IMMUNOGEN INC
Form 8-K
December 10, 2013

# 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 9, 2013**

# 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 9, 2013 Biotest AG issued a press release on the presentation of BT-062 clinical findings at the 2013 American Society of Hematology (ASH) annual meeting. BT-062 is an antibody-drug conjugate (ADC) in development by Biotest. It comprises Biotest s CD138-targeting antibody with ImmunoGen s DM4 cancer-killing agent attached using one of ImmunoGen s engineered linkers, and is being developed under a 2006 agreement between the companies.

The findings reported are from a Biotest Phase I/IIa clinical trial that evaluates BT-062 (administered days 1, 8 and 15 of a 4-week cycle) when used in combination with lenalidomide (Revlimid®) and dexamethasone. To be eligible for enrollment, patients must have relapsed or relapsed/refractory multiple myeloma; previous treatment with lenalidomide and/or dexamethasone was allowed.

In the Phase I portion of the trial, three different dose levels of BT-062 80, 100, 120 mg/m2 were evaluated in combination with lenalidomide/dexamethasone to establish the maximum tolerated dose (MTD) of BT-062 when used with these drugs. In its Phase II portion now underway, a total of 37 patients are to receive BT-062 at its MTD with lenalidomide/dexamethasone to further evaluate safety and efficacy.

BT-062 was found to be well tolerated in combination with lenalidomide/dexamethasone at dose levels up to 100 mg/m2, which was determined to be the MTD.

Across the three dose levels tested, 15 patients were evaluable for efficacy at the time of data cutoff for presentation at ASH. All (100%) of these heavily pretreated patients had clinical benefit from therapy, achieving stable disease or better, and 11 of these 15 patients achieved a partial response or better, resulting in an objective response rate (ORR) of 73%.

- The ORR was comparable, 75%, in the subgroup of patients who were refractory to lenalidomide/dexamethasone.
- Eight of the nine evaluable patients who received BT-062 at its MTD had a partial response or better, for an ORR of 89%.

In addition to reporting these clinical data, Biotest also noted in its press release that it plans to evaluate BT-062 for the treatment of relevant solid tumors in a Phase I/IIa study, with patient enrollment planned to start in early 2014. This study will recruit patients with metastatic triple negative breast cancer and ones with metastatic urinary bladder cancer.

ImmunoGen has an opt-in right for BT-062 co-development and co-commercialization jointly with Biotest in the US at a later stage of its development.

Revlimid® is a registered trademark of Celgene Corporation.

**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 10, 2013

/s/ Daniel M. Junius

Daniel M. Junius
President and Chief Executive Officer