IMMUNOGEN INC Form 10-K August 28, 2014

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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, 2014

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

(State or other jurisdiction of incorporation or organization)

04-2726691

(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
Common Stock, \$.01 par value

Name of Each Exchange on Which Registered

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 (\S 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. \circ

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 Select Market, of voting stock held by non- affiliates at December 31, 2013: \$1,252,547,383 (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 20, 2014: 85,907,896 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 11, 2014 are incorporated by reference into Part III.

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ImmunoGen, Inc. Form 10-K

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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, 2014 unless otherwise indicated. For a description of the risk factors affecting or applicable to our business, see "Risk Factors," below.

Overview

We are a biotechnology company that develops targeted anticancer therapeutics. All of our wholly owned clinical and preclinical product candidates are antibody-drug conjugates, or ADCs. An ADC is a type of medicine that uses a monoclonal antibody to deliver a therapeutic agent to targeted cells.

We developed our ADC technology to enable the creation of highly effective, well-tolerated anticancer products. An ADC with our technology comprises an antibody that binds specifically to an antigen target found on the surface of cancer cells with one of our potent cancer-cell killing agents, or payloads, attached to the antibody using one of our engineered linkers. An ADC compound's antibody component enables it to bind to cancer cells that have its antigen on their surface and the payload agent serves to kill these cancer cells. We have tubulin-acting payload agents, such as DM1 and DM4, which are maytansinoids, and, more recently, we developed DNA-acting payload agents, such as DGN462, which we call IGNs. Our linkers are engineered to keep our payload agents securely attached to the antibody while traveling through the bloodstream and then control its release and activation once inside a cancer cell. The antibody component of an ADC may serve only as a targeting vehicle or it may also have anticancer activity, depending on the antigen target and the antibody selected.

We develop our own product candidates using our ADC technology. We now have three wholly owned, clinical-stage anticancer compounds IMGN853, IMGN289, and IMGN529 and have reported preclinical data for IMGN779, which we expect to be our next clinical-stage compound. IMGN779 is the first ADC with our IGN technology. We license to other companies limited rights to use our ADC technology with their antibodies to create products. The most advanced compound with our ADC technology is Roche's marketed product, Kadcyla® (ado-trastuzumab emtansine). Kadcyla was first commercialized in early 2013 and we began earning royalties on Kadcyla sales at that time. Seven other ADC compounds and one non-ADC, or "naked," antibody product candidate are in clinical testing through our partnerships. Our partnership agreements entitle us to earn milestone payments with agreed-upon achievements and, for therapies successfully developed and commercialized, royalties on product sales. Our current 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, the Roche Group and Sanofi. We also have a research agreement with CytomX Therapeutics that allows each company to develop probody-drug conjugates against a specified number of cancer targets using CytomX's Probody antibody masking technology with our payload agents and engineered linkers.

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

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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.

Pipeline: Wholly Owned and Partner Product Candidates

Listed in the tables below are the disclosed compounds in development through our own programs and our collaborations with other companies. All of these compounds are ADCs with the exception of SAR650984, which is a therapeutic antibody, and all of these compounds are in early clinical testing (Phase I and/or Phase II) with the exception of Kadcyla, which is marketed, and IMGN779, which is in preclinical testing. Additional earlier-stage compounds are in development by us and several of our partners. The results in early clinical trials may not be predictive of results obtained in subsequent clinical trials and there can be no assurance that any of our or our collaborators' product candidates, other than Kadcyla, will advance or will demonstrate the level of safety and efficacy necessary to obtain regulatory approval.

Compounds Wholly Owned by ImmunoGen

Compound	Lead Indication(s)	Target	
IMGN853 Ovarian cancer, endometrial cancer		Folate receptor α	
IMGN289 Head and neck cancers, non-small cell lung			
	cancers	EGFR	
IMGN529	Non-Hodgkin lymphoma	CD37	
IMGN779	Acute myeloid leukemia	CD33	

Collaborative Partner Compounds

Compound	Lead Indication(s)	Target	Partner
Kadcyla	Previously treated HER2-positive metastatic		
	breast cancer	HER2	Roche
AMG 172	Kidney cancer	CD70	Amgen
AMG 595	Glioblastoma	EGFRvIII	Amgen
BAY 94-9343	Mesothelioma, ovarian cancer	Mesothelin	Bayer
BT-062	Multiple myeloma, breast, bladder cancers	CD138	Biotest
SAR3419	Diffuse large B-cell lymphoma	CD19	Sanofi
SAR650984	Multiple myeloma	CD38	Sanofi
SAR566658	Solid tumors	CA6	Sanofi
SAR408701	Solid tumors	CEACAM5	Sanofi

IMGN853

We created our IMGN853 product candidate as a treatment for ovarian cancer, endometrial cancer, and potentially other cancers that highly express folate receptor α , or FR α . This ADC comprises a FR α -binding antibody with our potent DM4 payload agent attached using one of our engineered linkers.

IMGN853 is currently in Phase I clinical testing. During the initial dose-finding clinical research, IMGN853 was found to be generally well tolerated and to demonstrate evidence of anticancer activity. In July 2014, it was granted orphan drug status for ovarian cancer by the US FDA.

IMGN853 is now beginning assessment specifically for the treatment of $FR\alpha$ -positive platinum-resistant ovarian cancer and relapsed endometrial cancer. In this assessment, IMGN853 is being dosed once every three weeks. ImmunoGen research has indicated that dosing IMGN853 more frequently could further enhance efficacy without reducing tolerability, and dose finding is now underway with

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IMGN853 dosed weekly for three weeks followed by one week without treatment. ImmunoGen plans to select between these two schedules for more advanced IMGN853 clinical trials.

IMGN289

Our EGFR-targeting ADC, IMGN289, is a potential new treatment for cancers that highly express EGFR. These include squamous cell carcinoma of the head and neck, or SCCHN, and types of non-small cell lung cancer (NSCLC), including both squamous cell and non-squamous cell NSCLCs. IMGN289 comprises an ImmunoGen EGFR-binding antibody with our DM1 payload agent attached using one of our engineered linkers. In preclinical testing, the antibody component of IMGN289 was found to have meaningful anticancer activity against EGFR-positive cancer cells sensitive to EGFR inhibition. In these preclinical studies, the full product candidate, inclusive of the DM1, demonstrated superior activity against these cancers and also against EFGR-positive cancers not sensitive to EGFR inhibitors. This is attributed to the DM1 being able to kill EGFR-positive cancer cells through its mechanism, interference with tubulin formation, that is independent of the EGFR pathway.

IMGN289 advanced into clinical testing in late 2013. It is currently in the dose-finding portion of a Phase I clinical trial and no clinical data has been reported.

IMGN529

Our IMGN529 ADC is a potential new treatment for cancers that highly express CD37, such as non-Hodgkin lymphoma, or NHL, and chronic lymphocytic leukemia. ImmunoGen scientists have found the expression profile of CD37 on NHL subtypes to be similar to that of CD20, the target of Roche's Rituxan® (rituximab).

IMGN529 comprises an ImmunoGen CD37-targeting antibody with our DM1 payload agent attached using one of our engineered linkers. In preclinical testing, the antibody demonstrated notable anticancer activity that was further enhanced by the addition of the DM1. IMGN529 is currently in the dose-finding portion of a Phase I clinical trial assessing it in patients with NHL previously treated with other anticancer agents. Initial evidence of anticancer activity has been reported with IMGN529.

IMGN779

Preclinical-stage IMGN779 is a potential new treatment for acute myeloid leukemia. It comprises an ImmunoGen CD33-targeting antibody with one of our DNA-acting payload agent, DGN462, attached using one of our engineered linkers. We currently intend to submit an Investigational New Drug, or IND, application for it to the FDA during the latter half of 2015.

Kadcyla (previously referred to as T-DM1)

Kadcyla is a HER2-targeting ADC that comprises trastuzumab, which is the active component of Roche's antibody therapeutic, Herceptin® (trastuzumab), with our DM1 payload agent attached using one of our engineered linkers. Roche has global development and commercialization rights for Kadcyla under an ADC technology license from us.

Kadcyla was granted marketing approval in February 2013 by the U.S. Food and Drug Administration, or FDA, for the treatment of HER2-positive metastatic breast cancer in patients who previously received Herceptin and a taxane. It was approved for this use in Japan and in the European Union (EU) in September 2013 and November 2013, respectively. In some countries, such as the US, Kadcyla was able to be launched shortly after gaining marketing approval. In other countries, it is necessary to negotiate pricing with governmental authorities prior to launch. For example, Kadcyla was launched in Japan in April 2014 after such negotiations.

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Roche is developing Kadcyla for a number of additional uses, and currently has Phase III, or registration, trials underway assessing Kadcyla as a therapy for patients with:

Metastatic HER2-positive breast cancer not previously been treated Roche is assessing Kadcyla for this use in its MARIANNE trial. Roche has announced that it intends to use MARIANNE results, if favorable, to apply in 2015 for marketing approval of Kadcyla for this use.

Early stage HER2-positive breast cancer Roche has initiated three Phase III trials in this setting: its KATHERINE trial evaluates Kadcyla for the treatment of patients with residual invasive disease following pre-operative therapy; its KAITLIN trial assesses Kadcyla for adjuvant use; and its KRISTINE trial evaluates Kadcyla in the neoadjuvant setting.

Advanced HER2-positive gastric cancer Roche is evaluating Kadcyla for this use in its GATSBY trial. Roche has announced that it intends to use the results from GATSBY, if favorable, to apply in 2015 for marketing approval for this use.

Other Clinical-stage Compounds in Development by Our Partners

In addition to Kadcyla, eight other compounds are in clinical testing through our collaborations with other companies. In alphabetical order, these are:

AMG 172 This CD70-targeting ADC was created by Amgen under a license from ImmunoGen. It is currently in Phase I clinical testing for the treatment of patients with clear cell renal cell carcinoma. To our knowledge, no clinical data has been reported with AMG 172 to date.

AMG 595 This EGFRvIII-targeting ADC also was created by Amgen under a license from ImmunoGen. It is currently in Phase I clinical testing for the treatment of patients with glioblastoma and initial evidence of activity has been reported.

BAY 94-9343 This mesothelin-targeting ADC was created by Bayer under a license from ImmunoGen. Initial evidence of activity in mesothelioma has been reported. BAY 94-9343 is currently being assessed for the treatment of mesothelioma and ovarian cancer in early clinical trials.

BT-062 This CD138-targeting ADC was created by Biotest under a license from ImmunoGen. We have opt-in rights for co-development and co-commercialization of BT-062 with Biotest in the U.S. Encouraging findings with BT-062 in the treatment of multiple myeloma have been reported, both with the agent used alone and as part of a combination treatment regimen, and its development for this cancer is ongoing. The target for BT-062 also has been found to occur on several types of solid tumors, and in early 2014 this ADC began clinical testing for the treatment of triple-negative breast cancer and metastatic urinary bladder cancer.

SAR3419 This CD19-targeting ADC was initially created by ImmunoGen and licensed to Sanofi as part of a broad research collaboration. In Phase II clinical testing, SAR3419 showed what was concluded to be proof-of-concept efficacy as monotherapy in the treatment of diffuse large B-cell lymphoma, a difficult-to-treat lymphoma, in patients whose cancer had returned after treatment with other agents. These findings were reported at the annual meeting of the American Society of Clinical Oncology, or ASCO, in June 2014.

SAR650984 This product candidate is CD38-targeting therapeutic, or "naked", antibody initially created by ImmunoGen and licensed to Sanofi as part of a broad research collaboration. SAR650984 has shown promising activity in early clinical testing when used alone or as part of a combination regimen to treat patients with previously treated multiple myeloma. Sanofi has begun Phase II testing of SAR650984 for multiple myeloma.

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SAR566658 This CA6-targeting ADC also was initially created by ImmunoGen and licensed to Sanofi as part of a broad research collaboration. It is currently in Phase I clinical testing for the treatment of CA6-positive solid tumors, such as ovarian cancer, with initial evidence of activity reported.

SAR408701 This CEACAM5-targeting ADC was initially created by ImmunoGen and licensed to Sanofi as part of a broad research collaboration. Patient enrollment has opened in the first SAR408701 clinical trial.

Earlier-stage ADCs are in development through our collaborations with Amgen, CytomX, Lilly, Novartis, and Sanofi.

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, or ACS, estimates that in 2014 approximately 1.7 million new cases of cancer will be diagnosed in the U.S. and that approximately 586,000 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.

Below is information about incidence of cancers we are seeking to treat with our wholly owned compounds. In our clinical testing, we will define treatment subgroups of patients for the cancer types referenced.

IMGN853 Our IMGN853 compound is a potential treatment for epithelial ovarian cancer, endometrial cancer and potentially other cancers that highly express its target, FR α . Based on published sources, we believe approximately 22,000 new cases of ovarian cancer will be diagnosed in the US in 2014 and epithelial ovarian cancer accounts for approximately 85% to 90% of these ovarian cancer cases. We believe that approximately 52,600 cases of endometrial cancers will be diagnosed in the US in 2014.

IMGN289 Our IMGN289 compound is a potential treatment for many cases of head and neck cancer and types of NSCLC. The ACS estimates that approximately 55,000 new cases of head and neck cancers will be diagnosed in 2014. Research conducted at ImmunoGen found that over 90% of these types of cancer strongly express EGFR. Based on ACS estimates, we believe approximately 191,000 new cases of NSCLC will be diagnosed in the U.S. in 2014. This figure comprises three main subtypes adenocarcinoma, squamous cell carcinoma, and large cell carcinoma. These subtypes account for approximately 40%, 25-30%, and 10-15% of NSCLC diagnoses, respectively. Research with tumor samples conducted at ImmunoGen found that approximately 20% of adenocarcinoma cases and about half of squamous and of large cell carcinoma cases strongly express EGFR.

<u>IMGN529</u> We are assessing our IMGN529 compound for the treatment of NHL. Based on ACS estimates, we believe approximately 70,800 new cases of NHL will be diagnosed in the U.S. in 2014.

<u>IMGN779</u> Our preclinical IMGN779 compound is a potential treatment for acute myeloid leukemia, or AML. Based on ACS estimates, we believe approximately 18,900 new cases of AML will be diagnosed in the U.S. in 2014.

Out-licenses and Collaborations

We selectively license restricted access to our ADC technology to other companies to provide us with cash to fund our own product programs and to expand the utilization of our technology. These

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agreements typically provide the licensee with rights to use our ADC technology with its antibodies or related targeting vehicles 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 only receive royalty payments from our out-licenses after a product candidate developed under the license has been approved for marketing and commercialized. Additionally, the largest milestone payments under our existing collaborations usually are on later-stage events, such as commencement of pivotal clinical trials, product approval and achievement of defined annual sales levels. 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 a positive regulatory decision. We have a license with Roche relating to Kadcyla that provides us with royalty revenue and may provide us with additional milestone payments. Kadcyla is currently our only source of royalty revenue. Below is a table setting forth our active agreements and current status of the product candidates being developed thereunder:

Partner	Agreement Type	Effective Date(s)	Development Status ⁽¹⁾
Roche ⁽²⁾	Multiple single-targets	2000	Marketed
Amgen ⁽³⁾	Multiple 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
•			
CytomX	Right-to-test	2014	Research/Preclinical
•	-		

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

Roche has five single-target licenses. Pursuant to the license covering the target HER2, which was entered into in 2000, a product candidate, Kadcyla, has received marketing approval in the US, Japan and the EU, along with various other countries. The remaining four licenses were taken between 2005 and 2008 under another agreement established in 2000, and the development status of product candidates under each of those licenses is research/preclinical.

Amgen has four exclusive, single-target licenses, one of which has been sublicensed by Amgen to Oxford BioTherapeutics Ltd.

Sanofi, Novartis and Lilly each have the right to take a defined number of exclusive, single-target options that provide the right to take a defined number of single-target licenses, on pre-negotiated terms, to specified targets during the respective option periods. As of June 30, 2014, Novartis has taken two exclusive single-target licenses and one license to two related targets, one on an exclusive basis and the second on a non-exclusive basis; Lilly has taken an exclusive license to a single target; and, Sanofi has taken an exclusive license to a single target.

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Roche

In May 2000, we granted Genentech, now a unit of Roche, an exclusive development and commercialization license to use our maytansinoid ADC technology with antibodies, such as trastuzumab, or other proteins that target HER2. In February 2013, the US FDA granted marketing approval to the HER2-targeting ADC compound, Kadcyla. Roche received marketing approval for Kadcyla in Japan and in the EU in September 2013 and November 2013, respectively. It has also received marketing approval in various other countries around the world. 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 on the commercial sales of Kadcyla or any other resulting products as described below. To date we have received \$34 million of the \$44 million in potential milestone payments.

The royalty term is determined on a country-by-country basis, and is initially 10 years from the date of first commercial sale of Kadcyla in the country. If, on such 10th anniversary, Kadcyla is covered by a valid claim under any patents controlled by us (excluding patents jointly owned by us and Genentech), then royalties remain payable on sales of Kadcyla in that country for an additional 2 years and no more.

The following two territories are used in our agreement with Genentech to determine the Kadcyla sales levels for the calculation of the applicable tiered royalty levels: (1) the US and (2) the rest of the world. Royalties on sales of Kadcyla are paid quarterly based on net sales in each territory in accordance with a tiered structure calculated separately in each of the two territories as follows:

3% of net sales up to \$250 million in the calendar year;

3.5% of net sales above \$250 million and up to \$400 million in the calendar year;

4% of net sales above \$400 million and up to \$700 million in the calendar year; and

5% of net sales above \$700 million in the calendar year.

Royalties will be reduced to a flat 2% of net sales in any country at any time during the royalty term in which Kadcyla is not covered by a valid claim under any patents controlled by us (excluding patents jointly owned by us and Genentech or solely owned by Genentech) in such country. The sales in the country count towards the annual sales in that territory for purposes of calculation of sales tiers.

The license agreement also provides for certain adjustments to the royalties payable to us if Genentech makes certain third party license payments in order to exploit the ADC technology components of Kadcyla, although such adjustments would in no event reduce the royalties payable for any country below the greater of 50% of the royalties otherwise payable with respect to sales of Kadcyla in such country, or 2% of net sales in such country. As of the date of this annual report on Form 10-K, we are unaware of any facts or circumstances that would give rise to such an adjustment.

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.

In fiscal year 2014 we received two \$5 million milestone payments in connection with marketing approval of Kadcyla in Japan and in the EU. Through June 30, 2014, we have received and recognized a total of \$34.0 million in milestone payments under this agreement. The next potential milestone we will be entitled to receive will be a \$5 million regulatory milestone for marketing approval of Kadcyla for a first extended indication as defined in the agreement.

Roche, through its Genentech unit, also has licenses for the exclusive right to use our maytansinoid ADC technology with antibodies to four undisclosed targets, which were granted under the terms of a

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separate May 2000 right-to-test agreement with Genentech. For each of these licenses we received a \$1 million license fee and are entitled to receive up to a total of \$38 million in milestone payments and also royalties on the sales of any resulting products. We have not received any milestone payments from these agreements through June 30, 2014. Roche is responsible for the development, manufacturing, and marketing of any products resulting from these licenses. Roche no longer has the right to take additional licenses under the right-to-test agreement.

Amgen

Under a now-expired right-to-test agreement, in September 2009, November 2009 and December 2012, Amgen took three exclusive development and commercialization licenses, for which we received an exercise fee of \$1 million for each license taken. In May 2013, Amgen took one non-exclusive development and commercialization license, for which we received an exercise fee of \$500,000. In October 2013, the non-exclusive license was amended and converted to an exclusive license, for which Amgen paid an additional \$500,000 fee to us. Amgen has sublicensed its rights under this license to Oxford BioTherapeutics Ltd. We are entitled to receive up to a total of \$34 million in milestone payments for each exclusive license, plus royalties on the commercial sales of any resulting products.

In November 2011, the IND applications to the FDA for two compounds developed under the 2009 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 two 2009 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. The next potential milestones we will be entitled to receive under the December 2012 and May 2013 development and commercialization licenses will be a \$1 million development milestone for IND approval.

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.

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 exclusive right to use our maytansinoid ADC technology in the creation of products directed to these targets. The product candidates (targets) currently in development under the collaboration include SAR3419 (CD19), SAR650984 (CD38), SAR566658 (CA6) and SAR408701 (CEACAM5) and one earlier-stage compound that has yet to be disclosed. We are entitled to receive milestone payments potentially totaling \$21.5 million, per target, 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

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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 ImmunoGen.

Through June 30, 2014, we have received and recognized a total of \$16.5 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. In July 2014, Sanofi initiated a Phase II clinical trial for SAR650984 which triggered a \$3 million payment to us.

The next potential milestone we will be entitled to receive with respect to each of SAR3419 and SAR650984 will be a development milestone for initiation of a Phase III clinical trial, 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 SAR566658 will be a development milestone for initiation of a Phase IIb clinical trial (as defined in the agreement), which will result in a \$3 million payment being due. The next potential milestone we will be entitled to receive for each of SAR408701 and the unidentified target will be a development milestone for commencement of a Phase I clinical trial, which will result in each case in a \$1 million 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 ADC 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 specified targets for specified option periods and (c) upon exercise of those options, take exclusive licenses to use our maytansinoid ADC 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 renewed by Sanofi in August 2011 for its final three-year term ending August 31, 2014 by payment of a \$2 million extension fee. No additional extensions are included in this agreement, although any outstanding options will remain in effect for the remainder of their respective option terms.

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. In December 2013, Sanofi took its first exclusive development and commercialization license under the right-to-test agreement, for which we received an exercise fee of \$2 million. The next payment we could receive would either be a \$2 million development milestone payment with the initiation of a Phase I clinical trial under the first development and commercialization license taken, or a \$2 million exercise fee for the execution of a second license.

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

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country or the expiration for that country of the minimum royalty period specified in each development and commercialization license.

Biotest

In July 2006, we granted Biotest an exclusive development and commercialization license to our maytansinoid ADC technology for use with antibodies that target CD138. The product candidate BT-062 is 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. Through June 30, 2014, 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.

The agreement also provided us with the right to elect, at specific stages during the clinical evaluation of any compound created under the agreement, to participate in the U.S. development and commercialization of that compound in lieu of receiving the milestone payments not yet earned and royalties on sales in the U.S. Currently, 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 \$15 million. Upon exercise of this right, we would share equally with Biotest the associated further costs of product development and commercialization in the U.S. along with the profit, if any, from product sales in the U.S. We would also be entitled to receive royalties, on a reduced basis, on product sales outside the U.S.

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.

Bayer HealthCare

In October 2008, we granted Bayer HealthCare an exclusive development and commercialization license to our maytansinoid ADC technology for use with antibodies or other proteins that target mesothelin. The product candidate BAY 94-9343 is 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, 2014, 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. The agreement provides Novartis with a right to (a) test our ADC technology with individual antibodies provided 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 ADC 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 three-year term of the right-to-test agreement was extended by Novartis in October 2013 for an additional one-year period by payment of a \$5 million fee to the Company. In addition to the one-year extension taken in October 2013, the terms of the right-to-test agreement allow Novartis to extend the research term for one additional one-year period by payment of additional consideration. The terms of the right-to-test agreement require Novartis to exercise its options for the development and commercialization licenses by the end of the term of the research license.

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.

In March 2013, we and Novartis amended the right-to-test agreement so that Novartis can take a license to develop and commercialize products directed at two pre-defined and related undisclosed targets, one target licensed on an exclusive basis and the other target initially licensed on a non-exclusive basis. The target licensed on a non-exclusive basis may be converted to an exclusive target by notice and payment to us of an agreed upon fee of at least \$5 million, depending on specific circumstances. We received a \$3.5 million fee in connection with the execution of the amendment to the agreement. We may be required to credit this fee against future milestone payments if Novartis discontinues the development of a specified product under certain circumstances.

In connection with the amendment, in March 2013, Novartis took the license referenced above under the right-to-test agreement, as amended, enabling it to develop and commercialize products directed at the two targets. We received a \$1 million upfront fee with the execution of this license. Additionally, the execution of this license provides us the opportunity to receive milestone payments totaling \$199.5 million or \$238 million, depending on the composition of any resulting products, plus royalties on the commercial sales of any resulting products.

In October 2013 and November 2013, Novartis took its second and third exclusive licenses to single targets, each triggering a \$1 million payment to the Company and the opportunity to receive milestone payments totaling \$199.5 million for each license taken, plus royalties on the commercial sales of any resulting products. The next payment the Company could receive would either be a \$5 million development milestone for commencement of a Phase I clinical trial under any of these three licenses, or a \$1 million exercise fee for the execution of a fourth license.

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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.

Lilly

In December 2011, we entered into a three-year right-to-test agreement with 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 ADC 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 ADC 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. Lilly has the right to extend the three-year right-to-test period for up to two six-month periods by payment to us of additional consideration. Under the terms of the agreement, Lilly took an exclusive development and commercialization license to a single target in August 2013.

We received a \$20 million upfront payment in connection with the execution of the right-to-test agreement, and for the first development and commercialization license taken in August 2013 and amended in December 2013, we received an exercise fee in the amount of \$2 million and are entitled to receive up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. Lilly has the right to elect, at its discretion, which of the two additional development and commercialization licenses it has a right to take under the right-to-test agreement will have no exercise fee and which will have an exercise fee of \$2 million. With respect to any subsequent development and commercialization license taken, if Lilly elects that the \$2 million exercise fee is payable, we are entitled to receive, in addition to the exercise fee, up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. If Lilly elects that no exercise fee is payable when it takes a development and commercialization license, the Company is entitled to receive up to a total of \$200.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. The next payment we could receive would either be a \$5 million development milestone payment with the initiation of a Phase I clinical trial under the first development and commercialization license taken, or a \$2 million exercise fee for the execution of an additional license if Lilly elects to pay the exercise fee with respect to such license.

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.

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CytomX

In January 2014, we entered into a reciprocal right-to-test agreement with CytomX. The agreement provides CytomX with the right to test our ADC technology with CytomX Probodies to create Probody-drug conjugates (PDCs) directed to a specified number of targets under a right-to-test, or research, license, and to subsequently take an exclusive, worldwide license to use our ADC technology to develop and commercialize PDCs directed to the specified targets on terms agreed upon at the inception of the right-to-test agreement. We received no upfront cash payment in connection with the execution of the right-to-test agreement. Instead, we received reciprocal rights to CytomX's Probody technology whereby we were provided the right to test CytomX's Probody technology to create PDCs directed to a specified number of targets and to subsequently take exclusive, worldwide licenses to develop and commercialize PDCs directed to the specified targets on terms agreed upon at the inception of the right-to-test agreement. The terms of the right-to-test agreement require us and CytomX to each take its respective development and commercialization licenses by the end of the term of the research license. In addition, both we and CytomX are required to perform specific research activities under the right-to-test agreement on behalf of the other party for no monetary consideration.

With respect to the development and commercialization license that may be taken by CytomX, we are entitled to receive up to a total of \$160 million in milestone payments per license, plus royalties on the commercial sales of any resulting product. Assuming no annual maintenance fee is payable as described below, the next payment we could receive would be a \$1 million development milestone payment with commencement of a Phase I clinical trial.

With respect to any development and commercialization license that may be taken by us, we will potentially be required to pay up to a total of \$80 million in milestone payments per license, plus royalties on the commercial sales of any resulting product. Assuming no annual maintenance fee is payable as described below, the next payment we could be required to make is a \$1 million development milestone payment with commencement of a Phase I clinical trial.

In addition, each party may be liable to pay annual maintenance fees to the other party if the licensed PDC product candidate covered under each development and commercialization license has not progressed to a specified stage of development within a specified time frame.

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, 2014, our patent portfolio had a total of 472 issued patents worldwide and 569 pending patent applications worldwide that we own or license from third parties. We seek to protect our ADC 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, cell-killing agents (*e.g.*, tubulin-acting maytansinoids and DNA-acting cell-killing agents), and complete ADCs, 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 cell-killing agent technology to be a key component of our overall corporate strategy. We currently own 43 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

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in force until 2024-2025. We have one issued U.S. patent covering various aspects of our DNA-acting cell-killing agents, which will expire in 2030. We also have seven additional pending U.S. patent applications disclosing and claiming may other related embodiments of this technology. Patents that may issue from these applications will, if issued, expire between 2030 and 2033. In all cases, we are also applying for comparable patents in other jurisdictions, including Europe and Japan.

Our intellectual property strategy also includes pursuing patents directed to linkers, antibodies, conjugation methods, ADC formulations and the use of specific antibodies and ADCs 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 2021-2031, and any patents which may issue from the patent applications, cover antibody-maytansinoid conjugates using these linkers. We also have issued U.S. patents and pending patent applications covering methods of assembling ADCs from their constituent antibody, linker and cell-killing agent moieties. These issued patents will expire in 2021-2030, while any patents that may issue from pending patent applications also covering various aspects of these technologies will, if issued, expire between 2021 and 2034. We also have issued patents and pending patent applications related to monoclonal antibodies that may be a component of an ADC compound or may be developed as a therapeutic, or "naked," antibody anticancer compound.

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.

The rates at which we are entitled to receive royalties based on sales of Kadcyla in any particular country depend in part on whether the manufacture, use or sale of Kadcyla is covered by ImmunoGen patent rights in that country. In this regard, we own patents in the U.S. and Europe covering the composition of matter of Kadcyla that expire at the earliest in 2023 and 2024, respectively, and may be eligible for extension of those terms under applicable patent laws in those jurisdictions. We also own patents in the U.S. and Europe that cover various elements of the manufacture of Kadcyla, with expiration dates extending to at least 2027 and 2026, respectively. Notwithstanding these patent terms, the period during which we are entitled to receive royalties based on sales of Kadcyla in any country does not extend beyond the 12th anniversary of the date of the first commercial sale of Kadcyla in such country.

We cannot provide assurance that the patent applications will issue as patents or that