

IMMUNOGEN INC  
Form 10-K  
August 25, 2016  
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10 K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended June 30, 2016

OR  
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 (I.R.S. Employer  
of incorporation or organization) 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. Yes 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. Yes 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. Yes 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

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this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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.

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 Accelerated filer Non-accelerated filer Smaller reporting company  
(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). Yes 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, 2015: \$1,176,154,266 (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 18, 2016: 87,326,441 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 4, 2016 are incorporated by reference into Part III.

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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”, “our”, “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, 2016 unless otherwise indicated. For a description of the risk factors affecting or applicable to our business, see “Risk Factors,” below.

#### Company overview

ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using our proprietary antibody-drug conjugate, or ADC, technology. An ADC with our technology comprises an antibody that binds to a target found on tumor cells conjugated to one of our potent anti-cancer agents as a “payload” to kill the tumor cell once the ADC has bound to its target. ADCs are an expanding approach to the treatment of cancer, with two approved products and the number of agents in development more than doubling during the last five years.

We have established a leadership position in ADCs. Our technology is deployed in Roche’s Kadcyla® (ado-trastuzumab emtansine), the first ADC to demonstrate superiority over standard of care in a randomized pivotal trial, EMILIA, and gain FDA approval. Following Kadcyla are 12 clinical-stage ADCs with our technology: four wholly-owned by us and eight through our partnerships with Amgen, Bayer, Biotest, Lilly, Novartis, and Sanofi.

Our proprietary portfolio is led by mirvetuximab soravtansine, a first-in-class ADC targeting folate-receptor alpha, or FR $\alpha$ . Following a meeting with the U.S. Food and Drug Administration, or FDA, in July 2016, we are initiating a Phase 3 registration trial, FORWARD I, with mirvetuximab soravtansine for use as single-agent therapy to treat patients with platinum-resistant ovarian cancer whose tumors express high or medium levels of FR $\alpha$  and who have received up to three prior treatment regimens. Additionally, we are accruing patients in a companion study, FORWARD II, to evaluate mirvetuximab soravtansine in combination regimens to expand the number of patients with ovarian cancer eligible for treatment with the ADC. FORWARD II consists of cohorts assessing mirvetuximab soravtansine in combination with, in separate doublets, Avastin® (bevacizumab), pegylated liposomal doxorubicin, or PLD, and carboplatin. We have also entered into a collaboration with Merck under which Merck will provide Keytruda® (pembrolizumab) for evaluation in combination with mirvetuximab soravtansine as part of the FORWARD II study. We expect to begin reporting clinical findings from FORWARD II in the second quarter of 2017.

We have built a productive platform that continues to generate innovative and proprietary ADCs, including IMG779, our CD33-targeting product candidate for acute myeloid leukemia, or AML. IMG779 integrates one of our new DNA-alkylating IGN payload agents and is progressing through dose escalation in a Phase 1 trial in AML. We also are advancing IMG632, a preclinical CD123-targeting ADC that uses an even more potent IGN payload agent with a new engineered linker and novel antibody, which we are developing for hematological malignancies including AML.

In addition to fueling our organic growth, we also selectively license limited rights to use of our ADC technology to other companies. These licenses can provide us with cash through upfront and milestone payments, research and manufacturing support payments, and royalties on commercial sales, if any, as well as access to complementary technology and capabilities. The most advanced partner program is Roche’s marketed product, Kadcyla.

#### Our strategy

Our goal is to build a fully-integrated company capable of delivering innovative ADC therapies to cancer patients around the globe. We will attain this goal this goal by focusing on four strategic priorities:

- Complete development and commercialize mirvetuximab soravtansine. We are committed to executing on a speed-to-market strategy to complete development and obtain full approval for our lead program in platinum-resistant ovarian cancer. We have reviewed with the FDA the planned path to registration for mirvetuximab soravtansine and the design of our proposed Phase 3 trial, FORWARD I. With the benefit of the guidance provided by FDA, we are moving ahead with the study as designed and expect to enroll our first patient before year end.

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- Accelerate the development of our earlier-stage portfolio. We will prioritize product candidates with the highest potential for differentiation and, to this end, have emphasized ADCs deploying our new DNA-acting payload. With a potentially broad therapeutic index, we believe we can increase the number of cancers addressable by ADC therapies with this technology.
  - Continue to drive innovation in ADCs. We have generated significant expertise in understanding the factors that drive successful development of ADCs. This understanding has produced a comprehensive set of capabilities for antibody, linker, and payload development and ADC manufacturing. We have paired this platform with an in-house team experienced in developing and commercializing oncology products from the bench to the patient. We believe this depth of know-how, capabilities, and experience has positioned us for sustained leadership in ADCs for oncology.
  - Leverage partnerships to extend the impact of innovation. We will continue to leverage our platform to support our existing relationships and pursue new collaborations that expand the reach of our innovation, generate revenue, mitigate expenses, and expand our capabilities to enable more patients to be treated with ADCs deploying our technology.
- Having defined our strategic direction and corporate priorities, we have initiated a comprehensive review of our operations to ensure that we execute efficiently across the business and most effectively manage our cash. We expect to complete this review and communicate a revised operating plan before the end of 2016.

### ADCs and our technology platform

ADCs represent an increasingly important approach to cancer therapy for both solid tumors and hematological malignancies. In addition to two FDA-approved ADCs, the number of ADCs in development has more than doubled during the last five years to over 50 clinical candidates sponsored by more than 20 companies including Bayer, Lilly, Novartis, Pfizer, Roche, and Takeda. Twelve of these 50 candidates utilize ImmunoGen's technology, with additional ADCs in preclinical development.

Our ADC platform technology combines advanced chemistry and biochemistry with innovative approaches to antibody optimization and engineering to generate novel product candidates designed to offer improved efficacy and/or tolerability for an expanding array of malignancies. Our platform-innovation programs focus primarily on increasing the diversity and potency of our payload agents, advancing antibody-payload linkage and release technologies, and integration of novel approaches to antibody engineering.

We have developed tubulin-acting maytansinoid payload agents, which include DM1 and DM4. Our maytansinoid technology is utilized in Kadcyla, mirvetuximab soravtansine, anetumab ravtansine, and all other ADCs in development by us and our partners that entered the clinic prior to 2016. Recent laboratory studies conducted by ImmunoGen and academics indicate that maytansinoid ADCs can promote the maturation and activation of antigen-presenting dendritic cells and help potentiate the effect of immuno-oncology agents. We have entered into a collaboration with Merck to assess mirvetuximab soravtansine in combination with Merck's Keytruda in our Phase 1b/2 FORWARD II trial.

We also have developed a new class of DNA-acting payload agents, our indolino-benzodiazepines, which we call IGNs. Our IGNs alkylate DNA without cross-linking it, which we have found to provide important tolerability benefits in preclinical models. Our IMGN779 and IMGN632 product candidates utilize our IGN payload agents, as does Takeda's new GCC-targeting ADC. IGNs have the potential to markedly expand the opportunity for ADCs by enabling the development of effective, well-tolerated therapies for antigen targets not suitable for tubulin-acting approaches (e.g., due to limited antigen density or insensitivity to the mechanism of action).

Other enabling technologies in our portfolio include our growing array of stable engineered linkers, which direct the release and activation of the payload agent inside the cancer cell, alternative methods of site-specific and non-site-specific attachment of payload to antibody, and alternative antibody assessment, engineering and targeting

approaches. Our technology portfolio is designed to enable achievement of the most active, well-tolerated ADC for the target. In addition, we are collaborating with companies such as CytomX to gain access to novel approaches to antibody engineering such as masking technology.

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## Our product candidates

The following table depicts the current status of our product candidates in or near human clinical development and for which we retain all commercial rights:

## ImmunoGen Wholly-Owned

Product Candidate	Target	Lead Indication	Lead Stage
Mirvetuximab soravtansine	FR	Platinum-resistant ovarian cancer	Advancing to Phase 3 registration testing
IMGN529	CD37	DLBCL	Phase 2
Coltuximab ravtansine	CD19	DLBCL	Phase 2
IMGN779	CD33	AML	Phase 1
IMGN632	CD123	AML	Preclinical

## Mirvetuximab soravtansine

Mirvetuximab soravtansine is the first ADC to target FR , which is highly expressed on many ovarian cancers and some other types of solid tumors. Mirvetuximab soravtansine comprises an FR -binding antibody that serves to target the ADC to FR -positive cancer cells and our potent DM4 payload agent to kill the targeted cells. It is a potential treatment for FR -positive solid tumors including ovarian cancer and has been granted orphan drug status for ovarian cancer in the U.S. and the European Union, or the EU.

## Ovarian cancer – need for new treatment options

According to the World Health Organization, approximately 240,000 new cases of ovarian cancer are diagnosed globally each year. Ovarian cancer has the most deaths per year among gynecologic cancers, with the majority of patients diagnosed at an advanced stage.

Standard first-line therapy for ovarian cancer in the U.S. is a platinum-based regimen (e.g., carboplatin plus a taxane and potentially additional agents). Once the cancer becomes platinum resistant, a wide array of treatments may be used. Response rates with single-agent therapies (e.g., PLD, paclitaxel, topotecan) are limited – typically around 15% to 20%, with median progression-free survival, or PFS, of 3.5 to 4 months.

## Mirvetuximab soravtansine initial clinical testing

We initiated Phase 1 testing of mirvetuximab soravtansine to assess, among other factors, its safety, tolerability, and maximum tolerated dose, and to provide initial information on its anti-tumor activity. In the dose-finding stage, evidence of activity was seen in patients with FR -positive, platinum-resistant ovarian cancer. Based on this experience, we opened an expansion cohort to prospectively evaluate mirvetuximab soravtansine, dosed at 6 mg/kg once every 3 weeks, specifically for the treatment of patients diagnosed with FR -positive, platinum-resistant ovarian cancer.

To qualify for enrollment, patients needed to have platinum-resistant ovarian cancer treated with up to 5 prior treatment regimens. They also needed to have at least low FR expression on their tumor cells, defined as:

FR expression category	Percent of tumor cells with moderate (2+) or high (3+) FR expression	Percent of patients with ovarian cancer*
High	at least 75%	40%



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Medium	50% to 74%	20%
Low	25% to 49%	20%
Very low	Less than 25%	20%

\*ImmunoGen estimate based on the pre-screening patients for FR expression for mirvetuximab soravtansine ovarian cancer trials and on published data.

Findings in patients with FR -positive platinum-resistant ovarian cancer

The data from this 46-patient cohort were presented at the ASCO annual meeting in June 2016. All of the patients enrolled had previously been treated with a platinum agent and with a taxane therapy; approximately two-thirds of the patients had received prior Avastin. Among the 46 patients, 23 had high, 14 had medium and 9 patients had low

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expression of FR on their ovarian cancer. Half of the 46 patients had received 1, 2, or 3 prior regimens and half had received 4 or 5 prior regimens.

The findings reported at ASCO include that, for the full 46-patient cohort, mirvetuximab soravtansine demonstrated favorable single-agent activity, with a confirmed (RECIST 1.1) objective response rate, or ORR, of 26% and a median PFS of 4.8 months (95% confidence interval, 3.9 to 5.7 months). The greatest activity was seen among the patients who had high or medium expression of the target and had received up to 3 prior regimens.

Patients	ORR Confirmed responses only	Median PFS
All in study (n=46)	26%	4.8 months (95% CI, 3.9-5.7)
Those with high or medium FR who received up to 3 prior regimens (n=16)	44%	6.7 months (95% CI, 3.9-11.0)
Those with low FR who received 4 or 5 prior regimens (n=30)	17%	4.2 months (95% CI, 2.6-5.5)
Standard single-agent therapies based on product label and other published data	15%-20%	3.5 to 4 months

Mirvetuximab soravtansine was generally well tolerated. Incidence and severity of blurred vision was reduced from 55%, mostly Grade 2 in the first 20 patients enrolled, to 39%, mostly Grade 1 (least severe), among the 26 patients enrolled after methods such as use of lubricating eye drops were introduced to manage this side effect. Other side effects reported in more than 20% of patients were diarrhea, fatigue, nausea, vomiting, peripheral neuropathy, increased AST, keratopathy and abdominal pain.

Based on the single-agent activity seen with mirvetuximab soravtansine in difficult-to-treat platinum-resistant ovarian cancer, its safety and tolerability in the more than 160 patients treated to date, and our meeting with the FDA in July 2016, we are advancing this ADC into Phase 3 registration-enabling testing while also assessing it in combination regimens to potentially provide greater benefit to more patients.

#### FORWARD I – single-agent therapy for platinum-resistant disease

Our FORWARD I Phase 3 trial will assess mirvetuximab soravtansine as single-agent therapy for patients with platinum-resistant ovarian cancer who previously received up to three treatment regimens. To be eligible for enrollment, a patient's ovarian cancer also must have high or medium FR expression using an in vitro diagnostic test developed by Ventana Medical Systems, Inc. that is advancing in conjunction with this trial. We estimate that 5,000 to 7,000 patients per year in the U.S. meet these criteria, with a comparable number in Europe.

The Phase 3 trial design includes: (i) randomization of 333 patients 2:1 to mirvetuximab soravtansine or physician's choice, chosen among PLD, topotecan, and weekly paclitaxel; (ii) PFS as the primary endpoint of the trial; (iii) powering the trial to enable separate assessment of the primary endpoint in the full study population and in the subset with high FR expression; and (iv) inclusion of an interim analysis for futility.

Having met with the FDA to review the trial design, we expect to begin this Phase 3 trial in the fourth quarter of 2016. We currently anticipate having data from FORWARD I in 2019.

#### FORWARD II – combination therapy for expanded patient population

Cancer is often treated with combination regimens to enhance the treatment effect over single agents and to expand the eligible patient populations. Our FORWARD II Phase 1b/2 trial assesses mirvetuximab soravtansine in separate combinations with each of PLD, Avastin, and carboplatin, and is expected to begin evaluation with Merck's Keytruda in the second half of 2016. To qualify for enrollment in FORWARD II, patients must have at least low FR expression on their tumor cells. Patients with platinum-sensitive disease will be eligible for treatment with a combination of mirvetuximab soravtansine and carboplatin.

We expect to begin reporting clinical findings from FORWARD II in the second quarter of 2017.

#### Commercialization

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We presently intend to market mirvetuximab soravtansine ourselves in the U.S. and in Europe and to partner it in other geographies. Expanding into earlier lines of treatment through use in combination regimens could significantly expand the opportunity.

### IMGN779 and IMGN632 – first-in-class ADCs for AML

Our CD33-targeting IMGN779 product candidate for AML is the first ADC to use one of our new IGN payload agents that alkylate DNA without cross-linking it.

In preclinical studies, ImmunoGen scientists found improvements in therapeutic index, the difference between efficacious doses and dose-limiting toxicity, between our DNA-alkylating IGN payloads and matched DNA cross-linking agents, including the avoidance of prolonged toxicity.

We advanced IMGN779 into Phase 1 clinical testing for AML in April 2016 and expect to report the first clinical data with the agent in 2017. The IMGN779 Phase 1 trial will assess two schedules (weekly and biweekly administration) in the dose-finding stage and then utilize the selected dose and schedule in the planned expansion cohorts: (i) assessment in patients with AML in first relapse, and (ii) assessment in patients with relapsed/refractory AML.

The first disclosure of IMGN632, our CD123-targeting ADC, was at the European Hematology Meeting in June 2016. This potential new therapy for AML and certain other hematologic malignancies utilizes a new ImmunoGen IGN payload and engineered linker as well as a novel antibody. It is in IND-enabling preclinical testing.

### IMGN529 and coltuximab ravtansine – novel ADCs for B-cell malignancies

Our CD37-targeting ADC, IMGN529, has demonstrated single-agent activity in relapsed/refractory DLBCL in Phase 1 testing and striking synergy with rituximab in preclinical testing. IMGN529 is now in Phase 2 clinical testing in combination with rituximab. This novel ADC has orphan drug status for DLBCL in the U.S.

Our CD19-targeting ADC, coltuximab ravtansine, has demonstrated single-agent, proof-of-concept activity in Phase 2 clinical testing. We believe this product candidate is best advanced in a combination regimen.

### 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 2016 approximately 1,685,210 new cases of cancer will be

diagnosed in the U.S. and that approximately 600,000 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.

- Mirvetuximab soravtansine. Our mirvetuximab soravtansine compound is a potential treatment for ovarian cancer and potentially other cancers that highly express its target, FR . Based on published sources, we believe approximately 23,000 new cases of ovarian cancer will be diagnosed in the U.S. in 2016.
- IMGN779 and IMGN632. Our IMGN779 and IMGN632 compounds are each a potential treatment for AML. Based on ACS estimates, we believe approximately 20,000 new cases of AML will be diagnosed in the U.S. in 2016.
- IMGN529 and coltuximab ravtansine. Our IMGN529 compound and our coltuximab ravtansine compound are potential treatments for a type of non-Hodgkin lymphoma, or NHL, called DLBCL. Based on ACS estimates, we believe approximately 73,000 new cases of NHL will be diagnosed in the U.S. in 2016.

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## Out licenses and Collaborations

We selectively license restricted access to our ADC technology to other companies to expand the utilization of our technology and to provide us with cash to fund our own product programs. These 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 that we supply 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. Below is a table setting forth our active partnerships and current status of the most advanced program in the partnership:

Partner	Licensed targets	Status of Most Advanced Program
Roche	HER2, 4 other*	Marketed
Bayer	Mesothelin	Phase 2 designed to support registration
Sanofi	CD38, CA6, CEACAM5, LAMP1, 1 other *	Phase 2
Biotest	CD138	Phase 2
Novartis	pCadherin, 5 other*	Phase 1
Lilly	FGFR3, 2 other*	Phase 1
Amgen	2*†	Phase 1
CytomX	CD166	Research/Preclinical
Takeda	GCC	Research/Preclinical

\*Undisclosed

† Amgen has sublicensed one of its exclusive single-target licenses to Oxford BioTherapeutics Ltd.

## Roche

In 2000, we granted Genentech, now a unit of Roche, an exclusive license to develop and commercialize HER2-targeting ADCs with our maytansinoid technology. Roche's Kadcyra resulted from this license. Kadcyra was approved for marketing in the U.S., EU and Japan in 2013 based on the findings in the EMILIA Phase 3 trial. We received a \$2 million upfront payment from Roche upon execution of the agreement. We are entitled to receive up to a total of \$44 million in milestone payments, of which we have received \$34 million to date, and also tiered royalties on the commercial sales of Kadcyra or any other resulting products as described below.

In 2015, Immunity Royalty Holdings, L.P., or IRH, paid us \$200 million to purchase our right to receive 100% of the royalty payments on commercial sales of Kadcyra arising under our development and commercialization license with Genentech, until IRH has received aggregate Kadcyra royalties equal to \$235 million or \$260 million, depending on

when the aggregate Kadcyra royalties received by IRH reach a specified milestone. Once the applicable threshold is met, if ever, we will thereafter receive 85% and IRH will receive 15% of the Kadcyra royalties for the remaining royalty term.

The royalty term is determined on a country by country basis, and is initially 10 years from the date of first commercial sale of Kadcyra in the country. If, on such 10th anniversary, Kadcyra 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 Kadcyra in that country for an additional 2 years.

The royalty rate is based on the calendar-year sales of Kadcyra in two territories: (1) the U.S. and (2) the rest of the world. For each territory, the rate is: 3% of net sales up to \$250 million; 3.5% of net sales above \$250 million and up to \$400 million; 4% of net sales above \$400 million and up to \$700 million; and 5% of net sales above \$700 million in the that territory during the calendar year. Royalties will be reduced to a flat 2% of net sales in any country at any time

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during the royalty term in which Kadcyła 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 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 Kadcyła, 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 Kadcyła 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 are reasonably likely to 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 Kadcyła in Japan and in the EU.

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 separate, now expired 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, 2016. Roche is responsible for the development, manufacturing, and marketing of any products resulting from these licenses.

Bayer

In 2008, we granted Bayer an exclusive development and commercialization license to use our maytansinoid ADC technology with antibodies or other proteins that target mesothelin. 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 under this agreement, up to a total of \$170.5 million in milestone payments, plus tiered royalties between 4 - 7% on the commercial sales of any resulting products.

Bayer has developed anetumab ravtansine under this agreement, and in 2016 initiated a Phase 2 trial designed to support marketing registration for which we received a \$10 million milestone payment.

Bayer 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 royalty obligations, which are determined on a product by product and country by country basis. For each product and country, Bayer 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.

Sanofi

Collaboration Agreement



In 2003, we entered into a broad collaboration agreement with Sanofi (formerly Aventis) to discover, develop and commercialize antibody based products. The collaboration agreement provided Sanofi with worldwide development and commercialization rights to new antibody based products directed to targets that were included in the collaboration, including the exclusive right to use our maytansinoid ADC technology in the creation of products developed to these targets. No further targets may be added to this agreement and the product candidates (targets) as of June 30, 2016 in the collaboration include isatuximab (CD38), SAR566658 (CA6), SAR408701 (CEACAM5) and one earlier-stage program that has yet to be disclosed.

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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 ImmunoGen.

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 total milestones are categorized as follows: development milestones—\$7.5 million; and regulatory milestones—\$14 million. Through June 30, 2016, we have received and recognized an aggregate of \$20.5 million in milestone payments for compounds covered under this agreement now or in the past.

### Right to Test Agreement

Under a separate, now expired right-to-test agreement, in 2013, Sanofi took one exclusive development and commercialization license. Under this license, we received an exercise fee of \$2 million and are further entitled to receive up to a total of \$30 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones for each license are categorized as follows: development milestones—\$10 million; and regulatory milestones—\$20 million.

Pursuant to the license agreement noted above, in 2015, Sanofi initiated Phase I, first-in-human clinical testing of its ADC product candidate, SAR428926 (LAMP1), triggering a \$2 million development milestone payment to us which is included in license and milestone fee revenue for the year ended June 30, 2016.

The SAR428926 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, the 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 the development and commercialization license.

### Biotest

In 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 indatuximab ravtansine 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, 2016, we have received and recognized a total of \$500,000 in milestone payments under this agreement.

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 option 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

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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.

Novartis

Novartis took six exclusive development and commercialization licenses under a now-expired right to test agreement established in 2010. We received a \$45 million upfront payment in connection with the execution of the right to test agreement in 2010, and for each development and commercialization license taken for a specific target, we received an exercise fee of \$1 million and are entitled to receive up to a total of \$199.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. The initial three year term of the right to test agreement was extended by Novartis in 2013 for an additional one year period by payment of a \$5 million fee to us. We also are entitled to receive payments for research and development activities performed on behalf of Novartis. Novartis is responsible for the manufacturing, product development and marketing of any products resulting from this agreement.

In 2013, we and Novartis amended the right to test agreement so that Novartis could take a license to develop and commercialize products directed at two undisclosed, related 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 no longer be converted to an exclusive target due to the expiration of the right to test agreement. 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 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. 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. Also, in 2013, Novartis took its second and third exclusive licenses to single targets, and in 2014, took three remaining exclusive licenses, each with the opportunity to receive milestone payments totaling \$199.5 million, as outlined above, plus royalties on the commercial sales of any resulting products. In January 2015 and May 2015, Novartis initiated Phase I, first-in-human clinical testing of its cKit-targeting ADC product candidate, LOP628, and P-cadherin-targeting ADC product candidate, PCA062, respectively, triggering a \$5 million development milestone payment to us with each event.

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

Lilly took three exclusive development and commercialization licenses under a now expired right to test agreement established in 2011. We received a \$20 million upfront payment in connection with the execution of the right to test agreement in 2011. Under the terms of this right to test agreement, the first license had no associated exercise fee, and the second and third licenses each had a \$2 million exercise fee. The first development and commercialization license was taken in 2013 and the agreement was subsequently amended to provide Lilly with an extension provision and retrospectively include a \$2 million exercise fee for the first license in lieu of the fee due for either the second or third license. The second and third licenses were taken in 2014, with one including the \$2 million exercise fee and the other

not. Under the two licenses with the \$2 million exercise fee, we are entitled to receive up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. Under the license taken in 2014 without the exercise fee, we are entitled to receive up to a total of \$200.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. In September 2015, Lilly began Phase I evaluation of one of its ADC product candidates, FGFR3-targeting LY3076226, triggering a \$5 million milestone payment to us which is included in license and milestone fee revenue for the year ended June 30, 2016. We also are entitled to receive payments for delivery of cytotoxic agents to Lilly and research and development activities performed on behalf of Lilly. Lilly is responsible for the manufacturing, product development and marketing of any products resulting from this collaboration.

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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.

### Amgen

Amgen took three exclusive development and commercialization licenses under a now expired right to test agreement established in 2000. In 2013, Amgen took one non exclusive development and commercialization license. Later in 2013, the non exclusive license was amended and converted to an exclusive license, which Amgen sublicensed to Oxford BioTherapeutics Ltd. In 2015, Amgen advised the Company that it had discontinued development of two product candidates, AMG 595 and AMG 172 that had been covered by two of Amgen's four exclusive licenses, and in 2016, Amgen terminated these two licenses. For each of the two remaining development and commercialization licenses taken, we are entitled to receive up to a total of \$34 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones per license are categorized as follows: development milestones—\$9 million; regulatory milestones—\$20 million; and sales milestones—\$5 million. Amgen (or its sublicensee(s)) is responsible for the manufacturing, product development and marketing of any products resulting from these development and commercialization licenses.

In 2015, Amgen's IND application under the remaining license not sublicensed to Oxford BioTherapeutics became effective, triggering a \$1 million milestone payment to us which is included in license and milestone fee revenue for the year ended June 30, 2016.

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.

### CytomX

In 2014, we entered into a reciprocal right to test agreement with CytomX. The agreement provides CytomX with the right to test our payload agents and linkers with CytomX antibodies that utilize their proprietary antibody-masking technology, termed Probodies™ for a specified number of targets and to subsequently take an exclusive, worldwide license to use our technology to develop and commercialize Probody-drug conjugates 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 test our payload agents and linkers with ImmunoGen antibodies masked using CytomX technology to create Probody-drug conjugates directed to a specified number of targets and to subsequently take exclusive, worldwide licenses to develop and commercialize such conjugates 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.

In 2016, CytomX took its development and commercialization license for a specified target. An amendment of the agreement executed simultaneously with that license granted CytomX the right, for a specified period of time, to substitute the specified target with another as yet unspecified target. Accordingly, the revenue associated with this license is being deferred until the expiration of that substitution right. With respect to the development and commercialization license taken by CytomX, we are entitled to receive up to a total of \$160 million in milestone payments plus royalties on the commercial sales of any resulting product.

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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.

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

### Takeda

In 2015, we entered into a right to test agreement with Takeda Pharmaceutical Company Limited (Takeda) through its wholly owned subsidiary, Millennium Pharmaceuticals, Inc. The agreement provides Takeda with the right to (a) take exclusive options, with certain restrictions, to individual targets selected by Takeda for specified option periods, (b) test our maytansinoid and IGN ADC technology with Takeda's antibodies directed to the targets optioned under a right to test, or research, license, and (c) take exclusive licenses to use our ADC technology to develop and commercialize products to targets optioned for up to two individual targets on terms specified in the right to test agreement. Takeda must exercise its options for the development and commercialization licenses by the end of the three year term of the right to test agreement, after which any then outstanding options will lapse. Takeda has the right to extend the three year right to test period for one additional year by payment to us of \$4 million. Alternatively, Takeda has the right to expand the scope of the right to test agreement by payment to us of \$8 million. If Takeda opts to expand the scope of the right to test agreement, it will be entitled to take additional exclusive options, one of which may be exercised for an additional development and commercialization license, and the right to test period will be extended until the fifth anniversary of the effective date of the right to test agreement. Takeda is responsible for the manufacturing, product development and marketing of any products resulting from this collaboration.

We received a \$20 million upfront payment in connection with the execution of the right to test agreement and, for each development and commercialization license taken, are entitled to receive up to a total of \$210 million in milestone payments, plus royalties on the commercial sales of any resulting products. The first exclusive license, for GCC, was taken by Takeda in December 2015, and as a result, we recognized \$8.6 million of the \$25.9 million of arrangement consideration allocated to the development and commercialization licenses, which is included in license and milestone fee revenue for the year ended June 30, 2016. We also are entitled to receive payments for delivery of cytotoxic agents to Takeda and research and development activities performed on behalf of Takeda.

Takeda 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 Takeda's royalty obligations, which are determined on a product by product and country by country basis. For each product and country, Takeda'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.

### 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, 2016, our patent portfolio had a total of 765 issued patents worldwide and 749 pending patent applications worldwide. 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 59 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 2033. We also have several composition of matter patents covering various aspects of

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our DM4 cell killing agent and antibody maytansinoid conjugates incorporating DM4 that are expected to remain in force until 2024-2033. We have nine issued U.S. patents covering various aspects of our DNA acting cell killing agents, which will expire at various times between 2030 and 2035. We also have nine additional pending U.S. patent applications disclosing and claiming other related embodiments of this technology. Patents that may issue from these applications will, if issued, expire between 2030 and 2036. 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 2021-2032, while any patents that may issue from pending patent applications also covering various aspects of these technologies will, if issued, expire between 2021 and 2037. 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 Kadcyra in any particular country depend in part on whether the manufacture, use or sale of Kadcyra 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 Kadcyra 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 Kadcyra, 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 Kadcyra in any country does not extend beyond the 12th anniversary of the date of the first commercial sale of Kadcyra in such country.

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.

On October 29, 2014, the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, or PTAB, instituted an inter partes review, or IPR, of the claims in our U.S. Patent No. 8,337,856, or the '856 Patent, that covers Kadcyra. The PTAB issued a Final Written Decision on the matter in which all claims of the '856 were held to be not unpatentable. The Petitioner has appealed this decision to the Court of Appeals for the Federal Circuit, or CAFC. Briefs have been filed and we expect the CAFC to hear Oral Argument in the first quarter of 2017 and issue a final decision in second quarter of 2017. The '856 Patent is one of several U.S. patents we hold that pertain to Kadcyra. Consequently, any adverse outcome of the Appeal is not expected to impact either the royalty revenue we are entitled to receive from Roche on Kadcyra sales in the U.S., or the \$200 million royalty monetization transaction relating to our Kadcyra royalty stream that was consummated in 2015.

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.

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### 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, Takeda, AbbVie and Bristol Myers Squibb have programs to attach a 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. Additionally, there are non ADC therapies available and/or in development for the cancer types we and our partners are targeting. 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 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. Antibodies developed by certain of these companies have been approved for use as cancer therapeutics. In the future, new antibodies or other targeted therapies may compete with our product candidates. 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.

### 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.

#### 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 PHS Act, 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,

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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 current Good Laboratory Practices, or cGLP, 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 current Good Clinical Practices, or cGCP, to establish the safety and efficacy of the proposed drug for its intended use;
- development and approval of a companion diagnostic device if the FDA or the sponsor believes that its use is essential for the safe and effective use of a corresponding product;
- 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 clinical trials due to safety concerns about on going or proposed clinical trials or non compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with cGCP 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 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 provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase I: The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase II: This phase involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase III: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical trials are



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intended to establish the overall risk benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

Post approval trials, sometimes referred to as Phase IV, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of approval of an NDA or BLA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. Phase I, Phase II, and Phase III testing may not be completed successfully within any specified period, if at all.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase II, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the End of Phase II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical trial that they believe will support approval of the new drug. If this type of discussion occurs, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the design of the Phase III clinical trial protocol design and analysis that will form the primary basis of an efficacy claim.

According to FDA guidance for industry on the SPA process, a sponsor that meets the prerequisites may make a specific request for a special protocol assessment and provide information regarding the design and size of the proposed clinical trial. The FDA is required to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. A SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began. If the sponsor makes any unilateral changes to the approved protocol, the agreement will be invalidated.

For some of our product candidates, including mirvetuximab soravtansine and potentially others, we plan to work with collaborators to develop or obtain access to in vitro companion diagnostic tests to identify appropriate patients for these targeted therapies.

If a sponsor or the FDA believes that an in vitro companion diagnostic is essential for the safe and effective use of a corresponding therapeutic product, a sponsor will typically work with a sponsor of an in vitro companion diagnostic to develop the drug and the related diagnostic at the same time. In vitro diagnostic, or IVD, tests are regulated by the FDA as medical devices. The FDA issued a final guidance document in 2014, entitled "In Vitro Companion Diagnostic Devices" that is intended to assist companies developing a therapeutic product for which the use of an IVD test provides information that is essential for the safe and effective use of the corresponding therapeutic product and companies developing those IVD tests. Such tests, where the test results are essential rather than just helpful, were designated IVD companion diagnostic devices. It also issued a draft guidance on July 15, 2016, entitled, "Principles for



Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product” to serve as a practical guide to assist therapeutic product sponsors and IVD sponsors in developing a therapeutic product and an accompanying IVD companion diagnostic.

The FDA indicated that it will apply a risk-based approach to determine the regulatory pathway for IVD companion diagnostic devices, as it does with all medical devices. This means that the regulatory pathway will depend on the level of risk to patients, based on the intended use of the IVD companion diagnostic device and the controls necessary to provide a reasonable assurance of safety and effectiveness. The two primary types of marketing pathways

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for medical devices are clearance of a premarket notification under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or 510(k), and approval of a premarket approval application, or PMA. We expect that any IVD companion diagnostic device developed for use with our drug candidates will utilize the PMA pathway and that a clinical trial performed under an investigational device exemption, or IDE, will have to be completed before the PMA may be submitted.

The FDA expects that the therapeutic sponsor will address the need for an IVD companion diagnostic device in its therapeutic product development plan and that, in most cases, the therapeutic product and its corresponding IVD companion diagnostic device will be developed contemporaneously. If the companion diagnostic test will be used to make critical treatment decisions such as patient selection, treatment assignment, or treatment arm, it will likely be considered a significant risk device for which a clinical trial will be required.

The sponsor of the IVD companion diagnostic device will be required to comply with the FDA's IDE requirements that apply to clinical trials of significant risk devices. If the diagnostic test and the therapeutic drug are studied together to support their respective approvals, the clinical trial must meet both the IDE and IND requirements.

PMAs must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA may require several years to complete.

If the FDA evaluations of both the PMA and the manufacturing facilities are favorable, the FDA will either issue an approval order or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will send the applicant a not approvable letter or an order denying approval. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

After approval, the use of an IVD companion diagnostic device with a therapeutic product will be stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product. In addition, a diagnostic test that was approved through the PMA process or one that was cleared through the 510(k) process and placed on the market will be subject to many of the same regulatory requirements that apply to approved drugs.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA regulated products are required to register and disclose specified clinical trial information, which is publicly available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Information related to the

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product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. However, there are evolving rules and increasing requirements for publication of all trial related information, and it is possible that data and other information from trials involving drugs that never garner approval could require disclosure in the future.

### U.S. Review and Approval Processes

The results of product development, preclinical and other non clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in depth substantive review. FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA or BLA, or an approved letter following satisfactory completion of all aspects of the review process. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured.

NDAs or BLAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. Priority review for an NDA for a new molecular entity and original BLAs will be 6 months from the date that the NDA or BLA is filed. In addition, products studied for their safety and effectiveness in treating serious or life threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well controlled Phase IV clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA or BLA

identified by the FDA and may require additional clinical data, such as an additional pivotal Phase III trial or other significant and time consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase IV testing which involves clinical trials designed to further

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assess a drug's safety and effectiveness after NDA or BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Marketing approval may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

The Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs and biologics, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, BLAs and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. Orphan indications are exempt from PREA. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

### Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the filing of the relevant NDA.

Pediatric exclusivity is a type of marketing exclusivity available in the U.S. Under the Best Pharmaceuticals for Children Act, or BPCA, an additional six months of marketing exclusivity may be available if a sponsor conducts clinical trials in children in response to a written request from the FDA, or a Written Request. If the Written Request does not include clinical trials in neonates, the FDA is required to include its rationale for not requesting those clinical trials. The FDA may request studies on approved or unapproved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described clinical trials. To date, we have not received any Written Requests.

### Biologics Price Competition and Innovation Act of 2009

The Patient Protection and Affordable Care Act which included the Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA to create an abbreviated approval pathway for two types of “generic” biologics—biosimilars and interchangeable biologic products, and provides for a twelve year data exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however if pediatric clinical trials are performed and accepted by the FDA, the twelve year data exclusivity period will be extended for an additional six months. A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity

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and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical trials to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved. The first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

The FDA has issued a number of final and draft guidances in order to implement the law. On April 28, 2015, the FDA issued the following four final guidances: “Scientific Considerations in Demonstrating Biosimilarity to a Reference Product,” “Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product,” and “Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 Guidance for Industry,” and “Formal Meetings between the FDA and Biosimilar Biological Product Sponsors or Applicants” issued November 17, 2015. The draft guidances include: “Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product” issued May 13, 2014, “Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act” issued August 4, 2014, and “Biosimilars: Additional Questions and Answers Regarding Implementation of the Price Competition and Innovation Act of 2009,” issued May 12, 2015.

The guidance documents provide FDA’s current thinking on approaches to demonstrating that a proposed biological product is biosimilar to a reference product. The FDA intends to issue additional guidance documents in the future, and has identified considerations in demonstrating interchangeability to a reference product, labeling and nonproprietary naming as several of the issues that it hopes to address in calendar year 2015. Nonetheless, the absence of final guidance documents covering all biosimilars issues does not prevent a sponsor from seeking licensure of a biosimilar under the BPCIA, and the FDA recently approved two biosimilar applications in the U.S.

## Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use will be disclosed publicly by the FDA; the posting will also indicate whether a drug is no longer designated as an orphan drug. More than one product candidate may receive an orphan drug designation for the same indication. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to seven years of orphan product exclusivity, except in very limited circumstances. The FDA issued a final rule, effective August 12, 2013, intended to clarify several regulatory provisions, among which was a clarification of some of those limited circumstances. One of the provisions makes



clear that the FDA will not recognize orphan drug exclusive approval if a sponsor fails to demonstrate upon approval that the drug is clinically superior to a previously approved drug, regardless of whether or not the approved drug was designated an orphan drug or had orphan drug exclusivity. Thus orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA and we are not able to show the clinical superiority of our drug or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

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The FDA and the European Union granted Orphan Drug designation to mirvetuximab soravtansine, or IMGN853, when used for the treatment of ovarian cancer. Orphan drug designation provides us with seven years of market exclusivity that begins once mirvetuximab soravtansine receives FDA marketing approval for the use for which the orphan drug status was granted. Orphan medicinal product designation provides ImmunoGen with ten years of market exclusivity that begins once mirvetuximab soravtansine receives European approval for the use for which it was granted. We also have been granted Orphan Drug designation for IMGN529 by the FDA and the European Union for the treatment of diffuse large B cell lymphoma and may pursue these designations for other indications for other product candidates intended for qualifying patient populations.

## Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drugs that may be eligible for these programs are those for serious or life threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious diseases and fill an unmet medical need. The request may be made at the time of IND submission and generally no later than the pre BLA or pre NDA meeting. The FDA will respond within 60 calendar days of receipt of the request. Priority review, which is requested at the time of BLA or NDA submission, is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides an earlier approval of drugs to treat serious diseases, and that fill an unmet medical need based on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. Discussions with the FDA about the feasibility of an accelerated approval typically begin early in the development of the drug in order to identify, among other things, an appropriate endpoint. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post marketing clinical trials to confirm the appropriateness of the surrogate marker trial.

In the Food and Drug Administration Safety and Improvement Act, or FDASIA, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law required the FDA to issue related draft guidance within a year after the law's enactment and also promulgate confirming regulatory changes. The FDA published a final guidance on May 30, 2014, entitled "Expedited Programs for Serious Conditions—Drugs and Biologics." One of the expedited programs added by FDASIA is that for Breakthrough Therapy. A Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). A sponsor may request Breakthrough Therapy designation at the time that the IND is submitted, or no later than at the end of Phase II meeting. The FDA will respond to a Breakthrough Therapy designation request within sixty days of receipt of the request. A drug that receives Breakthrough Therapy designation is eligible for all fast track designation features, intensive guidance on an efficient drug development program, beginning as early as Phase I and commitment from the FDA involving senior managers. FDA has already granted this designation to at least 60 new drugs and seven to date have received approval.

## Post Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws and regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future

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inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

Any drug products manufactured or distributed by us or our partners pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

## Foreign Regulation

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. The decentralized procedure provides for approval by one or more “concerned” member states based on an assessment of an application performed by one member state, known as the “reference” member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state’s assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

As in the U.S., we may apply for designation of a product as an orphan drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product.

## Reimbursement

Sales of pharmaceutical products depend in significant part on the availability of third party reimbursement. Third party payors include government healthcare programs such as Medicare, managed care providers, private health insurers and other organizations. We anticipate third party payors will provide reimbursement for our products. However, these third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Our product candidates may not be considered cost effective. It is time consuming

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and expensive for us to seek reimbursement from third party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

Medicare is a federal healthcare program administered by the federal government that covers individuals age 65 and over as well as individuals with certain disabilities. Drugs may be covered under one or more sections of Medicare depending on the nature of the drug and the conditions associated with and site of administration. For example, under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which provide coverage for outpatient prescription drugs. Part D plans include both stand alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level.

Medicare Part B covers most injectable drugs given in an inpatient setting and some drugs administered by a licensed medical provider in hospital outpatient departments and doctors' offices. Medicare Part B is administered by Medicare Administrative Contractors, which generally have the responsibility of making coverage decisions. Subject to certain payment adjustments and limits, Medicare generally pays for a Part B covered drug based on a percentage of manufacturer reported average sales price which is regularly updated. We believe that most of our drugs, when approved, will be subject to the Medicare Part B rules.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for this research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our product candidates, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third party payors do not consider our products to be cost effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, ACA) enacted in March 2010, was expected to have a significant impact on the health care industry. ACA has resulted in expanded coverage for the uninsured and is expected to help contain overall healthcare costs. With regard to pharmaceutical products, among other things, ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of ACA on pharmaceutical companies as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet occurred. In addition, although the U.S. Supreme Court upheld the constitutionality of most of the ACA, some states have stated their intentions to not implement certain sections of ACA and some members of Congress are still working to repeal ACA. These challenges add to the uncertainty of the changes enacted as part of ACA.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member

state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally tend to be significantly lower.

#### Research and Development Spending

During each of the three years ended June 30, 2016, 2015 and 2014, we spent approximately \$148.1 million, \$111.8 million and \$107.0 million, respectively, on research and development activities.

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### Raw Materials and Manufacturing

We procure certain raw material components of finished conjugate, including antibodies, cytotoxic agents, and linker, for ourselves and on behalf of our collaborators. In order to meet our commitments to our collaborators as well as our own needs, we are required to enter into agreements with third parties to produce these components well in advance of our production needs. Our principal suppliers for these components include Boehringer Ingelheim, BSP Pharmaceuticals S.r.l., SAFC, Inc., Carbogen Amcis and Società Italiana Corticosteroidi S.r.l.

In addition, we operate a conjugate manufacturing facility. A portion of the cost of operating this facility, including the cost of manufacturing personnel, is incurred to conjugate material on behalf of our collaborators for which we receive payments based on the number of batches of preclinical and clinical materials produced on their behalf. Over the past few years, we have expanded and upgraded the capabilities of our manufacturing facility.

### Employees

As of June 30, 2016, we had 385 full time employees, of whom 330 were engaged in research and development activities. Of the 330 research and development employees, 172 employees hold post graduate degrees, of which 78 hold Ph.D. degrees and six hold M.D. degrees. We consider our relations with our employees to be good. None of our employees is covered by a collective bargaining agreement.

We have entered into confidentiality agreements with all of our employees, members of our board of directors and consultants. Further, we have entered into assignment of invention agreements with all of our employees.

### Third Party Trademarks

Avastin, Herceptin, Kadcyra, Keytruda and Rituxan are registered trademarks of their respective owners. Probody is a trademark of CytomX Therapeutics, Inc.

### Item 1A. Risk Factors

THE RISKS AND UNCERTAINTIES DESCRIBED BELOW ARE THOSE THAT WE CURRENTLY BELIEVE MAY MATERIALLY AFFECT OUR COMPANY. ADDITIONAL RISKS AND UNCERTAINTIES THAT WE ARE UNAWARE OF OR THAT WE CURRENTLY DEEM IMMATERIAL ALSO MAY BECOME IMPORTANT FACTORS THAT AFFECT OUR COMPANY.

We have a history of operating losses and expect to incur significant additional operating losses.

We have generated operating losses since our inception. As of June 30, 2016, we had an accumulated deficit of \$853.7 million. For the years ended June 30, 2016, 2015, and 2014, we generated losses of \$144.8 million, \$60.7 million and \$71.4 million, respectively. We may never be profitable. We expect to incur substantial additional operating expenses over the next several years as our research, development, preclinical testing, clinical trials and collaborator support activities continue. We intend to continue to invest significantly in our product candidates. Further, we expect to invest some of our resources to support our existing collaborators as they work to develop, test and commercialize ADC compounds. We or our collaborators may encounter technological or regulatory difficulties as part of this development and commercialization process that we cannot overcome or remedy. We may also incur substantial marketing and other costs in the future if we decide to establish marketing and sales capabilities to commercialize our product candidates. Our revenues to date have been primarily from upfront and milestone



payments, research and development support and clinical materials reimbursement from our collaborative partners and from royalties received from the commercial sales of Kadcyla (which we sold the cash rights to for a period of time in April 2015). We do not expect to generate revenues from the commercial sale of our internal product candidates in the near future, and we may never generate revenues from the commercial sale of internal products. Even if we do successfully develop products that can be marketed and sold commercially, we will need to generate significant revenues from those products to achieve and maintain profitability. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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If we are unable to obtain additional funding when needed, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market our product candidates.

We will continue to expend substantial resources developing new and existing product candidates, including costs associated with research and development, acquiring new technologies, conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing products as well as providing certain support to our collaborators in the development of their products. In addition, we have a recurring interest payment obligation on our Convertible Senior Notes and potentially a repayment obligation on July 1, 2021 unless holders of our debt convert it to shares of our stock. We believe that our current working capital and expected future payments from our existing collaboration arrangements will be sufficient to meet our current and projected operating and capital requirements through December 2017. However, we cannot provide assurance that such collaborative agreement funding will, in fact, be received. Should such future collaborator payments not be earned and paid as currently anticipated, we expect we could seek additional funding from other sources. We may need additional financing sooner due to a number of other factors as well, including:

- if either we incur higher than expected costs or we or any of our collaborators experience slower than expected progress in developing product candidates and obtaining regulatory approvals;
- acquisition of technologies and other business opportunities that require financial commitments.

Additional funding may not be available to us on favorable terms, or at all. We may raise additional funds through public or private financings, collaborative arrangements or other arrangements. Debt financing, if available, may involve covenants that could restrict our business activities. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, scale back or eliminate expenditures for some of our development programs, refinance or restructure our debt or grant rights to develop and market product candidates that we would otherwise prefer to internally develop and market. If we are required to grant such rights, the ultimate value of these product candidates to us may be reduced.

If our ADC technology does not produce safe, effective and commercially viable products, our business will be severely harmed.

Our ADC technology yields novel product candidates for the treatment of cancer. To date, only one ADC using our technology, Kadcyla, has obtained marketing approval. Our ADC product candidates and/or our collaborators' ADC product candidates may not prove to be safe, effective or commercially viable treatments for cancer and our ADC technology may not result in any future meaningful benefits to us or for our current or potential collaborative partners. Furthermore, we are aware of only two other compounds that are a conjugate of an antibody and a cytotoxic small molecule that have obtained marketing approval by the FDA and are based on technology similar to our ADC technology. One of these products was later taken off the market by its owner due to toxicity concerns. If our ADC technology fails to generate product candidates that are safe, effective and commercially viable treatments for cancer or such product candidates fail to obtain FDA approval, our business will be severely harmed.

Clinical trials for our and our collaborative partners' product candidates will be lengthy and expensive and their outcome is uncertain.

Before obtaining regulatory approval for the commercial sale of any product candidates, we and our collaborative partners must demonstrate through clinical testing that our product candidates are safe and effective for use in humans. Conducting clinical trials is a time consuming, expensive and uncertain process and typically requires years to complete. In our industry, the results from preclinical studies and early clinical trials often are not predictive of results obtained in later stage clinical trials. Some compounds that have shown promising results in preclinical studies or early clinical trials subsequently fail to establish sufficient safety and efficacy data necessary to obtain regulatory approval. At any time during the clinical trials, we, our collaborative partners, or the FDA might delay or halt any clinical trials

of our product candidates for various reasons, including:

- occurrence of unacceptable toxicities or side effects;
- ineffectiveness of the product candidate;
- insufficient drug supply;

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- negative or inconclusive results from the clinical trials, or results that necessitate additional studies or clinical trials;
  - delays in obtaining or maintaining required approvals from institutions, review boards or other reviewing entities at clinical sites;
  - delays in patient enrollment;
    - insufficient funding or a reprioritization of financial or other resources; or
  - other reasons that are internal to the businesses of our collaborative partners, which they may not share with us.
- Any failure or substantial delay in successfully completing clinical trials and obtaining regulatory approval for our product candidates or our collaborative partners' product candidates could severely harm our business.

We and our collaborative partners are subject to extensive government regulations and we and our collaborative partners may not be able to obtain necessary regulatory approvals.

We and our collaborative partners may not receive the regulatory approvals necessary to commercialize our product candidates, which would cause our business to be severely harmed. Pharmaceutical product candidates, including those in development by us and our collaborative partners, are subject to extensive and rigorous government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If our potential products or our collaborators' potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, complex, expensive and uncertain. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish the product candidate's safety and efficacy. Data obtained from preclinical studies and clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. The approval process may take many years to complete and may involve ongoing requirements for post marketing studies. Any FDA or other regulatory approvals of our or our collaborative partners' product candidates, once obtained, may be withdrawn. The effect of government regulation may be to:

- delay marketing of potential products for a considerable period of time;
- limit the indicated uses for which potential products may be marketed;
- impose costly requirements on our activities; and
- place us at a competitive disadvantage to other pharmaceutical and biotechnology companies.

We may encounter delays or rejections in the regulatory approval process because of additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Failure to comply with FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our product candidates or us. Outside the U.S., our ability to market a product is contingent upon receiving clearances from the appropriate regulatory authorities. The foreign regulatory approval process includes similar risks to those associated with the FDA approval process. In addition, we are, or may become, subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. If we fail to comply with the laws and regulations pertaining to our business, we may be subject to sanctions, including the temporary or permanent suspension of operations, product recalls, marketing restrictions and civil and criminal penalties.

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Our and our collaborative partners' product candidates will remain subject to ongoing regulatory review even if they receive marketing approval. If we or our collaborative partners fail to comply with continuing regulations, these approvals could be lost and the sale of our or our collaborative partners' products could be suspended.

Even if we or our collaborative partners receive regulatory approval to market a particular product candidate, the approval could be conditioned on us or our collaborative partners conducting costly post approval studies or could limit the indicated uses included in product labeling. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us or our collaborative partners to withdraw it from the market or impede or delay our or our collaborative partners' ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product remain subject to extensive regulatory requirements. We or our collaborative partners may be slow to adapt, or we or our collaborative partners may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements.

If we or our collaborative partners fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or if previously unknown problems with our or our partners' products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

Any one of these could have a material adverse effect on our business or financial condition.

If our collaborative partners fail to perform their obligations under our agreements with them, or determine not to continue with clinical trials for particular product candidates, our business could be severely impacted.

Our strategy for the development and commercialization of our product candidates depends, in large part, upon the formation and maintenance of collaborative arrangements. Collaborations provide an opportunity for us to:

- generate cash flow and revenue;
- fund some of the costs associated with our internal research and development, preclinical testing, clinical trials and manufacturing;
- seek and obtain regulatory approvals faster than we could on our own;
  - successfully commercialize existing and future product candidates; and



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- secure access to targets which, due to intellectual property restrictions, would otherwise be unavailable to our technology.

If we fail to secure or maintain successful collaborative arrangements, the development and marketing of compounds that use our technology may be delayed, scaled back or otherwise may not occur. In addition, we may be unable to negotiate other collaborative arrangements or, if necessary, modify our existing arrangements on acceptable terms. We cannot control the amount and timing of resources our collaborative partners may devote to our product candidates.

Our collaborative partners may separately pursue competing product candidates, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborative efforts, or may decide, for reasons not known to us, to discontinue development of product candidates under our agreements with them. Any of our collaborative partners may slow or discontinue the development of a product candidate covered by a collaborative arrangement for reasons that can include, but are not limited to:

- a change in the collaborative partner's strategic focus as a result of merger, management changes, adverse business events, or other causes;
- a change in the priority of the product candidate relative to other programs in the collaborator's pipeline;
- a reassessment of the patent situation related to the compound or its target;
- a change in the anticipated competition for the product candidate;
- preclinical studies and clinical trial results; and
- a reduction in the financial resources the collaborator can or is willing to apply to the development of new compounds.

Even if our collaborative partners continue their collaborative arrangements with us, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Also, our collaborative partners may fail to perform their obligations under the collaborative agreements or may be slow in performing their obligations. Our collaborative partners can terminate our collaborative agreements under certain conditions. The decision to advance a product that is covered by a collaborative agreement through clinical trials and ultimately to commercialization is in the discretion of our collaborative partners. If any collaborative partner were to terminate or breach our agreements, fail to complete its obligations to us in a timely manner, or decide to discontinue its development of a product candidate, our anticipated revenue from the agreement and from the development and commercialization of the products would be severely limited. If we are not able to establish additional collaborations or any or all of our existing collaborations are terminated and we are not able to enter into alternative collaborations on acceptable terms, or at all, our continued development, manufacture and commercialization of our product candidates could be delayed or scaled back as we may not have the funds or capability to continue these activities. If our collaborators fail to successfully develop and commercialize ADC compounds, our business prospects would be severely harmed.

We depend on a small number of collaborators for a substantial portion of our revenue. The loss of, or a material reduction in activity by, any one of these collaborators could result in a substantial decline in our revenue.

We have and will continue to have collaborations with a limited number of companies. As a result, our financial performance depends on the efforts and overall success of these companies. Also, the failure of any one of our collaborative partners to perform its obligations under its agreement with us, including making any royalty, milestone or other payments to us, could have an adverse effect on our financial condition. Further, any material reduction by any one of our collaborative partners in its level of commitment of resources, funding, personnel, and interest in continued development under its agreement with us could have an adverse effect on our financial condition. Also, if consolidation trends in the healthcare industry continue, the number of our potential collaborators could decrease, which could have an adverse impact on our development efforts. If a present or future collaborator of ours were to be involved in a business combination, the collaborator's continued pursuit and emphasis on our product development program could be delayed, diminished or terminated.





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Royalties from commercial sales of Kadcyla will likely fluctuate and will impact our reported royalty revenues and rights to receive future payments from the commercial sale of Kadcyla under our license agreement with Roche and our royalty purchase agreement with Immunity Royalty Holdings, L.P., or IRH.

Roche's Kadcyla is currently the only product with respect to which we are entitled to receive royalties that has received marketing approval. In April 2015, IRH paid us \$200 million to purchase our right to receive 100% of the royalty payments on commercial sales of Kadcyla arising under our development and commercialization license with Roche, through its Genentech unit, until IRH has received aggregate Kadcyla royalties equal to \$235 million or \$260 million, depending on when the aggregate Kadcyla royalties received by IRH reach a specified milestone. Once the applicable threshold is met, if ever, we will thereafter receive 85% and IRH will receive 15% of the Kadcyla royalties for the remaining royalty term. These royalty revenues may fluctuate considerably because they depend upon, among other things, the rate of growth of sales of Kadcyla as well as the mix of U.S. based sales and ex U.S. based sales and our valid patent claims. While the royalty purchase transaction with IRH has mitigated any impact that fluctuations in these royalty revenues may have on our financial condition, negative fluctuations could delay, diminish or eliminate our right to resume receiving 85% of the royalty in the future, as described above.

Royalty rates under our license agreements with our collaborators may vary over the royalty term depending on our intellectual property rights and the presence of competing products.

Most of our license agreements with our collaborators provide that the royalty rates are subject to downward adjustment in the absence of ImmunoGen patent rights covering various aspects of the manufacture, use or sale of the products developed under such licenses, or in the presence of competition from certain third party products. For example, we expect the royalty rate for Sanofi's isatuximab anti CD38 naked antibody compound to be reduced to low single digits because of (1) competitor development of alternative anti CD38 antibody compounds, and (2) the lack of ImmunoGen patent rights covering isatuximab, since our ADC related patent rights do not pertain to the compound and our isatuximab specific patent rights were assigned to Sanofi under the terms of the applicable license.

We depend on our collaborative partners for the determination of royalty payments. We may not be able to detect errors and payment calculations may call for retroactive adjustments.

The royalty payments we receive are determined by our collaborative partners based on their reported net sales. Each collaborative partner's calculation of the royalty payments is subject to and dependent upon the adequacy and accuracy of its sales and accounting functions, and errors may occur from time to time in the calculations made by a collaborative partner. Our agreement with Genentech provides us the right to audit the calculations and sales data for the associated royalty payments related to sales of Kadcyla; however, such audits may occur many months following our recognition of the royalty revenue, may require us to adjust our royalty revenues in later periods and generally require audit related cost on our part.

If our collaborative partners' requirements for clinical materials to be manufactured by us are significantly lower than we have estimated, our financial results and condition could be adversely affected.

We procure certain components of finished conjugate, including DM1, DM4, IGN payload agents, and linker, on behalf of several of our collaborators. In order to meet our commitments to our collaborative partners, we are required to enter into agreements with third parties to produce these components well in advance of our production of clinical materials on behalf of our collaborative partners. If our collaborative partners do not require as much clinical material as we have contracted to produce and we are unable to use these materials for our own products, we may not be able to recover our investment in these components and we may suffer losses. Collaborators have discontinued development of product candidates in the past and in the periods subsequent to these discontinuations, we had significantly reduced demand for DM1 and DM4 which adversely impacted our financial results.

In addition, we operate a conjugate manufacturing facility. A portion of the cost of operating this facility, including the cost of manufacturing personnel, is reimbursed by our collaborators based on the number of batches of preclinical and clinical materials produced on their behalf. If we produce fewer batches of clinical materials for our collaborators, a smaller amount of the cost of operating the conjugate manufacturing facility will be charged to our collaborative partners and our financial condition could be adversely affected.

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If our product requirements for clinical trials are significantly higher than we estimated, the inability to procure additional antibody or fill/finish services in a timely manner could impair our ability to initiate or advance our clinical trials.

We rely on third party suppliers to manufacture antibodies used in our own proprietary compounds. Due to the specific nature of the antibody and availability of production capacity, there is significant lead time required by these suppliers to provide us with the needed materials. If our antibody requirements for clinical materials to be manufactured are significantly higher than we estimated, we may not be able to readily procure additional antibody which would impair our ability to advance our clinical trials currently in process or initiate additional trials. We also rely on third parties to convert the bulk drug substance we manufacture into filled and finished vials of drug product for clinical use. Unanticipated difficulties or delays in the fill/finish process could impair our ability to advance our clinical trials currently in process or initiate additional trials. There can be no assurance that we will not have supply problems that could delay or stop our clinical trials or otherwise could have a material adverse effect on our business.

We currently rely on one third party manufacturer with commercial production experience to produce our cell killing agents, DM1 and DM4.

We rely on a third party supplier to manufacture one of the materials used to make ADC compounds. Our cell killing agents DM1 and DM4, collectively DMx, are manufactured from a precursor, ansamitocin P3. We currently use a single supplier, Società Italiana Corticosteroidi S.r.l., that converts ansamitocin P3 to DMx. Any delay or interruption in our supply of DMx could lead to a delay or interruption in our manufacturing operations, preclinical studies and clinical trials of our product candidates and our collaborators' product candidates, which could negatively affect our business.

We may be delayed or unable to establish the manufacturing capabilities necessary to develop and commercialize our and our collaborative partners' potential products.

Currently, we have one conjugate manufacturing facility that we use to manufacture conjugated compounds for us and several of our collaborative partners for preclinical studies and early stage clinical testing. Several of our partners have contracted for separate, large scale manufacturing capacity to make materials to support potential future commercialization of their ADC compounds. We do not currently have the manufacturing capacity needed to make our product candidates for commercial sale. In addition, our manufacturing capacity may be insufficient to complete all clinical trials contemplated by us and our collaborative partners over time. We intend to rely in part on third party contract manufacturers to produce sufficiently large quantities of drug materials that are and will be needed for later stage clinical trials and commercialization of our potential products. We are currently in the process of developing relationships with third party manufacturers that we believe will be necessary to continue the development of our product candidates. Third party manufacturers may not be able to meet our needs with respect to timing, quantity or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability.

We have one conjugate manufacturing facility and any prolonged and significant disruption at that facility could impair our ability to manufacture our and our collaborative partners' product candidates for clinical testing.

Currently, in certain cases, we are contractually obligated to manufacture Phase I and non pivotal Phase II clinical products for companies licensing our ADC technology. We manufacture this material, as well as material for our own product candidates, in our conjugate manufacturing facility. We have only one such manufacturing facility in which

we can manufacture clinical products. Our current manufacturing facility contains highly specialized equipment and utilizes complex production processes developed over a number of years that would be difficult, time consuming and costly to duplicate. Any prolonged disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture products for clinical testing on our own and would cause us to seek additional third party manufacturing contracts, thereby increasing our development costs. Even though we carry business interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available or any losses which may be excluded under our insurance policies. Certain events, such as natural disasters, fire, political disturbances, sabotage or business accidents, which could impact our current or future facilities, could have

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a significant negative impact on our operations by disrupting our product development efforts until such time as we are able to repair our facility or put in place third party contract manufacturers to assume this manufacturing role.

Unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives applicable to our product candidates could limit our potential product revenue.

Antibody based anticancer products are often much more costly to produce than traditional chemotherapeutics and tend to have significantly higher prices. Factors that help justify the price include the high mortality associated with many types of cancer and the need for more and better treatment options.

Regulations governing drug pricing and reimbursement vary widely from country to country. Some countries require approval of the sales price of a drug before it can be marketed. Some countries restrict the physicians that can authorize the use of more expensive medications. Some countries establish treatment guidelines to help limit the use of more expensive therapeutics and the pool of patients that receive them. In some countries, including the U.S., third party payers frequently seek discounts from list prices and are increasingly challenging the prices charged for medical products. Because our product candidates are in the development stage, we do not know the level of reimbursement, if any, we will receive for any products that we are able to successfully develop. If the reimbursement for any of our product candidates is inadequate in light of our development and other costs, our ability to achieve profitability would be affected.

We believe that the efforts of governments and third party payors to contain or reduce the cost of healthcare will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. A number of legislative and regulatory proposals to change the healthcare system in the U.S. and other major healthcare markets have been proposed and adopted in recent years. For example, the U.S. Congress enacted a limited prescription drug benefit for Medicare recipients as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. While the program established by this statute may increase demand for any products that we are able to successfully develop, if we participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than prices we might otherwise obtain. Non Medicare third party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries. The ACA will also require discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the ACA imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers. The financial impact of these discounts, increased rebates and fees and the other provisions of the ACA on our business is unclear and there can be no assurance that our business will not be materially adversely affected by the ACA. In addition, ongoing initiatives in the U.S. have increased and will continue to increase pressure on drug pricing. The announcement or adoption of any such initiative could have an adverse effect on potential revenues from any product candidate that we may successfully develop.

We may be unable to establish sales and marketing capabilities necessary to successfully commercialize our potential products.

We currently have no direct sales or marketing capabilities. We may rely on third parties to market and sell most of our primary product candidates or we may outlicense these products prior to the time when these capabilities are needed. If we decide to market our potential products through a direct sales force, we would need either to hire a sales force with expertise in pharmaceutical sales or to contract with a third party to provide a sales force which meets our needs. We may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for our potential products and be competitive. In addition, co promotion or other marketing arrangements with third parties to commercialize potential products could significantly limit the revenues we derive from these potential products, and these third parties may fail to commercialize our compounds successfully.

If our product candidates or those of our collaborative partners do not gain market acceptance, our business will suffer.

Even if clinical trials demonstrate the safety and efficacy of our and our collaborative partners' product candidates and the necessary regulatory approvals are obtained, our and our collaborative partners' products may not gain market acceptance among physicians, patients, healthcare payors and other members of the medical community.

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The degree of market acceptance of any products that we or our collaborative partners develop will depend on a number of factors, including:

- their level of clinical efficacy and safety;
- their advantage over alternative treatment methods;
- our/the marketer's and our collaborative partners' ability to gain acceptable reimbursement and the reimbursement policies of government and third party payors; and
  - the quality of the distribution capabilities of the party(ies) responsible to market and distribute the product(s).

Physicians may not prescribe any of our future products until such time as clinical data or other factors demonstrate the safety and efficacy of those products as compared to conventional drugs and other treatments. Even if the clinical safety and efficacy of therapies using our products is established, physicians may elect not to recommend the therapies for any number of other reasons, including whether the mode of administration of our products is effective for certain conditions, and whether the physicians are already using competing products that satisfy their treatment objectives. Physicians, patients, third party payors and the medical community may not accept and use any product candidates that we, or our collaborative partners, develop. If our products do not achieve significant market acceptance and use, we will not be able to recover the significant investment we have made in developing such products and our business will be severely harmed.

We may be unable to compete successfully.

The markets in which we compete are well established and intensely competitive. We may be unable to compete successfully against our current and future competitors. Our failure to compete successfully may result in lower volume sold, pricing reductions, reduced gross margins and failure to achieve market acceptance for our potential products. Our competitors include research institutions, pharmaceutical companies and biotechnology companies, such as Pfizer, Seattle Genetics, Roche, Takeda AbbVie and Bristol Myers Squibb. Many of these organizations have substantially more experience and more capital, research and development, regulatory, manufacturing, human and other resources than we do. As a result, they may:

- develop products that are safer or more effective than our product candidates;
- obtain FDA and other regulatory approvals or reach the market with their products more rapidly than we can, reducing the potential sales of our product candidates;
- devote greater resources to market or sell their products;
- adapt more quickly to new technologies and scientific advances;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled scientific workers from the limited pool of available talent;
- more effectively negotiate third party licensing and collaboration arrangements; and
- take advantage of acquisitions or other opportunities more readily than we can.

A number of pharmaceutical and biotechnology companies are currently developing products targeting the same types of cancer that we target, and some of our competitors' products have entered clinical trials or already are commercially available.

Our product candidates, if approved and commercialized, will also compete against well established, existing, therapeutic products that are currently reimbursed by government healthcare programs, private health insurers and health maintenance organizations. In addition, if our product candidates are approved and commercialized, we may face competition from biosimilars. The route to market for biosimilars was established with the passage of the ACA in March 2010. The ACA establishes a pathway for the FDA approval of follow on biologics and provides twelve years data





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exclusivity for reference products and an additional six months exclusivity period if pediatric studies are conducted. In Europe, the European Medicines Agency has issued guidelines for approving products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of one of our potential products were approved in the U.S. or Europe, it could have a negative effect on sales and gross profits of the potential product and our financial condition.

We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for relationships with academic and research institutions and for licenses to proprietary technology. In addition, we anticipate that we will face increased competition in the future as new companies enter our markets and as scientific developments surrounding antibody based therapeutics for cancer continue to accelerate. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us.

If we are unable to protect our intellectual property rights adequately, the value of our technology and our product candidates could be diminished.

Our success depends in part on obtaining, maintaining and enforcing our patents and other proprietary rights and our ability to avoid infringing the proprietary rights of others. Patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving, is surrounded by a great deal of uncertainty and involves complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. Accordingly, our pending patent applications may not result in issued patents or in patent claims as broad as in the original applications. Although we own numerous patents, the issuance of a patent is not conclusive as to its validity or enforceability. Through litigation, a third party may challenge the validity or enforceability of a patent after its issuance.

Patents and applications owned or licensed by us may become the subject of interference, opposition, nullity, or other proceedings in a court or patent office in the U.S. or in a foreign jurisdiction to determine validity, enforceability or priority of invention, which could result in substantial cost to us. An adverse decision in such a proceeding may result in our loss of rights under a patent or patent application. It is unclear how much protection, if any, will be given to our patents if we attempt to enforce them or if they are challenged in court or in other proceedings. A competitor may successfully invalidate our patents or a challenge could result in limitations of the patents' coverage. In addition, the cost of litigation or interference proceedings to uphold the validity of patents can be substantial. If we are unsuccessful in these proceedings, third parties may be able to use our patented technology without paying us licensing fees or royalties. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time consuming. In an infringement proceeding, a court may decide that a patent of ours is not valid. Even if the validity of our patents were upheld, a court may refuse to stop the other party from using the technology at issue on the ground that its activities are not covered by our patents.

The Leahy Smith America Invents Act was signed into law on September 16, 2011, and became fully effective in March 2013. In general, the legislation attempts to address issues surrounding the enforceability of patents and the increase in patent litigation by, among other things, moving to a first inventor to file system, establishing new procedures for challenging patents and establishing different methods for invalidating patents. Governmental rule making implementing the new statute is evolving and will continue to introduce new substantive rules and procedures, particularly with regard to post grant proceedings such as inter partes review and post grant review. In due course, the courts will interpret various aspects of the law and related agency rules in ways that we cannot predict, potentially making it easier for competitors and other interested parties to challenge our patents, which, if successful, could have a material adverse effect on our business and prospects. In addition, as the United States Supreme Court

has become increasingly active in reviewing U.S. patent law in recent years, and the extent to which their recent decisions will affect our ability to enforce certain types of claims under our U.S. patents or obtain future patents in certain areas is difficult to predict at this time.

Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U.S.

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In addition to our patent rights, we also rely on unpatented technology, trade secrets, know how and confidential information. Third parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We may not be able to effectively protect our rights in unpatented technology, trade secrets, know how and confidential information. We require each of our employees, consultants and corporate partners to execute a confidentiality agreement at the commencement of an employment, consulting or collaborative relationship with us. Further, we require that all employees enter into assignment of invention agreements as a condition of employment. However, these agreements may not provide effective protection of our information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

Any inability to license proprietary technologies or processes from third parties which we use in connection with the development and manufacture of our product candidates may impair our business.

Other companies, universities and research institutions have or may obtain patents that could limit our ability to use, manufacture, market or sell our product candidates or impair our competitive position. As a result, we would have to obtain licenses from other parties before we could continue using, manufacturing, marketing or selling our potential products. Any necessary licenses may not be available on commercially acceptable terms, if at all. If we do not obtain required licenses, we may not be able to market our potential products at all or we may encounter significant delays in product development while we redesign products or methods that are found to infringe on the patents held by others.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights held by third parties and we may be unable to protect our rights to, or to commercialize, our product candidates.

Patent litigation is very common in the biotechnology and pharmaceutical industries. Third parties may assert patent or other intellectual property infringement claims against us with respect to our technologies, products or other matters. From time to time, we have received correspondence from third parties alleging that we infringe their intellectual property rights. Any claims that might be brought against us alleging infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages and limit our ability to use the intellectual property subject to these claims. Even if we were to prevail, any litigation would be costly and time consuming and could divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit, we may be forced to stop or delay developing, manufacturing or selling potential products that incorporate the challenged intellectual property unless we enter into royalty or license agreements. There may be third party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our products or processes. In addition, we sometimes undertake research and development with respect to potential products even when we are aware of third party patents that may be relevant to our potential products, on the basis that such patents may be challenged or licensed by us. If our subsequent challenge to such patents were not to prevail, we may not be able to commercialize our potential products after having already incurred significant expenditures unless we are able to license the intellectual property on commercially reasonable terms. We may not be able to obtain royalty or license agreements on terms acceptable to us, if at all. Even if we were able to obtain licenses to such technology, some licenses may be non exclusive, thereby giving our competitors access to the same technologies licensed to us. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations, which could severely harm our business.

We use hazardous materials in our business, and any claims relating to improper handling, storage or disposal of these materials could harm our business.

Our research and development and manufacturing activities involve the controlled use of hazardous materials, chemicals, biological materials and radioactive compounds. We are subject to federal, state and local laws and

regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could exceed our resources. We may be required to incur significant costs to comply with these laws in the future. Failure to comply with these laws could result in fines and the revocation of permits, which could prevent us from conducting our business.

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We face product liability risks and may not be able to obtain adequate insurance.

While we secure waivers from all participants in our clinical trials, the use of our product candidates during testing or after approval entails an inherent risk of adverse effects, which could expose us to product liability claims. Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

We may not have sufficient resources to satisfy any liability resulting from these claims. We currently have product liability insurance for products which are in clinical testing, however, our coverage may not be adequate in scope to protect us in the event of a successful product liability claim. Further, we may not be able to maintain our current insurance or obtain general product liability insurance on reasonable terms and at an acceptable cost if we or our collaborative partners begin commercial production of our proposed product candidates. This insurance, even if we can obtain and maintain it, may not be sufficient to provide us with adequate coverage against potential liabilities.

Failure to comply with the Foreign Corrupt Practices Act, or FCPA, and other similar anti-corruption laws and anti-money laundering laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations could subject us to significant penalties and damage our reputation.

We are subject to the FCPA, which generally prohibits U.S. companies and intermediaries acting on their behalf from offering or making corrupt payments to “foreign officials” for the purpose of obtaining or retaining business or securing an improper business advantage. The FCPA also requires companies whose securities are publicly listed in the United States to maintain accurate books and records and to maintain adequate internal accounting controls. We are also subject to other similar anti-corruption laws and anti-money laundering laws, as well as export control laws, customs laws, sanctions laws and other laws that apply to our activities in the countries where we operate. Certain of the jurisdictions in which we conduct or expect to conduct business have heightened risks for public corruption, extortion, bribery, pay-offs, theft and other fraudulent practices. In many countries, health care professionals who serve as investigators in our clinical studies, or may prescribe or purchase our any product candidates if they are approved, are employed by a government or an entity owned or controlled by a government. Dealings with these investigators, prescribers and purchasers are subject to regulation under the FCPA. Under these laws and regulations, as well as other anti-corruption laws, anti-money-laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions.

Our employees, independent contractors, principal investigators, contract research organizations, or CROs, consultants and collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and collaborators may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (1) laws or regulations in jurisdictions where we are performing activities in relation to our product candidates, including those laws requiring the reporting of true, complete and accurate information to such authorities; (2) manufacturing regulations and

standards; (3) applicable laws prohibiting the promotion of a medical product for a use that has not been cleared or approved; (4) fraud and abuse, anti-corruption laws and anti-money laundering laws, as well as similar laws and regulations and other laws; or (5) laws that require the reporting of true and accurate financial information and data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to laws intended to prevent

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fraud, bias, misconduct, kickbacks, self-dealing and other abusive practices, and these laws may differ substantially from country to country. Misconduct by these parties could also include the improper use of information obtained in the course of clinical trials or performing other services, which could result in investigations, sanctions and serious harm to their or our reputation.

We depend on our key personnel and we must continue to attract and retain key employees and consultants.

We depend on our key scientific and management personnel. Our ability to pursue the development of our current and future product candidates depends largely on retaining the services of our existing personnel and hiring additional qualified scientific personnel to perform research and development. We will also need to hire personnel with expertise in clinical testing, government regulation, manufacturing, marketing and finance. Attracting and retaining qualified personnel will be critical to our success. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non profit research institutions. Failure to retain our existing key management and scientific personnel or to attract additional highly qualified personnel could delay the development of our product candidates and harm our business.

Our stock price can fluctuate significantly and results announced by us and our collaborators can cause our stock price to decline.

Our stock price can fluctuate significantly due to business developments announced by us and by our collaborators, or as a result of market trends and daily trading volume. The business developments that could impact our stock price include disclosures related to clinical findings with compounds that make use of our ADC technology, new collaborations and clinical advancement or discontinuation of product candidates that make use of our ADC technology. Our stock price can also fluctuate significantly with the level of overall investment interest in small cap biotechnology stocks.

Our operating results have fluctuated in the past and are likely to continue to do so in the future. Our revenue is unpredictable and may fluctuate due to the timing of non recurring licensing fees, decisions of our collaborative partners with respect to our agreements with them, reimbursement for manufacturing services, the achievement of milestones and our receipt of the related milestone payments under new and existing licensing and collaboration agreements. Revenue historically recognized under our prior collaboration agreements may not be an indicator of revenue from any future collaboration. In addition, our expenses are unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, which may include obligations to manufacture or supply product or payments owed by us under licensing or collaboration agreements. It is possible that our quarterly and/or annual operating results will not meet the expectations of securities analysts or investors, causing the market price of our common stock to decline. We believe that quarter to quarter and year to year comparisons of our operating results are not good indicators of our future performance and should not be relied upon to predict the future performance of our stock price.

The potential sale of additional shares of our common stock (including securities convertible into shares of our common stock) may cause our stock price to decline.

On June 20, 2016, we sold \$100 million aggregate principal amount of our 4.50% Convertible Senior Notes due 2021, which are convertible into shares of our common stock at any time prior to the maturity date of the Notes at an initial conversion rate of 238.7775 shares per \$1,000 principal amount of Notes, which is equal to an initial conversion price of approximately \$4.19 per share. Conversion of all of the Notes at the initial conversion rate will result in the issuance of 23,877,750 shares of our common stock. The potential sale of additional shares of our common stock may be dilutive to our shares outstanding and may cause our stock price to decline.

We do not intend to pay cash dividends on our common stock.

We have not paid cash dividends since our inception and do not intend to pay cash dividends in the foreseeable future. Therefore, shareholders will have to rely on appreciation in our stock price, if any, in order to achieve a gain on an investment.

#### A WARNING ABOUT FORWARD LOOKING STATEMENTS

This report includes forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to analyses and other information which are based on forecasts of future results and



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estimates of amounts that are not yet determinable. These statements also relate to our future prospects, developments and business strategies.

These forward looking statements are identified by their use of terms and phrases, such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will” and other similar terms and phrases, including reference to assumptions. These statements are contained in the “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections, as well as other sections of this Annual Report on Form 10 K.

These forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from those contemplated by our forward looking statements. These known and unknown risks, uncertainties and other factors are described in detail in the “Risk Factors” section and in other sections of this Annual Report on Form 10 K. We disclaim any intention or obligation to update or revise any forward looking statements, whether as a result of new information, future events or otherwise.

### Item 1B. Unresolved Staff Comments

None.

### Item 2. Properties

We lease approximately 110,000 square feet of laboratory and office space in a building located at 830 Winter Street, Waltham, MA. The term of the 830 Winter Street lease expires on March 31, 2026, with an option for us to extend the lease for two additional five year terms. We also lease approximately 43,850 square feet of space at 333 Providence Highway, Norwood, MA, which serves as our conjugate manufacturing facility and office space. The 333 Providence Highway lease expires on June 30, 2018, with an option for us to extend the lease for an additional five year term. Due to space requirements, in April 2013, we entered into a lease agreement for the rental of 7,507 square feet of office space at 100 River Ridge Drive, Norwood, MA. The lease expires in September, 2018, with an option for us to extend the lease for an additional five year term. We entered into a sublease in December 2014 for this space, effective January 2015 through the remaining initial term of the lease. In February 2016, we entered into a lease agreement for the rental of 10,281 square feet of additional office space at 930 Winter Street, Waltham, MA. The lease expires on August 31, 2021.

### Item 3. Legal Proceedings

From time to time we may be a party to various legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

#### Item 3.1. Executive Officers of the Registrant

ImmunoGen’s executive officers are appointed by the Board of Directors at the first meeting of the Board following the annual meeting of shareholders or at other Board meetings as appropriate, and hold office until the first Board meeting following the next annual meeting of shareholders and until a successor is chosen, subject to prior death, resignation or removal. Information regarding our executive officers is presented below.

Mark J. Enyedy, age 52, joined ImmunoGen in May 2016, and has served as our President and Chief Executive Officer since that date. Prior to joining ImmunoGen, he served in various executive capacities at Shire plc, a pharmaceutical company, from 2013 to May 2016, including as Executive Vice President and Head of Corporate Development from 2014 to May 2016, where he led Shire's strategy, M&A and corporate planning functions and provided commercial oversight of Shire's pre-Phase 3 portfolio. Prior to joining Shire he served as Chief Executive Officer of Proteostasis, a biopharmaceutical company, from 2011 to 2013. Prior to joining Proteostasis he served for 15 years at Genzyme Corporation, a biotechnology company, most recently as President of the Transplant, Oncology, and Multiple Sclerosis divisions. Mr. Enyedy holds a JD from Harvard Law School and practiced law prior to joining Genzyme. Mr. Enyedy is also a director of Fate Therapeutics, Inc.

Richard J. Gregory, age 58, joined ImmunoGen in 2015, and has served as our Executive Vice President and Chief Scientific Officer since that date. Prior to joining ImmunoGen, he spent 25 years at Genzyme Corporation, a

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biotechnology company, in roles of increasing responsibility, including Senior Vice President and Head of Research from 2003 until Genzyme's acquisition by Sanofi in 2011, and Head of Research and Development for Genzyme from 2011 through 2014. Dr. Gregory holds a PhD from the University of Massachusetts, Amherst, and completed his post doctoral work at the Worcester Foundation for Experimental Biology.

John M. Lambert, PhD, age 65, joined ImmunoGen in 1987, and has served as Executive Vice President and Distinguished Research Fellow since January 2015. Prior to that he served as our Executive Vice President and Chief Scientific Officer from 2008 through 2014. Dr. Lambert holds a PhD in Biochemistry from University of Cambridge in England, and completed his postdoctoral work at the University of California at Davis and at Glasgow University in Scotland.

David B. Johnston, age 61, joined ImmunoGen in 2013, and has served as our Executive Vice President and Chief Financial Officer since that date. Prior to joining ImmunoGen, Mr. Johnston served as Chief Financial Officer of AVEO Pharmaceuticals, Inc., a biotechnology company, from 2007 to 2013. Prior to that he spent nine years at Genzyme Corporation, a biotechnology company, in roles of increasing responsibility, including Vice President, Finance and Chief Financial Officer of Genzyme Biosurgery from 1999 to 2003, and as Senior Vice President, Finance, Corporate Planning and Analysis from 2003 to 2007. Mr. Johnston holds a Master of Business Administration from the University of Michigan.

Charles Q. Morris, MB, ChB, MRCP (UK), age 51, joined ImmunoGen in 2012, and has served as our Executive Vice President and Chief Development Officer since that date. Prior to joining ImmunoGen, he served as Executive Vice President and Chief Medical Officer of Allos Therapeutics, Inc., a biotechnology company, from 2010 until its acquisition in 2012. Prior to that he served as Vice President, Worldwide Clinical Research, at Cephalon, Inc., a biotechnology company, from 2008 to 2010. Dr. Morris holds his medical degrees from Sheffield University Medical School and is a member of the Royal College of Physicians of London. On August 3, 2016, Dr. Morris provided notice to ImmunoGen of his intention to resign, effective as of the close of business on September 2, 2016, in order to pursue another professional opportunity closer to his primary residence in Pennsylvania.

Sandra Poole, age 52, joined ImmunoGen in 2014, and has served as our Executive Vice President of Technical Operations since July 1, 2015. Prior to that she served as our Senior Vice President, Technical Operations, from her date of hire through June 2015. Prior to joining ImmunoGen, she spent 15 years at Genzyme Corporation, a biotechnology company, and its subsidiaries in roles of increasing responsibility, including as Senior Vice President overseeing various technical operations within Genzyme from 2009 to 2013, and as Senior Vice President, Biologics Manufacturing from 2013 to September 2014. Ms. Poole holds a master's degree in chemical engineering from the University of Waterloo in Ontario.

Craig Barrows, age 61, joined ImmunoGen in 2007, and has served as our Vice President, General Counsel and Secretary since that date.

Ellie Harrison, age 61, joined ImmunoGen in 2014, and has served as our Vice President and Chief Human Resources Officer since that date. Prior to joining ImmunoGen, she served as Senior Vice President of Human Resources of Blue Cross and Blue Shield of Rhode Island, a healthcare provider, from 2013 to 2014. Prior to that she served as a Managing Director and Senior Human Resources Advisor to the global consumer banking organization of Citigroup, a financial institution, from 2009 to 2012.

Peter J. Williams, age 62, joined ImmunoGen in August 2009, and has served as our Vice President, Business Development since that date.

Item 4. Mine Safety Disclosures

None.

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## PART II

## Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

## Market Price of Our Common Stock and Related Stockholder Matters

Our common stock is quoted on the NASDAQ Global Select Market under the symbol "IMGN." The table below sets forth the high and low closing price per share of our common stock as reported by NASDAQ:

	Fiscal Year 2016		Fiscal Year 2015	
	High	Low	High	Low
First Quarter	\$ 19.39	\$ 9.54	\$ 12.74	\$ 10.28
Second Quarter	\$ 13.95	\$ 10.04	\$ 11.00	\$ 5.34
Third Quarter	\$ 12.85	\$ 7.02	\$ 9.55	\$ 5.85
Fourth Quarter	\$ 9.76	\$ 2.98	\$ 15.88	\$ 7.91

As of August 18, 2016, the closing price per share of our common stock was \$3.06, as reported by NASDAQ, and we had approximately 503 holders of record of our common stock.

We have not paid any cash dividends on our common stock since our inception and do not intend to pay any cash dividends in the foreseeable future.

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## Equity Compensation Plan Information (in thousands)

	(a)	(b)	(c)
Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders <sup>(1)</sup>	11,813	\$ 13.03	3,351
Equity compensation plans not approved by security holders	—	—	—
Total	11,813	\$ 13.03	3,351

<sup>(1)</sup> These plans consist of the Restated Stock Option Plan and the 2006 Employee, Director and Consultant Equity Incentive Plan.

## Recent Sales of Unregistered Securities; Uses of Proceeds from Registered Securities; Issuer Repurchases of Equity Securities

None.

## Item 6. Selected Financial Data

The following table (in thousands, except per share data) sets forth our consolidated financial data for each of our five fiscal years through our fiscal year ended June 30, 2016. The information set forth below should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10 K.

	Year Ended June 30,				
	2016	2015	2014	2013	2012
Consolidated Statement of Operations Data:					
Total revenues	\$ 60,002	\$ 85,541	\$ 59,896	\$ 35,535	\$ 16,357
Total operating expenses	184,993	139,996	131,427	108,544	89,614
Non-cash interest expense on liability related to sale of future royalty	20,130	5,437	—	—	—
Other income (expense), net	304	(847)	167	198	(62)
Net loss	\$ (144,817)	\$ (60,739)	\$ (71,364)	\$ (72,811)	\$ (73,319)
Basic and diluted net loss per common share	\$ (1.67)	\$ (0.71)	\$ (0.83)	\$ (0.87)	\$ (0.95)

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Basic and diluted weighted average common shares outstanding	86,976	86,038	85,481	84,063	76,814
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 245,026	\$ 278,109	\$ 142,261	\$ 194,960	\$ 160,938
Total assets	287,085	313,823	165,318	213,596	180,308
Long-term convertible notes	100,000	—	—	—	—
Shareholders' (deficit) equity	(82,304)	35,104	75,699	121,847	83,890

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### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

#### Overview

Since our inception, we have been principally engaged in the development of targeted anticancer agents referred to as antibody drug conjugates, or ADCs. An ADC with our technology consists of a manufactured antibody that binds specifically to an antigen target found on the surface of cancer cells with one of our proprietary, highly potent cancer-killing agents attached. Its antibody component enables an ADC compound to bind specifically to a tumor cell with the target antigen on its surface, which the cancer-killing agent can then kill. The cancer-killing agent is attached to the antibody using one of our engineered linkers, which control the release and activation of the cancer-killing agent inside the tumor cell. With some ADC compounds, the antibody component also has anticancer activity of its own. Our ADC technology is designed to enable the creation of highly effective, well tolerated anticancer products. Our lead ADC product candidates employ either DM1 or DM4 as the cancer-killing agent. Both DM1 and DM4, collectively DMx, are our proprietary derivatives of maytansine and kill tumor cells by disrupting a process, tubulin formation, the cancer cells undergo more frequently than most healthy cells. We also have developed DNA-alkylating agents that we call IGNs. Our IMGN779 ADC is the first IGN-utilizing ADC to advance into clinical testing.

We use our proprietary ADC technology in conjunction with our extensive antibody expertise to develop our own anticancer product candidates. We also enter into agreements that enable companies to use our ADC technology to develop and commercialize product candidates to specified targets. Under the terms of our agreements, we are generally entitled to upfront fees, milestone payments, and royalties on any commercial product sales. In addition, under certain agreements we are compensated for research and development activities performed at our collaborative partner's request at negotiated prices which are generally consistent with what other third parties would charge. We are compensated to manufacture preclinical and clinical materials and deliver cytotoxic agent material at negotiated prices which are generally consistent with what other third parties would charge. Currently, our partners include Amgen, Bayer, Biotest, Lilly, Novartis, Roche, Sanofi and Takeda. We also have a research agreement with CytomX Therapeutics that allows each company to develop product candidates to a specified number of cancer targets using CytomX's Probody™ antibody-masking technology with our payload agents and engineered linkers. We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements. Details for some of our major and recent collaborative agreements can be found in this Form 10 K under Item 1. Business.

To date, we have not generated revenues from commercial sales of internal products and we expect to incur significant operating losses for the foreseeable future. As of June 30, 2016, we had approximately \$245.0 million in cash and cash equivalents compared to \$278.1 million as of June 30, 2015.

We anticipate that future cash expenditures will be partially offset by collaboration derived proceeds, including milestone payments and upfront fees. Accordingly, period to period cash balances may fluctuate dramatically based upon the timing of receipt of the proceeds. We believe that our established collaborative agreements, while subject to specified milestone achievements, will provide funding to assist us in meeting obligations under our collaborative agreements while also assisting in providing funding for the development of internal product candidates and technologies. However, we can give no assurances that such collaborative agreement funding will, in fact, be realized in the time frames we expect, or at all. Should we or our partners not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to secure alternative financing arrangements, find additional partners and/or defer or limit some or all of our research, development and/or clinical projects. However, we cannot provide assurance that any such opportunities presented by additional partners or alternative financing arrangements will be entirely available to us, if at all.

#### Critical Accounting Policies



We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an on going basis, we evaluate our estimates, including those related to our collaborative agreements, clinical trial accruals, inventory and stock based compensation. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

We believe the following critical accounting policies reflect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

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Revenue Recognition

We enter into licensing and development agreements with collaborative partners for the development of monoclonal antibody based anticancer therapeutics. The terms of these agreements contain multiple deliverables which may include (i) licenses, or options to obtain licenses, to our ADC technology, (ii) rights to future technological improvements, (iii) research activities to be performed on behalf of the collaborative partner, (iv) delivery of cytotoxic agents and (v) the manufacture of preclinical or clinical materials for the collaborative partner. Payments to us under these agreements may include upfront fees, option fees, exercise fees, payments for research activities, payments for the manufacture of preclinical or clinical materials, payments based upon the achievement of certain milestones and royalties on product sales. We follow the provisions of the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 605-25, "Revenue Recognition—Multiple Element Arrangements," and ASC Topic 605-28, "Revenue Recognition—Milestone Method," in accounting for these agreements. In order to account for these agreements, we must identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on whether certain criteria are met, including whether the delivered element has stand alone value to the collaborator. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

At June 30, 2016, we had the following two types of agreements with the parties identified below:

- Development and commercialization licenses, which provide the party with the right to use our ADC technology and/or certain other intellectual property to develop compounds to a specified antigen target:

Amgen (two exclusive single target licenses\*)

Bayer HealthCare (one exclusive single target license)

Biotest (one exclusive single target license)

Lilly (three exclusive single target licenses)

Novartis (five exclusive single target licenses and one license to two related targets: one target on an exclusive basis and the second target on a non-exclusive basis)

Roche, through its Genentech unit (five exclusive single target licenses)

Sanofi (one exclusive single target license and one exclusive license to multiple individual targets)

Takeda, through its wholly owned subsidiary, Millennium Pharmaceuticals, Inc. (one exclusive single target license)

- Research license/option agreement for a defined period of time to secure development and commercialization licenses to use our ADC technology to develop anticancer compounds to specified targets on established terms (referred to herein as right to test agreements):

CytomX

Takeda, through its wholly owned subsidiary, Millennium Pharmaceuticals, Inc.

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\*Amgen has sublicensed one of its exclusive single-target licenses to Oxford BioTherapeutics Ltd.

There are no performance, cancellation, termination or refund provisions in any of the arrangements that contain material financial consequences to us.

Development and Commercialization Licenses

The deliverables under a development and commercialization license agreement generally include the license to our ADC technology with respect to a specified antigen target, and may also include deliverables related to rights to future technological improvements, research activities to be performed on behalf of the collaborative partner and the manufacture of preclinical or clinical materials for the collaborative partner.

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Generally, development and commercialization licenses contain non refundable terms for payments and, depending on the terms of the agreement, provide that we will (i) at the collaborator's request, provide research services at negotiated prices which are generally consistent with what other third parties would charge, (ii) at the collaborator's request, manufacture and provide to it preclinical and clinical materials or deliver cytotoxic agents at negotiated prices which are generally consistent with what other third parties would charge, (iii) earn payments upon the achievement of certain milestones and (iv) earn royalty payments, generally until the later of the last applicable patent expiration or 10 to 12 years after product launch. In the case of Kadcyła, however, the minimum royalty term is 10 years and the maximum royalty term is 12 years on a country by country basis, regardless of patent protection. Royalty rates may vary over the royalty term depending on our intellectual property rights and/or the presence of comparable competing products. We may provide technical assistance and share any technology improvements with our collaborators during the term of the collaboration agreements. We do not directly control when or whether any collaborator will request research or manufacturing services, achieve milestones or become liable for royalty payments. As a result, we cannot predict when or if we will recognize revenues in connection with any of the foregoing.

In determining the units of accounting, management evaluates whether the license has stand alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of ADC technology research expertise in the general marketplace. If we conclude that the license has stand alone value and therefore will be accounted for as a separate unit of accounting, we then determine the estimated selling prices of the license and all other units of accounting based on market conditions, similar arrangements entered into by third parties, and entity specific factors such as the terms of our previous collaborative agreements, recent preclinical and clinical testing results of therapeutic products that use our ADC technology, our pricing practices and pricing objectives, the likelihood that technological improvements will be made, and, if made, will be used by our collaborators and the nature of the research services to be performed on behalf of our collaborators and market rates for similar services.

Upfront payments on development and commercialization licenses may be recognized upon delivery of the license if facts and circumstances dictate that the license has stand alone value from the undelivered elements, which generally include rights to future technological improvements, research services, delivery of cytotoxic agents and the manufacture of preclinical and clinical materials.

We recognize revenue related to research services that represent separate units of accounting as they are performed, as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is probable. We recognize revenue related to the rights to future technological improvements over the estimated term of the applicable license.

We may also provide cytotoxic agents to our collaborators or produce preclinical and clinical materials for them at negotiated prices which are generally consistent with what other third parties would charge. We recognize revenue on cytotoxic agents and on preclinical and clinical materials when the materials have passed all quality testing required for collaborator acceptance and title and risk of loss have transferred to the collaborator. Arrangement consideration allocated to the manufacture of preclinical and clinical materials in a multiple deliverable arrangement is below our full cost, and our full cost is not expected to ever be below our contract selling prices for our existing collaborations. During the fiscal years ended June 30, 2016, 2015 and 2014, the difference between our full cost to manufacture preclinical and clinical materials on behalf of our collaborators as compared to total amounts received from collaborators for the manufacture of preclinical and clinical materials was \$6.9 million, \$9.2 million, and \$2.3 million, respectively. The majority of our costs to produce these preclinical and clinical materials are fixed and then allocated to each batch based on the number of batches produced during the period. Therefore, our costs to produce these materials are significantly impacted by the number of batches produced during the period. The volume of preclinical and clinical materials we produce is directly related to the number of clinical trials we and our collaborators are

preparing for or currently have underway, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period such trials last. Accordingly, the volume of preclinical and clinical materials produced, and therefore our per batch costs to manufacture these preclinical and clinical materials, may vary significantly from period to period.

We may also produce research material for potential collaborators under material transfer agreements. Additionally, we perform research activities, including developing antibody specific conjugation processes, on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. We record amounts received for research materials produced or services performed as a component of research and development support revenue. We also develop conjugation processes for materials for later stage testing

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and commercialization for certain collaborators. We are compensated at negotiated rates and may receive milestone payments for developing these processes which are recorded as a component of research and development support revenue.

Our development and commercialization license agreements have milestone payments which for reporting purposes are aggregated into three categories: (i) development milestones, (ii) regulatory milestones, and (iii) sales milestones. Development milestones are typically payable when a product candidate initiates or advances into different clinical trial phases. Regulatory milestones are typically payable upon submission for marketing approval with the FDA or other countries' regulatory authorities or on receipt of actual marketing approvals for the compound or for additional indications. Sales milestones are typically payable when annual sales reach certain levels.

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Non refundable development and regulatory milestones that are expected to be achieved as a result of our efforts during the period of substantial involvement are considered substantive and are recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive because we do not contribute effort to the achievement of such milestones are generally achieved after the period of substantial involvement and are recognized as revenue upon achievement of the milestone, as there are no undelivered elements remaining and no continuing performance obligations, assuming all other revenue recognition criteria are met.

Under our development and commercialization license agreements, we receive royalty payments based upon our licensees' net sales of covered products. Generally, under these agreements we are to receive royalty reports and payments from our licensees approximately one quarter in arrears, that is, generally in the second or third month of the quarter after the licensee has sold the royalty bearing product or products. We recognize royalty revenues when we can reliably estimate such amounts and collectability is reasonably assured. As such, we generally recognize royalty revenues in the quarter reported to us by our licensees, or one quarter following the quarter in which sales by our licensees occurred.

## Right to Test Agreements

Our right to test agreements provide collaborators the right to (a) test our ADC technology for a defined period of time through a research, or right to test, license, (b) take options, for a defined period of time, to specified targets and (c) upon exercise of those options, secure or "take" licenses to develop and commercialize products for the specified targets on established terms. Under these agreements, fees may be due to us (i) at the inception of the arrangement (referred to as "upfront" fees or payments), (ii) upon taking an option with respect to a specific target (referred to as option fees or payments earned, if any, when the option is "taken"), (iii) upon the exercise of a previously taken option to acquire a development and commercialization license(s) (referred to as exercise fees or payments earned, if any, when the development and commercialization license is "taken"), or (iv) some combination of all of these fees.

The accounting for right to test agreements is dependent on the nature of the option granted to the collaborative partner. Options are considered substantive if, at the inception of a right to test agreement, we are at risk as to whether the collaborative partner will choose to exercise the options to secure development and commercialization licenses. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options. None of our right to test agreements entered into subsequent to the adoption of Accounting Standards Update, or ASU, No. 2009 13 has been determined to contain substantive options. For right to test agreements where the options to secure development and commercialization licenses to our ADC technology are not considered substantive, we consider the development and commercialization

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license to be a deliverable at the inception of the agreement and apply the multiple element revenue recognition criteria to determine the appropriate revenue recognition. Subsequent to the adoption of ASU No. 2009-13, we determined that our research licenses lack stand-alone value and are considered for aggregation with the other elements of the arrangement and accounted for as one unit of accounting.

We do not directly control when or if any collaborator will exercise its options for development and commercialization licenses. As a result, we cannot predict when or if we will recognize revenues in connection with any of the foregoing.

## Inventory

We review our estimates of the net realizable value of our inventory at each reporting period. Our estimate of the net realizable value of our inventory is subject to judgment and estimation. The actual net realizable value of our inventory could vary significantly from our estimates. We consider quantities of raw materials in excess of twelve month projected usage that are not supported by firm, fixed collaborator orders and projections at the time of the assessment to be excess. During fiscal years 2016, 2015 and 2014, we obtained additional quantities of DMx from our supplier which amounted to more material than would be required by our collaborators over the next twelve months and as a result, we recorded \$1.1 million, \$1.0 million and \$364,000, respectively, of charges to research and development expense related to raw material inventory identified as excess. Our collaborators' estimates of their clinical material requirements are based upon expectations of their clinical trials, including the timing, size, dosing schedule and the maximum tolerated dose likely to be reached for the compound being evaluated. Our collaborators' actual requirements for clinical materials may vary significantly from their projections. Significant differences between our collaborators' actual manufacturing orders and their projections could result in our actual twelve month usage of raw materials varying significantly from our estimated usage at an earlier reporting period. Such differences and/or reductions in collaborators' projections could indicate that we have excess raw material inventory and we would then evaluate the need to record write downs, which would be included as charges to research and development expense.

## Stock based Compensation

As of June 30, 2016, we are authorized to grant future awards under one share based compensation plan, which is the ImmunoGen, Inc. 2006 Employee, Director and Consultant Equity Incentive Plan. The stock based awards are accounted for under ASC Topic 718, "Compensation—Stock Compensation," pursuant to which the estimated grant date fair value of awards is charged to the statement of operations over the requisite service period, which is the vesting period. Such amounts have been reduced by our estimate of forfeitures for unvested awards.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option pricing model. Expected volatility is based exclusively on historical volatility data of our stock. The expected term of stock options granted is based exclusively on historical data and represents the period of time that stock options granted are expected to be outstanding. The expected term is calculated for and applied to one group of stock options as we do not expect substantially different exercise or post-vesting termination behavior amongst our employee population. The risk-free rate of the stock options is based on the U.S. Treasury rate in effect at the time of grant for the expected term of the stock options. Estimated forfeitures are based on historical data as well as current trends. Stock compensation cost related to stock options and restricted stock incurred during the years ended June 30, 2016, 2015 and 2014 was \$21.9 million, \$15.3 million and \$15.6 million, respectively. During fiscal year 2016, we recorded approximately \$3.1 million of stock compensation cost related to the modification of certain outstanding common stock options with the former Chief Executive Officer's succession plan. Stock compensation cost related to director deferred share units recorded during the years ended June 30, 2016, 2015 and 2014 was \$380,000, \$389,000 and \$433,000, respectively.



Future stock based compensation may significantly differ based on changes in the fair value of our common stock and our estimates of expected volatility and the other relevant assumptions.

## Results of Operations

### Revenues

Our total revenues for the year ended June 30, 2016 were \$60.0 million compared with \$85.5 million and \$59.9 million for the years ended June 30, 2015 and 2014, respectively. The \$25.5 million decrease in revenues in fiscal year 2016 is attributable to a decrease in license and milestone fees, royalty revenue and clinical materials revenue, partially offset by an increase in non cash royalty revenue and research and development support revenue. The

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\$25.6 million increase in revenues in fiscal year 2015 compared to fiscal 2014 is attributable to an increase in license and milestone fees, royalty revenue, non cash royalty revenue and clinical materials revenue, partially offset by a decrease in research and development support revenue, all of which are discussed below.

Revenue from license and milestone fees for the year ended June 30, 2016 decreased approximately \$30.9 million to \$26.9 million from \$57.8 million in the year ended June 30, 2015. Revenue from license and milestone fees for the year ended June 30, 2014 was \$39.5 million. Included in license and milestone fees for the year ended June 30, 2016 is \$8.6 million of license revenue earned upon the execution of a development and commercialization license taken by Takeda, a \$5 million development milestone achieved under a license agreement with Lilly, a \$1 million development milestone achieved under a license agreement with Amgen, a \$2 million development milestone achieved under a license agreement with Sanofi and a \$10 million development milestone achieved under a license agreement with Bayer. Included in license and milestone fees for the year ended June 30, 2015 is \$15.6 million of license revenue earned upon the execution of two development and commercialization licenses by Lilly, \$25.7 million of license revenue earned upon the execution of three development and commercialization licenses by Novartis, two \$5 million development milestones achieved under our collaboration agreement with Novartis and \$4 million in development milestones achieved under our collaboration agreement with Sanofi. Also, during fiscal 2015, we made a change in estimate to our period of substantial involvement as it relates to an exclusive license with Sanofi which resulted in an increase to license and milestone fees of \$1.5 million in fiscal 2015 compared to amounts that would have been recognized pursuant to the Company's previous estimate. Additionally, during fiscal 2015, Janssen Biotech terminated its exclusive development and commercialization license with us, and as a result, we recognized the remaining \$241,000 of the \$1 million upfront fee received upon execution of the license which had been previously deferred. Included in license and milestone fees for the year ended June 30, 2014 is \$7.8 million of license revenue earned upon the execution of a development and commercialization license by Lilly, two \$5 million regulatory milestones achieved under our collaboration agreement with Roche, \$18.2 million of license revenue earned upon the execution of two development and commercialization licenses and a one year extension of the original term of the multi target agreement by Novartis, and \$2.2 million of revenue from Amgen related to a modification of an existing arrangement. The amount of license and milestone fees we earn is directly related to the number of our collaborators, the collaborators' advancement of the product candidates, and the overall success in the clinical trials of the product candidates. As such, the amount of license and milestone fees may vary widely from quarter to quarter and year to year. Total revenue recognized from license and milestone fees from each of our collaborative partners in the years ended June 30, 2016, 2015 and 2014 is included in the following table (in thousands):

License and Milestone Fees Collaborative Partner:	Year Ended June 30,		
	2016	2015	2014
Amgen	\$ 1,017	\$ 17	\$ 2,351
Bayer HealthCare	10,000	—	—
Biotest	12	25	25
Janssen	—	241	—
Lilly	5,023	15,644	7,830
Novartis	180	35,915	18,353
Roche	—	—	10,000
Sanofi	2,009	5,973	896
Takeda	8,674	—	—
Total	\$ 26,915	\$ 57,815	\$ 39,455

Deferred revenue of \$32.9 million at June 30, 2016 represents payments received from our collaborators pursuant to our license agreements which we have yet to earn pursuant to our revenue recognition policy. Included within this amount is \$13 million of non cash consideration recorded in connection with our arrangement with CytomX during

fiscal 2014.

In February 2013, the US FDA granted marketing approval to Kadcyla, an ADC product resulting from one of our development and commercialization licenses with Roche, through its Genentech unit. We receive royalty reports and payments related to sales of Kadcyla from Roche one quarter in arrears. In accordance with our revenue recognition policy, \$25.3 million of non-cash royalties on net sales of Kadcyla for the twelve month period ended March 31, 2016 were recorded and included in royalty revenue for the year ended June 30, 2016 and \$5.5 million of non-cash royalties and \$13.9 million of cash royalties on net sales of Kadcyla for the twelve month period ended March 31, 2015 is included in royalty revenue for the year ended June 30, 2015. We recorded \$10.3 million of cash royalties on net sales of

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Kadcyla for the twelve month period ended March 31, 2014 for the year ended June 30, 2014. Kadcyla sales occurring after January 1, 2015 are covered by a royalty purchase agreement whereby the associated cash is remitted to Immunity Royalty Holdings, L.P. See further details regarding royalty obligation in Note F of the Consolidated Financial Statements. We expect royalty revenue to increase in future periods as the underlying net sales of Kadcyla increase.

Research and development support revenue was \$4.0 million, \$2.8 million, and \$7.2 million for the fiscal years ended June 30, 2016, 2015 and 2014, respectively. These amounts primarily represent research funding earned based on actual resources utilized under our agreements with our collaborators as shown in the table below. Also included in research and development support revenue are fees for developing antibody specific conjugation processes on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. The amount of research and development support revenue we earn is directly related to the number of our collaborators and potential collaborators, the stage of development of our collaborators' product candidates and the resources our collaborators allocate to the development effort. As such, the amount of development fees may vary widely from quarter to quarter and year to year. Total revenue recognized from research and development support from each of our collaborative partners in the years ended June 30, 2016, 2015 and 2014 is included in the following table (in thousands):

Research and Development Support Collaborative Partner:	Year Ended June 30,		
	2016	2015	2014
Amgen	\$ 30	\$ 105	\$ 404
Biotest	338	645	783
CytomX	1,673	59	—
Lilly	479	1,207	2,906
Novartis	164	512	3,012
Takeda	1,066	264	—
Other	264	56	82
Total	\$ 4,014	\$ 2,848	\$ 7,187

Clinical materials revenue decreased by approximately \$1.9 million to \$3.6 million in the year ended June 30, 2016 compared to \$5.5 million in the year ended June 30, 2015. We earned clinical materials revenue of \$2.9 million during the year ended June 30, 2014. During the years ended June 30, 2016, 2015 and 2014, we shipped clinical materials in support of a number of our collaborators' clinical trials, as well as preclinical materials in support of certain collaborators' development efforts and DMx shipments to certain collaborators in support of development and manufacturing efforts. We are compensated at negotiated prices which are generally consistent with what other third parties would charge. The amount of clinical materials revenue we earn, and the related cost of clinical materials charged to research and development expense, is directly related to the number of clinical trials our collaborators who use us to manufacture clinical materials are preparing or have underway, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period, if any, during which patients in the trial receive clinical benefit from the clinical materials, and the demand our collaborators have for clinical grade material for process development and analytical purposes. As such, the amount of clinical materials revenue and the related cost of clinical materials charged to research and development expense may vary significantly from quarter to quarter and year to year.

#### Research and Development Expenses

Our research and development expenses relate to (i) research to evaluate new targets and to develop and evaluate new antibodies, linkers and cytotoxic agents, (ii) preclinical testing of our own and, in certain instances, our collaborators'

product candidates, and the cost of our own clinical trials, (iii) development related to clinical and commercial manufacturing processes and (iv) manufacturing operations which also includes raw materials. Our research and development efforts have been primarily focused in the following areas:

- evaluation of potential antigen targets;
- evaluation of internally developed and/or in licensed product candidates and technologies;
- development and evaluation of additional cytotoxic agents and linkers;
- activities related to the process, preclinical and clinical development of our internal product candidates;

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- process improvements to our ADC technology;
- process improvements related to the production of IGNs;
- process improvements related to the production of DM1, DM4 and strain development of their precursor, ansamitocin P3;
- operation and maintenance of our conjugate manufacturing facility, including production of our own and our collaborators' clinical materials;
- production costs for the supply of clinical material for our internal product candidates, including antibody supply, conjugation services and fill/finish services;
- production costs for the supply of IGNs and DMx for our and our partners' preclinical and clinical activities;
- non pivotal and pivotal development activities with contract manufacturers for conjugation, fill/finish services and the antibody component of our internal product candidates, linkers, and DM1, DM4 and their precursor, ansamitocin P3; and
- activities pursuant to our development and license agreements with various collaborators.

Research and development expense for the year ended June 30, 2016 increased \$36.3 million to \$148.1 million from \$111.8 million for the year ended June 30, 2015. Research and development expense was \$107.0 million for the year ended June 30, 2014. During the year ended June 30, 2014, we recorded a \$12.8 million non cash charge to research and development expense for technology rights obtained under the collaboration agreement executed with CytomX in January 2014. We had no such charges in fiscal years 2016 and 2015. The increases in fiscal years 2016 and 2015 are primarily due to: (i) increased clinical trial costs, particularly related to mirvetuximab soravtansine; (ii) greater third-party costs related to internal product program advancement; (iii) increase in facility related expenses due primarily to additional laboratory and office space occupied since July 2014 and increased depreciation and amortization related to major capital equipment and improvements; and (iv) increased personnel expenses, principally due to recent hiring and incentive compensation. Research and development salaries and related expenses increased by \$10.6 million to \$63.2 million in the year ended June 30, 2016 compared to the year ended June 30, 2015 and increased by \$5 million in the year ended June 30, 2015 compared to the year ended June 30, 2014. The average number of our research personnel increased to 295 for the year ended June 30, 2016 compared to 266 for the year ended June 30, 2015. We had an average of 250 for the year ended June 30, 2014. Included in salaries and related expenses for the year ended June 30, 2016 is \$12.2 million of stock compensation costs compared to \$9.9 million and \$10.3 million of stock compensation costs for fiscal years 2015 and 2014, respectively. The higher stock compensation costs in fiscal year 2016 compared to fiscal years 2015 and 2014 are driven by increases in the number of annual options granted due to increases in personnel, as well as higher stock prices in fiscal 2015.

We are unable to accurately estimate which potential product candidates, if any, will eventually move into our internal preclinical research program. We are unable to reliably estimate the costs to develop these products as a result of the uncertainties related to discovery research efforts as well as preclinical and clinical testing. Our decision to move a product candidate into the clinical development phase is predicated upon the results of preclinical tests. We cannot accurately predict which, if any, of the discovery stage product candidates will advance from preclinical testing and move into our internal clinical development program. The clinical trial and regulatory approval processes for our product candidates that have advanced or that we intend to advance to clinical testing are lengthy, expensive and uncertain in both timing and outcome. As a result, the pace and timing of the clinical development of our product candidates is highly uncertain and may not ever result in approved products. Completion dates and development costs will vary significantly for each product candidate and are difficult to predict. A variety of factors, many of which are outside our control, could cause or contribute to the prevention or delay of the successful completion of our clinical trials, or delay or prevent our obtaining necessary regulatory approvals. The costs to take a product through clinical trials are dependent upon, among other factors, the clinical indications, the timing, size and design of each clinical trial, the number of patients enrolled in each trial, and the speed at which patients are enrolled and treated. Product candidates may be found to be ineffective or to cause unacceptable side effects during clinical trials, may take longer to progress through clinical trials than anticipated, may fail to receive necessary regulatory approvals or may prove impractical to manufacture in commercial quantities at reasonable cost or with acceptable quality.



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The lengthy process of securing FDA approvals for new drugs requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals, would materially adversely affect our product development efforts and our business overall. Accordingly, we cannot currently estimate, with any degree of certainty, the amount of time or money that we will be required to expend in the future on our product candidates prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of our clinical trials, we are currently unable to estimate when, if ever, our product candidates that have advanced into clinical testing will generate revenues and cash flows.

We do not track our research and development costs by project. Since we use our research and development resources across multiple research and development projects, we manage our research and development expenses within each of the categories listed in the following table and described in more detail below (in thousands):

	Year Ended June 30,		
	2016	2015	2014
Research and Development Expense			
Research	\$ 24,754	\$ 20,729	\$ 30,793
Preclinical and Clinical Testing	68,855	42,546	34,562
Process and Product Development	12,535	8,468	8,296
Manufacturing Operations	41,933	40,025	33,307
Total Research and Development Expense	\$ 148,077	\$ 111,768	\$ 106,958

**Research**—Research includes expenses associated with activities to evaluate new targets and to develop and evaluate new antibodies, linkers and cytotoxic agents for our products and in support of our collaborators. Such expenses primarily include personnel, fees to in license certain technology, facilities and lab supplies. Research expenses increased \$4.1 million to \$24.8 million in fiscal year 2016 from fiscal year 2015 and decreased \$10.1 million to \$20.7 million in fiscal year 2015 from fiscal year 2014. The increase in fiscal year 2016 was principally due to increases in salaries and related expenses and facility-related expenses, as well as an increase in lab supplies driven by increased internal and partner activities. The decrease in fiscal year 2015 was principally due to a \$12.8 million non cash charge recorded for technology rights obtained under the collaboration agreement executed with CytomX in January 2014, partially offset by an increase in salaries and related expenses and an increase in facility related expenses.

**Preclinical and Clinical Testing**—Preclinical and clinical testing includes expenses related to preclinical testing of our own and, in certain instances, our collaborators' product candidates, regulatory activities, and the cost of our own clinical trials. Such expenses include personnel, patient enrollment at our clinical testing sites, consultant fees, contract services, and facility expenses. Preclinical and clinical testing expenses increased \$26.4 million to \$68.9 million in fiscal year 2016 from fiscal year 2015 and increased \$7.9 million to \$42.5 million in fiscal year 2015 from fiscal year 2014. The increase in fiscal year 2016 was principally the result of (i) greater clinical trial costs incurred related to the expanded mirvetuximab soravtansine studies, as well as costs incurred related to the IMG529 combo study and IMG779 study which both initiated in the current year, partially offset by lower costs related to the IMG289 study that was discontinued in fiscal 2015; (ii) increased contract service expense driven by increased activities to advance our internal programs, particularly mirvetuxmab soravtansine; and, (iii) an increase in salaries and related expenses. The increase in fiscal year 2015 was principally the result of an increase in contract service expense driven primarily by increased study activities related to mirvetuximab soravtansine and IMG289, and to a lesser extent, higher salaries and related expenses and an increase in facility related expenses. Partially offsetting these increases, clinical trial costs decreased marginally due primarily to decreased costs incurred related to the IMG901 007 study, partially offset by increased costs related to the mirvetuximab soravtansine and IMG529 studies during the current year.



Process and Product Development—Process and product development expenses include costs for development of clinical and commercial manufacturing processes for our own and collaborator compounds. Such expenses include the costs of personnel, contract services and facility expenses. Total development expenses increased \$4.0 to \$12.5 million in fiscal year 2016 from fiscal year 2015 and expenses increased \$172,000 to \$8.5 million in fiscal year 2015 from fiscal year 2014. The increase in fiscal year 2016 was primarily the result of an increase in salaries and related expenses, as well as an increase in contract service expense driven primarily by IGN development activities. The increase in fiscal year 2015 was primarily the result of an increase in facility related expenses.

Manufacturing Operations—Manufacturing operations expense includes costs to manufacture preclinical and clinical materials for our own and our collaborators' product candidates, quality control and quality assurance activities and costs to support the operation and maintenance of our conjugate manufacturing facility. Such expenses include personnel, raw materials for our and our collaborators' preclinical studies and clinical trials, non pivotal and pivotal

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development costs with contract manufacturing organizations, manufacturing supplies, and facilities expense. Manufacturing operations expense increased \$1.9 million to \$41.9 million in fiscal year 2016 from fiscal year 2015 and increased \$6.7 million to \$40.0 million in fiscal year 2015 from fiscal year 2014. The increase in fiscal year 2016 was primarily the result of a decrease in costs capitalized into inventory due to a lesser number of manufactured batches of conjugated materials on behalf of our collaborators and an increase in salaries and related expenses. Partially offsetting these increases, costs of clinical materials revenue charged to research and development expense decreased due to timing of orders and release of such clinical materials from our partners and antibody development and supply expense decreased driven primarily by supply required in fiscal 2015 not needed in fiscal 2016 for our currently discontinued IMG289 program. The increase in fiscal year 2015 was primarily the result of i) an increase in cost of clinical materials revenue charged to research and development expense due to timing of orders and release of such clinical materials from our partners; (ii) an increase in contract service expense driven by increased third party conjugation activities to prepare for commercial scale and increased cytotoxic agent activities; (iii) an increase in antibody development and supply expense driven primarily by commercial ready activities for mirvetuximab soravtansine; and (iv) an increase in salaries and related expenses.

Antibody development and supply expense in anticipation of potential future clinical trials, as well as our ongoing trials, was \$8.6 million in fiscal year 2016, \$8.8 million in fiscal year 2015, and \$7.2 million in fiscal year 2014. The process of antibody production is lengthy due in part to the lead time to establish a satisfactory production process at a vendor. Accordingly, costs incurred related to antibody production and development have fluctuated from period to period and we expect these cost fluctuations to continue in the future.

#### General and Administrative Expenses

General and administrative expenses for the year ended June 30, 2016 increased \$8.7 million to \$36.9 million from \$28.2 million for the year ended June 30, 2015. General and administrative expenses for the year ended June 30, 2014 were \$24.5 million. The increases in fiscal years 2016 and 2015 were primarily due to increases in salaries and related expenses, as well as increases in professional service fees. Contributing to the increase in salaries and related expenses for fiscal 2016 is a \$3.1 million non-cash stock compensation charge related to the modification of certain outstanding common stock options with the former Chief Executive Officer's succession plan. No similar charges were recorded in fiscal years 2015 and 2014.

#### Investment Income, net

Investment income for the years ended June 30, 2016, 2015 and 2014 was \$325,000, \$69,000 and \$44,000, respectively. The increase in fiscal 2016 is due to a greater average cash balance during the period driven by the proceeds received in the fourth quarter of fiscal 2015 resulting from the sale of future royalties, which is further discussed below.

#### Non Cash Interest Expense on Liability Related to Sale of Future Royalty

In April 2015, Immunity Royalty Holdings, L.P., or IRH, purchased our right to receive 100% of the royalty payments on commercial sales of Kadcyra arising under our development and commercialization license with Genentech, until IRH has received aggregate royalties equal to \$235 million or \$260 million, depending on when the aggregate royalties received by IRH reach a specified milestone. As described in Note F to our Consolidated Financial Statements, this royalty sale transaction has been recorded as a liability that amortizes over the estimated royalty payment period as Kadcyra royalties are remitted directly to the purchaser. We impute interest on the transaction and record interest expense at the effective interest rate, which we currently estimate to be approximately 9.6%. There are a number of factors that could materially affect the estimated interest rate, in particular, the amount and timing of royalty payments from future net sales of Kadcyra, and we will assess this estimate on a periodic basis. As a result,

future interest rates could differ significantly and any such change in interest rate will be adjusted prospectively.

Other (Expense) Income, net

Other (expense) income, net for the years ended June 30, 2016, 2015 and 2014 was \$(21,000), \$(916,000) and \$123,000, respectively. In fiscal 2016, we recorded \$138,000 of interest expense related to convertible senior notes issued in June 2016, the details of which are discussed further below. No similar charges were recorded in fiscal years 2015 and 2014. We incurred \$96,000, \$(910,000), and \$120,000 in foreign currency exchange gains (losses) related to obligations with non U.S. dollar based suppliers and Euro cash balances maintained to fulfill them during the years ended June 30, 2016, 2015 and 2014, respectively.

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## Liquidity and Capital Resources

	As of June 30,	
	2016	2015
	(In thousands)	
Cash and cash equivalents	\$ 245,026	\$ 278,109
Working capital	193,341	256,370
Shareholders' (deficit) equity	(82,304)	35,104

	Year Ended June 30,		
	2016	2015	2014
	(In thousands)		
Cash used for operating activities	\$ (124,476)	\$ (55,291)	\$ (53,650)
Cash used for investing activities	(10,376)	(7,425)	(8,185)
Cash provided by financing activities	101,769	198,564	9,136

## Cash Flows

We require cash to fund our operating expenses, including the advancement of our own clinical programs, and to make capital expenditures. Historically, we have funded our cash requirements primarily through equity financings in public markets and payments from our collaborators, including license fees, milestones, research funding, royalties and more recently, convertible debt. As of June 30, 2016, we had approximately \$245 million in cash and cash equivalents. Net cash used for operating activities was \$124.5 million, \$55.3 million and \$53.7 million during the years ended June 30, 2016, 2015 and 2014, respectively. The principal use of cash in operating activities for all periods presented was to fund our net loss, adjusted for non-cash items. Cash used for operating activities in fiscal 2015 benefited from the \$20 million upfront payment received from Takeda in March 2015 with the execution of a right to test agreement between the companies.

Net cash used for investing activities was \$10.4 million, \$7.4 million and \$8.2 million for the years ended June 30, 2016, 2015 and 2014, respectively, and represent cash outflows from capital expenditures. Capital expenditures for the years ended June 30, 2016, 2015 and 2014 consisted primarily of leasehold improvements to the laboratory and office space at our corporate headquarters and manufacturing facility, laboratory equipment and computer software applications.

Net cash provided by financing activities was \$101.8 million, \$198.6 million and \$9.1 million for the years ended June 30, 2016, 2015 and 2014, respectively. In June 2016, we issued Convertible 4.5% Senior Notes with an aggregate principal amount of \$100 million. We received net proceeds of approximately \$96.6 million from the sale of the Convertible Notes after deducting fees and expenses of approximately \$3.4 million. See Note E to our Consolidated Financial Statements for further details regarding the terms of the transaction.

As discussed above, in April 2015, Immunity Royalty Holdings, L.P. purchased our right to receive 100% of the royalty payments on commercial sales of Kadcyra. At consummation of the transaction in April 2015, we received gross cash proceeds of \$200 million. We recorded these cash proceeds as a deferred royalty obligation liability which is being amortized over the expected royalty recovery period. As part of this transaction, the Company incurred approximately \$5.9 million in transaction costs.

Net cash provided by financing activities for the years ended June 30, 2016, 2015 and 2014 include the proceeds from the exercise of approximately 555,000, 651,000 and 1.1 million stock options, respectively.

We anticipate that our current capital resources and expected future collaborator payments under existing collaborations will enable us to meet our operational expenses and capital expenditures roughly through December 2017. However, we cannot provide assurance that such collaborative agreement funding will, in fact, be received. Should we or our partners not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects.

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## Contractual Obligations

Below is a table that presents our contractual obligations and commercial commitments as of June 30, 2016 (in thousands):

	Payments Due by Period				
	Total	Less than One Year	1-3 Years	4-5 Years	More than 5 Years
Waltham lease obligations(1)	\$ 69,767	\$ 6,792	\$ 14,167	\$ 14,556	\$ 34,252
Other operating lease obligations(1)	2,257	1,110	1,147	—	—
Liability related to the sale of future royalties(2)	193,372	15,138	51,592	71,111	55,531
Convertible 4.5% senior notes(3)	100,000	—	—	100,000	—
Total	\$ 365,396	\$ 23,040	\$ 66,906	\$ 185,667	\$ 89,783

(1) Lease agreements were signed in July 2007, November 2010 and April 2013, and amended in December 2013 and April 2014. In December 2014, we entered into a sublease for 7,507 square feet of office space at 100 River Ridge Drive, Norwood, MA through July 2018. We will receive approximately \$250,000 in minimum rental payments over the remaining term of the sublease, which is not included in the table above.

(2) See Note F to the Consolidated Financial Statements in Item 8 for discussion of this liability.

(3) See Note E to the Consolidated Financial Statements in Item 8 for discussion of the convertible senior notes.

In addition to the above table, we are contractually obligated to make future success based development, regulatory or sales milestone payments in conjunction with certain collaborative agreements. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, we may be required to pay such amounts. Therefore, the timing of any future payment is not reasonably estimable. As a result, these contingent payments have not been included in the table above or recorded in our consolidated financial statements. As of June 30, 2016, the maximum amount that may be payable in the future under our current collaborative agreements is \$162 million, \$1.4 million of which is reimbursable by a third party under a separate agreement.

In addition, we are party to a license agreement covering the manufacture of the antibodies used in certain of our product candidates which, under certain circumstances, requires periodic payments once the product reaches a specified stage of clinical development, and royalties on commercial sales of the product. We believe that the license agreement, by its terms, does not obligate us to make any further payments thereunder and accordingly, we have not accrued a potential payment of £300,000 for one of our product candidates that has reached this stage.

## Change in fiscal year

On June 15, 2016 the company's Board of Directors approved a change in our fiscal year from a fiscal year ending on the last day of June of each year to a calendar fiscal year ending on the last day of December of each year, effective January 1, 2017. Accordingly we will be issuing six month transitional financial statements as of December 31, 2016, and calendar year financial statements thereafter.

## Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-9, Revenue from Contracts with Customers (Topic 606), to clarify the principles for recognizing revenue. This update provides a comprehensive new revenue recognition model that requires revenue to be recognized in a manner to depict the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the

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FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectibility, non-cash consideration and the presentation of sales and other similar taxes collected from customers. These standards have the same effective date and transition date of January 1, 2018. The new revenue standard allows for either full retrospective or modified retrospective application. We are currently evaluating the timing of its adoption, the transition method to apply and the impact that this guidance will have on our financial statements and related disclosures.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This new standard gives a company's management the final responsibilities to decide whether there's substantial doubt about the company's ability to continue as a going concern and to provide related footnote disclosures. The standard provides guidance to management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that companies commonly provide in their footnotes. Under the new standard, management must decide whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the company's ability to continue as a going concern within one year after the date that the financial statements are issued, or within one year after the date that the financial statements are available to be issued when applicable. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. Accordingly, the standard is effective for us on January 1, 2017. We have not yet completed our analysis of the impact of the adoption of this guidance. Refer to Note A, Nature of Business and Plan of Operations, of our consolidated financial statements for further discussion.

In April 2015, the FASB issued ASU 2015-03, Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. To simplify presentation of debt issuance costs, this new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by this update. This guidance is effective for annual reporting beginning after December 15, 2015, including interim periods within the year of adoption, and calls for retrospective application, with early application permitted. Accordingly, the standard is effective for us on July 1, 2016. Our consolidated balance sheet as of June 30, 2016 includes in assets \$7.8 million of debt issuance costs classified as deferred financing costs.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes (Topic 740). To simplify the presentation of deferred income taxes, the amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. We implemented the recommendations of this Update prospectively in the second quarter of fiscal year 2016, resulting in a reduction of long-term assets and current liabilities of approximately \$843,000 as of December 31, 2015. The prior period balances were not retrospectively adjusted.

In January 2016, the FASB issued ASU 2016-1, Recognition and Measurement of Financial Assets and Financial Liabilities (Topic 825). The amendments in this Update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities (including other ownership interests, such as partnerships, unincorporated joint ventures, and limited liability companies) to be measured at fair value with changes in the fair value recognized through net income. The amendments allow equity investments that do not have readily determinable fair values to be remeasured at fair value either upon the occurrence of an observable price change or upon identification of an impairment. The amendments also require enhanced disclosures about those investments. The amendments improve financial reporting by providing



relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This guidance is effective for annual reporting beginning after December 15, 2017, including interim periods within the year of adoption, and calls for prospective application, with early application permitted. Accordingly, the standard is effective for us on January 1, 2018. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-2, Leases (Topic 842) that primarily requires lessees to recognize most leases on their balance sheets but record expenses on their income statements in a manner similar to current accounting. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The guidance is effective for fiscal years beginning after December 15, 2018, including interim

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periods within those fiscal years, and calls for retrospective application, with early adoption permitted. Accordingly, the standard is effective for us on January 1, 2019. We are currently evaluating the impact of this guidance on our financial statements and the timing of adoption.

In March 2016, the FASB issued ASU 2016-9, Improvements to Employee Share-Based Payment Accounting (Topic 718) that changes the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. The guidance is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods with early adoption permitted. Accordingly, the standard is effective for us on January 1, 2017. We are currently evaluating the impact of this guidance on our financial statements and the timing of adoption.

Off Balance Sheet Arrangements

None.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not currently own derivative financial instruments in our investment portfolio. Accordingly, we do not believe there is any material market risk exposure with respect to derivative or other financial instruments that would require disclosure under this item.

Our foreign currency hedging program uses either forward contracts or a Euro denominated bank account to manage the foreign currency exposures that exist as part of our ongoing business operations. Our foreign currency risk management strategy is principally designed to mitigate the future potential financial impact of changes in the value of transactions, anticipated transactions and balances denominated in foreign currency, resulting from changes in foreign currency exchange rates. Our market risks associated with changes in foreign currency exchange rates are currently limited to a Euro denominated bank account as we have no forward contracts at June 30, 2016.

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Item 8. Financial Statements and Supplementary Data

IMMUNOGEN, INC.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of ImmunoGen, Inc.

We have audited the accompanying consolidated balance sheets of ImmunoGen, Inc. as of June 30, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, shareholders' (deficit) equity and cash flows for each of the three years in the period ended June 30, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of ImmunoGen, Inc. at June 30, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended June 30, 2016, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), ImmunoGen, Inc.'s internal control over financial reporting as of June 30, 2016, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated August 25, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

August 25, 2016

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IMMUNOGEN, INC.

## CONSOLIDATED BALANCE SHEETS

In thousands, except per share amounts

	June 30, 2016	June 30, 2015
<b>ASSETS</b>		
Cash and cash equivalents	\$ 245,026	\$ 278,109
Accounts receivable	883	5,088
Unbilled revenue	1,409	714
Inventory	907	2,935
Current portion of deferred financing costs	1,674	1,159
Prepaid and other current assets	4,881	4,175
Total current assets	254,780	292,180
Property and equipment, net of accumulated depreciation	22,704	16,254
Deferred financing costs, net of current portion	6,171	4,415
Other assets	3,430	974
Total assets	\$ 287,085	\$ 313,823
<b>LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY</b>		
Accounts payable	\$ 11,510	\$ 8,138
Accrued compensation	10,724	8,346
Other accrued liabilities	9,713	10,441
Current portion of deferred lease incentive	772	646
Current portion of liability related to the sale of future royalties	15,138	7,906
Current portion of deferred revenue	13,582	333
Total current liabilities	61,439	35,810
Deferred lease incentive, net of current portion	6,236	6,301
Deferred revenue, net of current portion	19,288	40,855
Convertible 4.5% senior notes	100,000	—
Liability related to the sale of future royalties, net of current portion	178,234	191,756
Other long-term liabilities	4,192	3,997
Total liabilities	369,389	278,719
Commitments and contingencies (Note I)		
Shareholders' (deficit) equity:		
Preferred stock, \$.01 par value; authorized 5,000 shares; no shares issued and outstanding	—	—
Common stock, \$0.01 par value; authorized 150,000 shares; issued and outstanding 87,209 and 86,579 shares as of June 30, 2016 and June 30, 2015, respectively	872	866
Additional paid-in capital	770,511	743,108
Accumulated deficit	(853,687)	(708,870)
Total shareholders' (deficit) equity	(82,304)	35,104
Total liabilities and shareholders' (deficit) equity	\$ 287,085	\$ 313,823

The accompanying notes are an integral part of the consolidated financial statements.



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IMMUNOGEN, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

In thousands, except per share amounts

	Year Ended June 30,		
	2016	2015	2014
Revenues:			
License and milestone fees	\$ 26,915	\$ 57,815	\$ 39,455
Royalty revenue	195	13,867	10,346
Non-cash royalty revenue related to the sale of future royalties	25,299	5,484	—
Research and development support	4,014	2,848	7,187
Clinical materials revenue	3,579	5,527	2,908
Total revenues	60,002	85,541	59,896
Operating Expenses:			
Research and development	148,077	111,768	106,958
General and administrative	36,916	28,228	24,469
Total operating expenses	184,993	139,996	131,427
Loss from operations	(124,991)	(54,455)	(71,531)
Investment income, net	325	69	44
Non-cash interest expense on liability related to the sale of future royalties and convertible senior notes	(20,130)	(5,437)	—
Other (expense) income, net	(21)	(916)	123
Net loss	\$ (144,817)	\$ (60,739)	\$ (71,364)
Basic and diluted net loss per common share	\$ (1.67)	\$ (0.71)	\$ (0.83)
Basic and diluted weighted average common shares outstanding	86,976	86,038	85,481
Total comprehensive loss	\$ (144,817)	\$ (60,739)	\$ (71,364)

The accompanying notes are an integral part of the consolidated financial statements.

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IMMUNOGEN, INC.

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' (DEFICIT) EQUITY

In thousands

	Common Stock		Additional Paid-In	Accumulated	Total Shareholders' (Deficit) Equity
	Shares	Amount	Capital	Deficit	
Balance at June 30, 2013	84,725	\$ 847	\$ 697,767	\$ (576,767)	\$ 121,847
Net loss	—	—	—	(71,364)	(71,364)
Stock options exercised	1,134	11	9,125	—	9,136
Stock option and restricted stock compensation expense	—	—	15,647	—	15,647
Directors' deferred share units converted	44	1	(1)	—	—
Directors' deferred share unit compensation	—	—	433	—	433
Balance at June 30, 2014	85,903	\$ 859	\$ 722,971	\$ (648,131)	\$ 75,699
Net loss	—	—	—	(60,739)	(60,739)
Stock options exercised	651	7	4,422	—	4,429
Restricted stock award	25	—	—	—	—
Stock option and restricted stock compensation expense	—	—	15,326	—	15,326
Directors' deferred share unit compensation	—	—	389	—	389
Balance at June 30, 2015	86,579	\$ 866	\$ 743,108	\$ (708,870)	\$ 35,104
Net loss	—	—	—	(144,817)	(144,817)
Stock options exercised	555	5	5,156	—	5,161
Restricted stock award	75	1	(1)	—	—
Stock option and restricted stock compensation expense	—	—	21,868	—	21,868
Directors' deferred share unit compensation	—	—	380	—	380
Balance at June 30, 2016	87,209	\$ 872	\$ 770,511	\$ (853,687)	\$ (82,304)

The accompanying notes are an integral part of the consolidated financial statements.



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IMMUNOGEN, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

In thousands

	Year Ended June 30,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	\$ (144,817)	\$ (60,739)	\$ (71,364)
Adjustments to reconcile net loss to net cash used for operating activities:			
Non-cash royalty revenue related to sale of future royalties	(25,299)	(5,484)	—
Non-cash interest expense on liability related to sale of future royalties and convertible senior notes	20,130	5,437	—
Depreciation and amortization	5,327	5,513	4,598
(Gain) Loss on sale/disposal of fixed assets	(21)	7	20
Gain on forward contracts	—	—	(2)
Non-cash licensing fee	—	—	12,830
Stock and deferred share unit compensation	22,248	15,715	16,080
Deferred rent	161	195	297
Change in operating assets and liabilities:			
Accounts receivable	4,205	(3,192)	(1,896)
Unbilled revenue	(695)	615	792
Inventory	2,028	15	(2,247)
Prepaid and other current assets	(706)	(1,855)	571
Restricted cash	—	—	2,231
Other assets	(2,456)	(761)	4
Accounts payable	2,649	3,319	321
Accrued compensation	2,378	1,481	712
Other accrued liabilities	(1,434)	3,248	(394)
Deferred revenue, net of non-cash upfront license payment	(8,318)	(20,155)	(16,675)
Proceeds from landlord for tenant improvements	144	1,350	472
Net cash used for operating activities	(124,476)	(55,291)	(53,650)
Cash flows from investing activities:			
Purchases of property and equipment, net	(10,376)	(7,425)	(8,184)
Payments from settlement of forward contracts	—	—	(1)
Net cash used for investing activities	(10,376)	(7,425)	(8,185)
Cash flows from financing activities:			
Proceeds from stock options exercised	5,161	4,429	9,136
Proceeds from sale of future royalties, net of \$5,865 of transaction costs	—	194,135	—
Proceeds from issuance of convertible 4.5% notes, net of \$3,392 of transaction costs	96,608	—	—
Net cash provided by financing activities	101,769	198,564	9,136
Net change in cash and cash equivalents	(33,083)	135,848	(52,699)
Cash and cash equivalents, beginning of period	278,109	142,261	194,960
Cash and cash equivalents, end of period	\$ 245,026	\$ 278,109	\$ 142,261
The accompanying notes are an integral part of the consolidated financial statements.			



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IMMUNOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

AS OF JUNE 30, 2016

A. Nature of Business and Plan of Operations

ImmunoGen, Inc. (the Company) was incorporated in Massachusetts in 1981 and is focused on the development of antibody based anticancer therapeutics. The Company has incurred operating losses and negative cash flows from operations since inception, incurred a net loss of approximately \$144.8 million during the fiscal year ended June 30, 2016, and has an accumulated deficit of approximately \$853.7 million as of June 30, 2016. The Company has primarily funded these losses through payments received from its collaborations and equity and convertible debt financings. To date, the Company has no product revenue and management expects operating losses to continue for the foreseeable future.

At June 30, 2016, the Company had \$245 million of cash and cash equivalents on hand. The Company anticipates that its current capital resources and expected future collaborator payments under existing collaborations will enable it to meet its operational expenses and capital expenditures through approximately December 2017. The Company may raise additional funds through equity or debt financings or generate revenues from collaborative partners through a combination of upfront license payments, milestone payments, royalty payments, research funding, and clinical material reimbursement. There can be no assurance that the Company will be able to obtain additional debt or equity financing or generate revenues from collaborative partners on terms acceptable to the Company or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition and require the Company to defer or limit some or all of its research, development and/or clinical projects.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, the development by its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, manufacturing and marketing limitations, collaboration arrangements, third party reimbursements and compliance with governmental regulations.

On June 15, 2016 the company's Board of Directors approved a change in the Company's fiscal year from a fiscal year ending on the last day of June of each year to a calendar fiscal year ending on the last day of December of each year, effective January 1, 2017. Accordingly the Company will be issuing six month transitional financial statements as of December 31, 2016, and calendar year financial statements thereafter.

B. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, ImmunoGen Securities Corp., ImmunoGen Europe Limited and Hurricane, LLC. All intercompany transactions and balances have been eliminated.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (U.S.) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Subsequent Events

The Company has evaluated all events or transactions that occurred after June 30, 2016 up through the date the Company issued these financial statements. The Company did not have any material recognizable or unrecognizable subsequent events.

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## Related party transaction

During fiscal year 2016, the Company entered into a transaction with Sanofi to purchase drug product along with the master and working cell banks for a product that Sanofi previously discontinued and had returned its rights back to the Company. The Company entered into this transaction, at a cost of €1.6 million, in order to continue development of the product, or make it more attractive to re-license the target to another partner. A relationship between an executive from the Company and an executive from Sanofi qualified this transaction as potentially between related parties, and accordingly, the audit committee of the Board of Directors of the Company approved the terms and conditions of the transaction, believing that it was in the best interest of the Company to proceed and that it was done at an arms-length amount. The transaction was substantially completed during the year; however, as of June 30, 2016, \$44,000 is classified as a prepaid expense and approximately \$258,000 more will be payable when a deliverable still pending from Sanofi is received.

## Revenue Recognition

The Company enters into licensing and development agreements with collaborative partners for the development of monoclonal antibody based anticancer therapeutics. The terms of these agreements contain multiple deliverables which may include (i) licenses, or options to obtain licenses, to the Company's antibody drug conjugate, or ADC, technology, (ii) rights to future technological improvements, (iii) research activities to be performed on behalf of the collaborative partner, (iv) delivery of cytotoxic agents and (v) the manufacture of preclinical or clinical materials for the collaborative partner. Payments to the Company under these agreements may include upfront fees, option fees, exercise fees, payments for research activities, payments for the manufacture of preclinical or clinical materials, payments based upon the achievement of certain milestones and royalties on product sales. The Company follows the provisions of the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 605 25, "Revenue Recognition—Multiple Element Arrangements," and ASC Topic 605 28, "Revenue Recognition—Milestone Method," in accounting for these agreements. In order to account for these agreements, the Company must identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on whether certain criteria are met, including whether the delivered element has stand alone value to the collaborator. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

At June 30, 2016, the Company had the following two types of agreements with the parties identified below:

- Development and commercialization licenses, which provide the party with the right to use the Company's ADC technology and/or certain other intellectual property to develop compounds to a specified antigen target:

Amgen (two exclusive single-target licenses(1))

Bayer (one exclusive single-target license)

Biotest (one exclusive single-target license)

CytomX (one exclusive single-target license)

Lilly (three exclusive single-target licenses)

Novartis (five exclusive single-target licenses and one license to two related targets: one target on an exclusive basis and the second target on a non-exclusive basis)

Roche, through its Genentech unit (five exclusive single-target licenses)

Sanofi (one exclusive single-target license and one exclusive license to multiple individual targets)

Takeda, through its wholly owned subsidiary, Millennium Pharmaceuticals, Inc. (one exclusive single-target license)

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(1) Amgen has sublicensed one of its exclusive single-target licenses to Oxford BioTherapeutics Ltd.

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- Research license/option agreement for a defined period of time to secure development and commercialization licenses to use the Company's ADC technology to develop anticancer compounds to specified targets on established terms (referred to herein as right-to-test agreements):

CytomX

Takeda, through its wholly owned subsidiary, Millennium Pharmaceuticals, Inc.

There are no performance, cancellation, termination or refund provisions in any of the arrangements that contain material financial consequences to the Company.

### Development and Commercialization Licenses

The deliverables under a development and commercialization license agreement generally include the license to the Company's ADC technology with respect to a specified antigen target, and may also include deliverables related to rights to future technological improvements, research activities to be performed on behalf of the collaborative partner and the manufacture of preclinical or clinical materials for the collaborative partner.

Generally, development and commercialization licenses contain non refundable terms for payments and, depending on the terms of the agreement, provide that the Company will (i) at the collaborator's request, provide research services at negotiated prices which are generally consistent with what other third parties would charge, (ii) at the collaborator's request, manufacture and provide to it preclinical and clinical materials or deliver cytotoxic agents at negotiated prices which are generally consistent with what other third parties would charge, (iii) earn payments upon the achievement of certain milestones and (iv) earn royalty payments, generally until the later of the last applicable patent expiration or 10 to 12 years after product launch. In the case of Kadcyła, however, the minimum royalty term is 10 years and the maximum royalty term is 12 years on a country by country basis, regardless of patent protection. Royalty rates may vary over the royalty term depending on the Company's intellectual property rights and/or the presence of comparable competing products. The Company may provide technical assistance and share any technology improvements with its collaborators during the term of the collaboration agreements. The Company does not directly control when or whether any collaborator will request research or manufacturing services, achieve milestones or become liable for royalty payments. As a result, the Company cannot predict when or if it will recognize revenues in connection with any of the foregoing.

In determining the units of accounting, management evaluates whether the license has stand alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of ADC technology research expertise in the general marketplace. If the Company concludes that the license has stand alone value and therefore will be accounted for as a separate unit of accounting, the Company then determines the estimated selling prices of the license and all other units of accounting based on market conditions, similar arrangements entered into by third parties, and entity specific factors such as the terms of the Company's previous collaborative agreements, recent preclinical and clinical testing results of therapeutic products that use the Company's ADC technology, the Company's pricing practices and pricing objectives, the likelihood that technological improvements will be made, and, if made, will be used by the Company's collaborators and the nature of the research services to be performed on behalf of its collaborators and market rates for similar services.

Upfront payments on development and commercialization licenses may be recognized upon delivery of the license if facts and circumstances dictate that the license has stand alone value from the undelivered elements, which generally include rights to future technological improvements, research services, delivery of cytotoxic agents and the

manufacture of preclinical and clinical materials.

The Company recognizes revenue related to research services that represent separate units of accounting as they are performed, as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is probable. The Company recognizes revenue related to the rights to future technological improvements over the estimated term of the applicable license.

The Company may also provide cytotoxic agents to its collaborators or produce preclinical and clinical materials at negotiated prices which are generally consistent with what other third parties would charge. The Company



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recognizes revenue on cytotoxic agents and on preclinical and clinical materials when the materials have passed all quality testing required for collaborator acceptance and title and risk of loss have transferred to the collaborator. Arrangement consideration allocated to the manufacture of preclinical and clinical materials in a multiple deliverable arrangement is below the Company's full cost, and the Company's full cost is not expected to ever be below its contract selling prices for its existing collaborations. During the fiscal years ended June 30, 2016, 2015 and 2014, the difference between the Company's full cost to manufacture preclinical and clinical materials on behalf of its collaborators as compared to total amounts received from collaborators for the manufacture of preclinical and clinical materials was \$6.9 million, \$9.2 million and \$2.3 million, respectively. The majority of the Company's costs to produce these preclinical and clinical materials are fixed and then allocated to each batch based on the number of batches produced during the period. Therefore, the Company's costs to produce these materials are significantly impacted by the number of batches produced during the period. The volume of preclinical and clinical materials the Company produces is directly related to the number of clinical trials the Company and its collaborators are preparing for or currently have underway, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period such trials last. Accordingly, the volume of preclinical and clinical materials produced, and therefore the Company's per batch costs to manufacture these preclinical and clinical materials, may vary significantly from period to period.

The Company may also produce research material for potential collaborators under material transfer agreements. Additionally, the Company performs research activities, including developing antibody specific conjugation processes, on behalf of its collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. The Company records amounts received for research materials produced or services performed as a component of research and development support revenue. The Company also develops conjugation processes for materials for later stage testing and commercialization for certain collaborators. The Company is compensated at negotiated rates and may receive milestone payments for developing these processes which are recorded as a component of research and development support revenue.

The Company's development and commercialization license agreements have milestone payments which for reporting purposes are aggregated into three categories: (i) development milestones, (ii) regulatory milestones, and (iii) sales milestones. Development milestones are typically payable when a product candidate initiates or advances into different clinical trial phases. Regulatory milestones are typically payable upon submission for marketing approval with the U.S. Food and Drug Administration, or FDA, or other countries' regulatory authorities or on receipt of actual marketing approvals for the compound or for additional indications. Sales milestones are typically payable when annual sales reach certain levels.

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Non refundable development and regulatory milestones that are expected to be achieved as a result of the Company's efforts during the period of substantial involvement are considered substantive and are recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive because we do not contribute effort to the achievement of such milestones are generally

achieved after the period of substantial involvement and are recognized as revenue upon achievement of the milestone, as there are no undelivered elements remaining and no continuing performance obligations, assuming all other revenue recognition criteria are met.

Under the Company's development and commercialization license agreements, the Company receives royalty payments based upon its licensees' net sales of covered products. Generally, under these agreements the Company is to receive royalty reports and payments from its licensees approximately one quarter in arrears, that is, generally in the second or third month of the quarter after the licensee has sold the royalty bearing product or products. The Company recognizes royalty revenues when it can reliably estimate such amounts and collectability is reasonably assured. As such,

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the Company generally recognizes royalty revenues in the quarter reported to the Company by its licensees, or one quarter following the quarter in which sales by the Company's licensees occurred.

Right to Test Agreements

The Company's right to test agreements provide collaborators the right to (a) test the Company's ADC technology for a defined period of time through a research, or right to test, license, (b) take options, for a defined period of time, to specified targets and (c) upon exercise of those options, secure or "take" licenses to develop and commercialize products for the specified targets on established terms. Under these agreements, fees may be due to the Company (i) at the inception of the arrangement (referred to as "upfront" fees or payments), (ii) upon taking an option with respect to a specific target (referred to as option fees or payments earned, if any, when the option is "taken"), (iii) upon the exercise of a previously taken option to acquire a development and commercialization license(s) (referred to as exercise fees or payments earned, if any, when the development and commercialization license is "taken"), or (iv) some combination of all of these fees.

The accounting for right to test agreements is dependent on the nature of the options granted to the collaborative partner. Options are considered substantive if, at the inception of a right to test agreement, the Company is at risk as to whether the collaborative partner will choose to exercise the options to secure development and commercialization licenses. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options. None of the Company's right to test agreements entered into subsequent to the adoption of Accounting Standards Update, or ASU, No. 2009-13, "Revenue Arrangements with Multiple Deliverables" on July 1, 2010 has been determined to contain substantive options. For right to test agreements where the options to secure development and commercialization licenses to the Company's ADC technology are not considered substantive, the Company considers the development and commercialization licenses to be a deliverable at the inception of the agreement and applies the multiple element revenue recognition criteria to determine the appropriate revenue recognition. Subsequent to the adoption of ASU No. 2009-13, the Company determined that its research licenses lack stand-alone value and are considered for aggregation with the other elements of the arrangement and accounted for as one unit of accounting.

The Company does not directly control when or if any collaborator will exercise its options for development and commercialization licenses. As a result, the Company cannot predict when or if it will recognize revenues in connection with any of the foregoing.

Inventory

Inventory costs relate to clinical trial materials being manufactured for sale to the Company's collaborators. Inventory is stated at the lower of cost or market as determined on a first in, first out (FIFO) basis.

Inventory at June 30, 2016 and 2015 is summarized below (in thousands):

	June 30,	
	2016	2015
Raw materials	\$ 317	\$ 279
Work in process	590	2,656
Total	\$ 907	\$ 2,935

Raw materials inventory consists entirely of proprietary cell killing agents the Company developed as part of its ADC technology. All raw materials inventory is currently procured from two suppliers.

Work in process inventory consists of conjugate manufactured for sale to the Company's collaborators to be used in preclinical and clinical studies. All conjugate is made to order at the request of the collaborators and subject to the terms and conditions of respective supply agreements. As such, no excess reserve for work in process inventory is required. As discussed above, the Company's costs to manufacture conjugate on behalf of its partners are greater than the supply prices charged to partners, and therefore costs are capitalized into inventory at the supply prices.

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Raw materials inventory cost is stated net of write downs of \$1.4 million as of June 30, 2016 and June 30, 2015. The write downs represent the cost of raw materials that the Company considers to be in excess of a twelve month supply based on firm, fixed orders and projections from its collaborators as of the respective balance sheet date.

Due to yield fluctuations, the actual amount of raw materials that will be produced in future periods under third party supply agreements is highly uncertain. As such, the amount of raw materials produced could be more than is required to support the development of the Company's collaborators' product candidates. Such excess supply, as determined under the Company's inventory reserve policy, is charged to research and development expense.

The Company produces preclinical and clinical materials for its collaborators either in anticipation of or in support of preclinical studies and clinical trials, or for process development and analytical purposes. Under the terms of supply agreements with its collaborators, the Company generally receives rolling six month firm, fixed orders for conjugate that the Company is required to manufacture, and rolling twelve month manufacturing projections for the quantity of conjugate the collaborator expects to need in any given twelve month period. The amount of clinical material produced is directly related to the number of collaborator anticipated or on going clinical trials for which the Company is producing clinical material, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period, if any, during which patients in the trial receive clinical benefit from the clinical materials. Because these elements are difficult to estimate over the course of a trial, substantial differences between collaborators' actual manufacturing orders and their projections could result in the Company's usage of raw materials varying significantly from estimated usage at an earlier reporting period. To the extent that a collaborator has provided the Company with a firm, fixed order, the collaborator is required by contract to reimburse the Company the full negotiated price of the conjugate, even if the collaborator subsequently cancels the manufacturing run.

The Company capitalizes raw material as inventory upon receipt and accounts for the raw material inventory as follows:

- a) to the extent that the Company has up to twelve months of firm, fixed orders and/or projections from its collaborators, the Company capitalizes the value of raw materials that will be used in the production of conjugate subject to these firm, fixed orders and/or projections;
- b) the Company considers more than a twelve month supply of raw materials that is not supported by firm, fixed orders and/or projections from its collaborators to be excess and establishes a reserve to reduce to zero the value of any such excess raw material inventory with a corresponding charge to research and development expense; and
- c) the Company also considers any other external factors and information of which it becomes aware and assesses the impact of such factors or information on the net realizable value of the raw material inventory at each reporting period.

During fiscal years 2016, 2015 and 2014, the Company obtained additional amounts of its cell-killing agents DMx from its supplier which yielded more material than would be required by the Company's collaborators over the next twelve months, and as a result, the Company recorded \$1.1 million, \$1.0 million and \$364,000, respectively, of charges to research and development expense related to raw material inventory identified as excess. Increases in the Company's on hand supply of raw materials, or a reduction to the Company's collaborators' projections, could result in significant changes in the Company's estimate of the net realizable value of such raw material inventory. Reductions in collaborators' projections could indicate that the Company has excess raw material inventory and the Company would then evaluate the need to record write downs as charges to research and development expense.

## Unbilled Revenue

The majority of the Company's unbilled revenue at June 30, 2016 and 2015 represents research funding earned based on actual resources utilized under the Company's various collaborator agreements.



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## Other Accrued Liabilities

Other accrued liabilities consisted of the following at June 30, 2016 and 2015 (in thousands):

	June 30,	
	2016	2015
Accrued contract payments	\$ 4,202	\$ 5,830
Accrued clinical trial costs	3,096	1,735
Accrued professional services	1,028	788
Accrued employee benefits	640	567
Accrued public reporting charges	192	192
Other current accrued liabilities	555	1,329
Total	\$ 9,713	\$ 10,441

## Research and Development Expenses

The Company's research and development expenses are charged to expense as incurred and relate to (i) research to evaluate new targets and to develop and evaluate new antibodies, linkers and cytotoxic agents, (ii) preclinical testing of its own and, in certain instances, its collaborators' product candidates, and the cost of its own clinical trials, (iii) development related to clinical and commercial manufacturing processes and (iv) manufacturing operations which also include raw materials. Payments made by the Company in advance for research and development services not yet provided and/or materials not yet delivered and accepted are recorded as prepaid expenses and are included in the accompanying Consolidated Balance Sheets as prepaid and other current assets.

## Income Taxes

The Company uses the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and income tax basis of assets and liabilities, as well as net operating loss carry forwards and tax credits and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. A valuation allowance against net deferred tax assets is recorded if, based on the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

## Financial Instruments and Concentration of Credit Risk

Cash and cash equivalents are primarily maintained with three financial institutions in the U.S. Deposits with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. The Company's cash equivalents consist of money market funds with underlying investments primarily being U.S. Government issued securities and high quality, short term commercial paper. Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. The Company held no marketable securities as of June 30, 2016. The Company's investment policy, approved by the Board of Directors, limits the amount it may invest in any one type of investment, thereby reducing credit risk concentrations.

## Cash and Cash Equivalents

All highly liquid financial instruments with maturities of three months or less when purchased are considered cash equivalents. As of June 30, 2016 and June 30, 2015, the Company held \$245.0 million and \$278.1 million, respectively, in cash and money market funds consisting principally of U.S. Government-issued securities and high quality, short-term commercial paper which were classified as cash and cash equivalents.

Non-cash Investing Activities

The Company had \$804,000 of accrued capital expenditures as of June 30, 2016 which have been treated as a non-cash investing activity and, accordingly, are not reflected in the consolidated statement of cash flows. Accrued capital expenditures as of June 30, 2015 were not material and are included in the consolidated statement of cash flows.

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## Fair Value of Financial Instruments

ASC Topic 820 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the U.S., and expands disclosures about fair value measurements. Fair value is defined under ASC Topic 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy to measure fair value which is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of June 30, 2016, the Company held certain assets that are required to be measured at fair value on a recurring basis. The following table represents the fair value hierarchy for the Company's financial assets measured at fair value on a recurring basis as of June 30, 2016 (in thousands):

	Fair Value Measurements at June 30, 2016 Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 219,918	\$ 219,918	\$ —	\$ —

As of June 30, 2015, the Company held certain assets that are required to be measured at fair value on a recurring basis. The following table represents the fair value hierarchy for the Company's financial assets measured at fair value on a recurring basis as of June 30, 2015 (in thousands):

	Fair Value Measurements at June 30, 2015 Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 269,304	\$ 269,304	\$ —	\$ —

The fair value of the Company's cash equivalents is based primarily on quoted prices from active markets.

The carrying amounts reflected in the consolidated balance sheets for accounts receivable, unbilled revenue, prepaid and other current assets, accounts payable, accrued compensation, and other accrued liabilities approximate fair value due to their short term nature. The carrying amount and estimated fair value of the convertible 4.5% senior notes was \$100.0 million and \$91.2 million, respectively, as of June 30, 2016. The fair value of the Convertible Notes is influenced by interest rates, the Company's stock price and stock price volatility and is determined by prices for the Convertible Notes observed in a market which is a Level 2 input for fair value purposes.



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## Property and Equipment

Property and equipment are stated at cost. The Company provides for depreciation based upon expected useful lives using the straight line method over the following estimated useful lives:

Machinery and equipment	5 years
Computer hardware and software	3 years
Furniture and fixtures	5 years
Leasehold improvements	Shorter of remaining lease term or 7 years

Equipment under capital leases is amortized over the lives of the respective leases or the estimated useful lives of the assets, whichever is shorter, and included in depreciation expense.

Maintenance and repairs are charged to expense as incurred. Upon retirement or sale, the cost of disposed assets and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the statement of operations. The Company recorded \$21,000, \$(7,000) and \$(20,000) of gains (losses) on the sale/disposal of certain furniture and equipment during the years ended June 30, 2016, 2015, and 2014, respectively.

## Impairment of Long Lived Assets

In accordance with ASC Topic 360, "Property, Plant, and Equipment," the Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful life of its long lived assets may warrant revision or that the carrying value of these assets may be impaired if impairment indicators are present. The Company evaluates the realizability of its long lived assets based on cash flow expectations for the related asset. Any write downs to fair value are treated as permanent reductions in the carrying amount of the assets. Based on this evaluation, the Company believes that, as of each of the balance sheet dates presented, none of the Company's long lived assets were impaired.

## Computation of Net Loss per Common Share

Basic and diluted net loss per share is calculated based upon the weighted average number of common shares outstanding during the period. During periods of income, participating securities are allocated a proportional share of income determined by dividing total weighted average participating securities by the sum of the total weighted average common shares and participating securities (the "two class method"). Shares of the Company's restricted stock participate in any dividends that may be declared by the Company and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to participating securities since they have no contractual obligation to share in the losses of the Company. Diluted (loss) income per share is computed after giving consideration to the dilutive effect of stock options that are outstanding during the period, except where such non-participating securities would be anti-dilutive.

The Company's common stock equivalents, as calculated in accordance with the treasury stock method for the options and the if-converted method for the convertible notes, are shown in the following table (in thousands):

	June 30, 2016	2015	2014
Options outstanding to purchase common	11,919	9,739	8,486

stock and unvested restricted stock Common stock equivalents under treasury stock method for options	735	770	1,820
Shares issuable upon conversion of convertible notes Common stock equivalents under if-converted method for convertible notes	23,878	—	—
	718	—	—

The Company's common stock equivalents have not been included in the net loss per share calculation because their effect is anti dilutive due to the Company's net loss position.

#### Stock based Compensation

As of June 30, 2015, the Company is authorized to grant future awards under one employee share based compensation plan, which is the ImmunoGen, Inc. 2006 Employee, Director and Consultant Equity Incentive Plan, or the 2006 Plan. At the annual meeting of shareholders on November 11, 2014, an amendment to the 2006 Plan was

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approved and an additional 5,500,000 shares were authorized for issuance under this plan. As amended, the 2006 Plan provides for the issuance of Stock Grants, the grant of Options and the grant of Stock Based Awards for up to 17,500,000 shares of the Company's common stock, as well as 1,676,599 shares of common stock which represent awards granted under the previous stock option plan, the ImmunoGen, Inc. Restated Stock Option Plan, or the Former Plan, that were forfeited, expired or were cancelled without delivery of shares of common stock or which resulted in the forfeiture of shares of common stock back to the Company between November 11, 2006 and June 30, 2014. Option awards are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Options vest at various periods of up to four years and may be exercised within ten years of the date of grant.

The stock based awards are accounted for under ASC Topic 718, "Compensation—Stock Compensation." Pursuant to Topic 718, the estimated grant date fair value of awards is charged to the statement of operations over the requisite service period, which is the vesting period. Such amounts have been reduced by an estimate of forfeitures of all unvested awards. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option pricing model with the weighted average assumptions noted in the following table. As the Company has not paid dividends since inception, nor does it expect to pay any dividends for the foreseeable future, the expected dividend yield assumption is zero. Expected volatility is based exclusively on historical volatility data of the Company's stock. The expected term of stock options granted is based exclusively on historical data and represents the period of time that stock options granted are expected to be outstanding. The expected term is calculated for and applied to one group of stock options as the Company does not expect substantially different exercise or post-vesting termination behavior amongst its employee population. The risk-free rate of the stock options is based on the U.S. Treasury rate in effect at the time of grant for the expected term of the stock options.

	Year Ended June 30,		
	2016	2015	2014
Dividend	None	None	None
Volatility	66.34 %	60.86 %	60.40 %
Risk-free interest rate	1.80 %	1.84 %	1.74 %
Expected life (years)	6.3	6.3	6.3

Using the Black-Scholes option pricing model, the weighted average grant date fair values of options granted during fiscal years 2016, 2015 and 2014 were \$8.91, \$6.04, and \$10.50 per share, respectively.

A summary of option activity under the 2006 Plan as of June 30, 2016, and changes during the twelve month period then ended is presented below (in thousands, except weighted average data):

	Number of Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life in Yrs	Aggregate Intrinsic Value
Outstanding at June 30, 2015	9,689	\$ 12.49		
Granted	3,340	\$ 14.34		
Exercised	(555)	\$ 9.30		
Forfeited/Canceled	(661)	\$ 14.84		
Outstanding at June 30, 2016	11,813	\$ 13.03	6.82	\$ —
Outstanding at June 30, 2016—vested or unvested and expected to vest	11,475	\$ 13.05	6.76	\$ —
Exercisable at June 30, 2016	6,453	\$ 12.63	5.30	\$ —

In May 2016, November 2012 and January 2015, the Company granted three officers of the Company 75,000, 50,000 and 25,000 shares of restricted stock, respectively, upon hire. Pursuant to the agreements, the shares vest ratably in annual installments over the subsequent four years. The fair value of the restricted stock was determined by the

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closing price on the date of grant. A summary of restricted stock activity under the 2006 Plan as of June 30, 2016, and changes during the twelve month period then ended is presented below (in thousands, except weighted average data):

	Number of Restricted Stock Shares	Weighted Average Exercise Price
Unvested at June 30, 2015	50,000	\$ 9.23
Awarded	75,000	\$ 5.65
Vested	(18,750)	\$ 10.13
Unvested at June 30, 2016	106,250	\$ 6.54

In August 2016, the Company granted 117,800 shares of restricted common stock to certain officers of the Company. These restrictions will lapse in three equal installments over five years upon the achievement of specified performance goals.

Stock compensation expense related to stock options and restricted stock awards granted under the 2006 Plan was \$21.9 million, \$15.3 million and \$15.6 million during the fiscal years ended June 30, 2016, 2015, and 2014, respectively. During fiscal year 2016, the Company recorded approximately \$3.1 million of stock compensation cost related to the modification of certain outstanding common stock options with the former Chief Executive Officer's succession plan. No similar charges were recorded in fiscal years 2015 and 2014. As of June 30, 2016, the estimated fair value of unvested employee awards was approximately \$26.6 million, net of estimated forfeitures. The weighted average remaining vesting period for these awards is approximately two years. Included in stock compensation expense for the fiscal years ended June 30, 2016, 2015 and 2014 are \$380,000, \$389,000 and \$433,000, respectively, of expense recorded for directors' deferred share units, the details of which are discussed in Note H of the Company's consolidated financial statements.

A summary of option activity for options vested during the fiscal years ended June 30, 2016, 2015 and 2014 is presented below (in thousands):

	Year Ended June 30,		
	2016	2015	2014
Total fair value of options vested	\$ 15,298	\$ 16,145	\$ 12,535
Total intrinsic value of options exercised	3,142	3,275	9,961
Cash received for exercise of stock options	5,161	4,429	9,136

**Comprehensive Loss**

The Company presents comprehensive loss in accordance with ASC Topic 220, Comprehensive Income. Comprehensive loss is comprised of the Company's net loss for the years ended June 30, 2016, 2015 and 2014.

**Segment Information**

During the three fiscal years ended June 30, 2016, the Company continued to operate in one reportable business segment under the management approach of ASC Topic 280, Segment Reporting, which is the business of discovery of monoclonal antibody based anticancer therapeutics.





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The percentages of revenues recognized from significant customers of the Company in the years ended June 30, 2016, 2015 and 2014 are included in the following table:

Collaborative Partner:	Year Ended June 30,					
	2016	2015	2014	2016	2015	2014
Bayer	17	—	—	%	%	%
Lilly	11	21	18	%	%	%
Novartis	1	43	38	%	%	%
Roche	43	23	34	%	%	%
Takeda	16	—	—	%	%	%

There were no other customers of the Company with significant revenues in the years ended June 30, 2016, 2015 and 2014.

## Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) (“ASU 2014-09”), to clarify the principles for recognizing revenue. This update provides a comprehensive new revenue recognition model that requires revenue to be recognized in a manner to depict the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectibility, non-cash consideration and the presentation of sales and other similar taxes collected from customers. These standards have the same effective date and transition date of January 1, 2018. The new revenue standard allows for either full retrospective or modified retrospective application. The Company is currently evaluating the timing of its adoption, the transition method to apply and the impact that this guidance will have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. This new standard gives a company’s management the final responsibilities to decide whether there’s substantial doubt about the company’s ability to continue as a going concern and to provide related footnote disclosures. The standard provides guidance to management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that companies commonly provide in their footnotes. Under the new standard, management must decide whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the company’s ability to continue as a going concern within one year after the date that the financial statements are issued, or within one year after the date that the financial statements are available to be issued when applicable. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. Accordingly, the standard is effective for the Company on January 1, 2017. The Company has not yet completed its analysis of the impact of the adoption of this guidance. Refer to Note A, Nature of Business and Plan of Operations for further discussion.

In April 2015, the FASB issued ASU 2015-03, Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. To simplify presentation of debt issuance costs, this new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by this update. This guidance is effective for annual reporting beginning after December 15, 2015, including interim periods within the year of adoption, and calls for retrospective application, with early application permitted. Accordingly, the standard is effective for the Company on July 1, 2016. The Company's

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consolidated balance sheet as of June 30, 2016 includes in assets \$7.8 million of debt issuance costs classified as deferred financing costs.

In July 2015, the FASB issued ASU 2015-11, Simplifying the Measurement of Inventory (Topic 330). To simplify the principles for subsequent measurement of inventory, this new standard requires inventory measured using any method other than LIFO or the retail method shall be measured at the lower of cost and net realizable value, rather than lower of cost or market. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, and calls for prospective application, with early application permitted. Accordingly, the standard is effective for the Company on January 1, 2017. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes (Topic 740). To simplify the presentation of deferred income taxes, the amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. The Company implemented the recommendations of this Update prospectively in the second quarter of fiscal year 2016, resulting in a reduction of long-term assets and current liabilities of approximately \$843,000 as of December 31, 2015. The prior period balances were not retrospectively adjusted.

In January 2016, the FASB issued ASU 2016-1, Recognition and Measurement of Financial Assets and Financial Liabilities (Topic 825). The amendments in this Update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities (including other ownership interests, such as partnerships, unincorporated joint ventures, and limited liability companies) to be measured at fair value with changes in the fair value recognized through net income. The amendments allow equity investments that do not have readily determinable fair values to be remeasured at fair value either upon the occurrence of an observable price change or upon identification of an impairment. The amendments also require enhanced disclosures about those investments. The amendments improve financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This guidance is effective for annual reporting beginning after December 15, 2017, including interim periods within the year of adoption, and calls for prospective application, with early application permitted. Accordingly, the standard is effective for the Company on January 1, 2018. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-2, Leases (Topic 842) that primarily requires lessees to recognize most leases on their balance sheets but record expenses on their income statements in a manner similar to current accounting. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and calls for retrospective application, with early adoption permitted. Accordingly, the standard is effective for the Company on January 1, 2019. The Company is currently evaluating the impact of this guidance on our financial statements and the timing of adoption.

In March 2016, the FASB issued ASU 2016-9, Improvements to Employee Share-Based Payment Accounting (Topic 718) that changes the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. The guidance is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods with early adoption permitted. Accordingly, the standard is effective for the Company on January 1, 2017. The Company is currently evaluating the impact of this guidance on our financial statements and the timing of adoption.

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## C. Agreements

## Significant Collaborative Agreements

## Roche

In 2000, the Company granted Genentech, now a unit of Roche, an exclusive license to use the Company's maytansinoid ADC technology with antibodies, such as trastuzumab, or other proteins that target HER2. Under the terms of this agreement, Roche has exclusive worldwide rights to develop and commercialize maytansinoid ADC compounds targeting HER2. In 2013, the HER2 targeting ADC compound, Kadcyla, was approved for marketing in the U.S., Japan and the European Union, or EU. Roche has also received marketing approval in various other countries around the world. Roche is responsible for the manufacturing, product development and marketing of any products resulting from the agreement. The Company is compensated for any preclinical and clinical materials that the Company manufactures under the agreement. The Company received a \$2 million non-refundable upfront payment from Roche upon execution of the agreement. The Company is also entitled to receive up to a total of \$44 million in milestone payments, plus royalties on the commercial sales of Kadcyla or any other resulting products. Total milestones are categorized as follows: development milestones—\$13.5 million; and regulatory milestones—\$30.5 million. Through June 30, 2016, the Company has received and recognized \$13.5 million and \$20.5 million in development and regulatory milestone payments, respectively, related to Kadcyla. The Company received two \$5 million regulatory milestone payments in connection with marketing approval of Kadcyla in Japan and in the EU, which is included in license and milestone fees for the fiscal year ended June 30, 2014. Based on an evaluation of the effort contributed to the achievement of these milestones in fiscal year 2014, the Company determined these milestones were not substantive. In consideration that there were no undelivered elements remaining, no continuing performance obligations and all other revenue recognition criteria had been met, the Company recognized the non-refundable payments as revenue upon achievement of the milestones. The next potential milestone the Company 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. Based on an evaluation of the effort contributed towards the achievement of this future milestone, the Company determined this milestone is not substantive.

The Company receives royalty reports and payments related to sales of Kadcyla from Roche one quarter in arrears. In accordance with the Company's revenue recognition policy, \$25.3 million of non-cash royalties on net sales of Kadcyla for the twelve-month period ended March 31, 2016 were recorded and included in royalty revenue for the year ended June 30, 2016 and \$5.5 million of non-cash royalties and \$13.9 million of cash royalties on net sales of Kadcyla for the twelve-month period ended March 31, 2015 is included in royalty revenue for the year ended June 30, 2015. The Company recorded \$10.3 million of cash royalties on net sales of Kadcyla for the twelve-month period ended March 31, 2014 for the year ended June 30, 2014. Kadcyla sales occurring after January 1, 2015 are covered by a royalty purchase agreement whereby the associated cash is remitted to Immunity Royalty Holdings, L.P, or IRH, as discussed further in Note F.

Roche, through its Genentech unit, also has licenses for the exclusive right to use the Company's maytansinoid ADC technology with antibodies to four undisclosed targets, which were granted under the terms of a separate, now expired 2000 right to test agreement with Genentech. For each of these licenses the Company received a \$1 million license fee and is entitled to receive up to a total of \$38 million in milestone payments and also royalties on the sales of any resulting products. The total milestones are categorized as follows: development milestones—\$8 million; regulatory milestones—\$20 million; and sales milestones—\$10 million. The Company has not received any milestone payments from these agreements through June 30, 2016. Roche is responsible for the development, manufacturing, and marketing of any products resulting from these licenses. The next potential milestone the Company will be entitled to receive under any of these agreements will be a development milestone for filing of an IND application which will result in a \$1 million payment being due. At the time of execution of each of these development and commercialization licenses,

there was significant uncertainty as to whether this milestone would be achieved. In consideration of this, as well as the Company's past involvement in the research and manufacturing these products, this milestone was deemed substantive. The Company received non-refundable technology access fees totaling \$5 million for the eight-year term of the right-to-test agreement. The upfront fees were deferred and recognized ratably over the period during which Genentech could elect to obtain product licenses.

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## Amgen

Under a now expired right to test agreement established in 2000, Amgen took three exclusive development and commercialization licenses, for which the Company 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 the Company 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 the Company. Amgen has sublicensed its rights under this license to Oxford BioTherapeutics Ltd. In December 2015, Amgen advised the Company that it had discontinued development of two product candidates, AMG 595 and AMG 172 that had been covered by two of Amgen's four exclusive licenses, and in February 2016, Amgen terminated these two licenses.

For each of the two remaining development and commercialization license taken, the Company is entitled to receive up to a total of \$34 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones per license are categorized as follows: development milestones—\$9 million; regulatory milestones—\$20 million; and sales milestones—\$5 million. Amgen (or its sublicensee(s)) is responsible for the manufacturing, product development and marketing of any products resulting from these development and commercialization licenses. Through June 30, 2016, the Company has received and recognized an aggregate of \$3 million in milestone payments for compounds covered under this agreement now or in the past. In September 2015, Amgen's IND application under the remaining license not sublicensed to Oxford BioTherapeutics became effective, triggering a \$1 million milestone payment to the Company which is included in license and milestone fee revenue for the year ended June 30, 2016. The next potential milestone the Company will be entitled to receive under this license 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 milestone the Company will be entitled to receive under the May 2013 license will be a \$1 million development milestone for an IND becoming effective. At the time of execution of each of these development and commercialization licenses, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's past involvement in the research and manufacturing of these product candidates, these milestones were deemed substantive.

Since a deliverable to the original right to test agreement was determined to be materially modified at the time the non exclusive license was converted to exclusive in October 2013, the Company accounted for the multiple element agreement in accordance with ACS 605 25 (as amended by ASU No. 2009 13). As a result, all of the deferred revenue recorded on the date of the modification and the new consideration received as part of the modification was allocated to all of the remaining deliverables at the time of amendment of the right to test agreement based on the estimated selling price of each element. The remaining amount represents consideration for previously delivered elements and was recognized upon the execution of the modification.

The outstanding licenses, including the exclusive license delivered upon the signing of the amendment, contain the rights to future technological improvements as well as options to purchase materials and research and development services. The Company concluded that additional materials and research and development services would be paid at a contractual price equal to the estimated selling price based estimated prices that would be charged by third parties for similar services. The estimated selling price of the right to technological improvements is the Company's best estimate of selling price and was determined by estimating the probability that technological improvements will be made and the probability that such technological improvements made will be used by Amgen. In estimating these probabilities, we considered factors such as the technology that is the subject of the development and commercialization licenses, our history of making technological improvements, and when such improvements, if any, were likely to occur relative to the stage of development of any product candidates pursuant to the development and commercialization licenses. The Company's estimate of probability considered the likely period of time that any improvements would be utilized, which was estimated to be ten years following delivery of a commercialization and development license. The value of any technological improvements made available after this ten year period was considered to be de minimis due to the

significant additional costs that would be incurred to incorporate such technology into any existing product candidates. The estimate of probability was multiplied by the estimated selling price of the development and commercialization licenses and the resulting cash flow was discounted at a rate of 13%, representing the Company's estimate of its cost of capital at the time of amendment of the right to test agreement.

The \$430,000 determined to be the estimated selling price of the future technological improvements is being recognized as revenue ratably over the period the Company is obligated to make available any technological improvements, which is equivalent to the estimated term of the agreement. The Company estimates the term of a development and commercialization license to be approximately 25 years, which reflects management's estimate of the



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time necessary to develop and commercialize products pursuant to the license plus the estimated royalty term. The Company reassesses the estimated term at the end of each reporting period.

After accounting for the undelivered elements at the estimated selling price, the Company had \$2.2 million of remaining allocable consideration which was determined to represent consideration for the previously delivered elements, including the exclusive license that was delivered upon the execution of the modification. This amount was recorded as revenue and is included in license and milestone fees for the year ended June 30, 2014.

Costs directly attributable to the Amgen collaborative agreement are comprised of compensation and benefits related to employees who provided research and development services on behalf of Amgen as well as costs of clinical materials sold. Indirect costs are not identified to individual collaborators. The costs related to the research and development services amounted to approximately \$15,000, \$62,000 and \$179,000 for fiscal years 2016, 2015 and 2014, respectively. The costs related to clinical materials sold were approximately \$664,000 for fiscal year 2014. There were no similar costs recorded in fiscal years 2016 and 2015.

## Sanofi

### Collaboration Agreement

In 2003, the Company 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 the Company's maytansinoid ADC technology in the creation of products developed to these targets. The product candidates (targets) as of June 30, 2016 in the collaboration include isatuximab (CD38), SAR566658 (CA6), SAR408701 (CEACAM5) and one earlier stage program that has yet to be disclosed.

The Company is entitled to receive milestone payments potentially totaling \$21.5 million, per target, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones—\$7.5 million; and regulatory milestones—\$14 million. Through June 30, 2016, the Company has received and recognized an aggregate of \$20.5 million in milestone payments for compounds covered under this agreement now or in the past, including a \$3 million development milestone related to initiation of a Phase IIb clinical trial (as defined in the agreement) for isatuximab and a \$1 million development milestone related to initiation of a Phase I clinical trial for SAR408701 which are included in license and milestone fee revenue for the year ended June 30, 2015. The next potential milestone the Company will be entitled to receive for each of SAR566658 and SAR408701 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 the Company will be entitled to receive with respect to isatuximab will be a development milestone for initiation of a Phase III clinical trial, which will result in a \$3 million payment being due. The next potential milestone the Company will be entitled to receive for the unidentified target will be a development milestone for commencement of a Phase I clinical trial, which will result in a \$1 million payment being due. At the time of execution of this agreement, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's past involvement in the research and manufacturing of these product candidates, these milestones were deemed substantive.

### Right-to-Test Agreement

Under a separate, now expired right-to-test agreement, in December 2013, Sanofi took one exclusive development and commercialization license. Under this license, the Company received an exercise fee of \$2 million and was recognizing this amount as revenue ratably over the Company's estimated period of its substantial involvement. The

Company had previously estimated this development period would conclude at the end of non-pivotal Phase II testing. During fiscal 2015, the Company determined it would not be substantially involved in the development and commercialization of the product based on Sanofi's current plans to develop and manufacture the product without the assistance of the Company. As a result of this determination, the Company recognized the balance of the upfront exercise fee during the first quarter of fiscal 2015. This change in estimate resulted in an increase to license and milestone fees of \$1.5 million for the year ended June 30, 2015 compared to amounts that would have been recognized pursuant to the Company's previous estimate.

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Under this license, the Company is entitled to receive up to a total of \$30 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones—\$10 million; and regulatory milestones—\$20 million. In October 2015, Sanofi initiated Phase I, first-in-human clinical testing of its ADC product candidate, SAR428926 (LAMP1), triggering a \$2 million development milestone payment to the Company which is included in license and milestone fee revenue for the year ended June 30, 2016. The next milestone payment the Company could receive would be a \$4 million development milestone for commencement of a Phase IIb clinical trial (as defined in the agreement) under this license. At the time of execution of this agreement, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's expected involvement in the research and manufacturing of this product candidate, these milestones were deemed substantive. Sanofi is responsible for the manufacturing, product development and marketing of any products resulting from the agreement.

## Biotest

In 2006, the Company granted Biotest an exclusive development and commercialization license to our maytansinoid ADC technology for use with antibodies that target CD138. The product candidate indatuximab ravtansine is in development under this agreement. Biotest is responsible for the manufacturing, product development and marketing of any products resulting from the agreement. The Company received a \$1 million upfront payment upon execution of the agreement and could receive up to \$35.5 million in milestone payments, as well as royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones—\$4.5 million; and regulatory milestones—\$31 million. The Company receives payments for manufacturing any preclinical and clinical materials made at the request of Biotest. In September 2008, Biotest began Phase I evaluation of indatuximab ravtansine which triggered a \$500,000 milestone payment to the Company. The next potential milestone the Company 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. At the time of execution of this agreement, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's past involvement in the research and manufacturing of this product, these milestones were deemed substantive.

The agreement also provided the Company with the right to elect at specific stages during the clinical evaluation of any compound created under this 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, the Company can exercise this right during an exercise period specified in the agreement by notice and payment to Biotest of an agreed upon option fee of \$15 million. Upon exercise of this right, the Company 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. The Company would also be entitled to receive royalties, on a reduced basis, on product sales outside the U.S.

Costs directly attributable to the Biotest collaborative agreement are comprised of compensation and benefits related to employees who provided research and development services on behalf of Biotest as well as costs of clinical materials sold. Indirect costs are not identified to individual collaborators. The costs related to the research and development services amounted to approximately \$160,000, \$309,000 and \$305,000 for fiscal years 2016, 2015 and 2014, respectively. The costs related to clinical materials sold were approximately \$1.8 million, \$3 million and \$670,000 for fiscal years 2016, 2015 and 2014, respectively.

## Bayer

In 2008, the Company granted Bayer an exclusive development and commercialization license to the Company's maytansinoid ADC technology for use with antibodies or other proteins that target mesothelin. Bayer HealthCare is

responsible for the research, development, manufacturing and marketing of any products resulting from the license. The Company received a \$4 million upfront payment upon execution of the agreement, and—for each compound developed and marketed by Bayer under this collaboration—the Company is entitled to receive a total of \$170.5 million in milestone payments, plus tiered royalties between 4 - 7% on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones—\$16 million; regulatory milestones—\$44.5 million; and sales milestones—\$110 million. Through June 30, 2016, the Company has received and recognized an aggregate of \$13 million in milestone payments under this agreement. In January 2016, Bayer initiated a Phase II clinical study designed to support registration of its ADC product candidate, anetumab ravtansine, triggering a \$10 million development milestone payment to the Company which is included in license and milestone fee revenue for

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the year ended June 30, 2016. The next potential milestone the Company will be entitled to receive will be either a development milestone for commencement of a pivotal clinical trial for a second indication for anetumab ravtansine which will result in a \$2 million payment being due or a regulatory milestone for filing of regulatory approval for its first indication for anetumab ravtansine which will result in a \$6 million payment being due. At the time of execution of this agreement, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's past involvement in the research and supply of cytotoxic agent for this product candidate, these milestones was deemed substantive.

The Company had previously deferred the \$4 million upfront payment received and was recognizing this amount as revenue ratably over the estimated period of substantial involvement. The Company had previously estimated this development period would conclude at the end of non-pivotal Phase II testing. During the first quarter of fiscal 2012, Bayer initiated Phase I clinical testing of its product candidate. In reaching this stage of clinical testing, Bayer developed its own processes for manufacturing required clinical material and produced clinical material in its own manufacturing facility. Considering that Bayer was able to accomplish this without significant reliance on the Company, and considering that the Company's expected future involvement would be primarily supplying Bayer with small quantities of cytotoxic agents for a limited period of time, the Company believed its period of substantial involvement would end prior to the completion of non-pivotal Phase II testing. As a result of this determination, beginning in September 2011, the Company recognized the balance of the upfront payment as revenue ratably through September 2012.

## Novartis

Novartis took six exclusive development and commercialization licenses under a now-expired right-to-test agreement established in 2010. The Company received a \$45 million upfront payment in connection with the execution of the right to test agreement in 2010, and for each development and commercialization license taken for a specific target, the Company received an exercise fee of \$1 million and is entitled to receive up to a total of \$199.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones—\$22.5 million; regulatory milestones—\$77 million; and sales milestones—\$100 million. 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. The Company also is entitled to receive payments for research and development activities performed on behalf of Novartis. Novartis is responsible for the manufacturing, product development and marketing of any products resulting from this agreement.

In March 2013, the Company and Novartis amended the right to test agreement so that Novartis could take a license to develop and commercialize products directed at two undisclosed, related 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 no longer be converted to an exclusive target due to the expiration of the right-to-test agreement. The Company received a \$3.5 million fee in connection with the execution of the amendment to the agreement. The Company 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. The Company received a \$1 million upfront fee with the execution of this license. Additionally, the execution of this license provides the Company the opportunity to receive milestone payments totaling \$199.5 million (development milestones—\$22.5 million; regulatory milestones—\$77 million; and sales milestones—\$100 million) or \$238 million (development milestones—\$22.5 million; regulatory milestones—\$115.5 million; and sales milestones—\$100 million), depending on the composition of any resulting products.

In October 2013 and November 2013, Novartis took its second and third exclusive licenses to single targets, and in October 2014, took three remaining exclusive licenses, each triggering a \$1 million payment to the Company and the opportunity to receive milestone payments totaling \$199.5 million, as outlined above, plus royalties on the commercial sales of any resulting products. In January 2015 and May 2015, Novartis initiated Phase I, first-in-human clinical testing of its cKit-targeting ADC product candidate, LOP628, and P-cadherin-targeting ADC product candidate, PCA062, respectively, triggering a \$5 million development milestone payment to the Company with each event, both of which are included in license and milestone fee revenue for the year ended June 30, 2015. The next payment the Company could receive would be either a \$7.5 million development milestone for commencement of a Phase II clinical trial under these two licenses or a \$5 million development milestone for commencement of a Phase I clinical trial under any of its other four licenses. At the time of execution of these agreements, there was significant uncertainty as to

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whether these milestones would be achieved. In consideration of this, as well as the Company's past involvement in the research and manufacturing of these product candidates, these milestones were deemed substantive. Additionally, the Company is entitled to receive royalties on product sales, if any.

In accordance with ACS 605-25 (as amended by ASU No. 2009-13), the Company identified all of the deliverables at the inception of the right to test agreement and subsequently when amended. The significant deliverables were determined to be the right to test, or research, license, the development and commercialization licenses, rights to future technological improvements, and the research services. The options to obtain development and commercialization licenses in the right to test agreement were determined not to be substantive and, as a result, the exclusive development and commercialization licenses were considered deliverables at the inception of the right to test agreement. Factors that were considered in determining the options were not substantive included (i) the overall objective of the agreement was for Novartis to obtain development and commercialization licenses, (ii) the size of the exercise fee of \$1 million for each development and commercialization license obtained is not significant relative to the \$45 million upfront payment that was due at the inception of the right to test agreement, (iii) the limited economic benefit that Novartis could obtain from the right to test agreement unless it exercised its options to obtain development and commercialization licenses, and (iv) the lack of economic penalties as a result of exercising the options.

The Company has determined that the research license together with the development and commercialization licenses represent one unit of accounting as the research license does not have stand-alone value from the development and commercialization licenses due to the lack of transferability of the research license and the limited economic benefit Novartis would derive if they did not obtain any development and commercialization licenses. The Company has also determined that this unit of accounting does have stand-alone value from the rights to future technological improvements and the research services. The rights to future technological improvements and the research services are considered separate units of accounting as each of these was determined to have stand-alone value. The rights to future technological improvements have stand-alone value as Novartis would be able to use those items for their intended purpose without the undelivered elements. The research services have stand-alone value as similar services are sold separately by other vendors.

The estimated selling prices for the development and commercialization licenses are the Company's best estimate of selling price and were determined based on market conditions, similar arrangements entered into by third parties, including the Company's understanding of pricing terms offered by its competitors for single-target development and commercialization licenses that utilize ADC technology, and entity-specific factors such as the pricing terms of the Company's previous single-target development and commercialization licenses, recent preclinical and clinical testing results of therapeutic products that use the Company's ADC technology, and the Company's pricing practices and pricing objectives. The estimated selling price of the right to technological improvements is the Company's best estimate of selling price and was determined by estimating the probability that technological improvements will be made and the probability that such technological improvements made will be used by Novartis. In estimating these probabilities, we considered factors such as the technology that is the subject of the development and commercialization licenses, our history of making technological improvements, and when such improvements, if any, were likely to occur relative to the stage of development of any product candidates pursuant to the development and commercialization licenses. The Company's estimate of probability considered the likely period of time that any improvements would be utilized, which was estimated to be ten years following delivery of a commercialization and development license. The value of any technological improvements made available after this ten year period was considered to be de minimis due to the significant additional costs that would be incurred to incorporate such technology into any existing product candidates. The estimate of probability was multiplied by the estimated selling price of the development and commercialization licenses and the resulting cash flow was discounted at a rate of 16%, representing the Company's estimate of its cost of capital at the time. The estimated selling price of the research services was based on third-party evidence given the nature of the research services to be performed for Novartis and market rates for similar services.

Upon payment of the extension fee in October 2013, the total arrangement consideration of \$60.2 million (which comprises the \$45 million upfront payment, the amendment fee of \$3.5 million, the \$5 million extension fee, the exercise fee for each license, and the expected fees for the research services to be provided under the remainder of the arrangement) was reallocated to the deliverables based on the relative selling price method as follows: \$55 million to the delivered and undelivered development and commercialization licenses; \$4.5 million to the rights to future technological improvements; and \$710,000 to the research services. The Company recorded \$25.7 million of the \$55 million of the arrangement consideration outlined above for the three development and commercialization licenses taken in October 2014, which is included in license and milestone fee revenue for the year ended June 30, 2015, \$17.2 million for the two development and commercialization licenses taken by Novartis in October 2013 and November 2013, which is included



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in license and milestone fee revenue for the year ended June 30, 2014, and \$11.1 million for the development and commercialization licenses taken in March 2013. The Company also recorded a cumulative catch up of \$1 million for the license delivered in March 2013 and the delivered portion of the license covering future technological improvements, which is included in license and milestone fee revenue for the year ended June 30, 2014.

Since execution of the first development and commercialization license taken in March 2013, the amount of the total arrangement consideration allocated to future technological improvements is being recognized as revenue ratably over the period the Company is obligated to make available any technological improvements, which is equivalent to the estimated term of the agreement. The Company estimates the term of a development and commercialization license to be approximately 25 years, which reflects management's estimate of the time necessary to develop and commercialize products pursuant to the license plus the estimated royalty term. The Company reassesses the estimated term at the end of each reporting period. The Company will recognize research services revenue as the related services are delivered.

Costs directly attributable to the Novartis collaborative agreement are comprised of compensation and benefits related to employees who provided research and development services on behalf of Novartis as well as costs of clinical materials sold. Indirect costs are not identified to individual collaborators. The costs related to the research and development services amounted to \$67,000, \$141,000 and \$1.4 million for fiscal years 2016, 2015 and 2014, respectively. The costs related to clinical materials sold were approximately \$644,000 and \$1.3 million for fiscal years 2015 and 2014, respectively. There were no similar costs recorded in fiscal year 2016.

## Lilly

Eli Lilly and Company (Lilly) took three exclusive development and commercialization licenses under a now-expired right-to-test agreement established in 2011. The Company received a \$20 million upfront payment in connection with the execution of the right to test agreement in 2011. Under the terms of this right-to-test agreement, the first license had no associated exercise fee, and the second and third licenses each had a \$2 million exercise fee. The first development and commercialization license was taken in August 2013 and the agreement was amended in December 2013 to provide Lilly with an extension provision and retrospectively include a \$2 million exercise fee for the first license in lieu of the fee due for either the second or third license. The second and third licenses were taken in December 2014, with one including the \$2 million exercise fee and the other not. Under the two licenses with the \$2 million exercise fee, the Company is entitled to receive up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. Under the license taken in December 2014 without the exercise fee, 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 total milestones are categorized as follows: development milestones—\$29 million for the two development and commercialization licenses with the \$2 million exercise fee, and \$30.5 million for the one development and commercialization license with no exercise fee; regulatory milestones—\$70 million in all cases; and sales milestones—\$100 million in all cases. In September 2015, Lilly began Phase I evaluation of one of its licensed ADC products which triggered a \$5 million milestone payment to the Company which is included in license and milestone fee revenue for the fiscal year ended June 30, 2016. The next payment the Company could receive would be either a \$9 million development milestone for commencement of a Phase II clinical trial under this license or a \$5 million development milestone payment with the initiation of a Phase I clinical trial under either of its other two development and commercialization licenses taken. At the time of execution of this agreement, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's expected involvement in the research and manufacturing of these product candidates, these milestones were deemed substantive. The Company also is entitled to receive payments for delivery of cytotoxic agents to Lilly and research and development activities performed on behalf of Lilly. Lilly is responsible for the manufacturing, product development and marketing of any products resulting from this collaboration.

In accordance with ASC 605-25 (as amended by ASU No. 2009-13), the Company identified all of the deliverables at the inception of the right to test agreement. The significant deliverables were determined to be the right to test, or research, license, the exclusive development and commercialization licenses, rights to future technological improvements, delivery of cytotoxic agents and the research services. The options to obtain development and commercialization licenses in the right to test agreement were determined not to be substantive and, as a result, the exclusive development and commercialization licenses were considered deliverables at the inception of the right to test agreement. Factors that were considered in determining the options were not substantive included (i) the overall objective of the agreement was for Lilly to obtain development and commercialization licenses, (ii) the size of the exercise fees of \$2 million for each development and commercialization license taken beyond the first license is not significant relative to the \$20 million upfront payment that was due at the inception of the right to test agreement,

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(iii) the limited economic benefit that Lilly could obtain from the right to test agreement unless it exercised its options to obtain development and commercialization licenses, and (iv) the lack of economic penalties as a result of exercising the options.

The Company has determined that the research license together with the development and commercialization licenses represent one unit of accounting as the research license does not have stand alone value from the development and commercialization licenses due to the lack of transferability of the research license and the limited economic benefit Lilly would derive if they did not obtain any development and commercialization licenses. The Company has also determined that this unit of accounting has stand alone value from the rights to future technological improvements, the delivery of cytotoxic agents and the research services. The rights to future technological improvements, delivery of cytotoxic agents and the research services are considered separate units of accounting as each of these was determined to have stand alone value. The rights to future technological improvements have stand alone value as Lilly would be able to use those items for their intended purpose without the undelivered elements. The research services and cytotoxic agents have stand alone value as similar services and products are sold separately by other vendors.

The estimated selling prices for the development and commercialization licenses are the Company's best estimate of selling price and were determined based on market conditions, similar arrangements entered into by third parties, including pricing terms offered by our competitors for single-target development and commercialization licenses that utilize antibody-drug conjugate technology, and entity-specific factors such as the pricing terms of the Company's previous single-target development and commercialization licenses, recent preclinical and clinical testing results of therapeutic products that use the Company's ADC technology, and the Company's pricing practices and pricing objectives. The estimated selling price of the rights to technological improvements is the Company's best estimate of selling price and was determined by estimating the probability that technological improvements will be made, and the probability that technological improvements made will be used by Lilly. In estimating these probabilities, we considered factors such as the technology that is the subject of the development and commercialization licenses, our history of making technological improvements, and when such improvements, if any, were likely to occur relative to the stage of development of any product candidates pursuant to the development and commercialization licenses. The company's estimate of probability considered the likely period of time that any improvements would be utilized, which was estimated to be ten years following delivery of a commercialization and development license. The value of any technological improvements made available after this ten year period was considered to be de minimis due to the significant additional costs that would be incurred to incorporate such technology into any existing product candidates. The estimate of probability was multiplied by the estimated selling price of the development and commercialization licenses and the resulting cash flow was discounted at a rate of 16%, representing the Company's estimate of its cost of capital at the time. The estimated selling price of the cytotoxic agent was based on third-party evidence given market rates for the manufacture of such cytotoxic agents. The estimated selling price of the research services was based on third party evidence given the nature of the research services to be performed for Lilly and market rates for similar services.

The total arrangement consideration of \$28.2 million (which comprises the \$20 million upfront payment, the exercise fee, if any, for each license, the expected fees for the research services to be provided and the cytotoxic agent to be delivered under the arrangement) was allocated to the deliverables based on the relative selling price method as follows: \$23.5 million to the development and commercialization licenses; \$0.6 million to the rights to future technological improvements, \$0.8 million to the sale of cytotoxic agent; and \$3.3 million to the research services. Upon execution of the development and commercialization license taken by Lilly in August 2013, the Company recorded \$7.8 million of the \$23.5 million of the arrangement consideration outlined above, which is included in license and milestone fee revenue for the year ended June 30, 2014. With this first development and commercialization license taken, the amount of the total arrangement consideration allocated to future technological improvements will commence to be recognized as revenue ratably over the period the Company is obligated to make available any technological improvements, which is the equivalent to the estimated term of the license. The Company

estimates the term of a development and commercialization license to be approximately 25 years, which reflects management's estimate of the time necessary to develop and commercialize therapeutic products pursuant to the license plus the estimated royalty term. The Company will reassess the estimated term at each subsequent reporting period. Upon execution of two development and commercialization licenses taken by Lilly in December 2014, the Company recognized as license revenue the remaining \$15.6 million of arrangement consideration allocated to the development and commercialization licenses, which is included in license and milestone fee revenue for the year ended June 30, 2015. The Company will recognize research services revenue and revenue from the delivery of cytotoxic agents as the related services and cytotoxic agents are delivered.

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Costs directly attributable to the Lilly collaborative agreement are comprised of compensation and benefits related to employees who provided research and development services on behalf of Lilly as well as costs of clinical materials sold. Indirect costs are not identified to individual collaborators. The costs related to the research and development services amounted to approximately \$182,000, \$499,000 and \$1.2 million for fiscal years 2016, 2015 and 2014 respectively. The costs related to clinical materials sold were approximately \$1.1 million, \$1.1 million and \$26,000 for fiscal years 2016, 2015 and 2014, respectively.

### CytomX

In January 2014, the Company entered into a reciprocal right-to-test agreement with CytomX Therapeutics, Inc. (CytomX). The agreement provides CytomX and the Company with the right to test the Company's ADC technology with CytomX masked antibodies, which it calls Probodies™, to create product candidates for a specified number of targets. Each company has defined rights to test the other company's technology with its technology under a right-to-test, or research, license, and to subsequently take an exclusive, worldwide license to use the other company's technology with its technology to develop and commercialize products for the specified targets on terms agreed upon at the inception of the right-to-test agreement. The Company received no upfront cash payment in connection with the execution of the right-to-test agreement. The terms of the right-to-test agreement require the Company and CytomX to each take its respective development and commercialization licenses by the end of the term of the research licenses. In addition, both the Company 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.

In February 2016, CytomX took its development and commercialization license for a specified target. An amendment of the agreement executed simultaneously with that license granted CytomX the right, for a specified period of time, to substitute the specified target with another as yet unspecified target. Accordingly, the revenue associated with this license is being deferred until the expiration of that substitution right. With respect to the development and commercialization license taken by CytomX, the Company is entitled to receive up to a total of \$160 million in milestone payments plus royalties on the commercial sales of any resulting product. The total milestones are categorized as follows: development milestones—\$10 million; regulatory milestones—\$50 million; and sales milestones—\$100 million. Assuming no annual maintenance fee is payable as described below, the next payment the Company could receive would be a \$1 million development milestone payment with commencement of a Phase I clinical trial. At the time of execution of the right to test agreement, there was significant uncertainty as to whether the milestone related to the Phase I clinical trial would be achieved. In consideration of this, as well as the Company's expected involvement in the research and manufacturing of any product candidate, this milestone was deemed substantive. CytomX is responsible for the manufacturing, product development and marketing of any PDC resulting from the development and commercialization license taken by CytomX under this collaboration.

With respect to any development and commercialization license that may be taken by the Company, the Company 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. The total milestones per license are categorized as follows: development milestones—\$7 million; regulatory milestones—\$23 million; and sales milestones—\$50 million. Assuming no annual maintenance fee is payable as described below, the next payment the Company could be required to make is a \$1 million development milestone payment with commencement of a Phase I clinical trial. The Company is responsible for the manufacturing, product development and marketing of any PDC resulting from any development and commercialization license taken by the Company under this collaboration.

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.

The arrangement was accounted for based on the fair value of the items exchanged. The items to be delivered to CytomX under the arrangement are accounted for under the Company's revenue recognition policy. The items to be received from CytomX are recorded as research and development expenses as incurred.

In accordance with ASC 605-25 (as amended by ASU No. 2009-13), the Company identified all of the deliverables at the inception of the right to test agreement. The significant deliverables were determined to be the right to test, or research, license, the exclusive development and commercialization license, rights to future technological improvements, and the research services. The research license in the right to test agreement was determined not to be substantive and, as a result, the exclusive development and commercialization license was

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considered a deliverable at the inception of the right to test agreement. Factors that were considered in determining the research license was not substantive included (i) the overall objective of the agreement is for CytomX to obtain a development and commercialization license, (ii) there are no exercise fees payable upon taking the development and commercialization license, (iii) the limited economic benefit that CytomX could obtain from the right to test agreement unless CytomX was able to take the development and commercialization license, and (iv) the lack of economic penalties as a result of taking the license.

The Company has determined that the research license from the Company to CytomX together with the development and commercialization license from the Company to CytomX represent one unit of accounting as the research license does not have stand alone value from the development and commercialization license due to the lack of transferability of the research license and the limited economic benefit CytomX would derive if they did not obtain any development and commercialization license. The Company has also determined that this unit of accounting has stand alone value from the rights to future technological improvements and the research services. The rights to future technological improvements and the research services are considered separate units of accounting as each of these was determined to have stand alone value. The rights to future technological improvements have stand alone value as CytomX would be able to use those items for their intended purpose without the undelivered elements. The research services have stand alone value as similar services are sold separately by other vendors.

The estimated selling price for the development and commercialization license is the Company's best estimate of selling price and was determined based on market conditions, similar arrangements entered into by third parties, including pricing terms offered by the Company's competitors for single target development and commercialization licenses that utilize antibody drug conjugate technology, and entity specific factors such as the pricing terms of the Company's previous single target development and commercialization licenses, recent preclinical and clinical testing results of therapeutic products that use the Company's ADC technology, and the Company's pricing practices and pricing objectives. In order to determine the best estimate of selling price, the Company determined the overall value of a license by calculating a risk adjusted net present value of a recent, comparable transaction the Company entered into with another collaborator. This overall value was then decreased by risk adjusting the net present value of the contingent consideration (the milestones and royalties) payable by CytomX under the development and commercialization license. This amount represents the value that a third party would be willing to pay as an upfront payment for this license to the Company's technology.

The estimated selling price of the rights to technological improvements is the Company's best estimate of selling price and was determined by estimating the probability that technological improvements will be made, and the probability that technological improvements made will be used by CytomX. In estimating these probabilities, the Company considered factors such as the technology that is the subject of the development and commercialization license, the Company's history of making technological improvements, and when such improvements, if any, were likely to occur relative to the stage of development of the product candidate pursuant to the development and commercialization license. The Company's estimate of probability considered the likely period of time that any improvements would be utilized, which was estimated to be ten years following delivery of the commercialization and development license. The value of any technological improvements made available after this ten year period was considered to be de minimis due to the significant additional costs that would be incurred to incorporate such technology into any existing product candidate. The estimate of probability was multiplied by the estimated selling price of the development and commercialization license and the resulting cash flow was discounted at a rate of 13%, representing the Company's estimate of its cost of capital at the time.

The estimated selling price of the research services was based on third party evidence given the nature of the research services to be performed for CytomX and market rates for similar services.

The total allocable consideration of \$13.1 million (which comprises the \$13.0 million that a third party would be willing to pay as an upfront payment for this license to the Company's technology plus \$140,000 for the fair value of fees for the research services to be provided) was allocated to the deliverables based on the relative selling price method as follows: \$12.7 million to the development and commercialization license; \$350,000 to the rights to future technological improvements and \$140,000 to the research services. The Company will recognize as license revenue the amount of the total allocable consideration allocated to the development and commercialization license when the substitution right under the license expires, as discussed previously above. At that time, the amount of the total allocable consideration allocated to future technological improvements will commence to be recognized as revenue ratably over the period the Company is obligated to make available any technological improvements, which is the equivalent to the estimated term of the license. The Company estimates the term of a development and commercialization license to be



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approximately 25 years, which reflects management's estimate of the time necessary to develop and commercialize therapeutic products pursuant to the license plus the estimated royalty term. The Company will be required to reassess the estimated term at each subsequent reporting period.

No license fee revenue has been recognized related to this agreement through June 30, 2016 as the research license was not considered to be substantive and a non-substitutable development and commercialization license had not been delivered at this time. The period for CytomX to exercise its substitution right expires in January 2017. Accordingly, the \$12.7 million allocated to the development and commercialization license is included in short-term deferred revenue as of June 30, 2016. The Company will recognize research services revenue as the related services are delivered.

The \$13.1 million of total allocable consideration to be accounted for as revenue described above is also the amount that was used to account for the expense of the licenses and research services the Company received or will receive from CytomX. Based on an estimate of the research services that CytomX will be providing to the Company for no monetary consideration, \$310,000 was allocated to such services and will be expensed over the period the services are provided. The balance of \$12.8 million pertains to technology rights received and these amounts have been charged to research and development expense during the year ended June 30, 2014 upon execution of the research agreement.

Costs directly attributable to the CytomX collaborative agreement are comprised of compensation and benefits related to employees who provided research and development services on behalf of CytomX. Indirect costs are not identified to individual collaborators. The costs related to the research and development services amounted to approximately \$868,000 and \$130,000 for fiscal years 2016 and 2015, respectively. There were no similar costs recorded in fiscal year 2014.

## Takeda

In March 2015, the Company entered into a right-to-test agreement with Takeda Pharmaceutical Company Limited (Takeda) through its wholly owned subsidiary, Millennium Pharmaceuticals, Inc. The agreement provides Takeda with the right to (a) take exclusive options, with certain restrictions, to individual targets selected by Takeda for specified option periods, (b) test the Company's ADC technology with Takeda's antibodies directed to the targets optioned under a right-to-test, or research, license, and (c) take exclusive licenses to use the Company's ADC technology to develop and commercialize products to targets optioned for up to two individual targets on terms specified in the right-to-test agreement. Takeda must exercise its options for the development and commercialization licenses by the end of the three-year term of the right-to-test agreement, after which any then outstanding options will lapse. Takeda has the right to extend the three-year right-to-test period for one additional year by payment to the Company of \$4 million. Alternatively, Takeda has the right to expand the scope of the right-to-test agreement by payment to the Company of \$8 million. If Takeda opts to expand the scope of the right-to-test agreement, it will be entitled to take additional exclusive options, one of which may be exercised for an additional development and commercialization license, and the right-to test period will be extended until the fifth anniversary of the effective date of the right-to-test agreement. Takeda is responsible for the manufacturing, product development and marketing of any products resulting from this collaboration.

The Company received a \$20 million upfront payment in connection with the execution of the right-to-test agreement and, for each development and commercialization license taken, is entitled to receive up to a total of \$210 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones—\$30 million; regulatory milestones—\$85 million; and sales milestones—\$95 million. The first potential milestone the Company will be entitled to receive will be a \$5 million development milestone payment with the initiation of a Phase I clinical trial under the first development and commercialization license taken. At the time of execution of this agreement, there was significant uncertainty as to

whether the milestone related to initiation of a Phase I clinical trial under the first development and commercialization license would be achieved. In consideration of this, as well as the Company's expected involvement in the research and manufacturing of these product candidates, this milestone was deemed substantive. The Company also is entitled to receive payments for delivery of cytotoxic agents to Takeda and research and development activities performed on behalf of Takeda.

In accordance with ASC 605-25 (as amended by ASU No. 2009-13), the Company identified all of the deliverables at the inception of the right-to-test agreement. The significant deliverables were determined to be the right-to-test, or research, license, the two exclusive development and commercialization licenses, rights to future technological

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improvements, the development and commercialization license contained in the option to expand the agreement and the research services. The options to obtain two development and commercialization licenses in the right-to-test agreement were determined not to be substantive and, as a result, the exclusive development and commercialization licenses were considered deliverables at the inception of the right-to-test agreement. Factors that were considered in determining the options were not substantive included (i) the overall objective of the agreement was for Takeda to obtain development and commercialization licenses, (ii) no additional consideration required for each development and commercialization license taken beyond the \$20 million upfront payment that was due at the inception of the right-to-test agreement, (iii) the limited economic benefit that Takeda could obtain from the right-to-test agreement unless it exercised its options to obtain development and commercialization licenses, and (iv) the lack of economic penalties as a result of exercising the options.

The option to expand the scope of the right-to-test agreement and obtain, among other deliverables, a third development and commercialization license was not determined to be substantive and, as a result, the third development and commercialization license was considered a deliverable at the inception of the right-to-test agreement. Factors that were considered in determining this option was not substantive included (i) the overall objective of the agreement was for Takeda to obtain development and commercialization licenses and (ii) the relative size of the \$8 million option payment in exchange for this third development and commercialization license and two year extension of the right-to-test period when compared to the \$20 million upfront payment in exchange for, among other deliverables, two development and commercialization licenses and the separate ability to extend the right-to-test period for one year in exchange for a \$4 million payment.

The Company has determined that the research license together with the development and commercialization licenses represent one unit of accounting as the research license does not have stand-alone value from the development and commercialization licenses due to the lack of transferability of the research license and the limited economic benefit Takeda would derive if they did not obtain any development and commercialization licenses. The Company has also determined that this unit of accounting has stand-alone value from the rights to future technological improvements, the license contained in the option to expand the agreement and the research services. The license contained in the option to expand the agreement has stand-alone value as it would result in an additional license with which Takeda would derive economic benefit. The rights to future technological improvements have stand-alone value as Takeda would be able to use those items for their intended purpose without the undelivered elements. The research services have stand-alone value as similar services are sold separately by other vendors.

The estimated selling prices for the development and commercialization licenses are the Company's best estimate of selling price and were determined based on market conditions, similar arrangements entered into by third parties, including pricing terms offered by our competitors for single-target development and commercialization licenses that utilize antibody-drug conjugate technology, and entity-specific factors such as the pricing terms of the Company's previous single-target development and commercialization licenses, recent preclinical and clinical testing results of therapeutic products that use the Company's ADC technology, and the Company's pricing practices and pricing objectives. The estimated selling price of the rights to technological improvements is the Company's best estimate of selling price and was determined by estimating the probability that technological improvements will be made, and the probability that technological improvements made will be used by Takeda. In estimating these probabilities, the Company considered factors such as the technology that is the subject of the development and commercialization licenses, our history of making technological improvements, and when such improvements, if any, were likely to occur relative to the stage of development of any product candidates pursuant to the development and commercialization licenses. The Company's estimate of probability considered the likely period of time that any improvements would be utilized, which was estimated to be ten years following delivery of a commercialization and development license. The value of any technological improvements made available after this ten year period was considered to be de minimis due to the significant additional costs that would be incurred to incorporate such technology into any existing product candidates. The estimate of probability was multiplied by the estimated selling

price of the development and commercialization licenses and the resulting cash flow was discounted at a rate of 13%, representing the Company's estimate of its cost of capital at the time. The estimated selling price of the research services was based on third-party evidence given the nature of the research services to be performed for Takeda and market rates for similar services.

The total arrangement consideration of \$31.4 million (which comprises the \$20 million upfront payment, the \$8 million payment to expand the agreement and the expected fees for the research services to be provided) was allocated to the deliverables based on the relative selling price method as follows: \$25.9 million to the three development and commercialization licenses; \$2.1 million to the rights to future technological improvements; and \$3.4 million to the research services. The first license was taken by Takeda in December 2015, and as a result, the Company recognized

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\$8.6 million of the \$25.9 million of arrangement consideration allocated to the development and commercialization licenses, which is included in license and milestone fee revenue for the year ended June 30, 2016. With this first development and commercialization license taken, the amount of the total arrangement consideration allocated to future technological improvements will commence to be recognized as revenue ratably over the period the Company is obligated to make available any technological improvements, which is the equivalent to the estimated term of the license. The Company estimates the term of a development and commercialization license to be approximately 25 years, which reflects management's estimate of the time necessary to develop and commercialize therapeutic products pursuant to the license plus the estimated royalty term. The Company will reassess the estimated term at each subsequent reporting period. The Company will recognize as license revenue an equal amount of the total remaining \$17.3 million of arrangement consideration allocated to the development and commercialization licenses as each individual license is delivered to Takeda upon Takeda's exercise of its remaining options to such licenses. The Company does not control when Takeda will exercise its options for development and commercialization licenses. As a result, the Company cannot predict when it will recognize the related license revenue except that it will be within the term of the research license. The Company will recognize research services revenue as the related services are delivered.

Costs directly attributable to the Takeda collaborative agreement are comprised of compensation and benefits related to employees who provided research and development services on behalf of Takeda. Indirect costs are not identified to individual collaborators. The costs related to the research and development services amounted to approximately \$469,000 and \$113,000 for fiscal years 2016 and 2015, respectively. There were no similar costs recorded in fiscal year 2014.

## Other Collaborative Agreements

In December 2004, the Company entered into a development and license agreement with a predecessor to Janssen Biotech (formerly known as Centocor), a wholly owned subsidiary of Johnson & Johnson. Under the terms of this agreement, Janssen was granted exclusive worldwide rights to develop and commercialize anticancer therapeutics that consist of the Company's maytansinoid cell killing agent attached to an  $\alpha$  v integrin targeting antibody that was developed by Janssen. Per notice to the Company, effective July 2014, Janssen relinquished its rights to the target. Accordingly, the Company recognized the remaining \$241,000 of the \$1 million upfront fee received from Janssen upon execution of the 2004 license agreement and is included in license and milestone fee revenue for the fiscal year ended June 30, 2015.

## D. Property and Equipment

Property and equipment consisted of the following at June 30, 2016 and 2015 (in thousands):

	June 30, 2016	2015
Leasehold improvements	\$ 34,743	\$ 32,355
Machinery and equipment	24,324	18,398
Computer hardware and software	8,277	6,897
Furniture and fixtures	3,636	3,290
Assets under construction	2,327	2,361
	\$ 73,307	\$ 63,301
Less accumulated depreciation	(50,603)	(47,047)

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Property and equipment, net	\$ 22,704	\$ 16,254
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Depreciation expense was approximately \$5.3 million, \$5.5 million and \$4.6 million for each of the years ended June 30, 2016, 2015 and 2014, respectively. Included in the table above, the Company's investment in equipment under capital leases was \$876,000, net of accumulated amortization of \$414,000, at June 30, 2016 and \$724,000, net of accumulated amortization of \$190,000, at June 30, 2015.

E. Convertible 4.5% Senior Notes

In June 2016, the Company issued Convertible 4.5% Senior Notes with an aggregate principal amount of \$100 million. The Company received net proceeds of approximately \$96.6 million from the sale of the Convertible Notes, after deducting fees and expenses of approximately \$3.4 million.

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The Convertible Notes are governed by the terms of an indenture between the Company, as issuer, and Wilmington Trust, National Association, as the trustee. The Convertible Notes are senior unsecured obligations and bear interest at a rate of 4.5% per year, payable semi-annually in arrears on January 1 and July 1 of each year, commencing on January 1, 2017. The Company recorded approximately \$138,000 of interest expense for the year ended June 30, 2016 which is included in other (expense) income, net in the consolidated statements of operations. The Convertible Notes will mature on July 1, 2021, unless earlier repurchased or converted. Holders may convert their notes at their option at any time prior to the close of business on the business day immediately preceding the stated maturity date. Upon conversion, the Company will deliver for each \$1,000 principal amount of converted notes a number of shares equally to the conversion rate, which will initially be 238.7775 shares of common stock, equivalent to an initial conversion price of approximately \$4.19. The conversion rate will be subject to adjustment in some circumstances, but will not be adjusted for any accrued and unpaid interest. In addition, if a “make-whole fundamental change” (as defined in the offering memorandum) occurs prior to the stated maturity date, the Company will increase the conversion rate for a holder who elects to convert its notes in connection with such make-whole fundamental change in certain circumstances. If the Company undergoes a fundamental change, subject to certain conditions, holders may require the Company to repurchase for cash all or part of their notes at a purchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change purchase date. In addition, upon an event of default, the holders may require the Company to repurchase for cash all of their notes at a purchase price equal to 100% of the principal amount, plus accrued and unpaid interest. Upon bankruptcy, this becomes an automatic repurchase obligation. Also, if the Company fails to comply with certain reporting requirements as described in the indenture it will constitute an event of default, however the Company may elect to pay additional interest at an annual rate equal to 0.5% of the principal amount for the 90 days following such event as a remedy for the default. Subsequent to the 90 days, if still in default, the principal amount of the notes and accrued interest may become immediately due and payable. If a “restricted event” occurs as described in the indenture that causes the notes not to become freely tradable by holders other than our affiliates after the first anniversary of the original issuance date of the notes, the Company would also become obligated to pay additional interest at an annual rate equal to 0.5% of the principal amount. The combined additional interest rate under these two circumstances, however, cannot exceed 0.5%.

The Company analyzed the terms of the Convertible Notes and determined that under current accounting guidance the notes would be entirely accounted for as debt and none of the terms of the notes require separate accounting. As part of the issuance of the Convertible Notes, the Company incurred \$3.4 million of transaction costs, which are capitalized in the accompanying consolidated balance sheet as deferred financing costs and will be amortized to interest expense ratably over the term of the Convertible Notes.

#### F. Liability Related to Sale of Future Royalties

In April 2015, IRH purchased the right to receive 100% of the royalty payments on commercial sales of Kadcyła arising under the Company’s development and commercialization license with Genentech, until IRH has received aggregate royalties equal to \$235 million or \$260 million, depending on when the aggregate royalties received by IRH reach a specified milestone. Once the applicable threshold is met, if ever, the Company will thereafter receive 85% and IRH will receive 15% of the Kadcyła royalties for the remaining royalty term. At consummation of the transaction in April 2015, the Company received cash proceeds of \$200 million. As part of this sale, the Company incurred \$5.9 million of transaction costs, which are capitalized in the accompanying consolidated balance sheet as deferred financing costs and will be amortized to interest expense over the estimated life of the royalty purchase agreement. Although the Company sold its rights to receive royalties from the sales of Kadcyła, as a result of its ongoing involvement in the cash flows related to these royalties, the Company will continue to account for these royalties as revenue and recorded the \$200 million in proceeds from this transaction as a liability related to sale of future royalties

(Royalty Obligation) that will be amortized using the interest method over the estimated life of the royalty purchase agreement.

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The following table shows the activity within the liability account during the year ended June 30, 2016 (in thousands):

	Year ended June 30, 2016	Period from inception to June 30, 2016
Liability related to sale of future royalties — beginning balance	\$ 199,662	\$ —
Proceeds from sale of future royalties	—	200,000
Non-cash Kadcyła royalty revenue	(25,299)	(30,783)
Non-cash interest expense recognized	19,009	24,155
Liability related to sale of future royalties — ending balance	\$ 193,372	\$ 193,372

As royalties are remitted to IRH, the balance of the Royalty Obligation will be effectively repaid over the life of the agreement. In order to determine the amortization of the Royalty Obligation, the Company is required to estimate the total amount of future royalty payments to be received and remitted to IRH as noted above over the life of the agreement. The sum of these amounts less the \$200 million proceeds the Company received will be recorded as interest expense over the life of the Royalty Obligation. Since inception, the Company's estimate of this total interest expense resulted in an effective annual interest rate of approximately 9.6%. The Company periodically assesses the estimated royalty payments to IRH and to the extent such payments are greater or less than its initial estimates, or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the amortization of the Royalty Obligation. There are a number of factors that could materially affect the amount and timing of royalty payments from Genentech, most of which are not within the Company's control. Such factors include, but are not limited to, changing standards of care, the introduction of competing products, manufacturing or other delays, biosimilar competition, patent protection, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates as the royalties remitted to IRH are made in U.S. dollars (USD) while significant portions of the underlying sales of Kadcyła are made in currencies other than USD, and other events or circumstances that could result in reduced royalty payments from Kadcyła, all of which would result in a reduction of non-cash royalty revenues and the non-cash interest expense over the life of the Royalty Obligation. Conversely, if sales of Kadcyła are more than expected, the non-cash royalty revenues and the non-cash interest expense recorded by the Company would be greater over the term of the Royalty Obligation.

In addition, the royalty purchase agreement grants IRH the right to receive certain reports and other information relating to the royalties and contains other representations and warranties, covenants and indemnification obligations that are customary for a transaction of this nature.

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## G. Income Taxes

The difference between the Company's expected tax benefit, as computed by applying the U.S. federal corporate tax rate of 34% to loss before the benefit for income taxes, and actual tax is reconciled in the following chart (in thousands):

	Year Ended June 30,		
	2016	2015	2014
Loss before income tax expense	\$ (144,817)	\$ (60,739)	\$ (71,364)
Expected tax benefit at 34%	\$ (49,238)	\$ (20,651)	\$ (24,264)
Permanent differences	345	818	215
Incentive stock options	2,501	1,948	1,738
State tax benefit net of federal benefit	(7,954)	(3,252)	(4,062)
Increase in valuation allowance, net	62,505	27,940	26,011
Federal research credit	(4,109)	(1,407)	(1,002)
Federal orphan drug credit	(4,241)	(5,471)	—
Expired loss and credit carryforwards	184	75	1,364
Other	7	—	—
Benefit for income taxes	\$ —	\$ —	\$ —

At June 30, 2016, the Company has net operating loss, or NOL, carryforwards of approximately \$377.9 million available to reduce federal taxable income, if any, that expire in 2028 through 2036 and \$214.0 million available to reduce state taxable income, if any, that expire in fiscal 2033 through fiscal 2036. Included in the federal and state carryforwards is \$27.0 million and \$20.5 million, respectively, related to deductions from the exercise of stock options and the related tax benefit which will result in an increase in additional paid in capital if and when realized through a reduction of taxes paid in cash. The Company also has federal and state credit carryforwards of approximately \$40.4 million available to offset federal and state income taxes, which expire beginning in 2017. Due to the degree of uncertainty related to the ultimate use of the loss carryforwards and tax credits, the Company has established a valuation allowance to fully reserve these tax benefits.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities as of June 30, 2016 and 2015 are as follows (in thousands):

	June 30,	
	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	\$ 139,791	\$ 89,362
Research and development tax credit carryforwards	36,879	25,131
Property and other intangible assets	2,395	2,532
Deferred revenue	12,911	16,179
Stock-based compensation	16,033	11,379
Deferred lease incentive	4,356	4,279
Other liabilities	3,726	3,177
Royalty sale	75,956	78,427
Total deferred tax assets	\$ 292,047	\$ 230,466
Deferred tax liabilities:		

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Accounting method change	(492)	(983)
Royalty sale transaction costs	(1,757)	(2,190)
Total deferred tax liabilities	\$ (2,249)	\$ (3,173)
Valuation allowance	(289,798)	(227,293)
Net deferred tax assets/(liabilities)	\$ —	\$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. As required by the provisions of ASC 740, the Company has determined that it is not more-likely-than-not that the tax benefits related to the federal and state deferred tax assets will be realized for financial reporting purposes.

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Accordingly, the deferred tax assets have been fully reserved at June 30, 2016 and 2015. The valuation allowance increased by \$62.5 million during 2016 due primarily to additional net loss incurred during the year and additional research and development tax credits earned during the year, partially offset by the expiration of net operating loss carryforwards.

Utilization of the NOL and credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future as provided by Section 382 of the Internal Revenue Code of 1986, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and credit carry forwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three year period. Since the Company's formation, it has raised capital through the issuance of capital stock on several occasions (both pre and post initial public offering) which, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition. During fiscal year 2015, the Company completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since its formation and determined no ownership change occurred under Section 382. The study has not been updated for fiscal year 2016. Additionally, the Company has not completed a Research and Development Credit Study; accordingly, it is probable that a portion of the tax credit carryforward may not be available to offset future income.

The Company accounts for uncertain tax positions under the recognition and measurement criteria of ASC 740-10. For those tax positions for which it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50% likelihood of being realized upon settlement with a taxing authority that has full knowledge of all relevant information. If the Company does not believe that it is not more likely than not that a tax benefit will be sustained, no tax benefit is recognized. As of June 30, 2016 and 2015, no uncertain tax positions have been recorded. Interest and penalties related to the settlement of uncertain tax positions, if any, will be reflected in income tax expense. The Company did not recognize any interest and penalties associated with unrecognized tax benefits in the accompanying consolidated financial statements. The Company does not expect any material changes to the unrecognized benefits within 12 months of the reporting date. Due to existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact our effective tax rate.

The statute of limitations for assessment by the Internal Revenue Service, or IRS, and state tax authorities is open for tax years ending June 30, 2013, 2014, 2015 and 2016, although carryforward attributes that were generated prior to fiscal year 2013 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period.

## H. Capital Stock

### Common Stock Reserved

At June 30, 2016, the Company has reserved 15.5 million shares of authorized common stock for the future issuance of shares under the 2006 Plan and the 2004 Director Plan. See "Stock Based Compensation" in Note B for a description of the 2006 Plan and the Former Plan and below for a description of the 2004 Director Plan.

### Stock Options

As of June 30, 2016, the 2006 Plan was the only employee share based compensation plan of the Company. During the year ended June 30, 2016, holders of options issued under the 2006 Plan and the Former Plan exercised their rights to acquire an aggregate of 555,000 shares of common stock at prices ranging from \$3.19 to \$17.00 per share. The total proceeds to the Company from these option exercises were approximately \$5.2 million.

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The Company granted options with an exercise price equal to the fair market value of the common stock on the date of such grant. The following options and their respective weighted average exercise prices per share were exercisable at June 30, 2016, 2015 and 2014:

	Exercisable (in thousands)	Weighted Average Exercise Price
June 30, 2016	6,453	\$ 12.63
June 30, 2015	5,380	\$ 11.89
June 30, 2014	4,637	\$ 9.79

## 2001 Non Employee Director Stock Plan

In November 2001, the Company's shareholders approved the establishment of the 2001 Non Employee Director Stock Plan, or the 2001 Director Plan, and 50,000 shares of common stock to be reserved for grant thereunder. The 2001 Director Plan provided for the granting of awards to Non Employee Directors and, at the election of Non Employee Directors, to have all or a portion of their awards in the form of cash, stock, or stock units. All stock or stock units are immediately vested. The number of stock or stock units issued was determined by the market value of the Company's common stock on the last date of the Company's fiscal quarter for which the services are rendered. The 2001 Director Plan was administered by the Board of Directors which was authorized to interpret the provisions of the 2001 Director Plan, determine which Non Employee Directors would be granted awards, and determine the number of shares of stock for which a stock right will be granted. The 2001 Director Plan was replaced in 2004 by the 2004 Non Employee Director Compensation and Deferred Share Unit Plan.

During the years ended June 30, 2016, 2015 and 2014, the Company recorded approximately \$(72,000), \$16,000, and \$(30,000) in (expense reduction) compensation expense, respectively, related to approximately 6,000 stock units outstanding under the 2001 Director Plan. The value of the stock units is adjusted to market value at each reporting period. No stock units have been issued under the 2001 Plan subsequent to June 30, 2004.

## 2004 Non Employee Director Compensation and Deferred Share Unit Plan

In June 2004, the Board of Directors approved the establishment of the 2004 Non Employee Director Compensation and Deferred Share Unit Plan, or the 2004 Director Plan. The 2004 Director Plan provided for the compensation of Non Employee Directors, awarding their annual retainers in the form of deferred share units, and, at their discretion, to have all or a portion of their other compensation such as meeting fees in the form of cash or deferred share units. The deferred share units for annual retainers vested one twelfth monthly over the next year after the award; other deferred share units vested immediately upon issuance. The number of deferred share units issued was determined by the market value of the Company's common stock on the last date of the Company's fiscal year prior to the fiscal year for which services were rendered. The deferred share units were to be paid out in cash to each non employee director based upon the market value of the Company's common stock on the date of such director's retirement from the Board of Directors of the Company. The 2004 Director Plan was administered by the Board of Directors.

The 2004 Director Plan was amended on September 5, 2006. Under the terms of the amended 2004 Director Plan, the redemption amount of deferred share units will be paid in shares of common stock of the Company under the 2006 Plan in lieu of cash. As a result of the change in payout structure, the value of the vested awards was transferred to additional paid in capital as of the modification date and the total value of the awards, as calculated on the modification date, was expensed over the remainder of the vesting period. Accordingly, the value of the share units is fixed and will no longer be adjusted to market value at each reporting period. In addition, the amended 2004 Director Plan changed the vesting for annual retainers to take place quarterly over the three years after the award and the

number of deferred share units awarded for all compensation is now based on the market value of the Company's common stock on the date of the award.

#### Compensation Policy for Non Employee Directors

On September 16, 2009, the Board adopted a new Compensation Policy for Non Employee Directors, which superseded the 2004 Plan and made certain changes to the compensation of its non employee directors. The policy was amended on November 11, 2009 to provide that, whenever the Board has a non employee Chairman in lieu of a Lead Director, the cash payment for the non employee Chairman of the Board shall be the same as the cash compensation that would otherwise have been payable to the Lead Director. Effective November 12, 2009, non employee directors became entitled to receive annual meeting fees and committee fees under the new policy. The new policy made changes to the

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equity portion of the non employee director compensation, but left the cash portion unchanged. Effective November 11, 2009, non employee directors became entitled to receive deferred stock units under the new policy as follows:

- New non employee directors will be initially awarded a number of deferred stock units having an aggregate market value of \$65,000, based on the closing price of our common stock on the date of their initial election to the Board. These awards will vest quarterly over three years from the date of grant, contingent upon the individual remaining a director of ImmunoGen as of each vesting date.
- On the first anniversary of a non employee director's initial election to the Board, such non employee director will be awarded a number of deferred stock units having an aggregate market value of \$30,000, based on the closing price of our common stock on such date of grant and pro rated based on the number of whole months remaining between the first day of the month in which such grant date occurs and the first October 31 following the grant date. These awards will generally vest quarterly over approximately the period from the grant date to the first November 1 following the grant date, contingent upon the individual remaining a director of ImmunoGen as of each vesting date.
- Thereafter, non employee directors in general will be annually awarded a number of deferred stock units having an aggregate market value of \$30,000, based on the closing price of our common stock on the date of our annual meeting of shareholders. These awards will vest quarterly over approximately one year from the date of grant, contingent upon the individual remaining a director of ImmunoGen as of each vesting date.

As with the 2004 Plan, vested deferred stock units are redeemed on the date a director ceases to be a member of the Board, at which time such director's deferred stock units will be settled in shares of our common stock issued under our 2006 Plan at a rate of one share for each vested deferred stock unit then held. Any deferred stock units that remain unvested at that time will be forfeited. The new policy provides that all unvested deferred stock units will automatically vest immediately prior to the occurrence of a change of control, as defined in the 2006 Plan. Pursuant to the Compensation Policy for Non- Employee Directors, the Company issued a retiring director 43,615 shares of common stock in November 2013.

In connection with the adoption of the new compensation policy, the Board also amended the 2004 Plan as follows:

- All unvested deferred stock awards (other than any unvested initial awards) were vested in full on September 16, 2009 unless the date such deferred stock units were credited to the non employee director was less than one year prior to September 16, 2009, in which case such unvested deferred stock units will vest on the first anniversary of the date such deferred stock units were credited to the non employee director.
- All unvested deferred stock awards will automatically vest immediately prior to the occurrence of a change of control.

On September 22, 2010, the Board revised the Compensation Policy for Non Employee Directors to provide that, in addition to the compensation they received previously, they would also become entitled to receive stock option awards having a grant date fair value of \$30,000, determined using the Black Scholes option pricing model measured on the date of grant, which would be the date of the annual meeting of shareholders.

On November 12, 2013, the Board amended the Compensation Policy for Non Employee Directors to make certain changes to the compensation of its non employee directors, including an increase in the fees paid in cash to the non employee directors. Under the terms of the amended policy, the redemption amount of deferred share units issued will continue to be paid in shares of common stock of the Company on the date a director ceases to be a member of the Board. Annual retainers vest quarterly over approximately one year from the date of grant, contingent upon the individual remaining a director of ImmunoGen as of each vesting date. The number of deferred share units awarded is now fixed per the plan on the date of the award and is no longer based on the market price of the Company's common stock on the date of the award. All unvested deferred stock awards will automatically vest immediately prior to the occurrence of a change of control.



In addition to the deferred share units, the Non Employee Directors are now also entitled to receive a fixed number of stock options instead of a fixed grant date fair value of options, determined using the Black Scholes option

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pricing model measured on the date of grant, which would be the date of the annual meeting of shareholders. These options vest quarterly over approximately one year from the date of grant. Any new directors will receive a pro-rated award, depending on their date of election to the Board. The directors received a total of 80,000 options in each fiscal year ended 2016, 2015 and 2014, and the related compensation expense is included in the amounts discussed in the “Stock Based Compensation” section of footnote B above.

Pursuant to the Compensation Policy for Non-Employee Directors, as amended, the Company recorded approximately:

- \$380,000 in compensation expense during the year ended June 30, 2016 related to the grant of 41,000 deferred share units and 12,000 deferred share units previously granted;
- \$389,000 in compensation expense during the year ended June 30, 2015 related to the grant of 31,000 deferred share units and 15,000 deferred share units previously granted; and
- \$433,000 in compensation expense during the year ended June 30, 2014 related to the grant of 28,000 deferred share units and 19,000 deferred share units previously granted.

I. Commitments and Contingencies

Leases

The Company currently has a lease agreement with CRP/King 830 Winter L.L.C. for the rental of approximately 110,000 square feet of laboratory and office space at 830 Winter Street, Waltham, MA through March 2026. The Company uses this space for its corporate headquarters and other operations. The Company may extend the lease for two additional terms of five years. Pursuant to lease amendments executed in December 2013 and April 2014, the Company received construction allowances of approximately \$746,000 and \$1.1 million, respectively, to build out office and lab space to the Company’s specifications, and will receive up to \$196,000 as a construction allowance pursuant to an amendment executed in December 2015. The Company is required to pay certain operating expenses for the leased premises subject to escalation charges for certain expense increases over a base amount.

In February 2016, the Company entered into a lease agreement with PDM 930 Unit, LLC for the rental of 10,281 square feet of additional office space at 930 Winter Street, Waltham, MA through August 31, 2021. The Company will receive up to approximately \$617,000 as a construction allowance to build out the office space to the Company’s specifications. The Company is required to pay certain operating expenses for the leased premises based on its pro-rata share of such expenses for the entire rentable space of the building.

The Company also leases 43,850 square feet of manufacturing and office space at 333 Providence Highway, Norwood, MA under an agreement through 2018 with an option to extend the lease for an additional term of five years. The Company is required to pay certain operating expenses for the leased premises subject to escalation charges for certain expense increases over a base amount.

Effective April 2013, the Company entered into a lease agreement with River Ridge Limited Partnership for the rental of 7,507 square feet of additional office space at 100 River Ridge Drive, Norwood, MA. The initial term of the lease was for five years and two months commencing in July 2013 with an option for the Company to extend the lease for an additional term of five years. The Company is required to pay certain operating expenses for the leased premises subject to escalation charges for certain expense increases over a base amount. The Company entered into a sublease in December 2014 for this space, effective January 2015 through the remaining initial term of the lease.

Facilities rent expense, net of sublease income, was approximately \$6.5 million, \$6.0 million and \$5.4 million during fiscal years 2016, 2015 and 2014, respectively.



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As of June 30, 2016, the minimum rental commitments, including real estate taxes and other expenses, for the next five fiscal years and thereafter under the non-cancelable operating lease agreements discussed above are as follows (in thousands):

2017	\$ 7,902
2018	8,056
2019	7,258
2020	7,254
2021	7,302
Thereafter	34,252
Total minimum lease payments	\$ 72,024
Total minimum rental income from subleases	(250)
Total minimum lease payments, net	\$ 71,774

There are no obligations under capital leases as of June 30, 2016, as all of the capital leases were single payment obligations which have all been made.

## Collaborations and Licenses

The Company is contractually obligated to make potential future success-based regulatory milestone payments in conjunction with certain collaborative agreements. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, the Company may be required to pay such amounts. Further, the timing of any future payment is not reasonably estimable. As of June 30, 2014, the maximum amount that may be payable in the future under the Company's current collaborative agreements is \$162 million, \$1.4 million of which is reimbursable by a third party under a separate agreement.

In addition, The Company is party to a license agreement covering the manufacture of the antibodies used in certain of product candidates which, under certain circumstances, requires periodic payments once the product reaches a specified stage of clinical development, and royalties on commercial sales of the product. The Company believes that the license agreement, by its terms, does not obligate it to make any further payments thereunder and accordingly, has not accrued a potential payment of £300,000 for one of its product candidates that has reached this stage.

## Litigation

The Company is not party to any material litigation.

## J. Employee Benefit Plans

The Company has a deferred compensation plan under Section 401(k) of the Internal Revenue Code (the 401(k) Plan). Under the 401(k) Plan, eligible employees are permitted to contribute, subject to certain limitations, up to 100% of their gross salary and the Company's matching contribution is 50% of the first 6% of the eligible employees' contributions. In fiscal years 2016, 2015 and 2014, the Company's contributions to the 401(k) Plan totaled approximately \$1.1 million, \$875,000, and \$710,000, respectively.



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## K. Quarterly Financial Information (Unaudited)

	Fiscal Year 2016			
	First Quarter Ended September 30, 2015	Second Quarter Ended December 31, 2015	Third Quarter Ended March 31, 2016	Fourth Quarter Ended June 30, 2016
	(In thousands, except per share data)			
Revenues:				
License and milestone fees	\$ 6,070	\$ 10,692	\$ 10,077	\$ 76
Royalty revenue	—	195	—	—
Non-cash royalty revenue related to the sale of future royalties	5,684	6,291	7,380	5,944
Research and development support	772	848	1,059	1,335
Clinical materials revenue	2,325	3	1,198	53
Total revenues	14,851	18,029	19,714	7,408
Expenses:				
Research and development	35,132	38,199	36,094	38,652
General and administrative	8,329	8,054	11,235	9,298
Total expenses	43,461	46,253	47,329	47,950
Loss from operations	(28,610)	(28,224)	(27,615)	(40,542)
Non-cash interest expense on liability related to sale of future royalty and senior convertible notes	(5,143)	(5,059)	(4,972)	(4,956)
Other income (expense), net	13	56	659	(424)
Net loss	\$ (33,740)	\$ (33,227)	\$ (31,928)	\$ (45,922)
Basic and diluted net loss per common share	\$ (0.39)	\$ (0.38)	\$ (0.37)	\$ (0.53)

	Fiscal Year 2015			
	First Quarter Ended September 30, 2014	Second Quarter Ended December 31, 2014	Third Quarter Ended March 31, 2015	Fourth Quarter Ended June 30, 2015
	(In thousands, except per share data)			
Revenues:				
License and milestone fees	\$ 6,234	\$ 41,417	\$ 5,078	\$ 5,086
Royalty revenue	4,166	4,625	5,099	(23)
Non-cash royalty revenue related to the sale of future royalties	—	—	—	5,484
Research and development support	776	832	532	708
Clinical materials revenue	2,027	1,426	718	1,356
Total revenues	13,203	48,300	11,427	12,611
Expenses:				
Research and development	28,018	27,647	25,666	30,437

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General and administrative	7,095	6,872	7,000	7,261
Total expenses	35,113	34,519	32,666	37,698
(Loss) income from operations	(21,910)	13,781	(21,239)	(25,087)
Non-cash interest expense on liability related to sale of future royalty	—	—	—	(5,437)
Other (expense) income, net	(372)	(146)	(379)	50
Net (loss) income	\$ (22,282)	\$ 13,635	\$ (21,618)	\$ (30,474)
Basic and diluted net (loss) income per common share	\$ (0.26)	\$ 0.16	\$ (0.25)	\$ (0.35)

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

1. Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of the end of such period, our disclosure controls and procedures were adequate and effective.

2. Internal Control Over Financial Reporting

(a) Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the U.S. and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of June 30, 2016. In making this assessment, management used the criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in 2013.

Based on this assessment, management has concluded that, as of June 30, 2016 our internal control over financial reporting is effective.

Ernst & Young LLP, our independent registered public accounting firm, has issued a report on the effectiveness of our internal control over financial reporting as of June 30, 2016. This report appears immediately below.

(b) Attestation Report of the Independent Registered Public Accounting Firm





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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of ImmunoGen, Inc.

We have audited ImmunoGen, Inc.'s internal control over financial reporting as of June 30, 2016, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework)(the COSO criteria). ImmunoGen, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, ImmunoGen, Inc. maintained, in all material respects, effective internal control over financial reporting as of June 30, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of ImmunoGen, Inc. as of June 30, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, shareholders' (deficit) equity and cash flows for each of the three years in the period ended June 30, 2016 and our report dated August 25, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

August 25, 2016

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(c)Changes in Internal Control Over Financial Reporting

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

3.Limitations on the Effectiveness of Controls

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or its internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within an organization have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of simple error or mistake.

Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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Item 9B. Other Information

None.

PART III

The information called for by Part III of Form 10 K (Item 10—Directors, Executive Officers and Corporate Governance of the Registrant, Item 11—Executive Compensation, Item 12—Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, Item 13—Certain Relationships and Related Transactions, and Director Independence, and Item 14—Principal Accounting Fees and Services) is incorporated by reference from our proxy statement related to our 2016 annual meeting of shareholders, which will be filed with the Securities and Exchange Commission not later than October 28, 2016 (120 days after the end of the fiscal year covered by this Annual Report on Form 10 K), except that information required by Item 10 concerning our executive officers appears in Part I, Item 3.1 of this Annual Report on Form 10 K.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Financial Statements:

(1) See “Index to Consolidated Financial Statements” at Item 8 of this Annual Report on Form 10 K. Schedules not included herein are omitted because they are not applicable or the required information appears in the accompanying Consolidated Financial Statements or Notes thereto.

(2) See Exhibit Index following the signature page to this Annual Report on Form 10 K.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Immunogen, Inc.

By: /s/Mark J. Enyedy  
 Mark J. Enyedy  
 President and  
 Chief Executive Officer  
 (Principal Executive Officer)

Dated: August 25, 2016

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Mark J. Enyedy Mark J. Enyedy	President, Chief Executive Officer and Director (Principal Executive Officer)	August 25, 2016
/s/ David B. Johnston David B. Johnston	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	August 25, 2016
/s/ Stephen McCluski Stephen McCluski	Chairman of the Board of Directors	August 25, 2016
/s/ Daniel M. Junius Daniel M. Junius	Director	August 25, 2016
/s/ Mark Goldberg, M.D. Mark Goldberg, M.D.	Director	August 25, 2016
/s/ Dean Mitchell Dean Mitchell	Director	August 25, 2016
/s/ Nicole Onetto, M.D. Nicole Onetto, M.D.	Director	August 25, 2016

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<i>/s/ Kristine Peterson</i> Kristine Peterson	Director	August 25, 2016
<i>/s/ Howard Pien</i> Howard Pien	Director	August 25, 2016
<i>/s/ Joseph Villafranca Ph.D.</i> Joseph Villafranca, Ph.D.	Director	August 25, 2016
<i>/s/ Richard Wallace</i> Richard Wallace	Director	August 25, 2016

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## EXHIBIT INDEX

Exhibit		Filed	Incorporated by Reference		
Number	Exhibit Description	with this Form 10 K	Form	Filing Date with SEC	Exhibit Number
3.1	Restated Articles of Organization, as amended		10 Q	April 30, 2010	3.1
3.1(a)	Articles of Amendment		10 Q	January 30, 2013	3.1
3.2	Amended and Restated By Laws		8 K	June 20, 2016	3.1
4.1	Article 4 of Restated Articles of Organization, as amended (see Exhibit 3.1)				
4.1(a)	Indenture, dated as of June 20, 2016, by and between the Registrant and Wilmington Trust, National Association, as Trustee		8-K	June 20, 2016	4.1
4.2	Form of Common Stock certificate		S 1	November 15, 1989 (File No. 33 31219)	4.2
4.2(a)	Form of Note representing the Registrant's 4.50% Convertible Senior Notes due 2021 (included as Exhibit A to the Indenture filed as Exhibit 4.1(a))				
10.1	Leases dated as of December 1, 1986 and June 21, 1988 by and between James H. Mitchell, Trustee of New Providence Realty Trust, lessor, and Charles River Biotechnical Services, Inc. ("Lessee"), together with Assignment of Leases dated June 29, 1989 between Lessee and the Registrant		S 1	September 22, 1989 (File No. 33 31219)	10.10
10.1(a)	First Amendment to Lease dated May 9, 1991 by and between James H. Mitchell, Trustee of New Providence Realty Trust, lessor, and the Registrant		S 1	November 6, 1991 (File No. 33 43725)	10.10a
10.1(b)	Confirmatory Second Amendment to Lease dated September 17, 1997 by and between James H. Mitchell, Trustee of New Providence Realty Trust, lessor, and the Registrant		10 K	September 26, 1997	10.10
10.1(c)	Third Amendment and Partial Termination of Lease dated as of August 8, 2000 by and between James H. Mitchell, Trustee of New Providence Realty Trust, lessor, and the Registrant		10 K	September 2, 2008	10.1(c)
10.1(d)	Fourth Amendment to Lease dated as of October 3, 2000 by and between James H. Mitchell, Trustee of New Providence Realty Trust, lessor, and the Registrant		10 K	September 2, 2008	10.1(d)
10.1(e)	Fifth Amendment to Lease dated as of June 7, 2001 by and between James H. Mitchell, Trustee of New Providence Realty Trust, lessor, and the		10 K	September 2, 2008	10.1(e)



10.1(f)	Registrant Sixth Amendment to Lease dated as of April 30, 2002 by and between Bobson 333 L.L.C., lessor, and the Registrant	10 K	September 2, 2008	10.1(f)
10.1(g)	Seventh Amendment to Lease dated as of October 20, 2005 by and between Bobson 333 L.L.C., lessor, and the Registrant	10 K	September 2, 2008	10.1(g)
10.1(h)	Eighth Amendment to Lease dated as of February 21, 2007 by and between Bobson 333 L.L.C., lessor, and the Registrant	10 K	September 2, 2008	10.1(h)

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Exhibit Number	Exhibit Description	Filed with this Form 10 K	Incorporated by Reference		
			Form	Filing Date with SEC	Exhibit Number
10.1(i)	Ninth Amendment to Lease dated as of November 17, 2010 by and between Bobson 333 LLC and the Registrant		8 K	November 18, 2010	10.1
10.2	Lease Agreement, dated as of July 27, 2007, by and between Intercontinental Fund III 830 Winter Street LLC, landlord, and the Registrant		10 Q	November 7, 2007	10.2
10.2(a)	First Amendment to Lease Agreement dated as of December 9, 2013, by and between Intercontinental Fund III 830 Winter Street LLC, landlord, and the Registrant		10 Q	February 5, 2014	10.1
10.2(b)	Second Amendment to Lease Agreement dated as of April 28, 2014, by and between Intercontinental Fund III 830 Winter Street LLC, landlord, and the Registrant		10 Q	May 2, 2014	10.1
10.2(c)	Third Amendment to Lease Agreement dated as of December 14, 2015 by and between CRP/King 830 Winter, L.L.C., landlord, and the Registrant		10-Q	February 4, 2016	10.1
10.3*	License Agreement dated effective May 2, 2000 by and between the Registrant and Genentech, Inc.		10 Q	October 31, 2011	10.1
10.3(a)*	Amendment to License Agreement for Anti HER2 Antibodies, dated as of May 3, 2006, between the Registrant and Genentech, Inc.		10 K	August 28, 2006	10.32
10.3(b)*	Amendment to License Agreements made effective as of March 11, 2009, between the Registrant and Genentech, Inc.		10 Q	May 7, 2009	10.1
10.3(c)	Third Amendment to License Agreement for Anti HER2 Antibodies, made effective as of December 18, 2012, between the Registrant and Genentech, Inc.		10 Q	January 30, 2013	10.11
10.4*	Collaboration and License Agreement dated as of July 30, 2003 by and between the Registrant and sanofi aventis U.S. LLC (as successor in interest to Aventis Pharmaceuticals Inc.)		10 K	August 28, 2014	10.4
10.4(a)	Amendment No. 1, dated as of August 31, 2006, to the Collaboration and License Agreement between the Registrant and sanofi aventis U.S. LLC		10 Q	October 30, 2014	10.4
10.4(b)	Amendment No. 2, dated as of December 7, 2007, to the Collaboration and License Agreement between the Registrant and sanofi aventis U.S. LLC		10 Q	October 30, 2014	10.5
10.4(c)	Amendment No. 3, dated as of August 31, 2008, to the Collaboration and License Agreement between the Registrant and sanofi aventis U.S. LLC		10 Q	October 30, 2014	10.6
10.5*	Collaborative Development and License Agreement dated as of July 7, 2006 by and between the Registrant and Biotest AG		10 Q	November 3, 2006	10.2
10.5(a)*	Amendment No. 1, dated August 23, 2006, to Collaborative Development and License Agreement by and between the Registrant and Biotest AG		10 Q	November 3, 2006	10.3



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Exhibit Number	Exhibit Description	Filed with this Form 10 K	Incorporated by Reference		
			Form	Filing Date with SEC	Exhibit Number
10.5(b)*	Amendment No. 2, dated December 10, 2014, to Collaborative Development and License Agreement by and between the Registrant and Biotest AG		10 Q	February 5, 2015	10.1
10.6*	Development and License Agreement dated as of October 20, 2008 by and between the Registrant and Bayer HealthCare AG		10 Q/A	October 10, 2012	10.1
10.7*	Multi Target Agreement dated as of October 8, 2010 by and between the Registrant and Novartis Institutes for BioMedical Research, Inc.		10 Q/A	August 19, 2015	10.2
10.7(a)*	First Amendment, effective as of March 29, 2013, to Multi Target Agreement by and between the Registrant and Novartis Institutes for BioMedical Research, Inc.		10 Q	May 6, 2013	10.1
10.8*	Clinical Supply Agreement effective as of December 12, 2010 by and between the Registrant and Società Italiana Corticosteroidi S.r.l. (Sicor)		10 Q	February 8, 2011	10.1
10.9*	Multi Target Agreement dated as of December 19, 2011 by and between the Registrant and Eli Lilly and Company		10 Q/A	August 19, 2015	10.3
10.9(a)*	First Amendment to Agreements dated as of December 9, 2013 by and between the Registrant and Eli Lilly and Company		10 Q	February 5, 2014	10.2
10.10*	Multi Target Agreement dated as of March 20, 2015 by and between the Registrant and Millennium Pharmaceuticals, Inc.		10 Q	May 8, 2015	10.1
10.11*	Royalty Purchase Agreement dated as of March 24, 2015 by and among the Registrant, Hurricane, LLC and Immunity Royalty Holdings, L.P.		10 Q	May 8, 2015	10.2
10.12†	2006 Employee, Director and Consultant Equity Incentive Plan, as amended and restated through November 11, 2014		8 K	November 13, 2014	10.1
10.12(a)†	Form of Incentive Stock Option Agreement for Executives		S 8	November 15, 2006	99.4
10.12(b)†	Form of Non Qualified Stock Option Agreement for Executives		S 8	November 15, 2006	99.5
10.12(c)†	Form of Non Qualified Stock Option Agreement for Directors		10 Q	October 29, 2010	10.1
10.12(d)†	Form of Director Deferred Stock Unit Agreement		10 Q	October 29, 2010	10.1
10.12(e)†	Form of Incentive Stock Option Agreement for all employees (including executives)		10 K	August 29, 2012	10.14(g)
10.12(f)†	Form of Non Qualified Stock Option Agreement for all employees (including executives)		10 K	August 29, 2012	10.14(h)
10.12(g)†	Form of Non Qualified Stock Option Agreement for Directors		10 K	August 29, 2012	10.14(i)

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10.12(h)†	Form of Restricted Stock Agreement for all employees (including executives)	S 8	November 21, 2012	99.1
10.12(i)†	Form of Incentive Stock Option for all employees (including executives)	8-K	April 26, 2016	10.1
10.12(j)†	Form of Non-Qualified Stock Option Agreement for all employees (including executives)	8-K	April 26, 2016	10.2

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Exhibit Number	Exhibit Description	Filed with this Form 10 K	Incorporated by Reference		
			Form	Filing Date with SEC	Exhibit Number
10.12(k)†	Form of Performance Based Restricted Stock Agreement dated August 12, 2016		8 K	August 17, 2016	10.1
10.13†	2001 Non Employee Director Stock Plan		S 8	December 18, 2001	99
10.14†	2004 Non Employee Director Compensation and Deferred Stock Unit Plan, as amended on September 16, 2009		10 Q	November 4, 2009	10.1
10.15†	Form of Proprietary Information, Inventions and Competition Agreement between the Registrant and each of its executive officers		10 Q	February 8, 2007	10.15
10.16†	Change in Control Severance Agreement dated as of November 30, 2012 between the Registrant and Craig Barrows		10 Q	January 30, 2013	10.1
10.17†	Change in Control Severance Agreement dated as of November 30, 2012 between the Registrant and John M. Lambert		10 Q	January 30, 2013	10.3
10.18†	Change in Control Severance Agreement dated as of November 30, 2012 between the Registrant and Charles Q. Morris		10 Q	January 30, 2013	10.4
10.19†	Change in Control Severance Agreement dated as of November 30, 2012 between the Registrant and Peter Williams		10 Q	January 30, 2013	10.7
10.20†	Compensation Policy for Non Employee Directors, as amended through November 12, 2013		10 Q	February 5, 2014	10.3
10.21†	Change in Control Severance Agreement dated as of December 30, 2013 between the Registrant and David B. Johnston		10 Q	February 5, 2014	10.6
10.22†	Change in Control Severance Agreement dated as of February 20, 2014 between the Registrant and Ellie Harrison		10 Q	May 2, 2014	10.3
10.23†	Severance Pay Plan for Vice Presidents and Higher		8 K	September 18, 2014	10.1
10.24†	Employment offer letter between the Registrant and Sandra E. Poole		10 Q	October 30, 2014	10.1
10.25†	Change in Control Severance Agreement dated as of September 15, 2014 between the Registrant and Sandra E. Poole		10 Q	October 30, 2014	10.2
10.26†	Summary of Annual Bonus Program		8 K	November 13, 2014	10.2
10.27†	Change in Control Severance Agreement dated as of January 5, 2015 between the Registrant and Richard J. Gregory		10 Q	February 5, 2015	10.3
10.28†	Amendment to Option Agreements between the Registrant and Daniel M. Junius		10-Q	May 4, 2016	10.1
10.29†					

X

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	Letter Agreement dated March 31, 2016 between the Registrant and Charles Q. Morris			
10.30†	Employment offer letter between the Registrant and Mark J. Enyedy	X		
10.31†	Change in Control Severance Agreement dated as of May 16, 2016 between the Registrant and Mark J Enyedy	X		
21	Subsidiaries of the Registrant		10-K	August 28, 2015 21
23	Consent of Ernst & Young LLP	X		

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Exhibit Number	Exhibit Description	Filed with this Form 10 K	Incorporated by Reference		
			Form	Filing Date with SEC	Exhibit Number
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002	X			
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002	X			
32	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002	X			
101.INS	XBRL Instance Document	X			
101.SCH	XBRL Taxonomy Extension Schema	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	X			

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\*Portions of this Exhibit were omitted, as indicated by [\*\*\*], and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment.

†Exhibit is a management contract or compensatory plan, contract or arrangement required to be filed as an exhibit to the annual report on Form 10-K.