IMMUNOGEN INC
Form 10-K
August 29, 2012

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended June 30, 2012

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission file number 0-17999

ImmunoGen, Inc.

Massachusetts	**04-2726691**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

830 Winter Street, Waltham, MA 02451
(Address of principal executive offices, including zip code)

(781) 895-0600
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $.01 par value	NASDAQ Global Select Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ý Yes o No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. o Yes ý No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ý Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ý Yes o No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ý	Accelerated filer o	Non-accelerated filer o	Smaller reporting company o
		(Do not check if a smaller reporting company)	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). o Yes ý No

Aggregate market value, based upon the closing sale price of the shares as reported by the NASDAQ Global Market, of voting stock held by non-affiliates at December 31, 2011: $886,501,851 (excludes shares held by executive officers and directors). Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant, or that such person is controlled by or under common control with the registrant. Common Stock outstanding at August 21, 2012: 84,104,625 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement to be delivered to shareholders in connection with the Annual Meeting of Shareholders to be held on November 13, 2012 are incorporated by reference into Part III.

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ImmunoGen, Inc.

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Item 1. ***Business***

In this Annual Report on Form 10-K, ImmunoGen, Inc. (ImmunoGen, Inc., together with its subsidiaries, is referred to in this document as "we", "us", "ImmunoGen", or the "Company"), incorporates by reference certain information from parts of other documents filed with the Securities and Exchange Commission. The Securities and Exchange Commission allows us to disclose important information by referring to it in that manner. Please refer to all such information when reading this Annual Report on Form 10-K. All information is as of June 30, 2012 unless otherwise indicated. For a description of the risk factors affecting or applicable to our business, see "Risk Factors," below.

The Company

We develop novel, targeted, antibody-based therapeutics for the treatment of cancer using our expertise in cancer biology, monoclonal antibodies, highly potent cytotoxic, or cell-killing, agents, and the design of linkers that enable these agents to remain stably attached to the antibodies while in the blood stream and be released in their fully active form after delivery to a cancer cell. An anticancer compound made using our Targeted Antibody Payload, or TAP, technology consists of a monoclonal antibody that binds specifically to an antigen target found on cancer cells with multiple copies of one of our proprietary cell-killing agents attached using one of our engineered linkers. Its antibody component enables a TAP compound to bind specifically to cancer cells that express its target antigen, the highly potent cytotoxic agent serves to kill the cancer cell and the engineered linker controls the release and activation of the cytotoxic agent inside the cancer cell. With some TAP compounds, the antibody component also has anticancer activity of its own. Our TAP technology is designed to enable the creation of highly effective, well-tolerated anticancer products.

The most advanced compound with our TAP technology is trastuzumab emtansine, often referred to as T-DM1, which is in global development by Roche through our collaboration with Genentech, a member of the Roche Group. Positive findings from the lead T-DM1 Phase III trial have been reported, and, in August 2012, Roche announced that it has submitted the T-DM1 marketing application in the U.S. and will submit it soon in Europe. Under the collaboration agreement, we are entitled to receive royalties on T-DM1 sales, if any, as well as milestone payments on defined regulatory events.

We have three wholly owned clinical-stage product candidates IMGN901, IMGN853, and IMGN529 and other TAP compounds in earlier stages of development. IMGN901 is a potential treatment for small-cell lung cancer, or SCLC, and other cancers that express CD56 and is in Phase II testing for the first-line treatment of SCLC. IMGN853 is a potential treatment for ovarian cancer, non-small cell lung cancer, or NSCLC, and other cancers that over-express its folate receptor target and began Phase I testing in mid-2012. IMGN529 is a potential treatment for non-Hodgkin's lymphoma, or NHL, and chronic lymphocytic leukemia and began Phase I testing in early 2012. We also have earlier stage compounds in development and expect to advance our next wholly owned compound to Investigational New Drug, or IND, application stage in mid-2013. In addition to our product programs, we continue to invest in our TAP technology, including the development of additional cytotoxic agents and engineered linkers, to maintain a leadership position in our field.

Part of our business model is to establish collaborations with other companies in order to provide us with cash and revenue short term and potential significant value long term. Collaborations also help expand the utilization of our TAP technology. Our current collaborative partners are: Amgen Inc., Bayer HealthCare (a subgroup of Bayer AG), Biotest AG, Eli Lilly and Company, or Lilly, Novartis Institutes for BioMedical Research, Inc., or Novartis, Genentech, Inc. and Sanofi. These partners have certain rights to use our TAP technology to development anticancer therapies and have product candidates in clinical and/or preclinical testing. Eight compounds, including T-DM1, are in clinical testing through our collaborations.

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We were organized as a Massachusetts corporation in 1981. Our principal offices are located at 830 Winter Street, Waltham, Massachusetts (MA) 02451, and our telephone number is (781) 895-0600. We maintain a website at *www.immunogen.com*, where certain information about us is available. Please note that information contained on the website is not a part of this document. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports are available free of charge through the "Investor Information" section of our website as soon as reasonably practicable after those materials have been electronically filed with, or furnished to, the Securities and Exchange Commission. We have adopted a Code of Corporate Conduct that applies to all our directors, officers and employees and a Senior Officer and Financial Personnel Code of Ethics that applies to our senior officers and financial personnel. Our Code of Corporate Conduct and Senior Officer and Financial Personnel Code of Ethics are available free of charge through the "Investor Information" section of our website.

Product Candidates

There are eleven compounds in clinical trials through our own programs and our collaborations with other companies; these are listed in the table below. The results in early clinical trials may not be predictive of results obtained in subsequent clinical trials and there can be no assurance that each of our or our collaborators' product candidates will advance or will demonstrate the level of safety and efficacy necessary to obtain regulatory approval.

	Current Stage
Lead Compound in Development through a Collaborative Partner	
Trastuzumab emtansine (T-DM1)	Registration
Compounds in Development by ImmunoGen	
IMGN901 (lorvotuzumab mertansine)	Phase II
IMGN853	Phase I
IMGN529	Phase I
Other Compounds in Development through Collaborative Partners	
SAR3419	Phase II
BT-062	Phase I
SAR650984*	Phase I
SAR566658	Phase I
BAY 94-9343	Phase I
First Amgen TAP compound "Amgen 1"	Phase I
Second Amgen TAP compound "Amgen 2"	Phase I

* *Non-conjugated or "naked" antibody therapeutic*

Trastuzumab Emtansine (T-DM1)

Trastuzumab emtansine, often referred to as T-DM1, is the most advanced compound in development using our TAP technology. T-DM1 consists of trastuzumab, which is the active component of Genentech's antibody therapeutic, Herceptin® (trastuzumab), with our DM1 cell-killing agent attached using our SMCC engineered linker. T-DM1 is in global development by Genentech's parent company, Roche, under a license with us.

T-DM1 is in Phase III testing for the treatment of HER2+ metastatic breast cancer, or mBC, and in June 2012 Roche reported its plans to initiate registration trials evaluating it for early stage HER2+ breast cancer, or eBC. Roche also is initiating a trial evaluating T-DM1 for HER2+ gastric cancer.

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Evaluation for HER2+ mBC

For HER2+ mBC previously treated with Herceptin and with a taxane Roche's lead T-DM1 Phase III trial, EMILIA, compares T-DM1, used alone, with Tykerb® (lapatinib) used together with Xeloda® (capecitabine) to treat HER2+ mBC in patients who have previously received Herceptin with a taxane. EMILIA has two co-primary endpoints: progression-free survival, or PFS, and overall survival, or OS. Findings from EMILIA were reported in June 2012 at the American Society of Clinical Oncology, or ASCO, annual meeting. Among the findings reported was that treatment with T-DM1 significantly improved PFS compared to treatment with Tykerb plus Xeloda, with a hazard ratio of 0.65 ($p<0.0001$). As expected, the OS data were not mature at the time of this analysis. A sufficient number of events (deaths) had occurred to establish median OS in the Tykerb plus Xeloda treatment arm but not in the T-DM1 treatment arm, and longer follow up is required. The EMILIA data reported also included that fewer T-DM1-treated patients experienced Grade 3 or higher adverse events, which are severe adverse events, than the patients treated with Tykerb plus Xeloda. In August 2012, Roche announced that, in updated results, treatment with T-DM1 significantly improved OS compared to treatment with Tykerb plus Xeloda, and thus both of the co-primary endpoints of the EMILIA trial had now been met. Roche also disclosed that it has submitted a Biologics License Application, or BLA, for T-DM1 to the U.S. Food and Drug Administration, or FDA, and that it expects to soon submit a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA.

For first-line treatment of HER2+ mBC In July 2010, Roche began a Phase III trial, MARIANNE, to assess T-DM1 for first-line treatment of HER2+ mBC. Current standard-of-care for this cancer is Herceptin used with a taxane, and MARIANNE compares T-DM1 to this treatment, both when used alone and when used with Roche's Perjeta® (pertuzumab) antibody. Roche intends to use MARIANNE results, if favorable, to apply in 2014 for approval of T-DM1 in the United States and Europe to treat this cancer, both used alone and used together with Perjeta.

For HER2+ mBC previously treated with Herceptin and with Tykerb Roche also has a Phase III trial, TH3RESA, underway assessing T-DM1 for this use. Patient dosing in this trial began in September 2011.

Evaluation for HER2+ eBC

In June 2012 Roche presented its three-pronged approach to developing T-DM1 for the treatment of HER2+ eBC: development for neoadjuvant use, for adjuvant use, and for patients with residual invasive disease following surgery. Roche has announced that it plans to initiate registration trials with T-DM1 in each of these uses in 2013.

Lorvotuzumab mertansine (IMGN901)

Our most advanced wholly owned product candidate is the TAP compound lorvotuzumab mertansine, which we also call IMGN901. We developed IMGN901 to target CD56, which is found on SCLC, Merkel cell carcinoma, multiple myeloma, ovarian cancers, carcinoid tumors, and other cancers of neuroendocrine origin. In early clinical testing, IMGN901 demonstrated evidence of activity when used alone to treat CD56+ cancers that had recurred after treatment with approved anticancer drugs.

We are evaluating IMGN901 for the first-line treatment of SCLC. Assuming this clinical trial is successful we intend to advance IMGN901 into pivotal clinical testing for this indication. We also are completing a Phase I clinical trial assessing IMGN901 for the treatment of multiple myeloma.

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Evaluation for SCLC

In March 2012 we began Phase II evaluation of IMGN901, used in combination with etoposide/carboplatin (E/C), as a treatment for newly diagnosed metastatic SCLC. E/C is a current standard care for this cancer. Patients enrolled in this trial, called NORTH, are randomized to receive either E/C or E/C plus IMGN901, with two patients randomized to the E/C plus IMGN901 group for every one patient randomized to the E/C alone group. The IMGN901 dose being used in the NORTH trial was established in the Phase I part of this trial.

The NORTH trial is designed to assess whether the addition of IMGN901 to E/C meaningfully improves patient outcomes. The primary endpoint of the NORTH trial is PFS. Secondary endpoints include PFS at 6 months, OS at 12 months, time to progression, OS, and overall response rate. An interim analysis focused on PFS at 6 months is planned after enrollment of the first 59 patients. The full NORTH trial is designed to include 120 patients.

Evaluation for Multiple Myeloma

IMGN901 is being assessed in a Phase I clinical trial for the treatment of multiple myeloma, used in combination with lenalidomide plus dexamethasone, a standard of care for this cancer. Promising data were presented at the ASCO meeting in June 2011 from the dose-finding portion of this clinical trial. Based on clinical findings to date, we believe IMGN901 is a promising treatment for multiple myeloma. However, because of the significant unmet medical need in SCLC, we have focused development on SCLC and currently have no plans to advance IMGN901 into pivotal testing for the treatment of multiple myeloma.

IMGN853

Our IMGN853 TAP compound targets folate receptor 1, or FOLR1, which is over-expressed on many cases of ovarian cancer, or OC, and also on other types of solid tumors, including NSCLC. IMGN853 consists of a FOLR1-targeting antibody with one of our potent cell-killing agents attached using one of our linkers engineered to counteract the multi-drug resistance that many cancers develop.

In July 2012 we advanced IMGN853 into clinical testing in a Phase I clinical trial intended to enable us to establish the path(s) to potential regulatory approval for IMGN853. The maximum-tolerated dose, or MTD, of IMGN853 will be established in the dose-escalation portion of this trial, which allows for single-patient cohorts at the initial, lower dose levels. Once the MTD is established, we plan to evaluate IMGN853 in patients with previously treated epithelial OC and in patients with previously treated adenocarcinoma NSCLC.

IMGN529

Our IMGN529 TAP compound targets CD37, which is expressed on B-cell malignancies such as NHL and chronic lymphocytic leukemia. Scientists have found the expression profile of CD37 on NHL subtypes to be similar to that of CD20, the target of Rituxan® (rituximab).

IMGN529 comprises an antibody that, in preclinical testing, has demonstrated meaningful anticancer activity, our DM1 cell-killing agent, and our SMCC engineered linker, thus paralleling T-DM1 in design. We believe IMGN529 is a highly differentiated product candidate for B-cell malignancies because it combines the anticancer activity of its antibody component with the actions of our potent cell-killing agent. In April 2012, we began Phase I clinical testing of IMGN529 for the treatment of NHL.

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Compounds in Development by Our Partners

In addition to T-DM1, seven other compounds are in clinical testing through our collaborations with other companies. Several of our collaborative partners also have TAP compounds in earlier stages of development, including our newest partners Novartis and Lilly.

SAR3419

We created the SAR3419 TAP compound and licensed it to Sanofi from our preclinical pipeline as part of a broader collaboration. SAR3419 targets CD19 and is a potential new treatment for CD19-expressing B-cell malignancies including NHL and B-cell acute lymphoblastic leukemia, or B-ALL. In Phase I clinical testing, SAR3419 showed encouraging efficacy and tolerability in the treatment of NHL previously treated with approved anticancer agents. Sanofi initiated Phase II clinical testing of SAR3419 in October 2011 and is evaluating it for both diffuse large B-cell lymphoma, a type of NHL, and in B-ALL.

BT-062

BT-062 was created by Biotest under a license agreement with us that grants Biotest rights to use our TAP technology with antibodies that target CD138, an antigen found on multiple myeloma and certain solid tumors. We have opt-in rights with respect to BT-062 in the United States. Encouraging early stage clinical data have been reported with BT-062 used as a single agent to treat multiple myeloma that had recurred after treatment with approved anticancer agents. In July 2012 Biotest began patient dosing in an early stage trial assessing BT-062 used as part of a combination regimen for this cancer. Biotest also is assessing BT-062 preclinically for the treatment of CD138-expressing solid tumors.

SAR650984 and SAR566658

These compounds also were licensed to Sanofi preclinically as part of a broader collaboration, and both are in early stage clinical testing. SAR650984 is a CD38-targeting therapeutic antibody for hematological malignancies. SAR566658 is a TAP compound for DS6-expressing solid tumors, including ovarian cancers. DS6 is also known as CA6.

BAY 94-9343

BAY 94-9343 was created by Bayer under a license agreement with us that grants Bayer rights to use our TAP technology with antibodies that target mesothelin. BAY 94-9343 advanced into Phase I clinical testing for the treatment of mesothelin-expressing solid tumors in September 2011.

Amgen 1 and Amgen 2

Two TAP compounds that we refer to as Amgen 1 and Amgen 2 advanced into clinical testing in early 2012 through our collaboration with Amgen. Both compounds were created by Amgen under license agreements with us granting Amgen rights to use our TAP technology with antibodies binding to the targets of Amgen 1 and Amgen 2.

Incidence of Relevant Cancers

Cancer remains a leading cause of death worldwide, and is the second leading cause of death in the U.S. The American Cancer Society estimates that in 2012 approximately 1.6 million new cases of cancer will be diagnosed in the U.S. and that approximately 577,000 people will die from the disease. The total number of people living with cancer significantly exceeds the number of patients diagnosed with cancer in a given year as patients can live with cancer for a year or longer. Additionally, the potential market for anticancer drugs exceeds the number of patients treated as many types of cancer typically are treated with multiple compounds at the same time and because patients often receive a number of drug regimens sequentially.

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T-DM1 Based on American Cancer Society and Roche estimates, we believe approximately 57,000 new cases of HER2+ breast cancer will be diagnosed in the U.S. in 2012. These include diagnoses for both early stage, or localized, disease and advanced, or metastatic, disease.

The first approvals of T-DM1 are expected to be for metastatic disease. Based on information reported by Roche in late 2011, we believe that the metastatic HER2+ breast cancer market in the U.S. consists of approximately 21,100 patients: 7,800 eligible for first-line treatment; 5,900 eligible for second-line treatment; 4,300 eligible for third-line treatment; and 3,100 eligible for fourth-line treatment.

IMGN901 We are assessing this compound in the clinic for the treatment of CD56+ SCLC and multiple myeloma. Based on our own studies and scientific literature, we believe that CD56 is expressed on approximately 89% of SCLC and 76% of multiple myeloma cases. Based on American Cancer Society estimates and other sources, we believe that approximately 29,400 new cases of SCLC will be diagnosed in the U.S. in 2012. SCLC tends to spread broadly through the body quite early in the course of the disease, and according to the American Cancer Society approximately two-thirds of SCLC patients have extensive disease at the time of diagnosis. Based on American Cancer Society estimates, we also believe that approximately 21,700 new cases of multiple myeloma will be diagnosed in the U.S. in 2012.

IMGN853 We are assessing our IMGN853 compound for the treatment of epithelial ovarian cancer and adenocarcinoma NSCLC. Based on American Cancer Society estimates, we believe approximately 19,000 and 90,000 new cases of these cancers will be diagnosed in the U.S. in 2012, respectively.

IMGN529 We are assessing our IMGN529 compound for the treatment of NHL. Based on American Cancer Society estimates, we believe approximately 70,000 new cases of NHL will be diagnosed in the U.S. in 2012.

Out-licenses and Collaborations

We selectively out-license restricted access to our TAP technology to other companies to provide us with cash to fund our own product programs and to expand the utilization of our technology. These agreements typically provide the licensee with rights to use our TAP technology with any of its antibodies and apply them to a defined target to develop products. The licensee is generally responsible for the development, clinical testing, manufacturing, registration and commercialization of any resulting product candidate. As part of these agreements, we are generally entitled to receive upfront fees, potential milestone payments, royalties on the sales of any resulting products and research and development funding based on activities performed at our collaborative partner's request. We are also compensated for preclinical and clinical materials supplied to our partners.

We will not receive royalty payments from a TAP technology out-license until a product candidate developed under the license is approved for marketing and commercialized, nor do we expect to receive significant individual milestones payments under our existing collaborations prior to the commencement of pivotal clinical trials or, in some cases, product approval. Achievement of product approval requires, at a minimum, favorable completion of preclinical development and evaluation, assessment of early-stage clinical trials, advancement into pivotal Phase II and/or Phase III clinical testing, completion of this later-stage clinical testing with favorable results, and completion of regulatory submissions and review. The only collaboration that may provide us with royalty revenue and significant milestone payments in the foreseeable future is our collaboration with Roche relating to

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T-DM1. Below is a table setting forth our active collaborations, the number of targets licensed and current status of the product candidates being developed thereunder:

Collaborator	Agreement Type	Effective Date(s)	Development Status[1]
Roche[2]	Multiple single-targets	2000	Registration
Amgen[3]	Right-to-test and single-targets	2000	Phase I
Sanofi	Multiple single-targets	2003	Phase II
Sanofi[4]	Right-to-test	2006	Research/Preclinical
Biotest	Single-target	2006	Phase I
Bayer HealthCare	Single-target	2008	Phase I
Novartis[4]	Right-to-test	2010	Research/Preclinical
Lilly[4]	Right-to-test	2011	Research/Preclinical

1 For collaborations involving multiple targets, development status denotes the most advanced program under the collaboration.

2 Roche has five single-target licenses. Pursuant to the license covering the target HER2, which was entered into in 2000, a product candidate, T-DM1, has been developed and Roche has submitted a marketing application for the compound. The remaining four licenses were entered into between 2005 and 2008, and the development status of product candidates under each of those licenses is research/preclinical.

3 Amgen has multiple outstanding exclusive and non-exclusive options providing it with the right to take single-target licenses, on pre-negotiated terms, to specified targets during the respective option periods. As of June 30, 2012, Amgen has taken two single-target licenses pursuant to the terms of its right-to-test agreement.

4 Sanofi, Novartis and Lilly each has the right to take multiple exclusive options providing it with the right to take single-target licenses, on pre-negotiated terms, to specified targets during the respective option periods.

Roche

In May 2000, we granted Roche, through its Genentech unit, an exclusive development and commercialization license to our maytansinoid TAP technology for use with antibodies or other proteins that target HER2, such as trastuzumab. The product candidate T-DM1 is currently in development under this agreement. We received a $2 million upfront payment from Roche upon execution of the agreement. We are also entitled to receive up to a total of $44 million in milestone payments, plus tiered royalties in the mid-single digits on the commercial sales of any resulting products. On an individual country basis, royalties on commercial sales will be reduced to the low-single digits at any time during the applicable royalty period that the product is not covered by ImmunoGen patent rights in that country.

Roche may terminate this agreement for convenience at any time upon 90 days' prior written notice to us. The agreement may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the agreement will continue in effect until the expiration of Roche's royalty obligations. For each product and country, Roche's royalty obligations commence with the first commercial sale of that product in that country, and extend for a period of 10 years from the date of that first commercial sale in that country, although if the product

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(or its manufacture, use or sale) is covered by an ImmunoGen patent in that country on such tenth anniversary, then the period during which royalties are payable is extended until 12 years from the date of the first commercial sale in that country.

Through June 30, 2012, we have received and recognized a total of $13.5 million in milestone payments under this agreement. The next potential milestone we will be entitled to receive will be a regulatory milestone for marketing approval of T-DM1. As this could occur first in either the U.S. or Europe, the next potential milestone due will be either $10.5 million with first approval in the U.S. or $5 million with first approval in Europe.

Amgen

In September 2000, we entered into a ten-year right-to-test agreement with Abgenix, Inc. which was later acquired by Amgen. The agreement provides Amgen with the right to (a) test our maytansinoid TAP technology with Amgen's antibodies under a right-to-test, or research, license, (b) take options, with certain restrictions, to individual targets selected by Amgen on either an exclusive or non-exclusive basis for specified option periods and (c) upon exercise of those options, take exclusive or non-exclusive licenses to use our maytansinoid TAP technology to develop and commercialize products directed to the specified targets on previously agreed-upon terms. Amgen no longer has the right to take additional options under the right-to-test agreement, although multiple outstanding options remain in effect for the remainder of their respective option periods.

For each exclusive development and commercialization license taken, we are entitled to receive an exercise fee of $1 million and up to a total of $34 million in milestone payments, plus royalties on the commercial sales of any resulting products.

Amgen may terminate each development and commercialization license for convenience upon prior notice to us. Each license 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 will continue in effect until the expiration of Amgen's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Amgen's royalty obligations commence with the first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in each development and commercialization license.

Under the right-to-test agreement, in September 2009 and November 2009, we entered into two development and commercialization licenses with Amgen and received an exercise fee of $1 million with each license taken. In November 2011, the Investigational New Drug (IND) applications for two compounds developed under the separate development and commercialization licenses became active, which triggered two $1 million milestone payments to us. The next potential milestone we will be entitled to receive under either of these development and commercialization licenses will be a development milestone for the first dosing of a patient in a Phase II clinical trial, which will result in a $3 million payment being due.

Sanofi

Collaboration Agreement

In July 2003, we entered into a broad collaboration agreement with Sanofi (formerly Aventis) to discover, develop and commercialize antibody-based products. The collaboration agreement provides Sanofi with worldwide development and commercialization rights to new antibody-based products directed to targets that are included in the collaboration, including the right to use our TAP technology and our humanization technology in the creation of products directed to these targets. The product

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candidates (targets) currently in development under the collaboration include SAR3419 (CD19), SAR650984 (CD38), SAR566658 (DS6, also known as CA6) and at least one earlier-stage compound that has yet to be disclosed. For each of the targets included in the collaboration at this time, we are entitled to receive up to a total of $21.5 million in milestone payments, plus royalties on the commercial sales of any resulting products.

The agreement may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the agreement will continue in effect until the expiration of Sanofi's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Sanofi's royalty obligations commence upon first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in the agreement.

The collaboration agreement also provides us an option to certain co-promotion rights in the U.S. on a product-by-product basis. The terms of the collaboration agreement allow Sanofi to terminate our co-promotion rights if there is a change in control of our company.

Through June 30, 2012, we have received and recognized a total of $16 million in milestone payments related to compounds covered under this agreement now and in the past, including a total of $8 million in milestone payments related to two product candidates previously in the collaboration that have been returned to us along with the rights to the respective targets. The next potential milestone we will be entitled to receive with respect to each of SAR566658 and for SAR650984 will be a development milestone for initiation of a Phase IIb clinical trial (as defined in the agreement), which will result in each case in a $3 million payment being due. The next potential milestone we will be entitled to receive with respect to SAR3419 will be for initiation of a Phase III clinical trial, which will result in a $3 million payment being due. The next potential milestone we will be entitled to receive for each of the unidentified targets will be a development milestone for commencement of a Phase I clinical trial, which will result in a $1 million payment being due, or a preclinical milestone which will result in a $500,000 payment being due.

Right-to-Test Agreement

In December 2006, we entered into a separate right-to-test agreement with Sanofi. The agreement provides Sanofi with the right to (a) test our maytansinoid TAP technology with Sanofi's antibodies to targets that were not included in the collaboration agreement described above under a right-to-test, or research, license, (b) take exclusive options, with certain restrictions, to individual targets selected by Sanofi for specified time periods and (c) upon exercise of those options, take exclusive licenses to use our maytansinoid TAP technology to develop and commercialize products directed to the specified targets on terms agreed upon at the inception of the right-to-test agreement. The right-to-test agreement had a three-year original term from the activation date that was extended on a one-time basis by Sanofi in August 2011for an additional three years by payment of a $2 million extension fee.

For each development and commercialization license taken, we are entitled to receive an exercise fee of $2 million and up to a total of $30 million in milestone payments, plus royalties on the commercial sales of any resulting products.

Each development and commercialization license may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, each license will continue in effect until the expiration of Sanofi's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Sanofi's royalty obligations commence with the first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in each development

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and commercialization license. No development and commercialization license has yet been taken under the right-to-test agreement.

Biotest

In July 2006, we granted Biotest an exclusive development and commercialization license to our maytansinoid TAP technology for use with antibodies that target CD138. The product candidate BT-062 is currently in development under this agreement. We received a $1 million upfront payment from Biotest upon execution of the agreement. We are also entitled to receive up to a total of $35.5 million in milestone payments, plus royalties on the commercial sales of any resulting products.

The agreement also provides us with the right to elect, at specific stages during the clinical evaluation of any compound created under the agreement, to participate in the United States development and commercialization of that compound in lieu of receiving the milestone payments not yet earned and royalties on sales in the United States. We can exercise this right during an exercise period specified in the agreement by notice and payment to Biotest of an agreed upon opt-in fee of $5 million or $15 million, depending on the stage of development. Upon exercise of this right, we would share equally with Biotest the associated costs of product development and commercialization in the United States along with the profit, if any, from product sales in the United States.

Biotest may terminate the agreement for convenience at any time prior to our election to participate in the U.S. development and commercialization of a compound created under this agreement upon prior notice to us. The agreement may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the agreement will continue in effect until the expiration of Biotest's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Biotest's royalty obligations commence upon first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in the agreement.

Through June 30, 2012, we have received and recognized a total of $500,000 in milestone payments under this agreement. The next potential milestone we will be entitled to receive will be a development milestone for commencement of a Phase IIb clinical trial (as defined in the agreement) which will result in a $2 million payment being due.

Bayer HealthCare

In October 2008, we granted BayerHealthCare an exclusive development and commercialization license to our maytansinoid TAP technology for use with antibodies or other proteins that target mesothelin. The product candidate BAY 94-9343 is currently in development under this agreement. We received a $4 million upfront payment upon execution of the agreement. We are also entitled to receive, for each product developed and marketed by Bayer HealthCare under this agreement, up to a total of $170.5 million in milestone payments, plus royalties on the commercial sales of any resulting products.

Bayer HealthCare may terminate the agreement for convenience at any time upon prior written notice to us. The agreement may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. We may also terminate the agreement upon the occurrence of specified events. Unless earlier terminated, the agreement will continue in effect until the expiration of Bayer HealthCare's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Bayer HealthCare's royalty obligations commence upon first commercial sale of that product in that country, and extend until the later of

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either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in the agreement.

Through June 30, 2012, we have received and recognized a total of $3 million in milestone payments under this agreement. The next potential milestone we will be entitled to receive will be a development milestone for commencement of a non-pivotal Phase II clinical trial, which will result in a $4 million payment being due.

Novartis

In October 2010, we entered into a right-to-test agreement with Novartis Institutes for BioMedical Research, Inc. (Novartis). The agreement provides Novartis with a right to (a) test our TAP technology with Novartis' antibodies directed to individual targets selected by Novartis under a right-to-test, or research, license, (b) take exclusive options, with certain restrictions, to individual targets selected by Novartis for specified option periods, and (c) upon exercise of those options take exclusive licenses to use our TAP technology to develop and commercialize products for a specified number of individual targets on terms agreed upon at the inception of the right-to-test agreement. The initial term of the right-to-test agreement is three years, which may be extended by Novartis for up to two additional one-year periods by the payment of additional consideration. Novartis must exercise its options for the development and commercialization licenses by the end of the term of the right-to-test agreement, after which any then outstanding options will lapse.

We received a $45 million upfront payment in connection with the execution of the right-to-test agreement, and we are also entitled to receive additional payments under the agreement for research and development activities performed on behalf of Novartis during the term of the agreement. For each development and commercialization license taken, we are entitled to receive an exercise fee of $1 million and up to a total of $199.5 million in milestone payments, plus royalties on the commercial sales of any resulting products.

Novartis may terminate any development and commercialization license for convenience upon prior notice to us. Each license may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, each development and commercialization license will continue in effect until the expiration of Novartis' royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Novartis' royalty obligations commence upon first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in each license. No development and commercialization license has yet been taken under the right-to-test agreement.

Lilly

In December 2011, the Company entered into a three-year right-to-test agreement with Eli Lilly and Company (Lilly). The agreement provides Lilly with the right to (a) take exclusive options, with certain restrictions, to individual targets selected by Lilly for specified option periods, (b) test our maytansinoid TAP technology with Lilly's antibodies directed to the optioned targets under a right-to-test, or research, license, and (c) upon exercise of those options take exclusive licenses to use our maytansinoid TAP technology to develop and commercialize products for a specified number of individual targets on terms agreed upon at the inception of the right-to-test agreement. Lilly must exercise its options for the development and commercialization licenses by the end of the term of the right-to-test agreement, after which any then outstanding options will lapse.

We received a $20 million upfront payment in connection with the execution of the agreement, and we are also entitled to receive additional payments under the agreement for research and development

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activities performed under the agreement on behalf of Lilly during the term of the research license. For the first development and commercialization license taken, we are entitled to receive up to a total of $200.5 million in milestone payments, plus tiered royalties in the mid-single to low-double digits on the commercial sales of any resulting products. For each subsequent development and commercialization license taken, we are entitled to receive an exercise fee of $2 million and up to a total of $199 million in milestone payments, plus royalties on the commercial sales of any resulting products.

Lilly may terminate any development and commercialization license for convenience upon prior notice to us. Each license may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. We may also terminate the agreement upon the occurrence of specified events. Unless earlier terminated, each development and commercialization license will continue in effect until the expiration of Lilly's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Lilly's royalty obligations commence upon first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in each license. No development and commercialization license has yet been taken under the right-to-test agreement.

In-Licenses

From time to time we may in-license certain rights to targets or technologies for use in conjunction with our internal efforts to develop TAP compounds and related technologies. These licenses include rights to certain antibodies. In exchange, we may be obligated to pay upfront fees, potential milestone payments and royalties on any product sales.

Patents, Trademarks and Trade Secrets

Our intellectual property strategy centers on obtaining patent protection for our proprietary technologies and product candidates. As of June 30, 2012, our patent portfolio had a total of 381 issued patents worldwide and 438 pending patent applications worldwide that we own or license from third parties. We seek to protect our TAP technology and our product candidates through a multi-pronged approach. In this regard, we have patents and patent applications covering antibodies and other cell-binding agents, linkers, maytansinoid and other cell-killing agents, and complete antibody-drug conjugates, or immunoconjugates, comprising these components and methods of making and using each of the above. Typically, multiple issued patents and pending patent applications cover various aspects of each product candidate.

We consider our maytansinoid technology to be a key component of our overall corporate strategy. We currently own 34 issued U.S. patents covering various embodiments of our maytansinoid technology including claims directed to certain maytansinoids, antibody-maytansinoid conjugates and other cell-binding agents used with maytansinoids, and methods of making and using the same. In all cases, we have received or are applying for comparable patents in other jurisdictions including Europe and Japan. We have issued patents that cover numerous aspects of the manufacture of both our DM1 and DM4 cell-killing agents. These issued patents remain in force until various times between 2020 and 2026. We also have several composition of matter patents covering various aspects of our DM4 cell-killing agent and antibody-maytansinoid conjugates incorporating DM4 that are expected to remain in force until 2024-2025.

Our intellectual property strategy also includes pursuing patents directed to linkers, antibodies, conjugation methods, immunoconjugate formulations and the use of specific antibodies and immunoconjugates to treat certain diseases. In this regard, we have issued patents and pending patent applications related to many of our linker technologies. These issued patents, expiring in 2021-2027, and any patents which may issue from the patent applications, cover antibody-maytansinoid conjugates

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using these linkers. We also have issued U.S. patents and pending patent applications covering methods of assembling immunoconjugates from their constituent antibody, linker and cell-killing agent moieties. These issued patents will expire in 2021-2027, while any patents that may issue from pending patent applications also covering various aspects of these technologies will, if issued, expire between 2021 and 2032. We also have issued patents and pending patent applications related to monoclonal antibodies that may be a component of a TAP compound or may be developed as a therapeutic, or "naked," antibody anticancer compound. Among these patents is an issued U.S. patent claiming a method of humanizing murine antibodies to avoid their detection by the human immune system. We have received patents in other jurisdictions, including Europe and Japan,that correspond to our antibody humanization U.S. patent. These patents will expire between 2013 and 2014.

We expect our continued work in each of these areas will lead to other patent applications. In all such cases, we will either be the assignee or owner of such patents or have an exclusive license to the technology covered by the patents. For example, we also own issued patents covering proprietary derivatives of non-maytansinoid cell-killing molecules. However, we do not currently consider these additional patent families to be material to our business.

We have in-licensed intellectual property relating to our IMGN901 product candidate from Dana-Farber Cancer Institute. We do not believe that the terms of this license are material to our business or prospects.

We cannot provide assurance that the patent applications will issue as patents or that any patents, if issued, will provide us with adequate protection against competitors with respect to the covered products, technologies or processes. Defining the scope and term of patent protection involves complex legal and factual analyses and, at any given time, the result of such analyses may be uncertain. In addition, other parties may challenge our patents in litigation or administrative proceedings resulting in a partial or complete loss of certain patent rights owned or controlled by ImmunoGen, Inc. Furthermore, as a patent does not confer any specific freedom to operate, other parties may have patents that may block or otherwise hinder the development and commercialization of our technology.

In addition, many of the processes and much of the know-how that are important to us depend upon the skills, knowledge and experience of our key scientific and technical personnel, which skills, knowledge and experience are not patentable. To protect our rights in these areas, we require that all employees, consultants, advisors and collaborators enter into confidentiality agreements with us. Further, we require that all employees enter into assignment of invention agreements as a condition of employment. We cannot provide assurance, however, that these agreements will provide adequate or any meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of such trade secrets, know-how or proprietary information. Further, in the absence of patent protection, we may be exposed to competitors who independently develop substantially equivalent technology or otherwise gain access to our trade secrets, know-how or other proprietary information.

Competition

We focus on highly competitive areas of product development. Our competitors include major pharmaceutical companies and other biotechnology firms. For example, Pfizer, Seattle Genetics, Roche and Bristol-Myers Squibb have programs to attach a proprietary cell-killing small molecule to an antibody for targeted delivery to cancer cells. Pharmaceutical and biotechnology companies, as well as other institutions, also compete with us for promising targets for antibody-based therapeutics and in recruiting highly qualified scientific personnel. Many competitors and potential competitors have substantially greater scientific, research and product development capabilities, as well as greater financial, marketing and human resources than we do. In addition, many specialized biotechnology

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firms have formed collaborations with large, established companies to support the research, development and commercialization of products that may be competitive with ours.

In particular, competitive factors within the antibody and cancer therapeutic market include:

- the safety and efficacy of products;
- the timing of regulatory approval and commercial introduction;
- special regulatory designation of products, such as Orphan Drug designation; and
- the effectiveness of marketing, sales, and reimbursement efforts.

Our competitive position depends on our ability to develop effective proprietary products, implement clinical development programs, production plans and marketing plans, including collaborations with other companies with greater marketing resources than ours, and to obtain patent protection and secure sufficient capital resources.

Continuing development of conventional and targeted chemotherapeutics by large pharmaceutical companies and biotechnology companies may result in new compounds that may compete with our product candidates. In addition, antibodies developed by certain of these companies have been approved for use as cancer therapeutics. In the future, additional antibodies may compete with our product candidates. In addition, other companies have created or have programs to create potent cell-killing agents for attachment to antibodies. These companies may compete with us for technology out-license arrangements.

Because of the acceptance of combination therapy for the treatment of cancer and the variety of genes and targets implicated in cancer incidence and progression, we believe that products resulting from applications of new technologies may be complementary to our own.

Such new technologies include, but are not limited to:

- the use of genomics technology to identify new gene-based targets for the development of anticancer drugs;
- the use of high-throughput screening to identify and optimize lead compounds;
- the use of gene therapy to deliver genes to regulate gene function; and
- the use of therapeutic vaccines.

Regulatory Matters

Government Regulation and Product Approval

Government authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the new drug application, or NDA, process and a new biologic must be approved by the FDA through the biologics license application, or BLA, process before it may be legally marketed in the U.S.

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U.S. Drug Development Process

In the U.S., the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or FDCA, and in the case of biologics, also under the Public Health Service Act, or PHSA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biologic may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

Once a pharmaceutical candidate is identified for development it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with good clinical practice regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually. In addition, timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be