

IMMUNOGEN INC

FORM 8-K (Current report filing)

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Address	830 WINTER ST WALTHAM, MA 02451
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**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): **August 28, 2017**

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**

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):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

ITEM 1.01. ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT

On August 28, 2017, ImmunoGen, Inc. (also referred to as “we”, “our”, “us”, or “ImmunoGen”) and Jazz Pharmaceuticals Ireland Limited (“Jazz”), a subsidiary of Jazz Pharmaceuticals plc, entered into a Collaboration and Option Agreement (the “Option Agreement”), pursuant to which we granted Jazz options to develop and commercialize, on an exclusive, worldwide basis, IMG779, IMG632, and a third antibody-drug conjugate (“ADC”) from our early research and development pipeline to be designated by Jazz within the first seven years of the Option Agreement term. Each of the foregoing three products is referred to herein as a “Collaboration Product.” Jazz is entitled to exercise its option with respect to each Collaboration Product during specified periods set forth in the Option Agreement. Each Collaboration Product for which Jazz has exercised its option is referred to herein as a “Licensed Product.” We have the right to co-commercialize with Jazz a single Licensed Product (except under certain limited circumstances under which we may be entitled to co-commercialize two Licensed Products), to be designated by us, in the United States.

Under the terms of the Option Agreement, we are entitled to receive a non-refundable \$75 million upfront option fee. Jazz has also agreed to provide up to \$100 million in development funding over seven years to support development of the Collaboration Products. Jazz has the right to opt out of a Collaboration Product under the Option Agreement upon prior notice to us, which would result in a pro-rata reduction of its obligation to provide development funding. We are obligated to use a specified level of efforts to advance the development of the Collaboration Products, and we are responsible for all development costs with respect to the Collaboration Products in excess of Jazz’s development funding.

Jazz may exercise its option with respect to each Collaboration Product at any time prior to a pivotal study or any time prior to a biologics license application (BLA) upon payment of an option exercise fee of mid-double digit millions or low triple digit millions, respectively. The option exercise fee for IMG632 is subject to certain adjustments depending on the indication(s) for which initial regulatory approval of this product is based. The option exercise fee would be reduced with respect to the Licensed Product designated by us for co-commercialization if Jazz exercised its option for that Licensed Product at the later stage of development. After any option exercise by Jazz, we will share equally with Jazz the costs associated with developing and obtaining regulatory approvals of each Licensed Product in the United States and the European Union, and Jazz will be solely responsible for such costs with respect to all other territories worldwide.

We are also entitled to receive milestone payments upon US and EU regulatory approvals for each Licensed Product, plus tiered royalties as a percentage of commercial sales which, depending on sales levels and the stage of development at the time of Jazz’s option exercise, range from the mid- to high-single digits in the lowest tier, to low 10’s to low 20’s in the highest tier. With respect to the Licensed Product designated by us for co-commercialization, in lieu of receiving a milestone payment based on receiving regulatory approval in the United States, or royalties on sales in the United States, we will share equally with Jazz the activities, costs, and profits associated with commercialization in the United States.

Jazz may opt out of a Collaboration Product or Licensed Product at any time for convenience upon prior notice to us. The Option Agreement and the license agreements associated with the Licensed Products (“License Agreements”) may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, each License Agreement will continue in effect until the expiration of Jazz’s royalty obligations, which are determined on a country-by-country basis. For each country, Jazz’s royalty obligations generally commence upon the first commercial sale of the Licensed Product in that country, and extend until the later of the expiration of the last-to-expire ImmunoGen patent covering the Licensed Product in that country or the expiration for that country of the minimum royalty period specified in the License Agreement. Any License Agreement for a Licensed Product being co-commercialized by the parties in the United States shall remain in effect as long as the parties continue to be engaged in such co-commercialization activities.

If Jazz does not exercise its option to a Collaboration Product or opts out of a Collaboration Product or a Licensed Product, rights to that product revert to us, and we may continue development and commercialization of that product without any further involvement by Jazz, except that we would pay Jazz royalties at a rate specified in the Option Agreement or License Agreement, as applicable, on our commercial sales of such product.

We have made customary representations and warranties, and have agreed to customary covenants, including, without limitation, indemnification, for transactions of this type.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(d): The following exhibit is being filed herewith:

<u>Exhibit No.</u>	<u>Exhibit</u>
99.1	Press Release of ImmunoGen, Inc. dated August 29, 2017

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: August 29, 2017

/s/ David B. Johnston

David B. Johnston
Executive Vice President and Chief Financial Officer



**Jazz Pharmaceuticals and ImmunoGen, Inc. Announce a
Strategic Collaboration and Option Agreement to Develop and Commercialize
Antibody-Drug Conjugate Products**

Strengthens Jazz hematology/oncology portfolio with options for innovative development candidates IMGN779 and IMGN632

**ImmunoGen to receive a \$75 million upfront payment, up to \$100 million in research support,
a co-commercialization option, and potential future opt-in fees, milestones and royalties**

ImmunoGen conference call to be held today at 8:00 AM EDT; Jazz conference call to be held today at 4:30 PM EDT

DUBLIN and Waltham, Mass. August 29, 2017 — Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and ImmunoGen, Inc. (Nasdaq: IMGN) today announced that the companies have entered into a collaboration and option agreement granting Jazz Pharmaceuticals exclusive, worldwide rights to opt into development and commercialization of two early-stage, hematology-related antibody-drug conjugate (ADC) programs, as well as an additional program to be designated during the term of the agreement. The programs covered under the agreement include IMGN779, a CD33-targeted ADC for the treatment of acute myeloid leukemia (AML) in Phase 1 testing, and IMGN632, a CD123-targeted ADC for hematological malignancies expected to enter clinical testing before the end of the year.

Under the terms of the agreement, ImmunoGen will be responsible for the development of the three ADC programs prior to any potential opt-in by Jazz. Following any opt-in, Jazz would be responsible for any further development as well as for potential regulatory submissions and commercialization.

As part of the agreement, Jazz will pay ImmunoGen an upfront payment of \$75 million. Additionally, Jazz will pay ImmunoGen up to \$100 million in development funding over seven years to support the three ADC programs. For each program, Jazz may exercise its opt-in right at any time prior to a pivotal study or any time prior to a biologics license application (BLA) upon payment of an option exercise fee of mid-double digit millions or low triple digit millions, respectively. For each program to which Jazz elects to opt-in, ImmunoGen would be eligible to receive milestone payments based on receiving regulatory approval of the applicable product, plus tiered royalties as a percentage of commercial sales by Jazz, which depending upon sales levels and the stage of development at the time of opt-in, range from mid- to high single digits in the lowest tier to low 10's to low 20's in the highest tier. After opt-in, Jazz and ImmunoGen would share costs associated with developing and obtaining regulatory approvals of the applicable product in the United States (U.S.) and the European Union. ImmunoGen has the right to co-commercialize in the U.S. one product (or two products, under certain limited circumstances) with U.S. profit sharing in lieu of Jazz's payment of the U.S. milestone and royalties to ImmunoGen.

“We are pleased to enter into this collaboration with ImmunoGen, a well-known leader in the field of ADC technology, with demonstrated success in creating ADC molecules, including the only FDA-approved ADC product to treat metastatic breast cancer. This investment supports our long-term commitment to expand our hematology/oncology portfolio with the potential addition of multiple innovative antibody drug conjugates,” said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. “We look forward to the advancement of these ADC programs and the potential synergy of these compounds with our current products and pipeline, as new therapeutic options for cancer patients are urgently needed.”

“This strategic partnership with Jazz significantly advances our goal of accelerating the development of our early-stage novel ADC assets. This deal joins us with a global partner, provides us with substantial funding to support these programs, and preserves the right to co-commercialize one of these assets,” said Mark Enyedy, president and chief executive officer of ImmunoGen. “Jazz has demonstrated the ability to bring innovative compounds to patients and will make an ideal partner to help develop and commercialize our novel ADC assets targeting AML, and more broadly, in the area of hematology/oncology. In addition, this partnership significantly strengthens our financial position and moves us closer to delivering upon our mission of bringing ADC therapies to patients.”

IMGN779 is a novel ADC that combines a high-affinity, humanized anti-CD33 antibody, a cleavable disulfide linker, and one of ImmunoGen’s novel indolino-benzodiazepine payloads, called IGNs, which alkylate DNA without crosslinking, resulting in potent preclinical anti-leukemia activity with relative sparing of normal hematopoietic progenitor cells(1),(2). IMGN779 is in Phase 1 clinical testing for the treatment of AML. IMGN632 is a preclinical stage humanized anti-CD123 antibody-based ADC that is a potential treatment for AML, blastic plasmacytoid dendritic cell neoplasm (BPDCN), myelodysplastic syndrome, B-cell acute lymphocytic leukemia, and other CD123-positive malignancies. IMGN632 uses a novel payload, linker, and antibody technology and in AML xenograft models has demonstrated a large therapeutic index(3). ImmunoGen expects to file an investigational new drug application (IND) for IMGN632 this quarter and enroll the first patient in a Phase 1 study before the end of the year.

Jazz Pharmaceuticals Conference Call Details

Jazz Pharmaceuticals will host a conference call and live audio webcast today at 4:30 p.m. EDT/9:30 p.m. IST to discuss this transaction. Interested parties may access the live audio webcast and slide presentation via the Investors section of the Jazz Pharmaceuticals website at www.jazzpharmaceuticals.com. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary to listen to the webcast. A replay of the webcast will be archived on the website for one week.

Jazz audio webcast/conference call:

U.S. Dial-In Number: +1 855 353 7924

International Dial-In Number: +1 503 343 6056

Passcode: 76457218

A replay of the conference call will be available through September 5, 2017 and accessible through one of the following telephone numbers, using the passcode below:

Replay U.S. Dial-In Number: +1 855 859 2056

Replay International Dial-In Number: +1 404 537 3406

Passcode: 76457218

ImmunoGen Conference Call Details

ImmunoGen will host a conference call and live audio webcast today at 8am EDT to discuss this transaction. Interested parties may access the live audio webcast via the Investors section of the ImmunoGen website at www.immunogen.com. A replay of the webcast will be archived on the website for approximately one week.

ImmunoGen audio webcast/conference call:

Dial-In Number: +1 719-457-2607

Passcode: 8332814

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. The company has a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology. In these areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Defitelio® (defibrotide sodium) and Vyxeos™ (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Erwinaze® and Defitelio® (defibrotide) in countries outside the U.S. For more information, please visit www.jazzpharmaceuticals.com.

About ImmunoGen

ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using its proprietary antibody-drug conjugate (ADC) technology. ImmunoGen's lead product candidate, mirvetuximab soravtansine, is in a Phase 3 trial for FRα-positive platinum-resistant ovarian cancer, and is in Phase 1b/2 testing in combination regimens for earlier-stage disease. ImmunoGen's ADC technology is used in Roche's marketed product, Kadcyla®, in other clinical-stage ImmunoGen product candidates, and in programs in development by Amgen, Bayer, Biotest, CytomX, Debiopharm, Lilly, Novartis, Sanofi and Takeda. More information about the Company can be found at www.immunogen.com.

Jazz Pharmaceuticals "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including, but not limited to, statements related to the potential exercise by Jazz Pharmaceuticals of its option rights with respect to certain early-stage product candidates covered by the collaboration and option agreement, the potential benefits of such product candidates and related development and regulatory activities, potential future payments to ImmunoGen by Jazz Pharmaceuticals, the potential exercise by ImmunoGen of its co-commercialization rights with respect to such product candidates, Jazz Pharmaceuticals' commitment to expand its hematology/oncology portfolio with the potential addition of multiple innovative antibody drug conjugates, the advancement of the ADC program covered by the collaboration and option agreement and the potential synergy of these compounds with Jazz Pharmaceuticals' current products and pipeline, the timing of such events and activities, and other statements that are not historical facts. These forward-looking statements are based on the company's current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in

such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: whether Jazz Pharmaceuticals will exercise its opt-in rights with respect to certain early-stage product candidates covered by the collaboration and option agreement, and, if exercised, Jazz Pharmaceuticals' ability to achieve the expected benefits (commercial or otherwise) from the acquisition of rights to such product candidates; whether ImmunoGen will exercise its co-commercialization rights with respect to such product candidates; pharmaceutical product development and clinical success thereof; the regulatory approval process; and effectively commercializing any product candidates acquired by Jazz Pharmaceuticals under the collaboration and option agreement; and other risks and uncertainties affecting the company and its development programs, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 and future filings and reports by the company. Other risks and uncertainties of which the company is not currently aware may also affect the company's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by the company on its website or otherwise. The company undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

ImmunoGen "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release includes forward-looking statements. For these statements, ImmunoGen claims the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including IMG779 and IMG632, including risks relating related to preclinical and clinical studies, their timing and results. A review of these risks can be found in ImmunoGen's Transition Report on Form 10-K for the six-month period ended December 31, 2016 and other reports filed with the Securities and Exchange Commission.

References:

- (1) S. Adams et al, Abstract P526, Presented at the 22nd Congress of the European Hematology Association, June 22-25, 2017.
- (2) Y. Kotvun et al. (2016) *Blood* 128:768.
- (3) S. Adams et al, Abstract 2832, Presented at the American Society of Hematology, December 3-6, 2016.

Jazz Pharmaceuticals Contacts:

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