phase II trial were presented by study investigators at the San Antonio Breast Cancer (SABC) Symposium being held in San Antonio, TX. 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. It was reported today that 112 patients were enrolled in this study, and that 107 of these patients were efficacy evaluable. At the time of data cut-off for presentation (8/29/08), the patients had a median follow up of 4.4 months (19 weeks). Final results are expected to be available in 2009 when all patients have at least 6 months of follow-up.

Baseline demographic, disease characteristics and prior therapy information were reported for the 112 patients enrolled. All of these patients had metastatic disease, with 68.7% having at least 3 distinct metastatic sites. They all had previously been treated with trastuzumab (Herceptin) plus chemotherapy, with a median time on trastuzumab of 76.6 weeks. Additionally, 55.4% of these patients also had received lapatinib (Tykerb) plus chemotherapy. The median duration of treatment with lapatinib among the patients who had received it was 26.3 weeks. Approximately two-thirds (67.9%) of the patients had received prior anthracycline therapy.

At the time of data cut-off for presentation, the 112 patients had received a median of 5.0 cycles of T-DM1. Two patients discontinued treatment due to adverse events considered to be possibly related to the study drug. Three of the 112 patients were dose-reduced from 3.6 mg/kg to 3.0 mg/kg for tolerability reasons, and these three patients were still receiving T-DM1 at the time of data cut-off.

The efficacy section of the presentation reported two types of findings: the overall objective response rate (Overall ORR) and the confirmed objective response rate (Confirmed ORR). The Overall ORR includes all complete responses (CRs) and partial responses (PRs) reported, whereas the Confirmed ORR includes only those CRs and PRs that were able to be confirmed with two consecutive scans taken at least 4 weeks apart. (Reasons a response would not be confirmed include that the data cut-off occurred before it could be confirmed, that the patient withdrew from the study before it could be confirmed, and that it was not sustained long enough to be confirmed.)

Among the entire 107 efficacy evaluable patients, the Overall ORR was 39.3% and the Confirmed ORR was 27.1%, with an explanatory note included that these findings include 19 patients who only had one post-baseline tumor assessment (i.e., they had not had the absolute minimum number of assessments needed to confirm a response). Thus, results were also reported for just those patients who had either had at least 6 months of follow-up or had discontinued treatment prior to the data cut-off date. Among these 76 patients, the

Overall ORR was 43.4% and the Confirmed ORR was 38.2%. Other activity information presented was:

- Sixty of the efficacy evaluable patients previously were treated with lapatinib. The activity of T-DM1 in these patients was found to be consistent with that in the entire study population (Overall ORR of 38.3%; Confirmed ORR of 21.7%).

- One of the inclusion criteria for the study is that patients have metastatic breast cancer that is HER2-positive (FISH+ and/or IHC3+). However, among the 86 efficacy evaluable patients where HER2 expression could be confirmed centrally, it was found that only 74.4% were HER2-positive by these criteria. Among the 64 patients confirmed to be HER2-positive, the Overall ORR was 50.0% and the Confirmed ORR was 34.4%.

The presentation conclusions include that T-DM1 shows single agent activity in patients with previously treated HER2-positive breast cancer, including patients previously treated with trastuzumab and with lapatinib, and appears to be well tolerated at the dose and schedule used.

**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: December 12, 2008

/s/ Daniel M. Junius

Daniel M. Junius
President and Chief Operating Officer