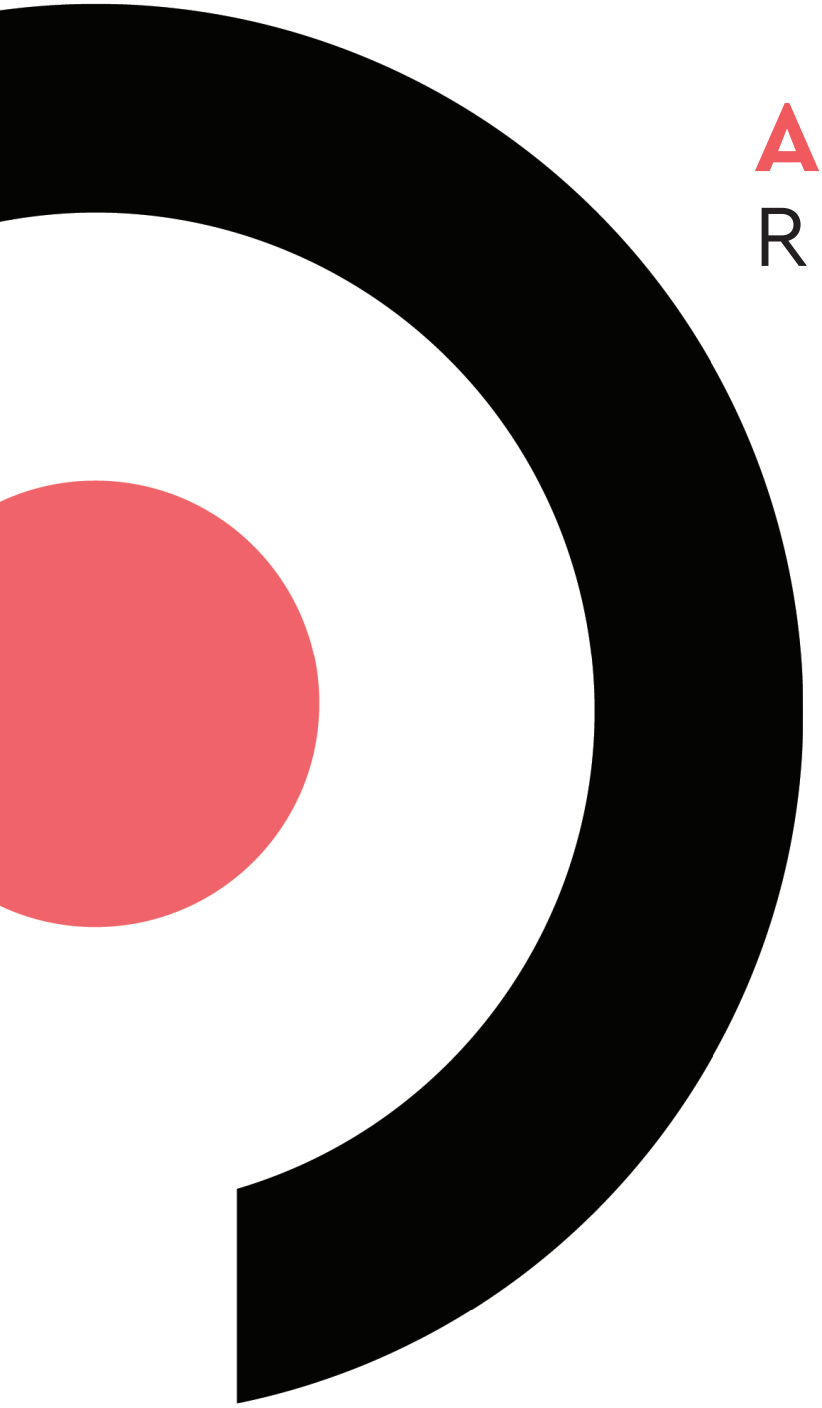


ANNUAL REPORT 2018

immunogen

NASDAQ: IMGN

MESSAGE TO OUR SHAREHOLDERS

We began 2018 with four overriding objectives for the business: complete the FORWARD I Phase 3 study for mirvetuximab soravtansine; advance our earlier-stage portfolio; build upon our leadership in ADCs through continued innovation with our platform; and strengthen our balance sheet. We met or exceeded each of these objectives.

Notwithstanding this strong performance, we were disappointed to report last month that FORWARD I did not meet the primary endpoint for the study. We do, however, see a consistent efficacy signal in the pre-specified subset of patients with high folate receptor alpha (FRα) expression and will be discussing with regulators this quarter a potential path to registration for this group of patients. As we look to refine our direction as an organization in light of these developments, we affirm our commitment to developing next-generation ADCs to bring more good days to patients and generating value for our shareholders.

ADVANCING MIRVETUXIMAB SORAVTANSINE

Exploring Avenues to Approval

We are exploring all options for the registration of mirvetuximab in ovarian cancer, both as a monotherapy and in combination. With the benefit of additional analyses of the data from FORWARD I, we have increased our confidence in mirvetuximab's efficacy in the high FRα patient population. Specifically, in comparison to chemotherapy, we have observed higher response rates, more durable responses, and longer progression-free and overall survival in patients with high FRα expression treated with mirvetuximab. Together with a differentiated safety profile, we believe the efficacy and tolerability of mirvetuximab demonstrate a favorable risk-benefit profile in these patients and we look forward to engaging with both FDA and EMA on potential avenues to approval.

FORWARD II

With our FORWARD II trial, we aim to expand the market opportunity for mirvetuximab into earlier lines of ovarian cancer. This study is assessing mirvetuximab in combination with Avastin® (bevacizumab – Genentech) as a doublet in patients with platinum resistant disease and with Avastin and carboplatin as a triplet in patients with platinum sensitive disease, as well as with Keytruda® (pembrolizumab – Merck) in more heavily pretreated patients. Over the course of 2018, we announced combination data from FORWARD II in over 100 patients with mirvetuximab doublets and also completed enrollment in December for the triplet in platinum sensitive patients. We also recently commenced an Avastin doublet in ovarian cancer patients for whom a non-platinum-based regimen would be an appropriate next therapy. These "platinum agnostic" patients will include those progressing after PARP inhibitor maintenance therapy, who represent an increasing share of the market.

We will be presenting data from the triplet and longer-term data from our doublets at medical meetings in 2019. In addition, we will evaluate combination studies as an independent path forward to support a registration in ovarian cancer.

ACCELERATING OUR EARLIER-STAGE PORTFOLIO

We are pursuing three additional programs in development, levering our highly productive research platform that continues to generate innovative and differentiated product candidates.

Our next generation IGN payloads have been integrated into two ADCs for the treatment of hematological malignancies: IMGN632 for acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN) and IMGN779 for AML, which we are developing in collaboration with Jazz Pharmaceuticals. Although there have been a number of recent approvals in AML, significant medical need remains, as more than 10,000 patients die from this disease each year in the United States and the five-year overall survival rate is roughly 25%.

Against this discouraging landscape, we have made significant progress with our IGN programs. In 2018, we received orphan designation for both programs in AML. In addition, we presented data in oral presentations at the American Society of Hematology (ASH) Annual Meeting demonstrating these agents exhibit favorable tolerability profiles and encouraging anti-tumor activity. We have moved forward with expansion cohorts in both programs and expect to present data from these studies at ASH later this year.

Beyond our IGN programs, we were pleased to transition our newest candidate, IMGC936, into development last fall in collaboration with MacroGenics. IMGC936 is a first-in-class ADC targeting ADAM9, an enzyme overexpressed in a range of solid tumors and implicated in tumor progression and metastasis. This ADC incorporates a number of innovations, including antibody engineering to extend half-life, site-specific conjugation with a fixed drug-antibody ratio to enable higher dosing, and a next-generation linker for improved stability and bystander activity. We recently reported encouraging safety and efficacy data from this program at the American Association of Cancer Research (AACR) Annual Meeting and expect to submit an IND for IMGC936 before year end.

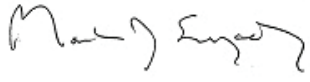
Finally, 2018 marked another year of sustained productivity from our research organization. Our team continues to expand our "toolbox" of linkers and payloads and to integrate novel approaches to antibody engineering, such as CytomX's Probody™ technology deployed with our anti-EpCAM PDC. These capabilities have enabled us to generate a diverse portfolio of research candidates with highly differentiated profiles, as evidenced by the 11 abstracts we reported at AACR this month.

LOOKING AHEAD

We start 2019 on a firm financial foundation, with roughly $270 million in cash on the balance sheet as of the end of March. With an experienced team, a strong portfolio, and these financial resources in hand, we will define a path forward for mirvetuximab, continue to advance our earlier-stage portfolio, and actively manage our operating expenses to extend our cash position. We look forward to updating you on our progress throughout the remainder of the year.

Thank you to the dedicated and passionate team at ImmunoGen, together with our scientific and clinical collaborators, board members and shareholders, for your continued support as we work to target a better now for people affected by cancer. We are grateful to the patients and their caregivers, physicians, and nurses, whose participation in our studies will enable us to realize the promise of ImmunoGen.

Sincerely,



Mark J. Enyedy

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 year ended December 31, 2018

OR

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

For the period from to

Commission file number 0-17999

ImmunoGen, Inc.

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

830 Winter Street, Waltham, MA 02451
(Address of principal executive offices, including zip code)
(781) 895-0600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☒ 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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 ☐
	Emerging growth company ☐

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

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 June 30, 2018: $1,425,536,472 (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 February 19, 2019: 149,409,825 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 June 20, 2019 are incorporated by reference into Part III.

ImmunoGen, Inc.

Form 10-K

TABLE OF CONTENTS

Incorporation of certain information by reference

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 December 31, 2018 unless otherwise indicated. For a description of the risk factors affecting or applicable to our business, see "Risk Factors," below.

Change in fiscal year

As previously reported, we changed our fiscal year end to December 31 from June 30, effective January 1, 2017. This annual report is for the twelve-month period of January 1, 2018 through December 31, 2018. References in this report to "fiscal year" refer to years ending June 30. References in this report to "transition period" refer to the six-month period ending December 31, 2016. For comparison purposes, unaudited data is shown for the twelve months ended December 31, 2016 and the six months ended December 31, 2015.

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 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 references 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 report.

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 report. 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.

PART I

Item 1. *Business*

Company Overview

ImmunoGen is a clinical-stage biotechnology company developing the next generation of antibody-drug conjugates (ADCs). By innovating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt disease progression and deliver more good days to people living with cancer. We call this our commitment to "target a better now."

An ADC with our proprietary technology comprises an antibody that binds to a target found on tumor cells and is 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 established, growing, and important approach to the treatment of cancer, with four approved products on the market and the number of agents in development growing significantly in recent years.

We have established a leadership position in ADCs, with a robust portfolio and a productive platform that has generated differentiated candidates for cancer treatment. Our proprietary portfolio is led by mirvetuximab soravtansine, a first-in-class ADC targeting folate-receptor alpha, or FRα. In late 2016, we initiated a Phase 3 registration trial, FORWARD I, with mirvetuximab for use as single-agent therapy to treat patients with platinum-resistant ovarian cancer. The FORWARD I Phase 3 trial randomized 366 patients 2:1 to receive either mirvetuximab or the physician's choice of

single-agent chemotherapy (pegylated liposomal doxorubicin, topotecan, or weekly paclitaxel). Eligibility criteria included patients with platinum-resistant ovarian cancer that expressed medium or high levels of FRα who had been treated with up to three prior regimens. The primary endpoint of this study was progression-free survival (PFS), which was assessed using the Hochberg procedure in the entire study population and in the subset of patients with high FRα expression. The Hochberg procedure enables the simultaneous testing of two overlapping populations. Under this statistical analysis plan, if the p-value of the primary endpoint in either population is greater than 0.05, the p-value in the other population needs to be less than or equal to 0.025 to achieve statistical significance.

On March 1, 2019, we announced that FORWARD I did not meet its PFS primary endpoint in either the entire study population or in the pre-specified subset of patients with high FRα expression. In the entire study population, the confirmed overall response rate was higher for mirvetuximab than for chemotherapy (22% vs 12%, p-value 0.015), without a significant difference in the primary endpoint of PFS (HR 0.98, p-value 0.897) or overall survival (HR 0.81, p-value 0.248). In the pre-specified high FRα subgroup (218/366, 60%), PFS was longer in patients who received mirvetuximab compared with chemotherapy (HR 0.69, p-value 0.049). Given that the p-value in the entire study population exceeded 0.05, the statistical analysis plan for the study required the p-value in the high subset to be less than or equal to 0.025 to achieve statistical significance. Confirmed overall response rate was higher for mirvetuximab than for chemotherapy (24% vs 10%, p-value 0.014) and overall survival was longer in patients who received mirvetuximab compared with chemotherapy (HR 0.62, p-value 0.033). Mirvetuximab was well-tolerated, with fewer patients experiencing grade 3 or greater adverse events (46% vs 61%), fewer dose reductions (20% vs 31%), and fewer discontinuations due to drug-related adverse events (5% vs 8%) compared with chemotherapy. The safety profile of mirvetuximab was confirmed, with the most common adverse events including nausea (54% all grades; 2% grade 3 or greater), diarrhea (44% all grades; 4% grade 3 or greater), and blurred vision (43% all grades; 3% grade 3 or greater).

We plan to conduct a full review of the FORWARD I data to determine potential next steps with mirvetuximab as a single agent, and assess our ongoing FORWARD II combination studies as a separate path forward to support a registration in ovarian cancer.

Mirvetuximab is also being assessed in multiple combinations in FORWARD II, a Phase 1b/2 study of the agent in combination with Avastin® (bevacizumab) or Keytruda® (pembrolizumab) in patients with Frα-positive platinum-resistant ovarian cancer, as well as a triplet combination of mirvetuximab plus carboplatin and bevacizumab in patients with recurrent platinum-sensitive ovarian cancer. In 2018, we presented combination data from more than 100 patients, beginning with data from the dose-escalation FORWARD II cohort evaluating mirvetuximab in combination with pembrolizumab at the Society of Gynecologic Oncology (SGO) Annual Meeting, which demonstrated encouraging efficacy and favorable tolerability in patients with platinum-resistant ovarian cancer. Based on these data, we enrolled an additional 35 patients with medium or high FRα expression levels in an expansion cohort in the FORWARD II study. Findings from the combined dose escalation and expansion cohorts were presented at the 2018 European Society for Medical Oncology (ESMO) Congress in October and confirmed the safety of the combination and the activity of mirvetuximab in heavily pretreated ovarian cancer patients in terms of response rate with a trend towards improved duration of response with the addition of pembrolizumab. We plan to present data from the mature cohort during 2019, the results of which will determine our approach to further development of this combination.

We also reported updated data from the FORWARD II dose-escalation cohort evaluating mirvetuximab in combination with carboplatin in patients with recurrent platinum-sensitive ovarian cancer. The updated data demonstrated a favorable safety profile along with an increased response rate and more durable benefit after longer-term follow up. In June, we presented data from the FORWARD II expansion cohort evaluating mirvetuximab in combination with bevacizumab at the American Society of Clinical Oncology (ASCO) Annual Meeting, which demonstrated anti-tumor activity with durable responses and favorable tolerability in patients with platinum-resistant ovarian cancer. Taken together, findings from these doublets supported the initiation of the ongoing FORWARD II cohort assessing a triplet combination of mirvetuximab plus carboplatin and bevacizumab in patients with recurrent platinum-sensitive ovarian cancer. We completed enrollment of the triplet in late 2018 and expect to report data from this cohort in 2019.

We have built a productive platform that continues to generate innovative and proprietary ADCs, including IMGN632, our CD123-targeting product candidate in clinical trials for patients with acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN), and IMGN779, our CD33-targeting product candidate in clinical trials for patients with AML. Initial data from the Phase 1 study of IMGN632 in patients with relapsed or refractory adult AML and BPDCN were presented at the American Society of Hematology (ASH) Annual Meeting in December 2018.

IMGN632 was shown to display anti-leukemic activity across all dose levels tested and a tolerable safety profile at doses up to 0.3 mg/kg. Enrollment in expansion cohorts is ongoing to identify the recommended Phase 2 dose and schedule for both AML and BPDCN. Updated data from the IMGN779 Phase 1 dose finding study in AML patients were also presented at ASH; these data show that IMGN779 continues to display a tolerable safety profile with repeat dosing across a wide range of doses explored in patients with relapsed AML, with anti-leukemic activity seen at doses ≥0.39 mg/kg in both schedules. Enrollment is ongoing to identify the recommended Phase 2 dose and schedule.

Collaborating on ADC development with other companies allows us to generate revenue, mitigate expenses, enhance our capabilities, and extend the reach of our proprietary platform. The most advanced partner program is Roche's marketed product, Kadcyla® (ado-trastuzumab emtansine). In October of 2018, Roche announced that, in a Phase 3 study (the "KATHERINE Study"), Kadcyla significantly improved invasive disease-free survival compared to Herceptin® (trastuzumab) in individuals with HER2-positive early breast cancer with residual disease after neoadjuvant treatment. Our ADC platform is used in candidates in clinical development with Bayer, Biotest, CytomX, Debiopharm, Novartis, Oxford BioTherapeutics/Menarini, and Sanofi. In addition, we have an ongoing strategic collaboration and option agreement with Jazz Pharmaceuticals plc to develop and co-commercialize ADCs, which we executed in August of 2017. Jazz has exclusive worldwide rights to opt into development and commercialization of IMGN779, IMGN632, and a third program to be named later from our early-stage pipeline. We also have a partnership with Takeda, who advanced their first candidate with our ADC technology deploying our IGN payload into clinical testing for solid tumors in the first half of 2018.

We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements. In addition to the discussion below for agreements with activity in the periods presented, details for all of our significant agreements can be found in Note C, Significant Collaborative Agreements, to our consolidated financial statements included in this report.

Our Strategy

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

- *Execute speed-to-market strategy for mirvetuximab.* Our first priority is to complete development and obtain full approval for mirvetuximab in ovarian cancer in the United States (U.S.) and European Union (EU).

- *Accelerate novel ADC pipeline.* We have prioritized our product candidates with the highest potential for differentiation and, to this end, we have emphasized ADCs deploying our novel DNA-alkylating payload, which we call IGNs. With a potentially broad therapeutic index, we believe we can increase the number of cancers addressable by ADC therapies with this technology.

- *Sustain leadership in ADC field through platform innovation.* 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 with the goal of bringing forward an Investigational New Drug (IND) application for candidates from our portfolio every 12-18 months. The latest addition to our development portfolio is IMGC936, a first-in-class ADC directed to ADAM-9 expressing tumors that we are co-developing with MacroGenics, Inc., and our goal is to file an IND for this program by the end of 2019.

- *Expand reach and strengthen financials through partnerships.* We will continue to lever 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.

ADCs and our Technology Platform

The molecular profile of tumors has increasingly formed the basis for treatment decisions for cancer patients. Within this evolving landscape, we believe ADCs will play an important and growing role by offering targeted therapy with the potential for stand-alone activity and a tolerability profile to enable combinations with existing and novel therapies to improve outcomes for people living with cancer. To this end, over the last five years, the number of ADCs in the clinic has more than doubled, with approximately 80 product candidates now under active evaluation, including more than 15 ADCs in late-stage development.

For more than three decades, we have provided leadership in ADC development with the most comprehensive "tool box" in the field. Together with the accumulated experience of our research team, these capabilities have enabled us to generate a pipeline of novel candidates optimized for individual tumor types with potent anti-tumor activity and tolerable safety profiles that includes ten product candidates currently in the clinic between us and our partners.

Our ADC platform combines advanced chemistry and biochemistry with innovative approaches to antibody optimization, with an emphasis on increasing the diversity and potency of our payload agents, advancing antibody-payload linkage and release technologies, and integrating novel antibody engineering technologies. Consistent with this approach, we have developed tubulin-acting maytansinoid payload agents, which include DM1 and DM4. Our maytansinoid technology is used in Kadcyla, mirvetuximab soravtansine, and all other ADCs in development by us and our partners that entered the clinic prior to 2016. Our new class of IGN payloads is used in IMGN779 and IMGN632, as well as in the GCC-targeting ADC, TAK-164, being developed by Takeda Pharmaceutical Company Limited (Takeda). which entered Phase 1 clinical testing in 2018. Other enabling technologies in our portfolio include a growing array of stable-engineered linkers, which direct the release and activation of the payload agent inside the cancer cell, alternative methods of conjugation and antibody assessment, screening, and targeting approaches to enable the optimal ADC design for the antigen target. In addition, we are collaborating with companies such as CytomX Therapeutics, Inc. to gain access to novel approaches to antibody engineering such as masking technology.

Our Product Candidates

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

ImmunoGen Wholly-Owned Product Candidate	**Target**	**Lead Indication**	**Lead Stage**
Mirvetuximab soravtansine	FRα	Platinum-resistant ovarian cancer	Phase 3
IMGN779*	CD33	AML	Phase 1
IMGN632*	CD123	AML, BPDCN	Phase I

**Subject to Collaboration and Option Agreement with Jazz.*

Mirvetuximab Soravtansine: First-in-class ADC Targeting FRα for Platinum-Resistant Ovarian Cancer

Our proprietary portfolio is led by mirvetuximab soravtansine, a first-in-class ADC targeting FRα. Mirvetuximab has a differentiated profile with a distinct mechanism of action and is the first ADC to enter pivotal development for the treatment of ovarian cancer. It comprises a FRα-binding antibody, which serves to target the ADC to FRα-expressing cancer cells, and our potent DM4 payload agent to kill the targeted cancer cells. It has demonstrated activity in platinum-resistant and platinum-sensitive ovarian cancer with a safety profile that supports expanded use as a combination agent. It has been granted orphan drug status for ovarian cancer in the U.S. and the European Union, as well as Fast Track Designation by the FDA.

We have developed a comprehensive strategy for mirvetuximab with the goals of displacing single-agent chemotherapy in the treatment of ovarian cancer and to be the preferred agent for combination treatment of the disease. Beyond ovarian cancer, we believe the opportunity for mirvetuximab may be further expanded with other FRα-positive cancers, including non-small cell lung, endometrial, and triple negative breast cancers.

Ovarian cancer is the fifth most common cause of cancer death in women in the U.S. Initial treatment typically entails tumor-debulking surgery, followed by platinum-based chemotherapy. Once the cancer becomes platinum-

resistant, patients may receive a wide array of treatments. There remains an urgent need to improve treatment of ovarian cancer, with current treatment options characterized by low response rates, short duration of response, and significant side effects.

FORWARD I: Single-agent therapy for platinum-resistant disease

We are conducting a Phase 3 registration trial, FORWARD I, with mirvetuximab for use as single-agent therapy to treat patients with platinum-resistant ovarian cancer whose tumors express high or medium levels of FRα and who have received up to three prior treatment regimens. We estimate 8,000 patients per year in the U.S. meet these criteria. FORWARD I enrolled a total of 366 patients, who were randomized 2:1 to mirvetuximab soravtansine, or physician's choice, which includes PEGylated liposomal doxorubicin, or PLD, or topotecan, or weekly paclitaxel. The primary endpoint of the trial is PFS, which will be assessed for high FRα expressers only and for all patients (high and medium FRα expressers). In 2018, we fully enrolled FORWARD I, and successfully completed an interim analysis after 80 PFS events. On March 1, 2019, we announced that FORWARD I did not meet its PFS primary endpoint in either the entire study population or in the pre-specified subset of patients with high-FRα expression. Based upon the efficacy signals we observed in the high FRα subset with PFS, confirmed overall response rate and overall survival, we are conducting additional analyses to further evaluate the potential benefit of mirvetuximab soravtansine for FRα-positive platinum-resistant ovarian cancer.

FORWARD II: Combination therapy for expanded patient population

Additionally, we are accruing patients in a companion study, FORWARD II, to evaluate mirvetuximab in combination regimens to potentially expand the number of patients with ovarian cancer eligible for treatment with the ADC, including to those with platinum-sensitive disease. We reported the first clinical data from FORWARD II at ASCO in June 2017. These data demonstrated that full doses of mirvetuximab combined in doublets with full doses of carboplatin, bevacizumab, and pembrolizumab yielded a favorable safety profile and encouraging efficacy. As a result, we advanced expansion cohorts for the bevacizumab and pembrolizumab combinations to Phase 2 testing in platinum-resistant disease and initiated a triplet combination evaluating mirvetuximab plus carboplatin and bevicizumab in patients with recurrent platinum-sensitive ovarian cancer. In 2019, we plan to present initial triplet and mature doublet expansion cohort data at a future medical meeting, and, while we continue to evaluate a mirvetuximab strategy in light of the FORWARD I data, we currently plan to enroll patients in an additional bevacizumab cohort in platinum-agnostic ovarian cancer.

IMGN779 and IMGN632: First-in-class ADCs for AML and Other Hematological Malignancies

We have also developed a new class of indolino-benzodiazepine DNA-acting payload agents that we refer to as IGNs. Our IGNs alkylate DNA without cross-linking, which we have found to provide a broad therapeutic index in preclinical models. Specifically, IGN ADCs have demonstrated the ability to retain the anti-tumor potency of crosslinking drugs with less toxicity to normal cells in *in vitro* and animal models. This potentially allows for repeat administration with reduced cumulative toxicity compared to an ADC with a crosslinking payload. Our IMGN632 and IMGN779 product candidates use our IGN payloads.

We are advancing IMGN632, a CD123-targeting ADC that utilizes one of our novel IGN payloads with a new engineered linker and novel antibody, which we are developing for hematological malignancies, including AML and BPDCN. In January 2018, we announced that the first patient was dosed in the Phase 1 trial of IMGN632. Since then, IMGN632 was granted Orphan-Drug Designation by the FDA as a treatment for AML and we presented encouraging data at ASH 2018 that showed anti-leukemic activity across all dose levels tested, including complete responses in both AML and BPDCN, and a tolerable safety profile at doses up to 0.3 mg/kg. In 2019, we are moving forward to establish the recommended Phase 2 dose and schedule for IMGN632 and initiate combination studies.

IMGN779 combines a high-affinity, humanized anti-CD33 antibody with a different IGN payload. Also granted Orphan-Drug Designation by the FDA, IMGN779 data presented at ASH 2018 showed tolerability with repeat dosing across a wide range of doses in patients with relapsed AML and demonstrated anti-leukemia activity in 41% of patients. In 2019, we are moving forward to identify the recommended Phase 2 dose and schedule to enable further development as a combination therapy in AML.

Collaborations and Out-Licenses

In conjunction with our strategy review in 2016, we have evolved our approach to partnering to prioritize relationships where we can gain access to complementary capabilities, strengthen our financial position, and create long-term value for the company by retaining co-development and co-commercialization rights. Our collaborations with Jazz Pharmaceuticals and MacroGenics reflect this approach to partnering.

We have selectively licensed restricted access to our ADC platform technology to other companies to expand the use 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 platform 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 only receive royalty payments from our ADC platform technology 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 in early-stage clinical trials, advancement into pivotal Phase 2 and/or Phase 3 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 ADC partnerships and current status of the most advanced program in each partnership:

Partner	Licensed targets	Status of Most Advanced Program
Roche	HER2, 4 other[1]	Marketed
Bayer	Mesothelin	Phase 2
Biotest	CD-138	Phase1/ 2
Novartis	cKit, pCadherin, CDH6, 2 others[1]	Phase 1
Oxford BioTherapeutics/Menarini	CD205[2]	Phase 1
CytomX	CD166	Phase 1
Takeda	GCC	Phase 1
Jazz	CD33[3], CD123[3]	Phase 1
Debiopharm	CD37[4]	Phase 2

[1] *Undisclosed*

[2] *Oxford BioTherapeutics and Menarini are developing MEN 1309, an ADC targeting CD205 and utilizing our DM4 payload, pursuant to a sublicense from Amgen, which in turn licensed our maytansinoid ADC technology to develop and commercialize ADCs targeting CD205.*

[3] *Jazz has exclusive worldwide rights to opt into development and commercialization of IMGN779 (CD33) and IMGN632 (CD123)*

[4] *Debiopharm has an exclusive license for Debio 1562 (formerly known as IMGN529)*

Below is a brief description of the business relationships underlying each of the foregoing programs. For more information concerning these relationships, including their ongoing financial and accounting impact on our business, please read Note C, Significant Collaborative Agreements, to our consolidated financial statements included in this report.

Roche

In 2000, we granted Genentech, now a unit of Roche, an exclusive development and commercialization license to use our maytansinoid technology with antibodies that target HER2. Roche's Kadcyla resulted from this license. Kadcyla was approved for marketing in the U.S., EU and Japan in 2013. 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 Kadcyla or any other resulting products as described below. Roche is responsible for the development, manufacturing, and marketing of any products resulting from this license.

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 Kadcyla arising under our development and commercialization license with Genentech, until IRH had received aggregate Kadcyla royalties equal to $235 million or $260 million, depending on when the aggregate Kadcyla royalties received by IRH reached a specified milestone. Once the applicable threshold would have been met, if ever, we would thereafter have received 85% and IRH would have received 15% of the Kadcyla royalties for the remaining royalty term. In January 2019, we sold our residual rights to receive royalty payments on commercial sales of Kadcyla to OMERS, the defined benefit pension plan for municipal employees in the Province of Ontario, Canada, for $65.2 million, net of $1.5 million of transaction fees. Simultaneously, OMERS purchased IRH's right to the royalties we previously sold to IRH as described above, therefore obtaining the rights to 100% of the royalties received from that date on.

We also granted Roche, through its Genentech unit, exclusive development and commercialization licenses to use our maytansinoid ADC technology with antibodies to four specified 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 are entitled to receive up to a total of $38 million in milestone payments and also royalties on the sales of any resulting products. Roche is responsible for the development, manufacturing, and marketing of any products resulting from these licenses. The standard termination provisions discussed below apply to 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 are 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, of which we have received $13 million to date, plus tiered royalties between 4 - 7% on the commercial sales of any resulting products. Bayer is responsible for the development, manufacturing, and marketing of any products resulting from this license. The standard termination provisions discussed below apply to this 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 are entitled to receive up to a total of $35.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. Biotest is responsible for the development, manufacturing, and marketing of any products resulting from this license. The standard termination provisions discussed below apply to this license.

Novartis

We granted Novartis exclusive development and commercialization licenses to our maytansinoid and IGN ADC technology for use with antibodies to six specified targets under a now-expired right-to-test agreement established in 2010. With respect to each license, we 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. Novartis is responsible for the manufacturing, product development, and marketing of any products resulting from this agreement. In May 2018, Novartis terminated one of its six development and commercialization licenses. The standard termination provisions discussed below apply to these licenses.

Oxford BioTherapeutics/Menarini

In 2013, we granted Amgen an exclusive development and commercialization license to our maytansinoid ADC technology for use with antibodies that target CD205 under a now-expired right-to-test agreement, which Amgen sublicensed to Oxford BioTherapeutics, which is developing MEN 1309 with Menarini. With respect to this license, 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. Amgen (or its sublicensee(s)) is responsible for the manufacturing, product development, and marketing of any products resulting from this development and commercialization license. The standard termination provisions discussed below apply to this license.

CytomX

In 2016, we granted CytomX an exclusive development and commercialization license to our maytansinoid and IGN ADC technology for use with Probodies™ that target CD166 under a now-expired reciprocal right-to-test agreement. 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. CytomX is responsible for the manufacturing, product development, and marketing of any products resulting from this license. The standard termination provisions discussed below apply to this license.

In 2017, we took exclusive development and commercialization licenses to CytomX's proprietary antibody-masking (Probody) technology for use with Probodies that target two specified targets under the same reciprocal right-to-test agreement. We terminated one of these licenses for convenience prior to the end of 2017. With respect to the remaining license, we are obligated to pay up to a total of $80 million in milestone payments, plus royalties on the commercial sales of any resulting product. We are responsible for the manufacturing, product development, and marketing of any products resulting from this license.

We may terminate the remaining license from CytomX for convenience at any time. The license may also 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 our royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, our 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 license. We may also be required to pay annual maintenance fees to CytomX if no product candidate under the license has progressed to a specified state of development within a specified time frame.

Takeda

In 2015, we granted Takeda an exclusive development and commercialization license to our maytansinoid and IGN ADC technology for use with antibodies that target GCC under a now-expired right-to-test agreement. We are entitled to receive up to a total of $210 million in milestone payments, plus royalties on the commercial sales of any resulting products. Takeda is responsible for the manufacturing, product development, and marketing of any products resulting from this license. The standard termination provisions discussed below apply to this license. In March 2018, the right-to-test agreement expired without Takeda exercising its option to a second license or extending or expanding the agreement as it had the right to do for a third license.

Jazz

In August 2017, we entered into a Collaboration and Option Agreement (the "Option Agreement") with a subsidiary of Jazz Pharmaceuticals plc, pursuant to which we granted Jazz options to develop and commercialize, on an exclusive, worldwide basis, IMGN779, IMGN632, and a third ADC from our early research and development pipeline to be designated by Jazz within the first seven years of the Option Agreement term. Each of the foregoing three products is referred to herein as a "Collaboration Product." Jazz is entitled to exercise its option with respect to each Collaboration Product during specified periods set forth in the Option Agreement. Each Collaboration Product for which Jazz has exercised its option is referred to herein as a "Licensed Product." We have the right to co-commercialize with Jazz a single Licensed Product (except under certain limited circumstances under which we may be entitled to co-commercialize two Licensed Products), to be designated by us, in the U.S.

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

Jazz may exercise its option with respect to each Collaboration Product at any time prior to a pivotal study or any time prior to a biologics license application (BLA) upon payment of an option exercise fee of mid-double digit millions or low-triple digit millions, respectively. The option exercise fee for IMGN632 is subject to certain adjustments

depending on the indication(s) for which initial regulatory approval of this product is based. The option exercise fee would be reduced with respect to the Licensed Product designated by us for co-commercialization if Jazz exercised its option for that Licensed Product at the later stage of development. After any option exercise by Jazz, we will share equally with Jazz the costs associated with developing and obtaining regulatory approvals of each Licensed Product in the U.S. and the European Union, and Jazz will be solely responsible for such costs with respect to all other territories worldwide.

We are also entitled to receive milestone payments upon US and EU regulatory approvals for each Licensed Product, plus tiered royalties as a percentage of commercial sales which, depending on sales levels and the stage of development at the time of Jazz's option exercise, range from the mid- to high-single digits in the lowest tier, to low 10's to low 20's in the highest tier. With respect to the Licensed Product designated by us for co-commercialization, in lieu of receiving a milestone payment based on receiving regulatory approval in the U.S., or royalties on sales in the U.S., we will share equally with Jazz the activities, costs, and profits associated with commercialization in the U.S. The standard termination provisions discussed below apply to the Option Agreement and the license agreements associated with the Licensed Products ("License Agreements"), except that any License Agreement for a Licensed Product being co-commercialized by the parties in the U.S. shall remain in effect as long as the parties continue to be engaged in such co-commercialization activities, subject to earlier termination in the event of a material breach.

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

Debiopharm

In May 2017, we entered into an Exclusive License and Asset Purchase Agreement with Debiopharm International, S.A., pursuant to which Debiopharm acquired our antibody-drug conjugate IMGN529, a potential new treatment for patients with CD37-positive B-cell malignancies, such as non-Hodgkin lymphoma (NHL). The transaction includes the sale to Debiopharm of specified intellectual property and other assets related to the IMGN529 program, and an exclusive license to additional intellectual property necessary or useful for Debiopharm to develop and commercialize IMGN529 (now known as Debio 1562).

Under the terms of the agreement, we received a $25 million upfront payment for the IMGN529 program and a $4.5 million milestone payment following the transfer of technology relating to IMGN529 to Debiopharm, which was completed in the fourth quarter of 2017. The final $500,000 for the milestone was received in January 2018. In addition, we are entitled to a $25 million milestone upon IMGN529/Debio 1562 entering a Phase 3 clinical trial. Except for the foregoing upfront and milestone payments, we will not be entitled to receive any additional milestone payments or royalties under the agreement.

Standard Termination Provisions

Standard termination provisions in our license agreements state that the partner 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 certain of these agreements upon the occurrence of specified events. Upon termination, the partner's rights to our intellectual property with respect to the applicable target are cancelled and could then be used by us or re-licensed for that target. Unless earlier terminated, the agreement will continue in effect until the expiration of partner's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, 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.

Other Agreements

From time to time we have entered into additional agreements with some of our collaborators pursuant to which we have provided certain CMC-related development and pre-pivotal ADC manufacturing services, or supplied ADC

payloads, to them with respect to products they are developing under their licenses with us, with respect to which we have been entitled to receive payments at mutually negotiated rates.

Patents, Trademarks and Trade Secrets

ImmunoGen has a substantial and robust intellectual property portfolio comprising more than 1,000 issued patents and over 600 pending patent applications on a worldwide basis. Our intellectual property strategy centers on obtaining high quality patent protection directed to various embodiments of our proprietary technologies and product candidates. Using this strategy, our ADC technology and our product candidates are protected through a multi layered approach. In this regard, we have patents and patent applications covering antibodies and other cell binding agents, linkers, cytotoxic payload agents (e.g., tubulin acting maytansinoids and DNA acting IGNs), conjugation methodologies and complete ADCs, comprising one or more of these components, as well as methods of making and using each of the above. Typically, multiple issued patents and pending patent applications cover various embodiments of each of ImmunoGen's and our licensees' product candidates.

We consider our tubulin-acting maytansinoid and DNA-acting IGN cytotoxic payload agent technologies to be key components of our overall patent strategy. With regard to our tubulin-acting maytansinoid cytotoxic payload agents, we currently own 22 issued U.S. patents covering various embodiments of our maytansinoid technology including those with claims directed to certain maytansinoids, including DM4, and methods of manufacturing of both DM1 and DM4, as well as methods of using the same. These issued patents remain in force until various times between 2020 and 2033. With regard to our IGN payload agents, we have 20 issued U.S. patents covering various aspects of our DNA-acting cytotoxic payload agents, which will expire at various times between 2030 and 2036. In all cases, we have received or are applying for comparable patents in other major commercial and manufacturing jurisdictions, including Europe, Japan, and China. In nearly all cases for both our maytansinoid and IGN patent portfolios, we have additional pending patent applications disclosing and claiming many other related and strategically important embodiments of these technologies which, upon issuance or grant, will extend our patent protection term over these technologies by several additional years.

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 21 issued patents related to many of our linker technologies, as well as additional pending patent applications disclosing and claiming many other related and strategically important embodiments of these linker technologies. The issued patents, expiring in 2021-2034, and any patents which may issue from the patent applications, cover the linkers, methods of making the linkers and antibody maytansinoid conjugates comprising these linkers. We also have 15 issued U.S. patents covering methods of assembling ADCs from their constituent antibody, linker, and cytotoxic payload agent moieties. These issued patents will expire in 2022-2037. In nearly all instances for both our linker and conjugation patent portfolios, we have additional pending patent applications disclosing and claiming many other related and strategically important embodiments of these technologies which, upon issuance or grant, will extend our patent protection term over these technologies by several additional years. In all cases, we have received or are applying for comparable patents in other major commercial and manufacturing jurisdictions including Europe, Japan, and China.

We also file, prosecute, and maintain a substantial portfolio of patents and patent applications specifically directed to ImmunoGen's and our licensees' ADC clinical candidates. In this regard, we craft a detailed patent protection strategy for each ADC as it approaches clinical evaluation. Such strategies make use of the patents and patent applications described in the preceding paragraphs, as well as ADC-specific filings, to create a multi-layered and multi-jurisdictional patent protection approach for each ADC as it enters the clinic. These ADC-specific patent strategies are intended to provide the exclusivity basis for revenue and royalties arising from commercial development of each of ImmunoGen's and our licensees' ADCs.

We expect our continued independent and collaborative work in each of these areas will lead to other patent applications. We will be the owner of all patents covering our independently generated inventions. In all other instances, we expect to either be the sole owner or co-owner of any patents covering collaboratively generated inventions insofar as they relate to co-developed products or our ADC platform technology, or otherwise have an exclusive or non-exclusive license to the technology covered by such patents.

We cannot provide assurance that pending 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. Furthermore, as a patent does not confer any specific freedom to operate, other parties may have patents that may block or otherwise hinder the development and commercialization of our technology.

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

Competition

We focus on highly competitive areas of product development. Our competitors include major pharmaceutical companies and other biotechnology firms. For example, Pfizer, Seattle Genetics, Roche, Astellas, AstraZeneca/MedImmune, and AbbVie 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, sales, 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, efficacy, and convenience of products;
- the timing of regulatory approvals and commercial introductions;
- special regulatory designation of products, such as orphan drug designation; and
- the effectiveness of marketing, sales, and reimbursement efforts.

Our competitive position depends on a combination of factors. These include effectively pursuing the development of proprietary products, the implementation of clinical development programs, the ability to appropriately manufacture, sell, and market our products, and obtain patent protection for our products. In addition, we must secure sufficient capital resources to accomplish all of the previously mentioned activities.

Continued 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 PHSA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, and local 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 adverse administrative or judicial actions. These actions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any such administrative or judicial 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 and other nonclinical 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 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 clinical 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 nonclinical testing may continue even after the IND is submitted and clinical trials have begun. 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 sponsor submits additional information that alleviates FDA concerns and FDA notifies the sponsor that the hold has been lifted.

Each clinical trial must be conducted under the supervision of one or more qualified investigators in accordance with cGCP requirements pursuant to a protocol included 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 and 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:*** These trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites and 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 information about the use of the approved drug in 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 or serious patient reactions. 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 may request meetings with the FDA. These meetings often occur prior to submission of an IND, at the end of Phase II, and before an NDA or BLA is submitted, but 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 or trials 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.

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, 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. Most sponsors of clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the 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.

Companion Diagnostics

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 or complementary diagnostic tests to identify appropriate patients for these targeted therapies.

If a sponsor or the FDA believes that a diagnostic test is essential for the safe and effective use of a corresponding therapeutic product, a sponsor will typically work with a collaborator to develop an *in vitro* diagnostic, or IVD. Companion diagnostics can be used to identify patients likely to be more responsive to a particular therapy or at increased risk for serious side effects as a result of treatment with a particular therapeutic product. They may also be useful for monitoring the response to treatment for the purpose of adjusting treatment or doses to achieve improved safety or effectiveness.

IVDs are regulated by the FDA as medical devices, and it issued a final guidance document in 2014, entitled "*In Vitro* Companion Diagnostic Devices" that is intended to assist companies developing *in vitro* companion diagnostic devices and companies developing therapeutic products that depend on the use of a specific *in vitro* companion diagnostic for the safe and effective use of the product. The FDA defined an IVD companion diagnostic device as a device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. The FDA 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 subsequently introduced the concept of complementary diagnostics that are distinct from companion diagnostics because they provide additional information about how a drug is used or identify patients who are likely to derive the greatest benefit from therapy without being required for the safe and effective use of that drug. The FDA has not yet provided much guidance on the regulation and use of complementary diagnostics, but several have been approved.

The FDA indicated that it will apply a risk-based approach to determine the regulatory pathway for IVD companion and complementary 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 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.

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.

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 are 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 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 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 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 other 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 need 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, 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 and will likely continue to publish new guidances as new issues relating to biosimilars and interchangeability are identified. The guidance documents provide FDA's current thinking on approaches to demonstrating that a proposed biological product is biosimilar to a reference product. Although the FDA intends to issue additional guidance documents in the future, the absence of final guidance documents covering all biosimilars issues does not prevent a sponsor from seeking licensure of a biosimilar under the BPCIA, as evidenced by the biosimilar products already approved by the FDA.

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.

The FDA and the European Medicines Agency, or EMA, in the European Union granted orphan designation to mirvetuximab soravtansine, or IMGN853, when used for the treatment of ovarian cancer. In the U.S., 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. In the EU, orphan designation will provide us with ten years of market exclusivity that begins after mirvetuximab soravtansine receives marketing authorization for the use for which it was granted. We may pursue these designations for other indications for other product candidates intended for qualifying patient populations.

Expedited Review and Approval; Breakthrough Therapy Designation

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.

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 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 (EMA) where it will be evaluated by the Committee for Medicinal Products for Human Use. A favorable opinion typically results in the grant by the EMA 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 EMA, 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 payers include government healthcare programs such as Medicare, managed care providers, private health insurers, and other organizations. We anticipate third-party payers will provide reimbursement for our products. However, these third-party payers 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 have incorporated certain health outcomes measures in our clinical studies, but may need to conduct expensive additional 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 and expensive for us to seek reimbursement from third-party payers. 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 in-patient 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 payers, 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 payers 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 and result in expanded coverage for the uninsured. With regard to pharmaceutical products, among other things, ACA was 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, some members of Congress and the President continue to express their strong desire to repeal the ACA, and as a result certain sections of the ACA have not been fully implemented or effectively repealed, for example, as part of the recently adopted Tax Cuts and Jobs Act, the U.S. Congress eliminated the ACA's individual mandate. These challenges add to the uncertainty of the changes enacted as part of ACA. Moreover, President Trump ran for office on a platform that supported the repeal of the ACA and one of his first actions after his inauguration was to sign an Executive Order commanding federal agencies to try to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. The Order also declares that the administration will seek the "prompt repeal" of the law and that the government should prepare to "afford the states more flexibility and control to create a more free and open healthcare market." At this time, the immediate impact of the Order or Congressional actions is not clear.

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 the years ended December 31, 2018, 2017, and 2016, the six months ended December 31, 2016 and 2015, and the fiscal year ended June 30, 2016, we spent $174.5, $139.7, $141.3, $66.6, $73.3, and $148.1 million, respectively, on research and development activities.

Manufacturing

We contract with third-party contract manufacturers, or CMOs, for the manufacture of our product candidates for both our clinical and potential commercial needs. Our CMO network manufactures antibody, linker, and payload, conjugates the foregoing to create bulk drug substance of our product candidates, and processes the bulk drug substance into vialed and labeled drug product for use in humans. As a result of the closure of our Norwood facility in 2018, we no longer operate manufacturing facilities for the production of our product candidates for clinical use, and we have no plans to build our own clinical or commercial scale manufacturing capabilities. Although we are reliant on third parties to manufacture our product candidates, we have personnel with extensive manufacturing experience to oversee the relationships with our CMOs.

CMOs are subject to extensive governmental regulations and we depend on them to manufacture our product candidates in accordance with current good manufacturing practices, or cGMP. We have an established quality assurance program to ensure that the CMOs involved in the manufacture of product candidates do so in accordance with cGMP and other applicable U.S. and foreign regulations. We believe that our current CMO network complies with such regulations.

Employees

As of December 31, 2018, we had 296 full-time employees, of whom 240 were engaged in research and development activities. Of the 240 research and development employees, 148 employees hold post-graduate degrees, of which 64 hold Ph.D. degrees and eight 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.

In February 2018, we determined to implement a new operating model that will rely on external manufacturing and quality testing for drug substance and drug product for our development programs. The implementation of this new operating model led to the ramp-down of manufacturing and quality activities at our Norwood facility during 2018, with a full decommissioning of the facility occurring in early 2019. Implementation of the new operating model resulted in a net reduction of our workforce by approximately 20 positions.

Third-Party Trademarks

Avastin, Herceptin, Kadcyla, and Keytruda are registered trademarks of their respective owners. Probody is a trademark of CytomX.

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 December 31, 2018, we had an accumulated deficit of $1.2 billion. 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. We may encounter technological or regulatory difficulties as part of this development and commercialization process that we cannot overcome or remedy. Our revenues to date have been primarily from upfront and milestone payments, research and development support and

clinical materials reimbursement from our collaborators, and from royalties received from the commercial sales of Kadcyla (which we sold partial cash rights to 2015 and the remainder in 2019). We do not expect to generate revenues from the commercial sale of our internal product candidates in the near term, 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.

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, establishing marketing and sales capabilities to commercialize our product candidates, as well as providing certain support to our collaborators in the development of their products. On March 1, 2019, we disclosed that our Phase 3 FORWARD I trial did not meet its PFS primary endpoint in either the entire study population or in the pre-specified subset of patients with high FRα expression, which will negatively affect our access to capital for at least the near term. However, we believe that our current working capital and the $65.2 million raised from the sale of our residual rights to Kadcyla royalties in January 2019, and expected future collaborator payments will be sufficient to meet our current and projected operating and capital requirements for at least the next 12 months. In addition, we cannot provide assurance that anticipated collaborator payments will, in fact, be received. Should such future collaborator payments not be received, we expect we could seek additional funding from other sources. We may elect or need to seek 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; and

- 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, including restructuring our operations, refinancing or restructuring 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 or if such products fail to obtain or maintain FDA approval, 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 as a result, our ADC technology may not result in any future meaningful benefits to us or for our current or potential collaborators. Furthermore, we are aware of only three other compounds that are based on technology similar to our ADC technology that have obtained marketing approval by the FDA. 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 or maintain FDA approval, our business will be severely harmed. On March 1, 2019, we disclosed that our Phase 3 FORWARD I trial did not meet its PFS primary endpoint in either the entire study population or in the pre-specified subset of patients with high FRα expression. While we plan to conduct a full review of the FORWARD I data to determine potential next steps with mirvetuximab as a single agent, and assess our ongoing FORWARD II combination studies as a potential path forward to support a registration in ovarian cancer, a decision to discontinue further development of mirvetuximab soravtansine as a monotherapy, as combination therapy, or both, may significantly harm our business and future prospects.

Clinical trials for our and our collaborators' 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 collaborators 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. For example, despite encouraging results from earlier clinical trials of mirvetuximab soravtansine, on March 1, 2019, we disclosed that our Phase 3 FORWARD I trial did not meet its PFS primary endpoint in either the entire study population or in the pre-specified subset of patients with high FRα expression. While we plan to conduct a full review of the FORWARD I data to determine potential next steps with mirvetuximab as a single agent, and assess our ongoing FORWARD II combination studies as a potential path forward to support a registration in ovarian cancer, a decision to discontinue further development of mirvetuximab soravtansine as a monotherapy, as combination therapy, or both, may significantly harm our business and future prospects.

At any time during the clinical trials, we, our collaborators, or the FDA or other regulatory authority 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, including delays in obtaining supplies/materials necessary for manufacturing such drugs;
- negative or inconclusive results from the clinical trials, or results that necessitate additional nonclinical 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;
- our or our collaborators' inability to develop and obtain approval for any companion *in vitro* diagnostic devices that the FDA or other regulatory authority may conclude must be used with such product candidates to ensure their safe use; or
- other reasons that are internal to the businesses of our collaborators and third-party suppliers, 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 collaborators' product candidates could severely harm our business.

Inadequate funding for the FDA, the SEC, and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including December 22, 2018 to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough employees and stop critical activities. If a prolonged government shutdown or a series of shutdowns occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to gain access to the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may be subject to, or may in the future become subject to, U.S. federal and state and foreign laws and regulations imposing obligations on how we collect, use, disclose, store, and process personal information. Our actual or perceived failure to comply with such obligations could result in liability or reputational harm and adversely affect our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In many activities, including the conduct of clinical trials, we are subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction, and disposal of personal data. We must comply with laws and regulations associated with the international transfer of personal data based on the location in which the personal data originates and the location in which such data are processed. While we strive to comply with all applicable privacy and security laws and regulations, legal standards for privacy continue to evolve and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others, or could cause reputational harm, which could have a material adverse effect on our business.

The legislative and regulatory landscape for privacy and data security continues to evolve. For example, the EU General Data Protection Regulation, or GDPR, which was effective as of May 25, 2018, introduced new data protection requirements in the European Union relating to the consent of the individuals to whom the personal data relate, the information provided to the individuals, the documentation we must retain, the security and confidentiality of the personal data, data breach notification, and the use of third party processors in connection with the processing of personal data. The GDPR has increased our responsibility and potential liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR. However, our ongoing efforts related to compliance with the GDPR may not be successful and could increase our cost of doing business. In addition, data protection authorities of the different EU member states may interpret the GDPR differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the European Union.

In the United States, California recently adopted the California Consumer Privacy Act of 2018, or CCPA, which will come into effect beginning in January 2020. The CCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the EU GDPR. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches.

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

We and our collaborators 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 collaborators, 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 outside of the U.S., 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 regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the authorities 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 collaborators' 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 regulatory policy during the period of product development, clinical trials, and regulatory review. Failure to comply with 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. 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.

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

Even if we or our collaborators receive regulatory approval to market a particular product candidate, the approval could be conditioned on us or our collaborators 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 collaborators to withdraw it from the market, or impede or delay our or our collaborators' ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to regulatory 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 do not have prior experience complying with regulations pertaining to products that have already received marketing approval and, therefore, we may be unable or slow to comply with existing regulations, including changes in existing regulatory requirements, or new regulations. Furthermore, our collaborators may be slow to adapt, or may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements pertaining to products that have already received approval.

If we or our collaborators 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 collaborators 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 affected.

The development and commercialization of our product candidates depends, in 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
- 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 collaborators may devote to our product candidates. Our collaborators 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 collaborators 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 collaborators continue their collaborative arrangements with us, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Also, our collaborators may fail

to perform their obligations under the collaborative agreements or may be slow in performing their obligations. Our collaborators 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 some cases, in the discretion of our collaborators. 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 could be severely limited or eliminated. 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 could 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 collaborators 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 collaborators 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. 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.

Royalty rates under our license agreements with our collaborators may vary over the royalty term depending on our intellectual property rights and the existence of certain third-party 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 if certain third-party products compete with the particular product covered by the license agreement.

We depend on our collaborators 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 may receive are determined by our collaborators 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 costs on our part.

If our product requirements for clinical trials are significantly higher than we estimated, the inability to procure additional antibody, or conjugation 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 manufacture bulk drug substance and convert it into filled and finished vials of drug product for clinical use. If our product requirements are significantly higher than we estimated, we may not be able to readily procure slots to manufacture bulk drug substance or to convert drug substance into filled and finished vials of drug product for clinical use. 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 third-party manufacturers to produce our antibodies, linkers, payloads, drug substance, and drug product, and any delay or interruption in such manufacturers' operations could impair our ability to advance clinical trials and commercialization of our product candidates.

We rely on third-party contract manufacturers to produce sufficiently large quantities of drug materials that are and will be needed for clinical trials and commercialization of our potential products. We have established relationships with third-party manufacturers to provide materials for our clinical trials, and are developing relationships with these and other third-party manufacturers that we believe will be necessary to continue the development of our product candidates and to supply commercial quantities of these product candidates, if they are approved. 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 applications for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability. Historically we manufactured non-pivotal drug substance, and performed quality testing for both drug substance and drug product, at our Norwood, Massachusetts manufacturing plant. In 2018, we implemented a new operating model that led to the discontinuation of our internal manufacturing and quality testing activities for drug substance and drug product for our development programs in connection with the closure of our Norwood facility, and we are now fully reliant on third-party contract manufacturers and contract research organizations for all manufacturing and quality testing activities for our development programs and future commercial products.

We are currently contractually required to obtain all of the DM4 used in mirvetuximab soravtansine from a single third-party manufacturer, and any delay or interruption in such manufacturer's operations could impair our ability to advance preclinical and clinical trials and commercialization of our product candidates and our collaborators' products candidates.

We rely on a sole third-party supplier, Società Italiana Corticosteroidi S.r.l, to manufacture the DM4 used in mirvetuximab soravtansine. Any delay or interruption in the operations of our sole third-party supplier and/or our supply of DM4 could lead to a delay or interruption in our manufacturing operations, preclinical studies, clinical trials, and commercialization of our product candidates and our collaborators' product candidates, which could negatively affect our business.

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

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 payers 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, which became effective in 2010, was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and institute additional health policy reforms. It also requires 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. The ACA has been under scrutiny by the U.S. Congress almost since its passage, and certain sections of the ACA have not been fully implemented or have effectively been repealed, for example, as part of the recently adopted Tax Cuts and Jobs Act, the U.S. Congress eliminated the ACA's individual mandate. The longevity of other key provisions of the ACA continues to be uncertain. 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.

In 2016, the 21st Century Cures Act was signed into law. This law is intended to enable the acceleration of the discovery, development and delivery of 21st century cures, among other things. Provisions in that law, such as those applying to precision medicine, technical updates to clinical trial databases, and advancing new drug therapies, could apply directly or indirectly to our activities and those of our collaborators. At this point, however, it is not clear how that law will be implemented and what effect it may have on our business.

We currently do not have the direct sales, marketing, or distribution capabilities necessary to successfully commercialize our products on a large scale and may be unable to establish such capabilities.

We hold the worldwide rights to commercialize mirvetuximab soravtansine, and currently intend to commercialize mirvetuximab soravtansine ourselves in the U.S. and the European Union. Alternatively, we may choose to rely on third parties to market and sell mirvetuximab soravtansine in different territories, either through distributor or outlicensing arrangements. At this time, we do not have any significant direct sales, marketing or distribution capabilities. In addition, co-promotion or other marketing arrangements with third parties to commercialize mirvetuximab soravtansine or other future potential products could significantly limit the revenues we derive from these compounds, and these third parties may fail to commercialize our compounds successfully.

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

Even if clinical trials demonstrate the safety and efficacy of our and our collaborators' product candidates and the necessary regulatory approvals are obtained, our and our collaborators' products may not gain market acceptance among physicians, patients, healthcare payers, and other members of the medical community. The degree of market acceptance of any products that we or our collaborators 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 collaborators' ability to gain acceptable reimbursement and the reimbursement policies of government and other third-party payers; 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 our products are established, physicians may elect not to recommend the therapies for any number of other reasons, including whether the physicians are already using competing products that satisfy their treatment objectives. 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, Astellas, AstraZeneca/MedImmune, and AbbVie. 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 ACA, which included the Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the Public Health Service Act to create an abbreviated approval pathway for two types of "generic" biologics—biosimilars and interchangeable biologic products. The BPCIA establishes a pathway for the FDA approval of follow-on biologics and provides twelve years data exclusivity for reference products and an additional six months exclusivity period if pediatric studies are conducted. In Europe, EMA 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 became fully effective in 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, the U.S. Supreme Court has become increasingly active in reviewing U.S. patent law in recent years, and the extent to which 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.

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 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 such 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.

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. While we currently have product liability insurance for products which are in clinical testing, 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 collaborators 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 U.S. 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 any of our 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, 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, contract research organizations, 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, 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 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. In addition, we have limited experience with respect to laws governing the commercial sale of pharmaceutical products and we will need to implement measures to ensure compliance with these laws before the commercialization of any of our product candidates, if approved. The failure to adequately implement these measures could negatively affect our sales and marketing activities and our business.

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, sales, marketing, distribution, 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 or competitors can cause our stock price to decline.

Our stock price can fluctuate significantly due to business developments announced by us and by our collaborators and competitors, or as a result of market trends and daily trading volume. The business developments that could affect 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 or product candidates that compete with our compounds or those of our collaborators. Our stock price can also fluctuate significantly with the level of overall investment interest in small-cap biotechnology stocks or for other reasons unrelated to our business.

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 collaborators with respect to our agreements with them, and 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 may cause our stock price to decline.

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest of existing shareholders will be diluted and the price of our stock may decline. The price of our common stock may also decline if the market expects us to raise additional capital through the sale of equity or convertible debt securities whether or not we actually plan to do so.

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.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

We lease approximately 120,000 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 leased approximately 43,850 square feet of space at 333 Providence Highway, Norwood, MA, which served as our conjugate manufacturing facility and also included office space. The 333 Providence Highway lease expired on February 28, 2019. In February 2018, we determined to implement a new operating model that will rely on external manufacturing and quality testing for drug substance and drug product for our development programs. The implementation of this new operating model led to the ramp-down of manufacturing and quality activities at our Norwood, Massachusetts facility during 2018, with a full decommissioning of the facility occurring in early 2019.

Due to space requirements, in 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 expired in September 2018. In 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 through August 31, 2021. We have been actively seeking to sub-lease this space.

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 55, joined ImmunoGen in 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 2016, including as Executive Vice President and Head of Corporate Development from 2014 to 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 and a director of Proteostasis Therapeutics, Inc., a biopharmaceutical company, from 2011 to 2013. Prior to joining Proteostasis, he served for 15 years at Genzyme Corporation, a biopharmaceutical 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 Akebia Therapeutics, Inc. and The American Cancer Society of Eastern New England. Within the past five years, he also served as a director of Fate Therapeutics, Inc. and Keryx Biopharmaceuticals, Inc.

Craig Barrows, age 64, joined ImmunoGen in 2007, and has served as our Executive Vice President, General Counsel and Secretary since 2016. Prior to that he served as Vice President, General Counsel and Secretary for more than five years.

Anna Berkenblit, MD, age 49, joined ImmunoGen in 2015, and has served as our Senior Vice President and Chief Medical Officer since February 2019. Prior to that, she served as our Vice President and Chief Medical Officer from 2015 to February 2019. Prior to joining ImmunoGen, she served as Senior Vice President and Head of Clinical Research at H3 Biomedicine Inc., a pharmaceutical company, from 2013 to 2015. Prior to that she served as Vice President and Head of Clinical Research at AVEO Pharmaceuticals, Inc., a biopharmaceutical company, from 2011 to 2013. Dr. Berkenblit holds a Doctor of Medicine degree from Harvard Medical School and a master's degree from the Harvard/MIT Health & Sciences clinical investigator training program.

Richard J. Gregory, PhD, age 61, 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 biopharmaceutical 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. Dr. Gregory is also a director of Homology Medicines, Inc. and ProMIS Neurosciences Inc.

Blaine H. McKee, PhD, age 53, joined ImmunoGen in 2018, and has served as our Executive Vice President and Chief Business Officer since that date. Prior to joining ImmunoGen, he served in various executive capacities at Shire PLC, a pharmaceutical company, from 2014 to 2018, including as Senior Vice President, Head of Corporate Development, from 2016 to 2018, and as Senior Vice President, Head of Transactions, from 2014 to 2016. Prior to that he served as Executive Vice President and Chief Business Officer at 480 Biomedical, Inc., a biotechnology company, from 2011 to 2014. Prior to that he served for 15 years at Genzyme Corporation, a biopharmaceutical company, most recently as Senior Vice President, Strategic Development of the Transplant, Oncology, and Multiple Sclerosis divisions. Dr. McKee holds a PhD in organic chemistry from Massachusetts Institute of Technology (MIT), and a Master of Business Administration from MIT's Sloan School of Management. Dr. McKee is also a director of VBI Vaccines Inc. and, within the past five years, he also served as a director of Biostage, Inc.

Thomas Ryll, PhD, age 58, joined ImmunoGen in 2015, and has served as our Vice President, Technical Operations, since 2017. Prior to that he served as Vice President, Process and Analytical Development, from his date of hire to 2017. Prior to joining ImmunoGen, he spent almost nine years at Biogen Inc. (formerly known as Biogen Idec Inc.), a biopharmaceutical company, in roles of increasing responsibility in the area of cell line culture development, including Senior Director in Biogen's technical development department. Dr. Ryll holds a PhD in biotechnology and biochemistry from the Technical University of Braunschweig, Germany, and completed his post-doctoral work at the Society for Biotechnology Research (now the Helmholtz Center for Infection Research) in Germany.

Theresa G. Wingrove, PhD, age 61, joined ImmunoGen in 2011, and has served as our Senior Vice President, Regulatory Affairs and Quality since February 2018. Prior to that she served as Vice President, Regulatory Affairs and Quality from 2017 to February 2018, and prior to that as Vice President, Regulatory Affairs for more than five years. Dr. Wingrove holds a PhD in biochemical toxicology from the University of Rochester School of Medicine and Dentistry, and completed her postdoctoral work at the University of Rochester Medical Center.

Item 4. ***Mine Safety Disclosures***

None.

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." As of February 19, 2019, the closing price per share of our common stock was $5.53, as reported by NASDAQ, and we had 340 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.

Equity Compensation Plan Information (in thousands)

	(a)	(b)	(c)
Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and holders[1]	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[2]	15,817	$ 10.20	8,874 [3]
Equity compensation plans not approved by security holders	—	—	—
Total	15,817	$ 10.20	8,874

(1) Does not include outstanding unvested restricted stock awards.

(2) These plans consist of the 2006, 2016 and 2018 Employee, Director and Consultant Equity Incentive Plans.

(3) Includes shares available for future issuance under the 2018 Employee, Director and Consultant Equity Incentive Plan and shares available for future issuance under the Company's Employee Stock Purchase 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 selected financial data. 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 report.

	Year Ended Dec. 31 2018	Year Ended Dec. 31 2017	Twelve Months Ended Dec. 31 2016 (unaudited)	Six Month Transition Period Ended Dec. 31 2016	Six Months Ended Dec. 31 2015 (unaudited)	Years Ended June 30, 2016	2015	2014
Consolidated Statement of Operations Data:								
Total revenues	$ 53,446	$ 115,447	$ 48,628	$ 21,506	$ 32,880	$ 60,002	$ 85,541	$ 59,896
Total operating expenses	214,895	174,429	184,271	88,992	89,714	184,993	139,996	131,427
Non-cash interest expense on liability related to sale of future royalty and convertible senior notes	10,631	13,682	18,593	8,665	10,202	20,130	5,437	—
Non-cash debt conversion expense	—	22,915	—	—	—	—	—	—
Other income (expense), net	3,237	(433)	(2,497)	(2,732)	69	304	(847)	167
Net loss	$ (168,843)	$ (96,012)	$ (156,733)	$ (78,883)	$ (66,967)	$ (144,817)	$ (60,739)	$ (71,364)
Basic and diluted net loss per common share	$ (1.21)	$ (0.98)	$ (1.80)	$ (0.91)	$ (0.77)	$ (1.67)	$ (0.71)	$ (0.83)
Basic and diluted weighted average common shares outstanding	139,946	98,068	87,029	87,102	86,904	86,976	86,038	85,481

	December 31, 2018	2017	2016	June 30, 2016	2015	2014
Consolidated Balance Sheet Data:						
Cash and cash equivalents	$ 262,252	$ 267,107	$ 159,964	$ 245,026	$ 278,109	$ 142,261
Total assets	295,381	294,676	198,864	287,085	313,823	165,318
Long-term convertible notes-net	2,064	2,050	96,965	96,628	—	—
Shareholders' equity (deficit)	10,972	(17,895)	(152,850)	(82,304)	35,104	75,699

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

Overview

We are a clinical-stage biotechnology company focused on developing the next generation of antibody-drug conjugates, or ADCs, to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer patients more good days. We call this our commitment to "target a better now."

An ADC with our proprietary technology comprises an antibody that binds to a target found on tumor cells and is 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 four approved products and the number of agents in development growing significantly in recent years.

We have established a leadership position in ADCs with a robust portfolio and a productive platform that has generated differentiated candidates for cancer treatment. Our proprietary portfolio is led by mirvetuximab soravtansine, a first-in-class ADC targeting folate-receptor alpha, or FRα. In late 2016, we initiated a Phase 3 registration trial, FORWARD I, with mirvetuximab for use as single-agent therapy to treat patients with platinum-resistant ovarian cancer whose tumors express medium or high levels of FRα and who have received up to three prior treatment regimens. In 2018, we fully enrolled FORWARD I, and successfully completed an interim analysis after 80 PFS events. On March 1, 2019, we announced that FORWARD I did not meet its PFS primary endpoint in either the entire study population or in the pre-specified subset of patients with high FRα expression. Based upon the efficacy signals we observed in the high FRα subset with PFS, confirmed overall response rate and overall survival, we are conducting additional analyses to further evaluate the potential benefit of mirvetuximab soravtansine for FRα-positive platinum-resistant ovarian cancer.

Mirvetuximab is also being assessed in multiple combinations in FORWARD II, a Phase 1b/2 study of the agent in combination with Avastin® (bevacizumab) or Keytruda® (pembrolizumab) in patients with Frα-positive platinum-resistant ovarian cancer, as well as a triplet combination of mirvetuximab plus carboplatin and bevacizumab in patients with recurrent platinum-sensitive ovarian cancer. In 2018, we presented combination data from more than 100 patients, beginning with data from the dose-escalation FORWARD II cohort evaluating mirvetuximab in combination with pembrolizumab at the Society of Gynecologic Oncology (SGO) Annual Meeting, which demonstrated encouraging efficacy and favorable tolerability in patients with platinum-resistant ovarian cancer. Based on these data, we enrolled an additional 35 patients with medium or high FRα expression levels in an expansion cohort in the FORWARD II study Findings from the combined dose escalation and expansion cohorts were presented at the 2018 European Society for Medical Oncology (ESMO) Congress in October and confirmed the safety of the combination and the activity of mirvetuximab in heavily pretreated ovarian cancer patients in terms of response rate with a trend towards improved duration of response with the addition of pembrolizumab. We plan to present data from the mature cohort during 2019, the results of which will determine our approach to further development of this combination.

We also reported updated data from the FORWARD II dose-escalation cohort evaluating mirvetuximab in combination with carboplatin in patients with recurrent platinum-sensitive ovarian cancer. The updated data demonstrated a favorable safety profile along with an increased response rate and more durable benefit after longer-term follow up. In June, we presented data from the FORWARD II expansion cohort evaluating mirvetuximab in combination with bevacizumab at the American Society of Clinical Oncology (ASCO) Annual Meeting, which demonstrated anti-tumor activity with durable responses and favorable tolerability in patients with platinum-resistant ovarian cancer. Taken together, findings from these doublets supported the initiation of the ongoing FORWARD II cohort assessing a triplet combination of mirvetuximab plus carboplatin and bevacizumab in patients with recurrent platinum-sensitive ovarian cancer. We completed enrollment of the triplet in late 2018 and expect to report data from this cohort in 2019.

We have built a productive platform that continues to generate innovative and proprietary ADCs, including IMGN632, our CD123-targeting product candidate in clinical trials for patients with acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN), and IMGN779, our CD33-targeting product candidate in clinical trials for patients with AML. Initial data from the Phase 1 study of IMGN632 in patients with relapsed or refractory adult AML and BPDCN were presented at the American Society of Hematology (ASH) Annual Meeting in December 2018. IMGN632 was shown to display anti-leukemic activity across all dose levels tested and a tolerable safety profile at doses up to 0.3 mg/kg. Enrollment in expansion cohorts is ongoing to identify the recommended Phase 2 dose and schedule for both AML and BPDCN. Updated data from the IMGN779 Phase 1 dose finding study in AML patients were also

presented at ASH; these data show that IMGN779 continues to display a tolerable safety profile with repeat dosing across a wide range of doses explored in patients with relapsed AML, with anti-leukemic activity seen at doses ≥0.39 mg/kg in both schedules. Enrollment is ongoing to identify the recommended Phase 2 dose and schedule.

In August 2017, we announced a strategic collaboration and option agreement with Jazz, to develop and co-commercialize ADCs. Jazz has exclusive worldwide rights to opt into development and commercialization of IMGN779, IMGN632, and a third program to be named later from our early-stage pipeline.

Over the last 38 years, ImmunoGen has assembled the most comprehensive “tool box” in the ADC field. Our platform technology combines advanced chemistry and biochemistry with innovative approaches to antibody optimization, with a focus 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. Combined with the accumulated experience of our research team, these capabilities have enabled us to generate a pipeline of novel candidates optimized for individual tumor types with potent anti-tumor activity and tolerable safety profiles that we can develop as monotherapies and in combination with existing and novel therapies.

Collaborating on ADC development with other companies allows us to generate revenue, mitigate expenses, enhance our capabilities, and extend the reach of our proprietary platform. The most advanced partner program is Roche’s marketed product, Kadcyla (ado-trastuzumab emtansine), the first ADC to demonstrate superiority over standard of care in a randomized pivotal trial, EMILIA, and gain FDA approval. Our ADC platform is used in candidates in clinical development with a number of partners. We have evolved our partnering approach to pursue relationships where we can gain access to technology and complementary capabilities, such as our technology swap with CytomX, as well as co-development and co-commercialization opportunities, such as our relationships with Jazz and MacroGenics. We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements. For more information concerning these relationships, including their ongoing financial and accounting impact on our business, please read Note C, “Significant Collaborative Agreements,” to our consolidated financial statements included in this report.

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 December 31, 2018, we had $262.3 million in cash and cash equivalents compared to $267.1 million as of December 31, 2017. In January 2019, we sold our residual rights to receive royalty payments on commercial sales of Kadcyla to OMERS, the defined benefit pension plan for municipal employees in the Province of Ontario, Canada, for $65.2 million, net of fees.

Change in fiscal year

As previously reported, we changed our fiscal year end to December 31 from June 30 effective January 1, 2017. This Annual report on Form 10-K is for the twelve months ended December 31, 2018, and we previously filed a transition report for the six-month period of July 1, 2016 through December 31, 2016, which we refer to as the transition period. References through management’s discussion and analysis to amounts related to the year ended December 31, 2016 and the six months ended December 31, 2015 are unaudited.

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 adopted ASC 606 on January 1, 2018, using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for 2018 reflect the application of ASC 606 guidance, while the reported results prior to 2018 were prepared under the guidance of ASC 605, “*Revenue Recognition*”, which is also referred to herein as "legacy GAAP" or the "previous guidance." Refer to Note B to the consolidated financial statements for further discussion on this change. We believe the following critical accounting policies reflect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We enter into licensing and development agreements with collaborators for the development of ADC therapeutics. The terms of these agreements contain multiple performance obligations 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) prior to the decommissioning of our Norwood facility in 2018, 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. Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under the agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when or as we satisfy each performance obligation.

We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determines those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied.

As part of the accounting for the arrangement, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract, which is discussed in further detail below.

At December 31, 2018, we had the following material 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 and commercialize anticancer compounds to a specified antigen target:

  Bayer (one exclusive single-target license)

  Biotest (one exclusive single-target license)

  CytomX (one exclusive single-target license)

  Fusion Pharmaceuticals (one exclusive single-target license)

  Novartis (five exclusive single-target licenses)

  Oxford BioTherapeutics/Menarini (one exclusive target license sublicensed from Amgen)

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

  Sanofi (five fully-paid, exclusive single-target licenses)

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

  Debiopharm (one exclusive single-compound license)

- Collaboration and option agreement for a defined period of time to secure development and commercialization licenses to develop and commercialize specified anticancer compounds on established terms:

  Jazz Pharmaceuticals

- Collaboration and license agreement to co-develop and co-commercialize a specified anticancer compound on established terms:

  MacroGenics

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 obligations 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 obligations related to rights to future technological improvements, research activities to be performed on behalf of the collaborative partner and, prior to the decommissioning of our Norwood facility in 2018, 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 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 preclinical and clinical materials or deliver cytotoxic agents at negotiated prices which are generally consistent with what other third parties would charge (which services we discontinued in 2018), (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. Royalty rates may vary over the royalty term depending on our intellectual property rights and/or the presence of comparable competing products. In the case of Sanofi, its licenses are fully-paid and no further milestones or royalties will be received. In the case of Debiopharm, no royalties will be received. 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 services, achieve milestones, or become liable for royalty payments.

In determining the performance obligations, management evaluates whether the license is distinct, and has significant standalone functionality, 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 and whether technological improvements are required for the continued functionality of the license. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. We estimate the stand-alone selling prices of the license and all other performance obligations 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.

We recognize revenue related to research services as the services are performed. 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 also develop conjugation processes for materials for later stage testing and commercialization for certain collaborators. We are compensated at negotiated rates and may receive milestone payments for developing these processes which are also recorded as a component of research and development support revenue. We may also produce research material for potential collaborators under material transfer agreements. We record amounts received for research materials produced or services performed as a component of research and development support revenue.

Prior to 2019, we also provided cytotoxic agents to our collaborators or produced preclinical and clinical materials (drug substance) at negotiated prices which were generally consistent with what other third parties would charge. We recognized revenue on cytotoxic agents and on preclinical and clinical materials when the materials had passed all quality testing required for collaborator acceptance and control was transferred to the collaborator. Arrangement consideration allocated to the manufacture of preclinical and clinical materials in a multiple-deliverable arrangement was below our full cost, and our full cost was never below its contract selling prices. During the twelve months ended December 31, 2018, 2017 and 2016, the six months ended December 31, 2016 and 2015, and the fiscal year ended June 30, 2016, 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 $1.4, $3.1, $3.7, $0.9, $4.1, and $6.9 million, respectively. The majority of our costs to produce these preclinical and clinical materials were fixed and then allocated to each batch based on the number of batches produced during the period. Therefore, our costs to produce these materials was significantly affected by the number of batches produced during the period. The volume of preclinical and clinical materials we produced was directly related to the scale and scope of preclinical activities and the number of clinical trials we and our collaborators were preparing for or currently had 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, varied significantly from period to period and exceeded the supply prices which represented the net realizable value of the related materials, which affected the margins recognized on such product sales. We discontinued producing preclinical and clinical materials for our collaborators by the end of 2018.

We recognize revenue related to the rights to future technological improvements over the estimated term of the applicable license.

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 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 arrangement that includes developmental and regulatory milestone payments, we evaluate whether the achievement of each milestone specifically relates to our efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of our efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service. If the milestone payment is not specifically related to our effort to satisfy a performance obligation or transfer a distinct good or service, the amount is allocated to all performance obligations using the relative standalone selling price method. In addition, we evaluate the milestone to determine whether the milestone is considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated; otherwise, such amounts are considered constrained and excluded from the transaction price. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development or regulatory milestones and any related constraint, and if necessary, adjust our estimate of the transaction price. Any such adjustments to the transaction price are allocated to the performance obligations on the same basis as at contract inception. Amounts allocated to a satisfied performance obligation shall be recognized as revenue, or as a reduction of revenue, in the period in which the transaction price changes.

For development and commercialization license agreements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied) in accordance with the royalty recognition constraint. Under our development and commercialization license agreements, except for the Sanofi and Debiopharm licenses, we receive royalty payments based upon our licensees' net sales of covered products. Generally, under the development and commercialization agreements, we receive royalty reports and payments from our licensees approximately one quarter in arrears. We estimate the amount of royalty revenue to be recognized based on historical and forecasted sales and/or sales information from its licensees if available.

Collaboration and Option Agreements/Right-to-Test Agreements

Our right-to-test agreements provide collaborators the right to test our ADC technology for a defined period of time through a research, or right-to-test, license. Under both right-to-test agreements and collaboration and option agreements, collaborators may (a) take options, for a defined period of time, to specified targets and (b) 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 the opt-in 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"), (iii) at the collaborator's request, after providing research services at negotiated prices which are generally consistent with what other third parties would charge, or (iv) some combination of all of these fees.

The accounting for collaboration and option agreements and right-to-test agreements is dependent on the nature of the options granted to the collaborative partner. Options are considered distinct performance obligations if they provide a collaborator with a material right. Factors that are considered in evaluating whether options convey a material right 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 fair value of the licenses, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options. As of December 31, 2018, all right-to-test agreements have expired.

If we conclude that an option provides the customer a material right, and therefore is a separate performance obligation, we then determine the estimated selling prices of the option and all other units of accounting based on an option pricing model using the following inputs: a) estimated fair value of each program, b) the amount the partner would pay to exercise the option to obtain the license and c) probability of exercise.

Upfront consideration allocated to development and commercialization licenses may be recognized upon delivery of the license if facts and circumstances dictate that the license has stand-alone functionality and is distinct from the undelivered performance obligations.

We do not 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.

In determining whether a collaboration and option agreement is within the scope of ASC 808, *Collaborative Arrangements*, management evaluates the level of involvement of both companies in the development and commercialization of the products to determine if both parties are active participants and if both parties are exposed to risks and rewards dependent on the commercial success of the licensed products. If the agreement is determined to be within the scope of ASC 808, we will segregate the research and development activities and the related cost sharing arrangement. Payments made by us for such activities will be recorded as research and development expense and reimbursements received from our partner will be recognized as an offset to research and development expense.

Clinical Trial Accruals

Clinical trial expenses are a significant component of research and development expenses, and we outsource a significant portion of these costs to third parties. Third party clinical trial expenses include investigator fees, site costs (patient costs), clinical research organization costs, and costs for central laboratory testing and data management. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as a prepaid asset or accrued clinical trial cost. These third party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future R&D activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. We also record accruals for estimated ongoing clinical research and development costs. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical clinical accrual estimates made by the Company have not been materially different from the actual costs.

Stock-based Compensation

As of December 31, 2018, we are authorized to grant future awards under one share-based compensation plan, which is the ImmunoGen, Inc. 2018 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 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 December 31, 2018, 2017 and 2016, the six months ended December 31, 2016 and 2015, and fiscal year 2016 was $16.4, $11.1, $19.8, $8.1, $10.2, and $21.9 million, respectively. During each of calendar and fiscal years 2016, we recorded $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 December 31, 2018, 2017 and 2016, the six months ended December 31, 2016 and 2015, and fiscal year 2016 was $361,000, $206,000, $431,000, $215,000, $164,000, and $380,000, 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 decreased $62.0 million to $53.4 million for the year ended December 31, 2018 compared to the prior year and increased $66.8 million to $115.4 million for the year ended December 31, 2017 compared to the year ended December 31, 2016. The decrease in revenues in calendar year 2018 compared to 2017 is attributable to a decrease in license and milestone fees and research and development support revenue, partially offset by an increase in non-cash royalty revenue and clinical materials revenue. The increase in revenues in calendar year 2017 compared to 2016 is attributable to an increase in license and milestone fees, non-cash royalty revenue and clinical materials revenue, partially offset by a decrease in research and development support revenue. Our total revenues for the six months ended December 31, 2016 decreased $11.4 million to $21.5 million compared to the six months ended December 31, 2015, which is attributable to a decrease in license and milestone fees, royalty revenue and clinical materials revenue, partially offset by a decrease in research and development support revenue, and our total revenues for the fiscal year ended June 30, 2016 were $60.0 million.

License and milestone fees

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 collaborators in the years ended December 31, 2018, 2017, and 2016, the six months ended December 31, 2016 and 2015, and the fiscal year ended June 30, 2016 is shown in the following table (in thousands):

License and Milestone Fees	Years Ended December 31, 2018	2017	2016 (unaudited)	Six Months Ended December 31, 2016	2015 (unaudited)	Year Ended June 30, 2016
Collaborative Partner:						
Amgen/Oxford BioTherapeutics/Menarini	$ 1,066	$ 17	$ 16	$ 8	$ 1,009	$ 1,017
Bayer HealthCare	16	—	10,000	—	—	10,000
Biotest	—	—	—	—	12	12
CytomX	14	13,665	—	—	—	—
Debiopharm	500	29,500	—	—	—	—
Fusion	750	—	—	—	—	—
Lilly	717	22	24	12	5,011	5,023
Novartis	1,189	180	5,180	5,090	90	180
Roche	46	—	—	—	—	—
Sanofi	—	36,000	1	—	2,008	2,009
Takeda	10,982	85	84	42	8,632	8,674
Total	$ 15,280	$ 79,469	$ 15,305	$ 5,152	$ 16,762	$ 26,915

Revenue from license and milestone fees decreased $64.2 million to $15.3 million for the year ended December 31, 2018 and increased $64.2 million to $79.5 million for prior year. Included in license and milestone fees for the year ended December 31, 2018 is $10.9 million of previously deferred license revenue earned upon the expiration of the right to execute a license or extend the research term specified under the right-to-test agreement with Takeda, a $500,000 payment received in January 2018 related to the delivery of IMGN529 clinical materials to Debiopharm, and $1 million and $500,000 of development milestones that were determined to be probable of occurring under our license agreements with Oxford BioTherapeutics Ltd. and Fusion, respectively, that were allocated to the previously delivered licenses. In May 2018, Novartis terminated one of its six development and commercialization licenses, and in October 2018, Lilly terminated its three development and commercialization licenses. As a result, we recorded the remaining $1.7 million balance of the upfront payments that had been allocated to future performance obligations under these licenses as revenue, which is included in license and milestone fees for 2018. Included in license and milestone fees for the prior year is $29.5 million of revenue related to the sale and transfer of our IMGN529 asset to Debiopharm, a $30 million paid-up license fee related to an amendment to our collaboration and license agreement with Sanofi, $6 million of development milestones achieved under the collaboration and license agreement with Sanofi prior to amendment, $12.7 million of non-cash license revenue earned upon the expiration of the right to replace the target specified under the development and commercialization license with CytomX and a $1 million development milestone achieved under said license agreement with CytomX. Included in license and milestone fees for the year ended December 31, 2016 are $15 million of development milestones achieved under license agreements with Bayer and Novartis.

Deferred revenue of $80.8 million as of December 31, 2018 includes a $75 million upfront payment related to the license options granted to Jazz in August 2017, with the remainder of the balance primarily representing consideration received from our collaborators pursuant to our license agreements, which we have yet to earn pursuant to our revenue recognition policy.

Non-cash royalty revenue related to the sale of future royalties

In February 2013, the U.S. FDA granted marketing approval to Kadcyla, an ADC 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, $32.2, $28.1, $26.2, $12.9, $12.0, and $25.3 million of non-cash royalties on net sales of Kadcyla were recorded and included in royalty revenue for the years ended December 31, 2018, 2017 and 2016, the six months ended December 31, 2016 and 2015, and the fiscal year ended June 30, 2016, respectively. Kadcyla sales occurring after January 1, 2015 are covered by a royalty purchase agreement whereby the associated cash was remitted to Immunity Royalty Holdings, L.P. subject to a residual cap. In January 2019, we sold our residual rights to receive royalty payments on commercial sales of Kadcyla to OMERS, the defined benefit pension plan for municipal employees in the Province of Ontario, Canada, for $65.2 million, net of $1.5 million of fees. Simultaneously, OMERS purchased IRH's right to the royalties the Company previously sold as described above, therefore obtaining the rights to 100% of the royalties received from that date on. See further details regarding royalty obligation in Note F of the Consolidated Financial Statements.

Research and development support revenue

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. Research and development support revenue decreased $2.1 million to $1.4 million for the year ended December 31, 2018 and decreased $1.7 million to $3.5 million for the prior year. Research and development support revenue increased $1.2 million to $2.8 million for the six months ended December 31, 2016 compared to the six months ended December 31, 2015, and was $4.0 million for the year ended June 30, 2016.

Clinical materials revenue

The amount of clinical materials revenue we earned, and the related cost of clinical materials charged to research and development expense, was directly related to the number of clinical trials our collaborators who used us to manufacture clinical materials were preparing or had 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 received clinical benefit from the clinical materials, and the demand our collaborators had 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 varied significantly from quarter to quarter and year to year. Clinical materials revenue increased $200,000 to $4.6 million for the year ended December 31, 2018 and increased $2.5 million to $4.4 million for the prior year. Clinical materials revenue decreased $1.6 million to $679,000 for the six months ended December 31, 2016 compared to the six months ended December 31, 2015, and was $3.6 million for the year ended June 30, 2016. During the periods presented, 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 were compensated at negotiated prices which were generally consistent with what other third-parties would charge. We discontinued producing preclinical and clinical materials for our collaborators by the end of 2018.

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) prior to 2019, manufacturing operations which also included 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;
- process improvements to our ADC technology;
- prior to 2019, 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 payloads for our and our partners' preclinical and clinical activities; and
- 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 payloads.

Research and development expense increased $34.7 million to $174.5 million for the year ended December 31, 2018 and decreased $1.6 million to $139.7 million for the prior year. The significant increase in 2018 from prior year

was primarily due to higher clinical trial costs driven largely by completion of patient enrollment in FORWARD I, increased costs related to the FORWARD II and IMGN632 trials, and higher external manufacturing costs in support of commercial validation of mirvetuximab soravtansine. Contract service expense also increased due to increased clinical, regulatory, and commercial-readiness efforts to support advancement of mirvetuximab soravtansine. The decrease in 2017 from 2016 was primarily due to a workforce reduction resulting from a strategic review in September 2016 and lower third-party service fees, partially offset by increased clinical trial and drug supply costs, particularly related to the FORWARD I and FORWARD II studies.

Research and development expense for the six months ended December 31, 2016 decreased $6.7 million to $66.6 million compared to the six months ended December 31, 2015 and was $148.1 million for the year ended June 30, 2016. The decrease in the 2016 transition period is primarily due to: (i) decreased third-party costs related to timing of activities to support pivotal development of mirvetuximab soravtansine; (ii) a decrease in cost of clinical materials revenue charged to research and development expense due to timing of orders of such clinical materials from our partners; (iii) an increase in costs capitalized into inventory due to a greater number of manufactured batches of conjugated materials on behalf of our collaborators; and (iv) decreased cytotoxic and antibody costs due to timing of supply requirements; partially offset by increased clinical trial costs, particularly related to the FORWARD I and FORWARD II studies.

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.

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):

	Years Ended December 31,			Six Months Ended December 31,		Year Ended June 30,
Research and Development Expense	2018	2017	2016	2016	2015	2016
			(unaudited)		(unaudited)	
Research	$ 24,218	$ 22,570	$ 24,825	$ 11,974	$ 11,903	$ 24,754
Preclinical and Clinical Testing	89,226	68,794	66,476	31,152	33,531	68,855
Process and Product Development	12,463	10,261	13,947	6,994	5,582	12,535
Manufacturing Operations	48,549	38,114	36,064	16,446	22,315	41,933
Total Research and Development Expense	$ 174,456	$ 139,739	$ 141,312	$ 66,566	$ 73,331	$ 148,077

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 $1.6 million to $24.2 million for the year ended December 31, 2018 and decreased $2.2 million to $22.6 million for the prior year. The increase in 2018 was principally due to increases in contract services, lab supply costs and facility costs allocated to these departments. The decrease in 2017 was principally due to a decrease in salaries and related expenses driven by a workforce reduction resulting from a strategic review in September 2016 and lower stock compensation expense, and to a lesser extent, a decrease in lab supplies and contract service expense driven by timing of certain internal and partner activities.

Research expenses increased $71,000 to $12.0 million for the six months ended December 31, 2016 compared to the six months ended December 31, 2015, and were $24.8 million for the year ended June 30, 2016.

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 $20.4 million to $89.2 million for the year ended December 31, 2018 and increased $2.3 million to $68.8 million for the prior year. The increase in 2018 was primarily the result of an increase in clinical trial costs principally driven by advancement of the FORWARD I, FORWARD II, and IMGN632 studies, an increase in salaries and related expenses driven by increases in personnel and stock compensation expense, and an increase in contract services to support commercial advancement of mirvetuximab soravtansine. Partially offsetting these increases, a higher credit was recorded against IMGN779 and IMGN632 development costs in 2018 resulting from a full-year of cost-sharing with Jazz pursuant to the collaboration agreement executed in August 2017. The increase in 2017 was primarily the result of an increase in clinical trial costs driven substantially by advancement of the FORWARD I study, partially offset by the following: (i) a decrease in salaries and related expenses driven by a workforce reduction resulting from a strategic review in September 2016 and lower stock compensation expense, (ii) a credit recorded against IMGN779 and IMGN632 development costs in the period resulting from cost-sharing with Jazz, and (iii) a decrease in contract services and consulting fees due to timing of certain activities.

Preclinical and clinical testing expenses decreased $2.4 million to $31.2 million for the six months ended December 31, 2016 compared to the six months ended December 31, 2015, and were $68.9 million for the year ended June 30, 2016. The decrease in the 2016 transition period was principally due to a decrease in contract service expense, particularly related to timing of certain activities to support pivotal development of mirvetuximab soravtansine, partially offset by greater clinical trial costs incurred related to the combination and Phase 3 mirvetuximab soravtansine studies, as well as costs incurred related to the IMGN779 study, which initiated in the second half of fiscal 2016, partially offset by lower costs related to the Phase I mirvetuximab soravtansine study that was winding down and lower costs related to the IMGN289 study that was discontinued in fiscal 2015.

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 expenses in this category increased $2.2 million to $12.5 million for the year ended December 31, 2018 and decreased $3.7 million to $10.3 million for the prior year. The increase in 2018 was principally due to increases in lab supply costs, allocated facility costs, salaries and related expenses driven by greater stock compensation expense, partially offset by a higher credit recorded against IMGN779 and IMGN632 development costs in 2018 resulting from a full-year of cost-sharing with Jazz pursuant to the collaboration agreement executed in August 2017. The decrease in 2017 was principally the result of: (i) a decrease in salaries and related expenses driven by a workforce reduction resulting from a strategic review in September 2016 and lower stock compensation expense; (ii) a decrease in contract services driven by decreased development activities related to our IGN cytotoxic agents; (iii) a credit recorded against IMGN779 and IMGN632 development costs in the period resulting from cost-sharing with Jazz; and (iv) a decrease in lab supplies.

Total process and product development expenses increased $1.4 million to $7.0 million in the six months ended December 31, 2016 from $5.6 million in the six months ended December 31, 2015, and were $12.5 million for the year ended June 30, 2016. The increase in the 2016 transition period was principally due to increases in salaries and related expenses and 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, which we have decommissioned. Such expenses include personnel, raw materials for our and our collaborators' preclinical studies and clinical trials, non-pivotal and pivotal development costs with contract manufacturing organizations, manufacturing supplies, and facilities expense. Manufacturing operations expense increased $10.4 million to $48.5 million for the year ended December 31, 2018 and increased $2.0 million to $38.1 million for the prior year. The increase in 2018 was principally the result of; (i) an increase in external manufacturing costs, including antibody development and supply expense; (ii) an increase in analytical service fees to transfer our products and certain of our collaborators' out of our Norwood plant; and (iii) increased depreciation expense related to accelerated amortization of Norwood leasehold improvements. Partially offsetting these increases, a higher credit was recorded against IMGN779 and IMGN632 development costs in 2018 resulting from a full-year of cost-sharing with Jazz pursuant to the collaboration agreement executed in August 2017. The increase in 2017 was principally the result of: (i) an increase in antibody development and supply expense; (ii) an increase in costs of clinical materials revenue charged to research and development expense due to timing of orders and release of such clinical materials from our partners; and (iii) an increase in cost of cytotoxic agents driven by timing of supply requirements for the IMGN779 and IMGN632 clinical studies. Partially offsetting these increases are the following: (i) a decrease in salaries and related expenses driven by a workforce reduction resulting from a strategic review in September 2016 and lower stock compensation expense; (ii) an increase in costs capitalized into inventory due to a greater number of manufactured batches of conjugated materials on behalf of our collaborators in 2017; (iii) a credit recorded against IMGN779 and IMGN632 development costs in 2017 resulting from cost-sharing with Jazz; (iv) a decrease in mirvetuximab soravtansine third-party conjugation costs driven by timing; and, (v) a decrease in contract services due primarily to DMx development activities conducted in 2016.

Manufacturing operations expenses decreased $5.9 million to $16.4 million in the six months ended December 31, 2016 from $22.3 million in the six months ended December 31, 2015, and were $41.9 million for the year ended June 30, 2016. The decrease in the 2016 transition period was principally due to (i) a decrease in cost of clinical materials revenue charged to research and development expense due to timing of orders from our partners and release of such clinical materials; (ii) a decrease in cost of cytotoxic agents driven by timing of supply requirements; (iii) an increase in costs capitalized into inventory due to a greater number of manufactured batches of conjugated materials on behalf of our collaborators during the period; (iv) a decrease in antibody development and supply expense driven primarily by timing of supply of coltuximab ravtansine; and (v) a decrease in salaries and related expenses.

Antibody development and supply expense in support of commercial validation and in anticipation of potential future clinical trials, as well as our ongoing trials, was $18.5, $12.5, $7.7, $4.3, $5.2, and $8.6, million for the years ended December 31, 2018, 2017, and 2016, the six months ended December 31, 2016 and 2015, and the fiscal year ended June 30, 2016, respectively. Activity and supply in support of commercial validation of mirvetuximab soravtansine drove the significant increases in 2018 and 2017. 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 increased $2.8 million to $36.7 million for the year ended December 31, 2018 and decreased $4.6 million to $33.9 million for the prior year. The increase in 2018 was principally due to an increase in third-party service fees and an increase in salaries and related expenses driven largely by greater stock compensation expense. The decrease in 2017 was primarily due to lower salaries and related expenses driven by a $3.3 million non-cash stock compensation charge recorded in 2016 resulting from the CEO transition and a decrease in professional service fees due to reengineering consulting services incurred in 2016, as well as decreased recruiting and patent fees in 2017. Partially offsetting these decreases, legal fees increased related to new partner agreements executed during 2017.

General and administrative expenses for the six months ended December 31, 2016 increased $1.6 million to $18.0 million compared to the six months ended December 31, 2015, and were $36.9 million for the year ended June 30, 2016. The increase in the 2016 transition period was primarily due to increased professional service fees relating to the Company's strategic review and resulting restructuring activities, partially offset by lower salaries and related expenses and lower administrative expenses.

Restructuring Charge

On September 26, 2016, the Board of Directors approved a plan to reengineer the business, resulting in a reduction of the workforce by approximately 17%, or 65 positions, which included the separation of 60 current employees. Communication of the plan to the affected employees was substantially completed on September 29, 2016. All of the workforce reduction was completed as of December 31, 2016. As a result of the workforce reduction, in the six months ended December 31, 2016, we recorded a restructuring charge totaling $4.4 million related to termination benefits and other related charges, of which $2.8 million was recorded as a one-time termination benefit, and $593,000 recorded as a benefit under an ongoing benefit plan. The related cash payments were substantially paid out by June 30, 2017. Additionally, approximately 762,000 stock options were forfeited in connection with the workforce reduction, and as a result, we recorded an approximate $837,000 credit to stock compensation expense which is included in research and development expense and general and administrative expense for the 2016 transition period.

In addition to the termination benefits and other related charges, we began seeking to sub-lease 10,281 square feet of unoccupied office space in Waltham that was leased in February 2016. Based on an estimate of the potential time it would take to find a tenant of approximately nine months, the anticipated sub-lease terms, and consideration of the tenant allowance that was given to us to build out the space, we determined we did not need to record a loss on the sub-lease. We also evaluated the balance of the leasehold improvements for potential impairment as of September 30, 2016. In performing the recoverability test, we concluded that a substantial portion of the leasehold improvements were not recoverable. We recorded an impairment charge of $970,000 related to these assets after comparing the fair value (using probability weighted scenarios with discounted cash flows) to the leasehold improvements' carrying value, leaving a $193,000 remaining cost basis. During 2017, based on further evaluation of the prospects for sub-leasing the space, the Company determined that additional time would be required to find a tenant. Accordingly, the calculation for the potential sub-lease loss was updated and it was determined that the remaining balance of the leasehold improvements was impaired. Also, due to additional time expected to secure a tenant, an additional lease loss was recorded based on the change in estimate of the sub-lease assumption. The total of these charges in 2017 was $779,000.

In February 2018, following an in-depth review of manufacturing and quality operations, the Board of Directors authorized management to implement a new operating model that will rely on external manufacturing and quality testing for drug substance and drug product for our development programs. The implementation of this new operating model led to the ramp-down of manufacturing and quality activities at the Norwood, Massachusetts facility during 2018, with a full decommissioning of the facility expected by early 2019. Implementation of the new operating model resulted in the separation of 22 employees. Communication of the plan to the affected employees was substantially completed on February 8, 2018.

In connection with the implementation of the new operating model, we recorded a one-time charge of $1.2 million for severance in the first quarter of 2018 related to a pre-existing plan. Additional expense was recorded for retention benefits over the remaining service period of the related employees, as well as marginal adjustments to

severance resulting from voluntary terminations, which totaled $2.3 million for the remainder of the year. Additionally, certain options held by the employees to be separated were modified to extend the exercise period, resulting in a stock compensation charge of $157,000 in the first quarter. Cash payments related to severance will be substantially paid out by the end of the second quarter of 2019. The retention benefits were paid out in the fourth quarter of 2018.

Investment Income, net

Investment income for the years ended December 31, 2018, 2017, and 2016, the six months ended December 31, 2016 and 2015, and the fiscal year ended June 30, 2016 was $4.2 million, $1.1 million, $473,000, $259,000, $111,000, and $325,000, respectively. The increase in 2018 is due to a greater average cash balance driven by $101.7 million of net proceeds generated from a public offering of common stock in October 2017 and $162.5 million of net proceeds generated from a public offering of common stock in June 2018. The increase in 2017 is due to a greater average cash balance driven by the proceeds received in June 2016 resulting from the senior convertible notes issuance, which is discussed further in Note E to our Consolidated Financial Statements, significant upfront license and milestone fee payments received from partners during the year, as well as $101.7 million of net proceeds generated from a public offering of common stock in October 2017.

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

In 2015, IRH purchased our right to receive 100% of the royalty payments on commercial sales of Kadcyla 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. In January 2019, OMERS purchased IRH's right to the royalties the Company previously sold as described above. 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 Kadcyla royalties are remitted directly to the purchaser. During the years ended December 31, 2018, 2017, and 2016, and the six months ended December 31, 2016 and 2015, and the fiscal year ended June 30, 2016, we recorded $10.6, $13.2, $18.4, $8.5, $10.2, and $20.1 million, respectively, of non-cash interest expense. The decrease in the years ended December 31, 2018 and 2017 and the six months ended December 31, 2016 is a result of a lower effective interest rate driven by lower projected royalty payments in the near term than previously estimated. We impute interest on the transaction and record interest expense at the effective interest rate, which we currently estimate to be 5.7%. 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 Kadcyla, and we 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.

Interest Expense on Convertible Senior Notes

In June 2016, the Company issued Convertible 4.5% Senior Notes with an aggregate principal amount of $100 million. 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. For the years ended December 31, 2018, 2017, and 2016, we recorded $95,000, $3.0 million, and $2.4 million, respectively, of interest expense. In the 2016 transition period and the fiscal year 2016, we recorded $2.3 million and $138,000, respectively, of interest expense. No similar charges were recorded in the six months ended December 31, 2015. During the second half of calendar 2017, $97.9 million of this debt was converted to common shares, which is discussed further below.

Non-Cash Debt Conversion Expense

During the second half of calendar 2017, we entered into privately negotiated exchange agreements with a number of holders of our outstanding Convertible Notes, pursuant to which we agreed to exchange, in a private placement, $97.9 million in aggregate principal amount of Convertible Notes held by the holders for 26.2 million newly issued shares of our common stock, equivalent to the number of shares based on the original conversion terms, plus an additional number of newly issued shares of common stock to be determined based on the volume-weighted average trading price of the common stock over certain trading days. As a result of the agreements, 2.8 million additional shares, were issued.

In accordance with ASC, Topic 470-20, "Debt – Debt with Conversion and Other Options," we recorded a non-cash debt conversion expense in the amount of $22.9 million in the prior year, the accounting details of which are further discussed in Note E to our Consolidated Financial Statements. In addition, accrued interest on the bonds of $743,000

which the noteholders forfeited, $2.5 million of deferred financing costs and $1.7 million of costs incurred to execute the conversions were charged to paid-in capital as a result of the issuance of common stock.

Other (Expense) Income, net

Other (expense) income, net for the years ended December 31, 2018, 2017, and 2016, and the six months ended December 31, 2016 and 2015, and the year ended June 30, 2016 was $(895,000), $1.5 million, $(583,000), $(742,000), $(42,000), and $117,000, respectively. This includes $(780,000), $1.6 million, $(422,000), $(586,000), $(68,000), and $96,000 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 same periods, respectively.

Liquidity and Capital Resources
(amounts in tables in thousands)

	As of December 31,	
	2018	2017
Cash and cash equivalents	$ 262,252	$ 267,107
Working capital	208,121	220,571
Shareholders' equity (deficit)	10,972	(17,895)

	Years Ended December 31			Six Months Ended December 31		Year Ended June 30
	2018	2017	2016	2016	2015	2016
			(unaudited)		(unaudited)	
Cash (used) provided by operating activities	$ (166,422)	$ 7,645	$ (142,642)	$ (83,656)	$ (65,490)	$ (124,476)
Cash used for investing activities	(5,246)	(1,116)	(6,655)	(1,406)	(5,127)	(10,376)
Cash provided by financing activities	166,813	100,614	96,978	—	4,791	101,769

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 and convertible debt financings in public markets and payments from our collaborators, including license fees, milestones, research funding, and royalties. We have also monetized our rights to receive royalties on Kadcyla for up-front consideration. As of December 31, 2018, we had $262.3 million in cash and cash equivalents. Net cash (used) provided by operating activities was $(166.4), $7.6, $(142.6), $(83.7), $(65.5), and $(124.5) million during the years ended December 31, 2018, 2017, and 2016, the six months ended December 31, 2016 and 2015, and for the year ended June 30, 2016, respectively. The principal use of cash in operating activities for all periods presented was to fund our net loss, adjusted for non-cash items, with the prior year benefiting from payments by Jazz, Debiopharm and Sanofi, totaling $137.8 million resulting in cash provided by operations.

Net cash used for investing activities was $5.2, $1.1, $6.7, $1.4, $5.1, and $10.4 million for the years ended December 31, 2018, 2017, and 2016, the six months ended December 31, 2016 and 2015, and the year ended June 30, 2016, respectively, and represent cash outflows from capital expenditures. Capital expenditures for all periods presented 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 $166.8, $100.6, $97.0, $4.8, and $101.8 million for the years ended December 31, 2018, 2017, and 2016, the six months ended December 31, 2015, and the year ended June 30, 2016, respectively. There was no cash provided by financing activities during the six months ended December 31, 2016. In June 2018, pursuant to a public offering, we issued and sold 15.8 million shares of our common stock resulting in net proceeds of $162.5 million. In October 2017, pursuant to a public offering, we issued and sold 16.7 million shares of our common stock resulting in net proceeds of $101.7 million. In June 2016, we issued Convertible 4.5% Senior Notes with an aggregate principal amount of $100 million for which we received net proceeds of $96.6 million after deducting fees and expenses of $3.4 million and of which $2.1 million remain outstanding. See Note E to our Consolidated Financial Statements for further details regarding the terms of this transaction.

Net cash provided by financing activities for the years ended December 31, 2018, 2017, and 2016, the six months ended December 31, 2015, and the year ended June 30, 2016 include proceeds from the exercise of 742,000, 191,000, 94,000, 461,000, and 555,000 stock options, respectively.

We anticipate that our current capital resources of $262.3 million and the $65.2 million raised from the sale of our residual rights to Kadcyla royalties in January 2019 will enable us to meet our operational expenses and capital expenditures for more than twelve months after the date of this report. We may raise additional funds through equity and debt financings or generate revenues from collaborators through a combination of upfront license payments, milestone payments, royalty payments and research funding. 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 or if we are not successful in securing future collaboration agreements, we may elect or be required to secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects. In light of the results of our FORWARD I trial, we plan to conduct a full review of the FORWARD I data to determine potential next steps with mirvetuximab soravtansine as a single agent, and assess our ongoing FORWARD II combination trials of mirvetuximab soravtansine in combination with other therapeutic agents as a potential path forward to support a registration in ovarian cancer. Additionally, we will be reviewing our 2019 operating plan to determine what measures will be taken to further extend our cash position.

Pursuant to a Sales Agreement dated March 3, 2017, with Cowen and Company, LLC, or Cowen, as sales agent, we may offer and sell, from time to time, through Cowen, shares of our common stock having an aggregate offering price of up to $50.0 million.

Contractual Obligations

Below is a table that presents our contractual obligations and commercial commitments as of December 31, 2018 (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]	$ 39,036	$ 5,251	$ 10,676	$ 10,773	$ 12,336
Other operating lease obligations[1]	247	247	—	—	—
Liability related to the sale of future royalties[2]	150,513	26,632	60,269	50,170	13,442
Convertible 4.5% senior notes[3]	2,100	—	2,100	—	—
Total	$ 191,896	$ 32,130	$ 73,045	$ 60,943	$ 25,778

(1) See Note J to the Consolidated Financial Statements in Item 8 for discussion of these leases.

(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, the Company is responsible for variable operating costs and real estate taxes approximating $3.0 million per year through March 2026.

Additionally, 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 December 31, 2018, the maximum amount that may be payable in the future under our current collaborative agreements is $80 million.

As of December 31, 2018, we have noncancelable obligations under certain agreements related to in-process and future manufacturing of antibody and cytotoxic agents required for clinical supply of our product candidates totaling $1.3 million, all of which will be paid in calendar 2019.

In the fourth quarter of 2018, we executed a commercial agreement, which superseded a previous letter agreement, with one of our manufacturers for future production of antibody through calendar 2022. Pursuant to the agreement, our noncancelable commitment is approximately €22 million at December 31, 2018.

Recent Accounting Pronouncements

The information set forth under Note B to the consolidated financial statements under the caption "Summary of Significant Accounting Policies" is incorporated herein by reference.

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 and relatively short duration of our investments, 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 December 31, 2018.

Item 8. ***Financial Statements and Supplementary Data***

IMMUNOGEN, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of ImmunoGen, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ImmunoGen, Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, shareholders' (deficit) equity and cash flows for each of the two years in the period ended December 31, 2018, the six month transition period ended December 31, 2016 and the year ended June 30, 2016 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, the six month transition period ended December 31, 2016 and the year 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) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, 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 March 1, 2019 expressed an unqualified opinion thereon.

Adoption of ASU No. 2014-09

As discussed in Note B to the consolidated financial statements, the Company changed its method of accounting for revenue in 2018 due to the adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), and the related amendments.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's Auditor since 2001.

Boston, Massachusetts

March 1, 2019

IMMUNOGEN, INC.

CONSOLIDATED BALANCE SHEETS

In thousands, except per share amounts

	December 31, 2018	December 31, 2017
ASSETS		
Cash and cash equivalents	$ 262,252	$ 267,107
Accounts receivable	1,701	2,649
Unbilled revenue	617	2,580
Contract asset	500	—
Non-cash royalty receivable	9,249	—
Inventory	—	1,038
Prepaid and other current assets	4,462	2,967
Total current assets	278,781	276,341
Property and equipment, net of accumulated depreciation	12,891	14,538
Other assets	3,709	3,797
Total assets	$ 295,381	$ 294,676
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Accounts payable	$ 11,365	$ 8,562
Accrued compensation	11,796	11,473
Other accrued liabilities	20,465	15,767
Current portion of deferred lease incentive	837	784
Current portion of liability related to the sale of future royalties, net of deferred financing costs of $753 and $772, respectively	25,880	17,779
Current portion of deferred revenue	317	1,405
Total current liabilities	70,660	55,770
Deferred lease incentive, net of current portion	4,675	5,129
Deferred revenue, net of current portion	80,485	93,752
Convertible 4.5% senior notes, net of deferred financing costs of $36 and $50, respectively	2,064	2,050
Liability related to the sale of future royalties, net of current portion and deferred financing costs of $1,536 and $2,373, respectively	122,345	151,634
Other long-term liabilities	4,180	4,236
Total liabilities	284,409	312,571
Commitments and contingencies (Note J)		
Shareholders' deficit:		
Preferred stock, $.01 par value; authorized 5,000 shares; no shares issued and outstanding	—	—
Common stock, $0.01 par value; authorized 200,000 shares; issued and outstanding 149,400 and 132,526 shares as of December 31, 2018 and December 31, 2017, respectively	1,494	1,325
Additional paid-in capital	1,192,813	1,009,362
Accumulated deficit	(1,183,335)	(1,028,582)
Total shareholders' equity (deficit)	10,972	(17,895)
Total liabilities and shareholders' equity (deficit)	$ 295,381	$ 294,676

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

IMMUNOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

In thousands, except per share amounts

	Years Ended December 31,		Six Months Ended December 31,	Year Ended June 30,
	2018	2017	2016	2016
Revenues:				
License and milestone fees	$ 15,280	$ 79,469	$ 5,152	$ 26,915
Royalty revenue	—	—	—	195
Non-cash royalty revenue related to the sale of future royalties	32,154	28,142	12,894	25,299
Research and development support	1,377	3,482	2,781	4,014
Clinical materials revenue	4,635	4,354	679	3,579
Total revenues	53,446	115,447	21,506	60,002
Operating expenses:				
Research and development	174,456	139,739	66,566	148,077
General and administrative	36,746	33,911	17,995	36,916
Restructuring charge	3,693	779	4,431	—
Total operating expenses	214,895	174,429	88,992	184,993
Loss from operations	(161,449)	(58,982)	(67,486)	(124,991)
Investment income, net	4,227	1,146	259	325
Non-cash interest expense on liability related to the sale of future royalties and convertible senior notes	(10,631)	(13,682)	(8,665)	(20,130)
Interest expense on convertible senior notes	(95)	(3,040)	(2,249)	(138)
Non-cash debt conversion expense	—	(22,915)	—	—
Other (expense) income, net	(895)	1,461	(742)	117
Net loss	$ (168,843)	$ (96,012)	$ (78,883)	$ (144,817)
Basic and diluted net loss per common share	$ (1.21)	$ (0.98)	$ (0.91)	(1.67)
Basic and diluted weighted average common shares outstanding	139,946	98,068	87,102	86,976
Total comprehensive loss	$ (168,843)	$ (96,012)	$ (78,883)	$ (144,817)

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

IMMUNOGEN, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' (DEFICIT) EQUITY

In thousands

	Common Stock		Additional Paid-In	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Deficit	Equity (Deficit)
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)
Net loss	—	—	—	(78,883)	(78,883)
Stock options exercised	—	—	—	—	—
Restricted stock award - net of forfeitures	92	1	—	—	1
Stock option and restricted stock compensation expense	—	—	8,121	—	8,121
Directors' deferred share unit compensation	—	—	215	—	215
Balance at December 31, 2016	87,301	$ 873	$ 778,847	$ (932,570)	$ (152,850)
Net loss	—	—	—	(96,012)	(96,012)
Stock options exercised	191	1	649	—	650
Issuance of common stock	16,675	167	101,496	—	101,663
Restricted stock award - net of forfeitures	2,146	21	(21)	—	—
Conversion of debt	26,160	262	117,067	—	117,329
Stock option and restricted stock compensation expense	—	—	11,119	—	11,119
Directors' deferred share units converted	53	1	(1)	—	—
Directors' deferred share unit compensation	—	—	206	—	206
Balance at December 31, 2017	132,526	$ 1,325	$ 1,009,362	$ (1,028,582)	$ (17,895)
Transition adjustment for ASC 606	—	—	—	14,090	14,090
Net loss	—	—	—	(168,843)	(168,843)
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	946	9	4,292	—	4,301
Issuance of common stock	15,755	158	162,354	—	162,512
Stock option and restricted stock compensation expense	—	—	16,445	—	16,445
Directors' deferred share units converted	173	2	(1)	—	1
Directors' deferred share unit compensation	—	—	361	—	361
Balance at December 31, 2018	149,400	$ 1,494	$ 1,192,813	$ (1,183,335)	$ 10,972

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

IMMUNOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

In thousands

	Years Ended December 31,		Six Months Ended December 31,	Year Ended June 30,
	2018	2017	2016	2016
Cash flows from operating activities:				
Net loss	$ (168,843)	$ (96,012)	$ (78,883)	$ (144,817)
Adjustments to reconcile net loss to net cash used for operating activities:				
Non-cash royalty revenue related to sale of future royalties	(32,154)	(28,142)	(12,894)	(25,299)
Non-cash interest expense on liability related to sale of future royalties and convertible senior notes	10,631	13,682	8,665	20,130
Non-cash debt conversion expense	—	22,915	—	—
Depreciation and amortization	7,411	5,963	3,074	5,327
Loss (gain) on sale/disposal of fixed assets and impairment charges	115	239	1,130	(21)
Stock and deferred share unit compensation	16,807	11,325	8,337	22,248
Deferred rent	(95)	91	88	161
Change in operating assets and liabilities:				
Accounts receivable	948	(623)	(1,143)	4,205
Unbilled revenue	1,963	4,198	(5,369)	(695)
Inventory	1,038	1,154	(1,285)	2,028
Contract asset	(500)	—	—	—
Prepaid and other current assets	(1,495)	2,419	(505)	(706)
Other assets	88	(777)	405	(2,456)
Accounts payable	2,667	771	(3,247)	2,649
Accrued compensation	323	4,527	(3,778)	2,378
Other accrued liabilities	3,839	4,375	960	(1,434)
Deferred revenue	(9,165)	61,540	747	(8,318)
Proceeds from landlord for tenant improvements	—	—	42	144
Net cash (used) provided by operating activities	(166,422)	7,645	(83,656)	(124,476)
Cash flows from investing activities:				
Purchases of property and equipment	(5,246)	(1,116)	(1,406)	(10,376)
Net cash used for investing activities	(5,246)	(1,116)	(1,406)	(10,376)
Cash flows from financing activities:				
Proceeds from issuance of common stock under stock plans	4,301	650	—	5,161
Proceeds from common stock issuance, net of $395 and $222 of transaction costs, respectively	162,512	101,663	—	—
Fees for debt conversion	—	(1,699)	—	—
Proceeds from issuance of convertible 4.5% notes, net of $3,392 of transaction costs	—	—	—	96,608
Net cash provided by financing activities	166,813	100,614	—	101,769
Net change in cash and cash equivalents	(4,855)	107,143	(85,062)	(33,083)
Cash and cash equivalents, beginning of period	267,107	159,964	245,026	278,109
Cash and cash equivalents, end of period	$ 262,252	$ 267,107	$ 159,964	$ 245,026
Supplemental cash flow information:				
Cash paid during the year for interest	$ 95	$ 4,685	$ —	$ —

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

IMMUNOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2018

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-drug conjugates, or ADCs. The Company has generally incurred operating losses and negative cash flows from operations since inception, incurred a net loss of approximately $168.8 million during the year ended December 31, 2018, and has an accumulated deficit of approximately $1.2 billion as of December 31, 2018. 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 December 31, 2018, the Company had $262.3 million of cash and cash equivalents on hand. The Company anticipates that its current capital resources and the $65.2 million raised from the sale of its residual rights to Kadcyla royalties in January 2019 (see Note F) will enable it to meet its operational expenses and capital expenditures for more than twelve months after these financial statements are issued. The Company may raise additional funds through equity or debt financings or generate revenues from collaborators through a combination of upfront license payments, milestone payments, royalty payments, and research funding. There can be no assurance that the Company will be able to obtain additional debt or equity financing or generate revenues from collaborators 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, complexities associated with managing collaboration arrangements, third-party reimbursements, and compliance with governmental regulations.

In June 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, in addition to financial statements as of and for the years ended December 31, 2018 and 2017, these financial statements contain six-month transitional financial statements as of and for the period ending December 31, 2016.

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, ImmunoGen (Bermuda) Ltd., ImmunoGen BioPharma (Ireland) 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 December 31, 2018 up through the date the Company issued these financial statements. In January 2019, the Company sold its residual rights to receive

royalty payments on commercial sales of Kadcyla to OMERS, the defined benefit pension plan for municipal employees in the Province of Ontario, Canada, for $65.2 million, net of fees.

On March 1, 2019, the Company announced that FORWARD I did not meet its PFS primary endpoint in either the entire study population or in the pre-specified subset of patients with high-FRα expression. The Company plans to conduct a full review of the FORWARD I data to determine potential next steps with mirvetuximab as a single agent, and assess its ongoing FORWARD II combination studies as a separate path forward to support a registration in ovarian cancer.

The Company did not have any other material recognizable or unrecognizable subsequent events.

Adoption of ASC Topic 606, Revenue from Contracts with Customers

The Company adopted Accounting Standards Codification Topic or ASC, 606 – *Revenue from Contracts with Customers*, (ASC 606) on January 1, 2018, using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for 2018 reflect the application of ASC 606 guidance, while the reported results prior to 2018 were prepared under the guidance of ASC 605, *Revenue Recognition* (ASC 605), which is also referred to herein as "legacy GAAP" or the "previous guidance."

Financial Statement Impact of Adopting ASC 606

The cumulative effect of applying the new guidance to all contracts with customers that were not completed as of December 31, 2017, was recorded as an adjustment to accumulated deficit as of the adoption date. As a result of applying the modified retrospective method to adopt the new revenue guidance, the following adjustments were made to accounts on the condensed consolidated balance sheet as of January 1, 2018:

IMMUNOGEN, INC.
ADJUSTED CONSOLIDATED BALANCE SHEET
In thousands, except per share amounts

	December 31, 2017	Adjustments Due to ASC 606	Balance at January 1, 2018
ASSETS			
Cash and cash equivalents	$ 267,107	$ —	$ 267,107
Accounts receivable	2,649	—	2,649
Unbilled revenue	2,580	—	2,580
Non-cash royalty receivable	—	8,900	8,900
Inventory	1,038	—	1,038
Prepaid and other current assets	2,967	—	2,967
Total current assets	276,341	8,900	285,241
Property and equipment, net of accumulated depreciation	14,538	—	14,538
Other assets	3,797	—	3,797
Total assets	$ 294,676	$ 8,900	$ 303,576
LIABILITIES AND SHAREHOLDERS' DEFICIT			
Accounts payable	$ 8,562	$ —	$ 8,562
Accrued compensation	11,473	—	11,473
Other accrued liabilities	15,767	—	15,767
Current portion of deferred lease incentive	784	—	784
Current portion of liability related to the sale of future royalties, net	17,779	—	17,779
Current portion of deferred revenue	1,405	41	1,446
Total current liabilities	55,770	41	55,811
Deferred lease incentive, net of current portion	5,129	—	5,129
Deferred revenue, net of current portion	93,752	(5,231)	88,521
Convertible 4.5% senior notes, net	2,050	—	2,050
Liability related to the sale of future royalties, net	151,634	—	151,634
Other long-term liabilities	4,236	—	4,236
Total liabilities	312,571	(5,190)	307,381
Shareholders' deficit:			
Preferred stock	—	—	—
Common stock	1,325	—	1,325
Additional paid-in capital	1,009,362	—	1,009,362
Accumulated deficit	(1,028,582)	14,090	(1,014,492)
Total shareholders' deficit	(17,895)	14,090	(3,805)
Total liabilities and shareholders' deficit	$ 294,676	$ 8,900	$ 303,576

Under the previous guidance, the Company deferred revenue pertaining to the transfer of certain exclusive commercialization and development licenses, and to account for these agreements under the legacy GAAP, the Company identified the deliverables included within the agreements and evaluated which deliverables represented separate units of accounting based on whether certain criteria were met, including whether the delivered element had stand-alone value to the collaborator. The consideration received was allocated among the separate units of accounting, and the applicable revenue recognition criteria were applied to each of the separate units. Under ASC 606, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is distinct from other performance obligations, is transferred to the customer and the customer is able to use and benefit from the license.

Under the previous guidance, milestones that were considered substantive because the Company contributed significant effort to the achievement of such milestones were recognized as revenue upon achievement of the milestone. Under ASC 606, if the achievement of a milestone is considered a direct result of the Company's efforts to satisfy a performance obligation or transfer a distinct good or service, the associated milestone value is allocated to that distinct good or service. If a milestone is not specifically related to the Company's effort to satisfy a performance obligation or transfer a distinct good or service, the amount is allocated to all performance obligations using the relative standalone selling price method.

Under ASC 606, the Company also evaluates the milestone to determine whether the milestone is probable of being achieved and estimates the amount to be included in the transaction price. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated, otherwise, such amounts are constrained and excluded from the transaction price until the probable threshold is met. The Company determined it was probable that a future $5.0 million milestone for Takeda enrolling a patient in a Phase I trial as of the date of adoption would occur and, accordingly, recorded a reduction to accumulated deficit of $4.6 million related to this previously delivered license as approximately $400,000 was allocated to undelivered rights to future technological improvements. The $5.0 million contract asset recorded for the probable milestone was netted against contract liabilities related to the specific contract.

Prior to the adoption of ASC 606, the Company recognized royalty revenue when it could reliably estimate such amounts and collectability was reasonably assured. As such, the Company generally recognized revenue for sales royalties in the quarter the amounts were reported to the Company by its licensees, or one quarter following the quarter in which sales by the Company's licensees occurred. Under ASC 606, if the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). As a result of recognizing royalties for sales in the fourth quarter of fiscal year 2017, the Company recognized a reduction to accumulated deficit of $8.9 million.

The net impact of these changes resulted in a $14.1 million reduction to accumulated deficit, a $5.2 million reduction to deferred revenue and an $8.9 million increase in non-cash royalty receivable.

The adoption of ASC 606 resulted in the acceleration of revenue through December 31, 2017, which in turn reduced the related net deferred tax asset by $3.9 million. As the Company fully reserves its net deferred tax assets, the impact was offset by the valuation allowance.

Impact of ASC 606 Revenue Guidance on Financial Statement Line Items

The following tables compare the reported condensed consolidated balance sheet and statement of operations, as of and for the year ended December 31, 2018, to the pro-forma amounts had the previous guidance been in effect:

IMMUNOGEN, INC.
PRO FORMA CONSOLIDATED BALANCE SHEET
In thousands, except per share amounts

	As of December 31, 2018	
	As reported	Pro forma as if the previous accounting was in effect
ASSETS		
Cash and cash equivalents	$ 262,252	$ 262,252
Accounts receivable	1,701	1,701
Unbilled revenue	617	617
Contract asset	500	—
Non-cash royalty receivable	9,249	—
Inventory	—	—
Prepaid and other current assets	4,462	4,462
Total current assets	278,781	269,032
Property and equipment, net of accumulated depreciation	12,891	12,891
Other assets	3,709	3,709
Total assets	$ 295,381	$ 285,632
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Accounts payable	$ 11,365	$ 11,365
Accrued compensation	11,796	11,796
Other accrued liabilities	20,465	20,465
Current portion of deferred lease incentive	837	837
Current portion of liability related to the sale of future royalties, net	25,880	25,880
Current portion of deferred revenue	317	297
Total current liabilities	70,660	70,640
Deferred lease incentive, net of current portion	4,675	4,675
Deferred revenue, net of current portion	80,485	83,710
Convertible 4.5% senior notes, net	2,064	2,064
Liability related to the sale of future royalties, net	122,345	122,345
Other long-term liabilities	4,180	4,180
Total liabilities	284,409	287,614
Shareholders' equity (deficit):		
Preferred stock	—	—
Common stock	1,494	1,494
Additional paid-in capital	1,192,813	1,192,813
Accumulated deficit	(1,183,335)	(1,196,289)
Total shareholders' equity (deficit)	10,972	(1,982)
Total liabilities and shareholders' equity (deficit)	$ 295,381	$ 285,632

As a result of adoption of ASC 606, a receivable is recorded for royalties earned during the current quarter rather than one quarter in arrears under the previous guidance. Deferred revenue increased under ASC 606 due to a greater amount of the transaction prices being allocated to the future technological improvement rights under ASC 606.

IMMUNOGEN, INC.
PRO FORMA CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
In thousands, except per share amounts

	Year ended December 31, 2018	
	As reported	Pro forma as if the previous accounting was in effect
Revenues:		
License and milestone fees	$ 15,280	$ 16,765
Non-cash royalty revenue related to the sale of future royalties	32,154	31,805
Research and development support	1,377	1,377
Clinical materials revenue	4,635	4,635
Total revenues	53,446	54,582
Operating Expenses:		
Research and development	174,456	174,456
General and administrative	36,746	36,746
Restructuring charge	3,693	3,693
Total operating expenses	214,895	214,895
Loss from operations	(161,449)	(160,313)
Investment income, net	4,227	4,227
Non-cash interest expense on liability related to the sale of future royalties and convertible senior notes	(10,631)	(10,631)
Interest expense on convertible senior notes	(95)	(95)
Other (expense) income, net	(895)	(895)
Net loss	$ (168,843)	$ (167,707)
Basic and diluted net loss per common share	$ (1.21)	$ (1.20)

Under the previous guidance, non-cash royalty revenue would have been lower than the amount recorded for the year ended December 31, 2018, due to higher Kadcyla sales in the fourth quarter of 2018 versus 2017 (because under the previous guidance, the Company recorded the royalties one quarter in arrears as previously described). License and milestone fee revenue for the year ended December 31, 2018 would have been higher due to a $5.0 million milestone that would have been included as license and milestone fee revenue in 2018 under the legacy accounting, however, due to its probability of occurring at the time of transition to ASC 606, it was recognized as part of the transition adjustment. Partially offsetting this change, less license and milestone fee revenue would have been recognized under the previous guidance related to a partner foregoing its remaining rights under a right-to-test agreement upon expiration in March 2018, as well as partners terminating their rights under certain development and commercialization licenses during the year. A greater amount of the transaction price was allocated to the expired and terminated material rights under ASC 606 than under the previous guidance.

The adoption of ASC 606 had no aggregate impact on the Company's cash flows from operations. The aforementioned impact resulted in offsetting shifts in cash flows through net losses and working capital accounts.

Revenue Recognition

The Company enters into licensing and development agreements with collaborators for the development of ADCs. The terms of these agreements contain multiple deliverables/performance obligations which may include (i) licenses, or options to obtain licenses, to the Company's 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) prior to the decommission of the Company's Norwood facility in 2018, 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.

Prior to 2018, the Company identified the deliverables included within the agreement and evaluated which deliverables represented separate units of accounting based on whether certain criteria are met, including whether the delivered element had stand-alone value to the collaborator in accordance with ASC 605. The consideration received

was allocated among the separate units of accounting, and the applicable revenue recognition criteria were applied to each of the separate units.

In 2018, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services in accordance with ASC 606. In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under the agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when or as the Company satisfies each performance obligation.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied.

As part of the accounting for the arrangement, the Company must develop assumptions that require judgment to determine the selling price for each deliverable under ASC 605 and performance obligation under ASC 606 that were identified in the contract, which is discussed in further detail below.

At December 31, 2018, the Company had the following material 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 and commercialize anticancer compounds to a specified antigen target:

  Bayer (one exclusive single-target license)

  Biotest (one exclusive single-target license)

  CytomX (one exclusive single-target license)

  Debiopharm (one exclusive single-compound license)

  Fusion Pharmaceuticals (one exclusive single-target license)

  Novartis (five exclusive single-target licenses)

  Oxford BioTherapeutics/Menarini (one exclusive single target license sublicensed from Amgen)

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

  Sanofi (five fully-paid, exclusive single-target licenses)

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

- Collaboration and option agreement for a defined period of time to secure development and commercialization licenses to develop and commercialize specified anticancer compounds on established terms:

  Jazz Pharmaceuticals

- Collaboration and license agreement to co-develop and co-commercialize a specified anticancer compound on established terms:

MacroGenics

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 obligations 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 obligations 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) prior to the decommissioning of the Company's Norwood facility in 2018, at the collaborator's request, manufacture and provide 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. Royalty rates may vary over the royalty term depending on the Company's intellectual property rights and/or the presence of comparable competing products. In the case of Sanofi, its licenses are fully-paid and no further milestones or royalties will be received. In the case of Debiopharm, no royalties will be received. 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, achieve milestones or become liable for royalty payments.

In determining the units of accounting under ASC 605, management evaluated whether the license had 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 concluded that the license had stand-alone value and therefore accounted for as a separate unit of accounting, the Company then determined the estimated selling prices of the license and all other units of accounting.

In determining the performance obligations under ASC 606, management evaluates whether the license is distinct, and has significant standalone functionality, 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 and whether technological improvements are required for the continued functionality of the license. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

The Company determined that the estimated selling price under ASC 605 and the stand-alone selling price under ASC 606 to be consistent. The estimates the selling prices of the license and all other deliverables under ASC 605 and performance obligations under ASC 606 are 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.

The Company recognizes revenue related to research services under ASC 605 and ASC 606 as the services are performed. 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 also develops conjugation processes for materials for later stage testing and

commercialization for certain collaborators. The Company is compensated at negotiated rates that are consistent with what other third parties would charge and may receive milestone payments for developing these processes which are also recorded as a component of research and development support revenue. The Company may also produce research material for potential collaborators under material transfer agreements. The Company records amounts received for research materials produced or services performed as a component of research and development support revenue.

The Company may also provide cytotoxic agents to its collaborators and previously produced preclinical and clinical materials (drug substance) at negotiated prices generally consistent with what other third parties would charge. The Company recognizes revenue on cytotoxic agents and, previously, on preclinical and clinical materials when the materials have passed all quality testing required for collaborator acceptance and control has transferred under ASC 606 to the collaborator, while ASC 605 required title and risk of loss to transfer. The majority of the Company's costs to produce these preclinical and clinical materials were 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 were significantly affected by the number of batches produced during the period. The volume of preclinical and clinical materials the Company produced was directly related to the scale and scope of preclinical activities and the number of clinical trials the Company and its collaborators were preparing for or currently had 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, varied significantly from period to period, which affected the margins recognized on such product sales.

The Company recognizes revenue related to the rights to future technological improvements under ASC 605 and ASC 606 over the estimated term of the applicable license.

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.

Under ASC 605, at the inception of each agreement that includes milestone payments, the Company evaluated whether each milestone was substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation included an assessment of whether (a) the consideration was 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 related solely to past performance and (c) the consideration was reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluated 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 was reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Non-refundable development and regulatory milestones that were expected to be achieved as a result of the Company's efforts during the period of substantial involvement were considered substantive and were recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria under ASC 605 were met. Milestones that were not considered substantive because the Company did not contribute effort to the achievement of such milestones were generally achieved after the period of substantial involvement and were recognized as revenue upon achievement of the milestone, as there were no undelivered elements remaining and no continuing performance obligations, assuming all other revenue recognition criteria under ASC 605 were met.

Under ASC 606, at the inception of each arrangement that includes developmental and regulatory milestone payments, the Company evaluates whether the achievement of each milestone specifically relates to the Company's efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of the Company's efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service. If the milestone payment is not specifically related to the Company's effort to satisfy a performance obligation or transfer a distinct good or service, the amount is allocated to all performance obligations using the relative standalone selling price method. In addition, the Company evaluates the milestone to determine whether the milestone is considered probable of being reached and estimates the

amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated; otherwise, such amounts are considered constrained and excluded from the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development or regulatory milestones and any related constraint, and if necessary, adjusts its estimate of the transaction price. Any such adjustments to the transaction price are allocated to the performance obligations on the same basis as at contract inception. Amounts allocated to a satisfied performance obligation shall be recognized as revenue, or as a reduction of revenue, in the period in which the transaction price changes.

For development and commercialization license agreements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue under ASC 606 at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied) in accordance with the royalty recognition constraint. Under the Company's development and commercialization license agreements, except for the Sanofi and Debiopharm licenses, the Company receives royalty payments based upon its licensees' net sales of covered products. Generally, under the development and commercialization agreements, the Company receives royalty reports and payments from its licensees approximately one quarter in arrears. The Company estimates the amount of royalty revenue to be recognized based on historical and forecasted sales and/or sales information from its licensees if available. Under ASC 605, royalty revenue was recognized when it could reliably estimate such amounts and collectability was reasonably assured. As such, the Company generally recognized revenue for sales royalties in the quarter the amounts were reported to the Company by its licensees, or one quarter following the quarter in which sales by the Company's licensees occurred.

Collaboration and Option Agreements/Right-to-Test Agreements

The Company's right-to-test agreements provide collaborators the right to test the Company's ADC technology for a defined period of time through a research, or right-to-test, license. Under both right-to-test agreements and collaboration and option agreements, collaborators may (a) take options, for a defined period of time, to specified targets and (b) 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 the opt-in 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"), (iii) at the collaborator's request, after providing research services at negotiated prices which are generally consistent with what other third parties would charge, or (iv) some combination of all of these fees.

The accounting for collaboration and option agreements and right-to-test agreements under ASC 605 and ASC 606 is dependent on the nature of the options granted to the collaborative partner.

Under ASC 605, options are considered substantive if, at the inception of the 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. The exercise price for non-substantive options are included in the initial consideration. In determining the units of accounting for substantive options, management evaluates whether the options have stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances. If the Company concludes that an option has stand-alone value and therefore will be accounted for as a separate unit of accounting, it then determines the estimated selling prices of the option and all other units of accounting based on an option pricing model using the following inputs; a) estimated fair value of each program, b) the amount the partner would pay to exercise the option to obtain the license, c) volatility during the expected term of the option and d) risk free interest rate. A risk adjusted discounted cash flow model is then used to estimate the fair value of the option with volatility determined using the stock prices of comparable companies. The cash flow is discounted at a rate representing the Company's estimate of its cost of capital at the time.

Under ASC 606, options are considered distinct performance obligations if they provide a collaborator with a material right. Factors that are considered in evaluating whether options convey a material right 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 fair value of the licenses, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options. As of December 31, 2018, all right-to-test agreements have expired.

If the Company concludes that an option provides the customer a material right, and therefore is a separate performance obligation, the Company then determines the estimated selling prices of the option and all other units of accounting using the following inputs: a) estimated fair value of each program, b) the amount the partner would pay to exercise the option to obtain the license and c) probability of exercise.

The Company does not 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.

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 functionality and is distinct from the undelivered elements.

In determining whether a collaboration and option agreement is within the scope of ASC 808, *Collaborative Arrangements*, management evaluates the level of involvement of both companies in the development and commercialization of the products to determine if both parties are active participants and if both parties are exposed to risks and rewards dependent on the commercial success of the licensed products. If the agreement is determined to be within the scope of ASC 808, the Company will segregate the research and development activities and the related cost sharing arrangement. Payments made by the Company for such activities will be recorded as research and development expense and reimbursements received from its partner will be recognized as an offset to research and development expense.

Transaction Price Allocated to Future Performance Obligations

Remaining performance obligations under ASC 606 represent the transaction price of contracts for which work has not been performed (or has been partially performed) and includes unexercised contract options that are considered material rights. As of December 31, 2018, the aggregate amount of the transaction price allocated to remaining performance obligations comprising deferred revenue was $80.8 million. The Company expects to recognize revenue on approximately .4%, 1.6%, and 98% of the remaining performance obligations over the next 12 months, 13 to 60 months, and 61 to 120 months, respectively, however it does not control when or if any collaborator will exercise its options for, or terminate existing development and commercialization licenses.

Contract Balances from Contracts with Customers

The following table presents changes in the Company's contract assets and contract liabilities during the year ended December 31, 2018 (in thousands):

	Balance at January 1, 2018 (ASC 606 adoption)	Additions	Deductions	Impact of Netting	Balance at End of Period
Contract asset	$ —	$ 500	$ (5,000)	$ 5,000	$ 500
Contract liabilities	$ 89,967	$ 730	$ (14,895)	$ 5,000	$ 80,802

During the year ended December 31, 2018, the Company recognized the following revenues as a result of changes in contract asset and contract liability balances in the respective periods (in thousands):

	Year Ended December 31, 2018
Revenue recognized in the period from:	
Amounts included in contract liabilities at the beginning of the period	$ 14,139
Performance obligations satisfied in previous periods	$ 1,476

As a result of adoption of ASC 606, a contract asset of $5 million was recorded for a probable milestone which was subsequently earned and paid during the year ended December 31, 2018. During 2018, a milestone from Fusion was deemed probable, and accordingly, a contract asset was created in the amount of $500,000. In December 2018, the Company recorded a $1 million development milestone earned under a sublicense agreement with Oxford BioTherapeutics Ltd. as revenue, which is included in accounts receivable as of December 31, 2018. Also, as a result of Takeda not executing a second license it had available, or extending or expanding its right-to-test agreement, the Company recognized $10.9 million of revenue previously deferred, with a net reduction in deferred revenue of $5.9 million due to contract asset and contract liability netting. In addition, $750,000 of the deferred revenue balance at December 31, 2017 was recognized as revenue during the year ended December 31, 2018 upon completion of the Debiopharm and another collaborator's performance obligations, $2.1 million of amortization of deferred revenue was recorded related to numerous collaborators' rights to technological improvements and $335,000 of deferred revenue was recognized upon shipment of clinical materials to a partner and is included in clinical material revenue.

The timing of revenue recognition, billings, and cash collections results in billed receivables, contract assets, and contract liabilities on the consolidated balance sheets. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded. Contract liabilities are recognized as revenue after control of the products or services is transferred to the customer and all revenue recognition criteria have been met.

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 December 31, 2018 or 2017. 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 December 31, 2018 and 2017, the Company held $262.3 million and $267.1 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 $715,000 and $482,000 of accrued capital expenditures as of December 31, 2018 and 2017 which have been treated as a non-cash investing activity and, accordingly, are not reflected in the consolidated statement of cash flows.

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 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 December 31, 2018, 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 December 31, 2018 (in thousands):

		Fair Value Measurements at December 31, 2018 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	$ 242,604	$ 242,604	$ —	$ —

As of December 31, 2017, 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 December 31, 2017 (in thousands):

		Fair Value Measurements at December 31, 2017 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	$ 240,013	$ 240,013	$ —	$ —

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 gross carrying amount and estimated fair value of the convertible 4.5% senior notes was $2.1 million and $2.8 million, respectively, as of December 31, 2018 compared to $2.1 million and $3.8 million, respectively, as of December 31, 2017. In the second half of 2017, $97.9 million of convertible debt outstanding was converted to 26,160,187 shares of the Company's common stock causing the decrease in the gross carrying amount. The estimated fair value per $1,000 note on the debt remaining as of December 31, 2018 decreased compared to December 31, 2017 due primarily to a decrease in the Company's stock price. 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 due to the low frequency of trades.

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 net realizable value as determined on a first-in, first-out (FIFO) basis.

Inventory at December 31, 2018 and 2017 is summarized below (in thousands):

	December 31, 2018	December 31, 2017
Raw materials	$ —	$ 40
Work in process	—	998
Total	$ —	$ 1,038

In February 2018, the Company made the decision to implement a new operating model that will rely on external manufacturing and quality testing for drug substance and drug product for its internal development programs, and would discontinue providing such services to its collaborators. The implementation of this new operating model led to the ramp-down and ultimate discontinuation of manufacturing and quality activities at the Company's Norwood, Massachusetts facility during 2018, and accordingly, there was no inventory on-hand as of December 31, 2018. Raw materials inventory historically consisted entirely of proprietary cell-killing agents the Company developed as part of its ADC technology.

Work in process inventory at December 31, 2017 consisted of drug substance manufactured for sale to the Company's collaborators to be used in preclinical and clinical studies. All conjugate was made to order at the request of the collaborators and subject to the terms and conditions of respective supply agreements. Based on historical reprocessing or reimbursement required for drug substance that did not meet specification and the status of conjugate on hand or conjugate shipped to collaborators but not yet released per the terms of the respective supply agreements, no reserve for work in process inventory was determined to be required at December 31, 2017. 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 which represent net realizable value.

Raw materials inventory cost is stated net of a $1.1 million write-down as of December 31, 2017. The write-down represents 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.

The Company produced 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 received rolling six-month firm, fixed orders for conjugate that the Company was required to manufacture, and rolling twelve-month manufacturing projections for the quantity of conjugate the collaborator expected to need in any given twelve-month period. The amount of clinical material produced was directly related to the number of collaborator anticipated or on-going clinical trials for which the Company was 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 had provided the Company with a firm, fixed order, the collaborator was required by contract to reimburse the Company the full negotiated price of the conjugate, even if the collaborator subsequently canceled the manufacturing run.

The Company capitalized raw material as inventory upon receipt and accounted for the raw material inventory as follows:

a) to the extent that the Company had up to twelve months of firm, fixed orders and/or projections from its collaborators, the Company capitalized 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 considered more than a twelve month supply of raw materials that was not supported by firm, fixed orders and/or projections from its collaborators to be excess and established 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 considered any other external factors and information of which it became aware and assessed

the impact of such factors or information on the net realizable value of the raw material inventory at each reporting period.

During the year ended December 31, 2017, the six month transition period ended December 31, 2016 and fiscal year 2016, 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 $403,000, $150,000, and $1.1 million, respectively, of charges to research and development expense related to raw material inventory identified as excess. There were no such excess charges during 2018.

Unbilled Revenue

Unbilled revenue substantially represents research funding earned based on actual resources utilized under the Company's various collaborator agreements.

Clinical Trial Accruals

Clinical trial expenses are a significant component of research and development expenses, and the Company outsources a significant portion of these costs to third parties. Third party clinical trial expenses include investigator fees, site costs (patient cost), clinical research organization costs, and costs for central laboratory testing and data management. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through cost. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as prepaid asset or accrued clinical trial cost. These third party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future R&D activities recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. The Company also records accruals for estimated ongoing clinical research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical clinical accrual estimates made by the Company have not been materially different from the actual costs.

Other Accrued Liabilities

Other accrued liabilities consisted of the following at December 31, 2018 and 2017 (in thousands):

	December 31, 2018	December 31, 2017
Accrued contract payments	$ 6,389	$ 4,901
Accrued clinical trial costs	11,087	8,400
Accrued professional services	1,171	723
Accrued employee benefits	651	574
Accrued public reporting charges	164	156
Other current accrued liabilities	1,003	1,013
Total	$ 20,465	$ 15,767

Deferred Revenue

Deferred revenue represents amounts related to partner agreements that have yet to be recognized as revenue. Included in the total of deferred revenue is $5.9 million related to the rights to future technological improvements for our partners at December 31, 2018 and $6.8 million at December 31, 2017. The balance of deferred revenue substantially relates to revenue to be recognized upon the granting of a license to partners.

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.

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 $(115,000), $(239,000), $(1.1 million), and $21,000 of (losses) gains on the sale/disposal of certain furniture and equipment during the years ended December 31, 2018 and 2017, the six months ended December 31, 2016, and the year ended June 30, 2016, 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. The year ended December 31, 2017 and the six months ended December 31, 2016 include $180,000 and $970,000, respectively, of leasehold impairment charges resulting from the restructuring, the details of which are further discussed in Note I. Based on this evaluation, the Company believes that, as of each of the balance sheet dates presented, none of the Company's remaining 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, convertible notes and restricted stock 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 unvested restricted stock and the if-converted method for the convertible notes, are shown in the following table (in thousands):

	Years Ended December 31,		Six Months Ended December 31,	Year Ended June 30,
	2018	2017	2016	2016
Options outstanding to purchase common stock, shares issuable under the employee stock purchase plan, and unvested restricted stock at end of period	17,380	14,290	13,878	11,919
Common stock equivalents under treasury stock method for options, shares issuable under the employee stock purchase plan, and unvested restricted stock	3,001	1,579	1	735
Shares issuable upon conversion of convertible notes at end of period	501	501	23,878	23,878
Common stock equivalents under if-converted method for convertible notes	501	501	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 December 31, 2018, the Company is authorized to grant future awards under one employee share-based compensation plan, which is the ImmunoGen, Inc. 2018 Employee, Director and Consultant Equity Incentive Plan, or the 2018 Plan. At the annual meeting of shareholders on June 20, 2018, the 2018 Plan was approved and provides for the issuance of Stock Grants, the grant of Options and the grant of Stock-Based Awards for up to 7,500,000 shares of the Company's common stock, as well as up to 19,500,000 shares of common stock which represent awards granted under the previous stock option plans, the ImmunoGen, Inc. 2016 and 2006 Employee, Director and Consultant Equity Incentive Plans, or the 2016 and 2006 Plans, that forfeit, expire, or cancel without delivery of shares of common stock or which resulted in the forfeiture of shares of common stock back to the Company subsequent to June 19, 2018. 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 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.

	Years Ended December 31,		Six Months Ended December 31,	Year Ended June 30,
	2018	2017	2016	2016
Dividend	None	None	None	None
Volatility	71.02 %	67.34 %	65.63 %	66.34 %
Risk-free interest rate	2.73 %	2.00 %	1.29 %	1.80 %
Expected life (years)	6.0	6.0	6.3	6.3

Using the Black-Scholes option-pricing model, the weighted average grant date fair values of options granted during the years ended December 31, 2018 and 2017, the six months ended December 31, 2016, and fiscal year 2016 were $6.70, $1.98, $1.76, and $8.91 per share, respectively.

A summary of option activity under the option plans as of December 31, 2018, 2017 and 2016, and changes during the years ended December 31, 2018 and 2017, six-month period ended December 31, 2016, and the fiscal year ended June 30, 2016 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	6.76	$ —
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	—
Outstanding at June 30, 2016	11,813	$ 13.03		
Granted	3,536	2.90		
Exercised	—	—		
Forfeited/Canceled	(1,670)	10.64		
Outstanding at December 31, 2016	13,679	10.70	6.55	$ 23
Outstanding at December 31, 2016—vested or unvested and expected to vest	13,516	10.76	6.52	$ 22
Exercisable at December 31, 2016	7,898	$ 13.15	4.70	—
Outstanding at December 31, 2016	13,679	$ 10.70		
Granted	1,589	3.21		
Exercised	(191)	3.42		
Forfeited/Canceled	(3,106)	10.33		
Outstanding at December 31, 2017	11,971	9.92	6.17	$ 13,513
Outstanding at December 31, 2017—vested or unvested and expected to vest	11,881	$ 9.96	6.15	$ 13,283
Exercisable at December 31, 2017	7,996	$ 12.16	4.97	$ 3,733
Outstanding at December 31, 2017	11,971	$ 9.92		
Granted	5,513	10.36		
Exercised	(742)	4.67		
Forfeited/Canceled	(1,178)	11.49		
Outstanding at December 31, 2018	15,564	$ 10.20	6.46	$ 5,818
Outstanding at December 31, 2018—vested or unvested and expected to vest	15,386	$ 10.21	6.43	$ 5,781
Exercisable at December 31, 2018	8,405	$ 11.47	4.45	$ 3,122

In September 2018, the Company granted 295,200 performance stock options to certain employees that will vest in two equal installments upon the achievement of specified performance goals within the next five years. These options are included in the table above. None of the awards subject to performance conditions have been expensed to date. The fair value of the performance based options that could be expensed in future periods is $1.8 million.

A summary of restricted stock activity under the option plans as of December 31, 2018, 2017, and 2016, and changes during the year ended December 31, 2018 and 2017, and the six-month period ended December 31, 2016, and the fiscal year ended June 30, 2016 is presented below (in thousands, except weighted-average data):

	Number of Restricted Stock Shares	Weighted-Average Grant Date Fair Value
Unvested at June 30, 2015	50	$ 9.23
Awarded	75	5.65
Vested	(19)	10.13
Unvested at June 30, 2016	106	$ 6.54
Awarded	118	3.15
Vested	—	—
Forfeited	(25)	7.52
Unvested at December 31, 2016	199	$ 4.41
Awarded	2,253	2.71
Vested	(25)	5.87
Forfeited	(108)	2.68
Unvested at December 31, 2017	2,319	$ 2.82
Vested	(503)	2.64
Unvested at December 31, 2018	1,816	$ 2.87

In August 2016, February 2017, and June 2017, the Company granted 117,800, 529,830, and 239,000 shares of restricted common stock with grant date fair values of $3.15, $2.47, and $4.71, respectively, to certain officers of the Company, however, 71,380 of these shares have subsequently been forfeited. These restrictions will lapse in three equal installments upon the achievement of specified performance goals within the next five years. None of the awards subject to performance conditions have been expensed to date. The fair value of the performance based shares that could be expensed in future periods is $2.6 million.

In June 2018, the Company's Board of Directors, with shareholder approval, adopted the Employee Stock Purchase Plan, or ESPP. An aggregate of 1,000,000 shares of common stock have been reserved for issuance under the ESPP. The ESPP is generally available to all employees who have been continuously employed for three months per year, have customary employment of more than five months in a calendar year, and more than 20 hours per week. Under the ESPP, eligible participants purchase shares of the Company's common stock at a price equal to 85% of the lesser of the closing price of the Company's common stock on the first business day and the final business day of the applicable plan purchase period. Plan purchase periods are six months and begin on January 1 and July 1 of each year, with purchase dates occurring on the final business day of the given purchase period. To pay for the shares, each participant authorizes periodic payroll deductions of up to 15% of his or her eligible cash compensation. All payroll deductions collected from the participant during a purchase period are automatically applied to the purchase of common stock on that period's purchase date provided the participant remains an eligible employee and has not withdrawn from the ESPP prior to that date and are subject to certain limitations imposed by the ESPP and the Internal Revenue Code. On December 31, 2018, 205,000 shares were issued to participating employees at a fair value of approximately $3.55 per share. The fair value of each ESPP award is estimated on the first day of the offering period using the Black-Scholes option-pricing model. The expected volatility used in the fair value calculation was 70.1%, the expected life was .5 years, the expected dividend yield was zero, and the risk-free rate was 2.14%. The Company recognizes share-based compensation expense equal to the fair value of the ESPP awards on a straight-line basis over the offering period.

Stock compensation expense related to stock options and restricted stock awards granted under the option plans was $16.4, $11.1, $8.1, and $21.9 million during the years ended December 31, 2018 and 2017, the six months ended December 31, 2016, and the fiscal year ended June 30, 2016, respectively. During the years ended December 31, 2018 and 2017, the Company recorded approximately $116,000 and $742,000 of stock compensation cost related to the modification of certain outstanding common stock options with former officers of the Company. During fiscal year 2016, the Company recorded $3.1 million of stock compensation cost related to the modification of certain outstanding common stock options with the former Chief Executive Officer. No similar charges were recorded in the six-month transition period ended December 31, 2016. As of December 31, 2018, the estimated fair value of unvested employee awards was $28.0 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 years ended December 31, 2018 and 2017,

the six months ended December 31, 2016, and the fiscal year ended June 30, 2016 are 361,000, 206,000, $215,000, and $380,000, 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 years ended December 31, 2018 and 2017 and the six months ended December 31, 2016, and the fiscal year ended June 30, 2016 is presented below (in thousands):

	Years Ended December 31,		Six Months Ended December 31,	Year Ended June 30,
	2018	2017	2016	2016
Total fair value of options vested	$ 7,496	$ 10,964	$ 17,121	$ 15,298
Total intrinsic value of options exercised	3,787	598	—	3,142
Cash received for exercise of stock options	4,301	650	—	5,161

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 all periods presented.

Segment Information

During all periods presented, 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 the discovery and development of ADCs for the treatment of cancer.

The percentages of revenues recognized from significant customers of the Company in the years ended December 31, 2018, and 2017, the six months ended December 31, 2016, and the year ended June 30, 2016 are included in the following table:

	Years Ended December 31,		Six Months Ended December 31,	Year Ended June 30,
Collaborative Partner:	2018	2017	2016	2016
Bayer	— %	— %	— %	17 %
CytomX	8 %	13 %	— %	— %
Debiopharm	2 %	26 %	— %	— %
Lilly	2 %	1 %	4 %	11 %
Novartis	2 %	— %	24 %	1 %
Roche	60 %	24 %	60 %	43 %
Sanofi	— %	31 %	— %	— %
Takeda	23 %	4 %	8 %	16 %

There were no other customers of the Company with significant revenues in the periods presented.

Other Recently Adopted Accounting Pronouncements

In January 2016, the FASB issued ASU 2016-1, *Recognition and Measurement of Financial Assets and Financial Liabilities (Topic 825).* The amendments in this ASU 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 did not have a material impact on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Stock Compensation – Scope of Modification Accounting (Topic 718)* regarding changes to terms and conditions of share-based payment awards. The ASU provides guidance about which changes to terms or conditions of a share-based payment award require an entity to apply modification accounting. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within that year. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Recently issued accounting pronouncements, not yet adopted

In February 2016, the FASB issued ASU 2016-2, *Leases (Topic 842)*. The purpose of this update is to increase the transparency and comparability among organizations by recognizing lease assets and liabilities on the balance sheet, including those previously classified as operating leases under current U.S. GAAP, and disclosing key information about leasing arrangements. Topic 842 as amended is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods. The Company currently plans to adopt the standard using the transition method provided by ASC Update No. 2018-11, *Leases (Topic 842): Targeted Improvements*. Under this method, the Company will initially apply the new leasing rules on January 1, 2019, rather than at the earliest comparative period presented in the financial statements. Prior periods presented will be in accordance with the existing lease guidance.

Upon transition, the Company plans to apply the package of practical expedients permitted under Topic 842 transition guidance to its entire lease portfolio at January 1, 2019. As a result, the Company is not required to reassess (i) whether any expired or existing contracts are or contain leases, (ii) the classification of any expired or existing leases, and (iii) initial direct costs for any existing leases. Furthermore, the Company will be electing not to separate lease and non-lease components for our leases. Instead, for these applicable classes of underlying assets, the Company will account for each separate lease component and the non-lease components associated with that lease component, as a single lease component. Lastly, the Company will be electing not to apply the recognition requirements of ASC 842 to short-term leases and instead to recognize the lease payments as lease cost on a straight-line basis over the lease term.

Although the Company has not finalized its process of evaluating the impact of adoption of the ASU on its consolidated financial statements, the Company expects to record an increase in the recorded amounts of assets and liabilities related to the recognition of new right-of-use assets and lease liabilities on the Company's balance sheet for leases currently classified as operating leases for an amount that is expected to range between $16 million to $19 million. The Company does not expect the adoption to have an impact to the statement of operations.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include all share-based payment transactions for acquiring goods and services from non-employees. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which the grantor acquires goods and services to be used or consumed in its own operations by issuing share-based payment awards. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under ASC 606. ASU 2018-07 is effective for annual periods beginning after December 15, 2018, with early adoption permitted. This ASU is not expected to have a material effect on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, ASU 2018-18 adds unit-of-account guidance to ASC Topic 808, *Collaborative Arrangements*, in order to align this guidance with ASC 606 and also precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. This guidance will be effective for annual reporting periods beginning after December 15, 2019, including interim periods within those annual reporting periods, and early adoption is permitted. The Company is currently evaluating the potential impact that ASU 2018-18 may have on the consolidated financial statements.

No other recently issued or effective ASUs had, or are expected to have, a material effect on the Company's results of operations, financial condition, or liquidity.

C. Agreements

Significant Collaborative Agreements

Roche

In 2000, the Company granted Genentech, now a unit of Roche, an exclusive development and commercialization 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, 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 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 December 31, 2018, the Company has received and recognized $13.5 million and $20.5 million in development and regulatory milestone payments, respectively, related to Kadcyla. 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.

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, $32.2, $28.1, $12.9, and $25.3 million of non-cash royalties on net sales of Kadcyla were recorded and included in royalty revenue for the years ended December 31, 2018 and 2017, the six-month period ended December 31, 2016, and the year ended June 30, 2016. Kadcyla sales occurring after January 1, 2015 are covered by a royalty purchase agreement whereby the associated cash, except for a residual tail, would have been remitted to Immunity Royalty Holdings, L.P, or IRH. In January 2019, the Company announced the sale of its residual tail to OMERS, the defined benefit pension plan for municipal employees in the Province of Ontario, Canada, for $65.2 million, net of fees, as discussed further in Note F. Simultaneously, OMERS purchased IRH's right to the royalties the Company previously sold as described above, therefore obtaining the rights to 100% of the royalties received from that date on.

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 December 31, 2018. 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.

Amgen/Oxford BioTherapeutics

Under a now-expired right-to-test agreement established in 2000, the Company granted Amgen three exclusive development and commercialization licenses, for which the Company received an exercise fee of $1 million for each license taken. In May 2013, the Company granted Amgen 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. (OBT). 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 subsequently terminated these two licenses. In August 2018, Amgen terminated one of its two remaining development and commercialization licenses leaving the sublicensed license as the last remaining license. As a result, the Company recorded the remaining $84,000 balance of the upfront payment that had been allocated to future performance obligations under this license as revenue, which is included in license and milestone fees for the year ended December 31, 2018.

For the remaining development and commercialization license, 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 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, development, and marketing of any products resulting from this development and commercialization license. Through December 31, 2018, the Company has received and recognized an aggregate of $4 million in milestone payments for compounds covered under this agreement now or in the past. In September 2015, Amgen's IND under the then 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. In December 2018, an IND filed by OBT was accepted, triggering a $1 million milestone payment to the Company. The next potential milestone the Company will be entitled to receive under the remaining license will be a development milestone for the first dosing of a patient in a U.S. Phase II clinical trial, which will result in a $3 million payment being due.

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 $15,000 for fiscal year 2016. There were no similar costs recorded after fiscal year 2016.

Sanofi

In 2003, the Company entered into a broad collaboration agreement with Sanofi (formerly Aventis Pharmaceuticals) 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 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. Through December 31, 2018, the Company recognized an aggregate of $26.5 million in development milestone payments for compounds covered under this agreement now or in the past, including $6 million of milestone payments received and included in license and milestone fee revenue for the year ended December 31, 2017.

In May 2017, the Company and an affiliate of Sanofi amended the license agreements covering all compounds in development by Sanofi using the Company's technology. Under the terms of the amended 2003 collaboration and license agreement, the Company granted Sanofi a fully-paid, exclusive license to develop, manufacture, and commercialize four experimental compounds in development. The Company also amended a separate 2013 exclusive license entered into pursuant to a separate, now-expired right-to-test agreement to grant Sanofi a fully-paid, exclusive license to develop, manufacture and commercialize another experimental compound being studied for the treatment of solid tumors. As consideration for these amendments, the Company received a $30 million payment and agreed to forego a limited co-promotion option in the U.S. with respect to the compounds covered by the 2003 agreement, as well as future milestones or royalties with respect to all licensed products.

In accordance with ASC-605-25, the Company determined that there were no remaining deliverables upon execution of the amendments, and accordingly, the $30 million was recognized as revenue and is included in license and milestone fee revenue for the year ended December 31, 2017.

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, 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. 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.

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 $50,000, $41,000, $22,000, and $160,000 for the years ended December 31, 2018 and 2017, the six months ended December 31, 2016, and fiscal year 2016, respectively. The costs related to clinical materials sold were $549,000 and $1.8 million for the six months ended December 31, 2016 and fiscal year 2016, respectively. There were no costs related to clinical materials sold for any subsequent periods.

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 which was recognized as revenue ratably over the Company's estimated period of substantial involvement which concluded in September 2012. 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 December 31, 2018, 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 the year ended June 30, 2016. In July 2017, Bayer announced that its Phase II clinical study did not meet its primary endpoint of progression-free survival. The safety and tolerability of anetumab ravtansine were consistent with earlier clinical findings and Bayer is continuing development in additional studies, including a Phase 1b multi-indication study in six different types of advanced solid tumors, and a Phase 1b combination-study in patients with recurrent platinum-resistant ovarian cancer. 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.

Novartis

The Company granted Novartis exclusive development and commercialization licenses to the Company's maytansinoid and IGN ADC technology for use with antibodies to six specified targets 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, 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.

In connection with the amendment, in March 2013, the Company granted Novartis 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. In May 2018, Novartis terminated the license. As a result, the Company recorded the remaining $978,000 balance of the upfront payment that had been allocated to future performance obligations under this license as revenue, which is included in license and milestone fees for the year ended December 31, 2018.

In October 2013 and November 2013, the Company granted Novartis its second and third exclusive licenses to single targets, and in October 2014, the three remaining exclusive licenses, each triggering a $1 million upfront 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. Novartis later discontinued clinical testing of LOP628. In December 2016, Novartis initiated Phase I, first-in-human clinical testing of its CDH6-targeting ADC product candidate, HKT288, triggering a $5 million milestone payment which the Company received in 2017. 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 three licenses or a $5 million development milestone for commencement of a Phase I clinical trial under one of its other two licenses.

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 $32,000, $17,000, and $67,000 for the year ended December 31, 2017, the six months ended December 31, 2016, and fiscal year 2016, respectively. There were no similar costs recorded in the year ended December 31, 2018.

Lilly

The Company granted Eli Lilly and Company (Lilly) 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 granted 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 granted in December 2014, with one including the $2 million exercise fee and the other not. 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. In October 2018, Lilly terminated its three development and commercialization licenses. As a result, the Company recorded the remaining $692,000 balance of the upfront payment that had been allocated to future performance obligations under this license as revenue, which is included in license and milestone fees for the year ended December 31, 2018.

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 $24,000, $74,000, $46,000, and $182,000 for the years ended December 31, 2018 and 2017, the six months ended December 31, 2016, and fiscal year 2016, respectively. The costs related to clinical materials sold were $1.2 million and $1.1 million for the year ended December 31, 2017 and fiscal year 2016, respectively. There were no similar costs recorded during the year ended December 31, 2018 and six months ended December 31, 2016.

CytomX

In 2016, the Company granted CytomX an exclusive development and commercialization license to the Company's maytansinoid ADC technology for use with Probodies™ that target CD166 under a now expired reciprocal right-to-test agreement. The Company neither received nor made an upfront cash payment in connection with the execution of the right-to-test agreement or the license agreement. An amendment of the agreement executed simultaneously with the 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 was deferred until the expiration of that substitution right in January 2017, whereupon the Company recognized $12.7 million of the $13 million of arrangement consideration allocated to the development and commercialization license, which is included in

license and milestone fee revenue for the year ended December 31, 2017. With respect to the development and commercialization license granted to 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. In June 2017, CytomX enrolled its first patient in a Phase 1 clinical trial for its product candidate, CX-2009, triggering a $1 million development milestone payment which is included in license and milestone fee revenue for the year ended December 31, 2017. Assuming no annual maintenance fee is payable as described below, the next payment the Company could receive would be a $3 million development milestone payment with commencement of a Phase II clinical trial. CytomX is responsible for the manufacturing, development, and marketing of any products resulting from the development and commercialization license taken by CytomX under this collaboration.

In 2017, we took exclusive development and commercialization licenses to CytomX's proprietary antibody-masking (Probody) technology for use with Probodies that target two specified targets under the same reciprocal right-to-test agreement. We terminated one of these licenses for convenience prior to the end of 2017. No upfront cash payments were made by the Company with the execution of these license agreements. With respect to the remaining license, the Company will potentially be required to pay up to a total of $80 million in milestone payments, 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, development and marketing of any products 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 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.

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 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 $195,000, $256,000, $427,000, and $868,000 for the years ended December 31, 2018 and 2017, the six months ended December 31, 2016, and for fiscal year 2016, respectively. The costs related to clinical materials sold were $3.5 million and $1.0 million for the years ended December 31, 2018 and 2017, respectively. There were no similar costs recorded during the six months ended December 31, 2016 and fiscal year 2016.

Takeda

In March 2015, the Company entered into a three-year 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 by the end of the term of the right-to-test agreement, after which any then outstanding options would lapse. Takeda had 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 had the right to expand the scope of the right-to-test agreement by payment to the Company of $8 million. Takeda is responsible for the manufacturing, 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 Company also is entitled to receive payments for delivery of cytotoxic agents to Takeda and research and development activities performed on behalf of Takeda.

A first license was granted to Takeda in December 2015, and as a result, the Company recognized $8.6 million of the 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 arrangement consideration allocated to future technological improvements commenced 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.

In March 2018, the right-to-test agreement expired without Takeda exercising its option to a second license or extending the agreement or expanding the agreement as it had the right to do for a third license. Accordingly, the remaining $10.9 million of revenue that had been deferred for such performance obligations was recognized as revenue and is included in license and milestone fees for the year ended December 31, 2018. In May 2018, Takeda enrolled its first patient in a Phase I clinical trial, triggering a $5 million milestone payment to the Company. Due to the likelihood of this milestone being attained, this milestone was recognized as a contract asset as part of the cumulative adjustment to transition to ASC 606. It had been previously allocated to the delivered license and the right to technological improvements. The next potential milestone payment the Company will be entitled to receive will be a $10 million development milestone payment with the initiation of a Phase II clinical trial. Takeda is responsible for the manufacturing, product development, and marketing of any products resulting from the remaining license.

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 $199,000, $913,000, $678,000, and $469,000 for the years ended December 31, 2018 and 2017, the six months ended December 31, 2016, and for fiscal year 2016, respectively. The costs related to clinical materials sold were $650,000 and $2.1 million for the years ended December 31, 2018 and 2017, respectively. There were no similar costs recorded during the six months ended December 31, 2016 and fiscal year 2016.

Fusion

In December 2016, the Company entered into an exclusive license agreement to a specified target with Fusion Pharmaceuticals Inc. The Company is entitled to receive up to a total of $50 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones—$15 million; and sales milestones—$35 million. During the year ended December 31, 2018, a development milestone related to dosing of a first patient in a Phase I clinical trial became probable of being attained, which resulted in a $500,000 contract asset and the related license and milestone fee revenue being recorded in the current period. The next potential milestone payment the Company will be entitled to receive will be a $1.5 million development milestone payment with the initiation of a Phase II clinical trial. Fusion is responsible for the manufacturing, development, and marketing of any products resulting from the license.

Debiopharm

In May 2017, Debiopharm International SA (Debiopharm) acquired the Company's IMGN529 program, a clinical-stage anti-CD37 ADC for the treatment of patients with B-cell malignancies, such as non-Hodgkin lymphomas (NHL). Under the terms of the Exclusive License and Asset Purchase agreement, the Company received a $25 million upfront payment for specified assets related to IMGN529 and a paid-up license to the Company's ADC technology and a $5 million milestone payment upon substantial completion of the transfer of ImmunoGen technologies related to the program (technology transfer), which was completed in the fourth quarter of 2017. $4.5 million was received for this milestone in December 2017, and the balance in January 2018 upon delivery of the final materials related to the transfer. Accordingly, the Company recorded $500,000 and $29.5 million of license and milestone fee revenue in 2018 and 2017, respectively. In addition, ImmunoGen is eligible for a second success-based milestone payment of $25 million upon IMGN529 entering a Phase 3 clinical trial. The milestone payment will be significantly reduced if a Phase 3 trial using the Company's technology but not the IMGN529 antibody commences prior to IMGN529 entering a Phase 3 trial. The Company does not believe this scenario is likely to occur.

Costs directly attributable to the Debiopharm agreement are comprised of compensation and benefits related to employees who provided research and development services on behalf of Debiopharm. Indirect costs are not identified to individual collaborators. The costs related to the research and development services amounted to $99,000 for the year ended December 31, 2018. There were no similar costs recorded in prior periods.

Jazz Pharmaceuticals

In August 2017, the Company entered into a collaboration and option agreement with Jazz Pharmaceuticals Ireland Limited (Jazz), a subsidiary of Jazz Pharmaceuticals plc, granting Jazz exclusive, worldwide rights to opt into development and commercialization of two early-stage, hematology-related ADC programs, as well as an additional program to be designated during the term of the agreement. The programs covered under the agreement include IMGN779, a CD33-targeted ADC for the treatment of acute myeloid leukemia (AML) in Phase 1 testing, IMGN632, a CD123-targeted ADC for hematological malignancies also in Phase 1 testing, and an early-stage program to be determined at a later date. Under the terms of the agreement, the Company will be generally responsible for the development of the three ADC programs prior to any potential opt-in by Jazz. Following any opt-in, Jazz would be generally responsible for any further development as well as for potential regulatory submissions and commercialization and Jazz and the Company would share costs associated with developing and obtaining regulatory approvals of the applicable product in the U.S. and EU. The Company has the right to co-commercialize in the U.S. one product (or two products, under certain limited circumstances) with U.S. profit sharing in lieu of Jazz's payment of the U.S. milestone and royalties to the Company.

As part of the agreement, Jazz made an upfront payment of $75 million to the Company. Additionally, Jazz will pay the Company up to $100 million in development funding over seven years to support the three ADC programs. For each program, Jazz may exercise its License Options at any time prior to a pivotal study or at any time prior to the filing of a biologics license application (BLA) upon payment of an option exercise fee of mid-double digit millions or low triple digit millions, respectively. For each program to which Jazz elects to opt-in, the Company would be eligible to receive milestone payments based on receiving regulatory approvals of the applicable product aggregating $100 million plus tiered royalties as a percentage of commercial sales by Jazz, which will vary depending upon sales levels and the stage of development at the time of opt-in.

Due to the involvement the Company and Jazz both have in the development and commercialization of the products, as well as both parties being part of the cost share agreement and exposed to significant risks and rewards dependent on the commercial success of the products, the arrangement has been determined to be a collaborative arrangement within the scope of ASC 808. Accordingly, the Company carved out the research and development activities and the related cost sharing arrangement with Jazz. Payments for such activities will be recorded as research and development expense and reimbursements received from Jazz will be recognized as an offset to research and development expense in the accompanying statement of operations during the development period. Included in research and development expense for the years ended December 31, 2018 and 2017, are $10.0 million and $3.3 million of credits related to reimbursements from Jazz.

The non-refundable, upfront arrangement consideration of $75 million was allocated to the three License Options. The amount allocated to the rights to future technological improvements under the relative selling price method was deemed immaterial, and therefore, not segregated from the License Options. The amounts allocated to the License Options will be recognized as revenue when exercised by Jazz or upon expiration. The Company does not control when Jazz will exercise its options for development and commercialization licenses. As a result, the Company cannot predict when it will recognize revenue related to the delivery of the licenses, and accordingly, the upfront payment of $75 million is included in long-term deferred revenue as of December 31, 2018.

D. Property and Equipment

Property and equipment consisted of the following at December 31, 2018 and 2017 (in thousands):

	December 31, 2018	December 31, 2017
Leasehold improvements	$ 20,684	$ 36,460
Machinery and equipment	22,558	23,123
Computer hardware and software	5,494	8,273
Furniture and fixtures	3,546	3,710
Assets under construction	113	416
	$ 52,395	$ 71,982
Less accumulated depreciation	(39,504)	(57,444)
Property and equipment, net	$ 12,891	$ 14,538

Depreciation expense was $7.4, $6.0, $3.1, and $5.3 million for the years ended December 31, 2018 and 2017, the six months ended December 31, 2016, and for the year ended June 30, 2016, respectively. Included in the table above, the Company's investment in equipment under capital leases was $595,000 and $449,000, net of accumulated amortization of $684,000 and $479,000, at December 31, 2018 and 2017, respectively.

E. Convertible 4.5% Senior Notes

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

During the second half of calendar 2017, the Company entered into privately negotiated exchange agreements with a number of holders of our outstanding Convertible Notes, pursuant to which the Company agreed to exchange, in a private placement, $97.9 million in aggregate principal amount of Convertible Notes held by the holders for 26,160,187 newly issued shares of our common stock, equivalent to the number of shares based on the original conversion terms, plus an additional number of newly issued shares of common stock determined based on the volume-weighted average trading price of the common stock over certain trading days. As a result of the agreements, 2,784,870 additional shares were issued.

In accordance with ASC, Topic 470-20, "Debt – Debt with Conversion and Other Options," based on the short period of time the conversion offer was open and the substantive conversion feature offer, the Company accounted for the conversion of $96.9 million of the debt as an inducement by expensing the fair value of the shares that were issued in excess of the original terms of the Convertible Notes. Due to the passage of time between the inducement offer and execution of the agreement, the Company accounted for the conversion of the other $1 million of the debt as an extinguishment by expensing the fair value of the shares that were issued in excess of net book value of the Convertible Notes. As a result, the Company recorded a non-cash debt conversion expense in the amount of $22.9 million in the year ended December 31, 2017. In addition, accrued interest on the bonds of $743,000 which the noteholders forfeited, $2.5 million of deferred financing costs and $1.7 million in transaction costs were charged to paid-in capital as a result of the issuance of common stock upon conversion.

The remaining $2.1 million of 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 $95,000, $3.0 million, $2.2 million and $138,000 of interest expense in the years ended December 31, 2018 and 2017, the six months ended December 31, 2016 and the year ended June 30, 2016, respectively. 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 equal 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.

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, of which $2.5 million was reclassed to equity upon conversion noted above. The remaining net unamortized balance of $50,000 was netted against the Convertible Notes in the accompanying consolidated balance sheet and is being amortized to interest expense ratably over the term of the Convertible Notes.

F. Liability Related to Sale of Future Royalties

In 2015, IRH purchased the right to receive 100% of the royalty payments on commercial sales of Kadcyla arising under the Company's development and commercialization license with Genentech, until IRH had received aggregate royalties equal to $235 million or $260 million, depending on when the aggregate royalties received by IRH reached a specified milestone. Once the applicable threshold was met, if ever, the Company would thereafter have received 85% and IRH would have received 15% of the Kadcyla royalties for the remaining royalty term. At consummation of the transaction the Company received cash proceeds of $200 million. As part of this sale, the Company incurred $5.9 million of transaction costs, which are presented net of the liability in the accompanying consolidated balance sheet and are being 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 Kadcyla, 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.

In January 2019, the Company sold its residual rights to receive royalty payments on commercial sales of Kadcyla to OMERS, the defined benefit pension plan for municipal employees in the Province of Ontario, Canada, for $65.2 million, net of fees. Simultaneously, OMERS purchased IRH's right to the royalties the Company previously sold as described above, therefore obtaining the rights to 100% of the royalties received from that date on.

The following table shows the activity within the liability account during the year ended December 31, 2018 and the period from inception (in thousands):

	Twelve Months Ended December 31, 2018	Period from inception to December 31, 2018
Liability related to sale of future royalties, net — beginning balance	$ 169,413	$ —
Proceeds from sale of future royalties, net	—	194,135
Kadcyla royalty payments received and paid	(31,805)	(103,624)
Non-cash interest expense recognized	10,617	57,714
Liability related to sale of future royalties, net — ending balance	$ 148,225	$ 148,225

As royalties are remitted to IRH and subsequently OMERS, 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 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 7.2% and a current effective interest rate of 5.7% as of December 31, 2018. The Company periodically assesses the estimated royalty payments to IRH/OMERS 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/OMERS are made in U.S. dollars (USD) while significant portions of the underlying sales of Kadcyla are made in currencies other than USD, and other events or

circumstances that could result in reduced royalty payments from Kadcyla, 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 Kadcyla 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/OMERS 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.

G. Income Taxes

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

	Years Ended December 31,		Six Months Ended December 31,	Year Ended June 30,
	2018	2017	2016	2016
Loss before income tax expense	$ (168,843)	$ (96,012)	$ (78,883)	$ (144,817)
Expected tax benefit at 21%, 34%, 34% and 34%, respectively	$ (35,457)	$ (32,644)	$ (26,820)	$ (49,238)
Permanent differences	(103)	25	15	345
Incentive stock options	1,144	1,528	1,313	2,501
State tax benefit net of federal benefit	(10,622)	(3,537)	(4,157)	(7,954)
Change in valuation allowance, net	53,706	(63,238)	32,922	62,505
Federal research credit	(2,466)	(2,204)	(1,232)	(4,109)
Federal orphan drug credit	(6,934)	(7,118)	(2,901)	(4,241)
Expired loss and credit carryforwards	—	—	—	184
Change in U.S. tax law	—	97,479	—	—
Debt inducement	—	8,044	—	—
Lease incentive	109	—	—	—
Stock option expirations	623	1,665	860	7
Benefit for income taxes	$ —	$ —	$ —	$ —

At December 31, 2018, the Company has net operating loss, or NOL, carryforwards of $665.6 million available to reduce federal taxable income, if any, that begin to expire in 2028 through 2037 and $194.0 million of the federal NOL carryforwards can be carried forward indefinitely. The Company has $501.1 million of NOL carryforwards available to reduce state taxable income, if any, that expire in 2033 through 2038. The Company also has federal and state credit carryforwards of $59.4 million and $13.0 million, respectively, available to offset federal and state income taxes, which expire beginning in 2019. 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 December 31, 2018 and 2017 are as follows (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 171,437	$ 118,672
Research and development tax credit carryforwards	69,710	58,606
Property and other intangible assets	297	2,272
Deferred revenue	22,075	25,997
Stock-based compensation	12,849	12,125
Deferred lease incentive	2,639	2,889
Other liabilities	2,920	3,037
Royalty sale	38,593	47,143
Total deferred tax assets	$ 320,520	$ 270,741
Deferred tax liabilities:		
Stock-based compensation	(156)	—
Royalty sale transaction costs	(625)	(859)
Total deferred tax liabilities	$ (781)	$ (859)
Valuation allowance	(319,739)	(269,882)
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. Accordingly, the deferred tax assets have been fully reserved at December 31, 2018 and 2017. The valuation allowance increased by $49.9 million during the year ended December 31, 2018 due primarily to additional net loss incurred during the year.

In December 2017, the Tax Cuts and Jobs Act, or the Tax Act ("TCJA"), was signed into law. Among other things, the Tax Act permanently lowers the corporate federal income tax rate to 21% from the existing maximum rate of 35%, effective for tax years including or commencing January 1, 2018. As a result of the reduction of the corporate federal income tax rate to 21%, U.S. GAAP requires companies to revalue their deferred tax assets and deferred tax liabilities as of the date of enactment, with the resulting tax effects accounted for in the reporting period of enactment. For 2017, this revaluation resulted in a provision of $97.5 million to income tax expense in continuing operations and a corresponding reduction in the valuation allowance. As a result, there was no impact to the Company's income statement as a result of the reduction in tax rates. The other provisions of the TCJA did not have a material impact on the consolidated financial statements.

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 beyond fiscal year 2015. Additionally, the Company has not completed a detailed Research and Development Credit Study (including the Orphan Drug Credit); 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 December 31, 2018 and 2017, 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 after June 30, 2014, although carryforward attributes that were generated prior to fiscal year 2014 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 December 31, 2018, the Company has reserved 24.7 million shares of authorized common stock for the future issuance of shares under the 2006, 2016, and 2018 Plans. See "Stock-Based Compensation" in Note B for a description of the 2018 Plan.

Stock Options

As of December 31, 2018, the 2018 Plan was the only employee share-based compensation plan of the Company under which grants can be made. During the year ended December 31, 2018, holders of options issued under the option plans exercised their rights to acquire an aggregate of 742,000 shares of common stock at prices ranging from $1.84 to $12.21 per share. The total proceeds to the Company from these option exercises were $3.5 million.

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 December 31, 2018, 2017, and 2016, and June 30, 2016:

	Exercisable (in thousands)	Weighted–Average Exercise Price
December 31, 2018	8,405	$ 11.47
December 31, 2017	7,996	$ 12.16
December 31, 2016	7,898	$ 13.15
June 30, 2016	6,453	$ 12.63

2001 Non-Employee Director Stock Plan

In 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 December 31, 2018 and 2017, the six months ended December 31, 2016, and the fiscal year ended June 30, 2016, the Company recorded $31,000, $28,000, $(7,000), and $(72,000) in compensation expense (expense reduction), respectively, related to approximately 6,000 stock units outstanding under the 2001 Director Plan.

The value of the stock units was adjusted to market value at each reporting period. A market value of $72,000 for the stock units was paid to a retiring director in June 2018, effectively terminating the plan.

2004 Non-Employee Director Compensation and Deferred Share Unit Plan

Under the 2004 Non-Employee Director Compensation and Deferred Share Unit Plan, or the 2004 Director Plan, as amended, between 2004 and 2009 non-employee directors were paid their annual retainers in the form of deferred stock units, based on the fair market value of the Company's common stock on the last date of the Company's fiscal year prior to the year for which services were rendered, and in cash, with the option, at their discretion, to have all or a portion of the cash portion paid in additional deferred stock units. All deferred stock units awarded under the 2004 Director Plan have vested, and 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 common stock of the Company issued under the 2006 Plan at a rate of one share for each vested.

Compensation Policy for Non-Employee Directors

In September 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 Compensation Policy for Non-Employee Directors, as amended as recently as March 2018, consists of three elements: cash compensation; deferred stock units; and stock options.

Cash Compensation

Each non-employee director receives annual meeting fees which are paid in quarterly installments in, at each director's election, either cash or deferred stock units.

Deferred Stock Units

Non-employee directors receive deferred stock units as follows:

- New non-employee directors are initially awarded 8,000 deferred stock units (6,500 deferred stock units prior to March 28, 2018), with each unit relating to one share of the Company's common stock. These awards vest quarterly over three years from the date of grant, contingent upon the individual remaining a director of the Company as of each vesting date.

- Thereafter, non-employee directors are annually awarded 4,000 deferred stock units (3,000 deferred stock units prior to March 28, 2018). If a non-employee director is first elected to the Board other than at an annual meeting of shareholders, such non-employee director's annual award of 4,000 deferred stock units will be pro-rated based on the number of days between his or her date of election and the date of grant of his or her first annual deferred stock unit award. These awards vest quarterly over approximately one year from the date of grant, contingent upon the individual remaining a director of the Company as of each vesting date.

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 generally be settled in shares of the Company's common stock issued under our 2018 Plan (or its predecessor plans, depending on the grant date of the deferred stock units) 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. All unvested deferred stock units will automatically vest immediately prior to the occurrence of a change of control, as defined in the 2018 Plan (or the substantially identical definition in the predecessor plans, as applicable). Pursuant to the Compensation Policy for Non-Employee Directors, in June 2018, February 2018 and January 2017, the Company issued retiring directors 95,497, 77,012, and 53,248 shares of common stock of the Company to settle outstanding deferred share units.

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

- $361,000 in compensation expense during the year ended December 31, 2018 related to the grant of 46,000 deferred share units and 10,500 deferred share units previously granted;

- $206,000 in compensation expense during the year ended December 31, 2017 related to the grant of 47,000 deferred share units and 12,000 deferred share units previously granted;

- $215,000 in compensation expense during the six months ended December 31, 2016 related to the grant of 37,000 deferred share units and 12,000 deferred share units previously granted;

- $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;

Stock Options

Non-employee directors also receive stock option awards as follows:

- *Initial Stock Option Awards.* Non-employee directors receive an initial stock option award covering 18,000 shares (10,000 shares prior to March 28, 2018) of our common stock on the date of his or her initial election or appointment to the Board, which is the grant date. These awards will have an exercise price equal to the market price of the Company's stock on the grant date, will vest quarterly over a three-year period from the grant date, and will expire on the tenth anniversary of the grant date, contingent upon the individual remaining a director of the Company during such period.

- *Annual Stock Option Awards.* Non-employee directors receive an annual stock option award covering 18,000 shares (10,000 shares prior to March 28, 2018) of our common stock on the date of our annual meeting of shareholders, which is the grant date. These awards will have an exercise price equal to the market price of the Company's stock on the grant date, will vest quarterly over approximately one year from the grant date, and will expire on the tenth anniversary of the grant date, contingent upon the individual remaining a director of the Company during such period.

- *Off-Cycle Initial Awards.* If a non-employee director is first elected to the Board other than at an annual meeting of shareholders, such non-employee director will receive an annual stock option award covering 18,000 shares (10,000 shares prior to March 28, 2018) of our common stock, pro-rated based on the number of days between his or her date of election and the date of grant of his or her first annual stock option award. These awards will have an exercise price equal to the market price of the Company's stock on the date of grant, will vest quarterly over approximately one year from the grant date, and will expire on the tenth anniversary of the grant date, contingent upon the individual remaining a director of the Company during such period.

All unvested stock option awards granted to non-employee directors will automatically vest immediately as of the date of a change of control, as defined in the 2018 Plan (or predecessor plans as applicable, which have substantially the identical terms).

On December 9, 2016 the Board amended the Compensation Policy for Non-Employee Directors to create a transition period due to the change in the year-end. Effectively, one-half of the annual compensation awards described above were awarded to the directors on December 9, 2016 and a full-year's compensation awarded on the date of the subsequent annual meetings. The directors received a total of 128,000 and 80,000 options in the years ended December 31, 2018 and 2017, 40,000 options in the six months ended December 31, 2016 and 80,000 options in the fiscal year ended June 30, 2016, and the related stock compensation expense is included in the amounts discussed in the "Stock-Based Compensation" section of footnote B above.

I. Restructuring Charge

In September 2016, the Board of Directors approved a plan to reengineer the business, resulting in a reduction of the workforce by approximately 17%, or 65 positions, which included the separation of 60 current employees. Communication of the plan to the impacted employees was substantially completed on September 29, 2016. All of the workforce reduction was completed as of December 31, 2016. As a result of the workforce reduction, in the six months ended December 31, 2016, the Company recorded a restructuring charge totaling $4.4 million related to termination benefits and other related charges, of which $2.8 million was recorded as a one-time termination benefit, and $593,000 recorded as a benefit under an ongoing benefit plan. The related cash payments initiated in October 2016 and were fully

paid out by December 31, 2017. Additionally, approximately 762,000 stock options were forfeited in connection with the workforce reduction, and as a result, the Company recorded an approximate $837,000 credit to stock compensation expense which is included in research and development expense and general and administrative expense for the six months ended December 31, 2016.

In addition to the termination benefits and other related charges, as a result of the September 2016 workforce reduction, the Company began seeking to sub-lease 10,281 square feet of unoccupied office space in Waltham that was leased in 2016. As of September 30, 2016, based on an estimate of the potential time it would take to find a tenant of approximately nine months, the anticipated sub-lease terms, and consideration of the tenant allowance that was given to the Company to build out the space, the Company determined it did not need to record a loss on the sub-lease. The Company also evaluated the balance of the leasehold improvements for potential impairment as of September 30, 2016. In performing the recoverability test, the Company concluded that a substantial portion of the leasehold improvements were not recoverable. The Company recorded an impairment charge of $970,000 related to these assets after comparing the fair value (using probability weighted scenarios with discounted cash flows) to the leasehold improvements' carrying value, leaving a $193,000 remaining cost basis. During 2017, based on further evaluation of the prospects for sub-leasing the space, the Company determined that additional time would be required to find a tenant. Accordingly, the calculation for the potential sub-lease loss was updated and it was determined that the remaining balance of the leasehold improvements was impaired. Also, due to the additional time that is expected to secure a tenant, additional lease loss was recorded based on the change in estimate of the sub-lease assumption. The total of these charges in 2017 was $779,000.

In February 2018, following an in-depth review of manufacturing and quality operations, the Board of Directors authorized management to implement a new operating model that will rely on external manufacturing and quality testing for drug substance and drug product for the Company's development programs. The implementation of this new operating model led to the ramp-down of manufacturing and quality activities at the Norwood, Massachusetts facility during 2018, with a full decommissioning of the facility expected by early 2019. Implementation of the new operating model resulted in the separation of 22 employees. Communication of the plan to the affected employees was substantially completed on February 8, 2018.

In connection with the implementation of the new operating model, the Company recorded a one-time charge of $1.2 million for severance in the first quarter related to a pre-existing plan. Additional expense was recorded for retention benefits over the remaining service period of the related employees, as well as marginal adjustments to severance resulting from voluntary terminations, which totaled $2.3 million. Additionally, certain options held by the employees to be separated were modified to extend the exercise period, resulting in a stock compensation charge of $157,000 in the first quarter. Cash payments related to severance will be substantially paid out by the end of the second quarter of 2019. The retention benefits were paid out in the fourth quarter of 2018.

A summary of activity against the restructuring charge related to the employee terminations is as follows:

	Employee Termination Benefits Costs
Initial charge related to employee benefits - March 2018	$ 1,189
Additional charges during the year	2,347
Payments during the period	(2,695)
Balance December 31, 2018	$ 841

J. Commitments and Contingencies

Leases

The Company currently has a lease agreement with CRP/King 830 Winter L.L.C. for the rental of approximately 120,000 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 through December 2015, the Company received construction allowances totaling approximately $2 million to build out office and lab space to the Company's specifications. The Company executed a fourth amendment to this lease in April 2018, leasing an additional

10,000 square feet of office space in order to accommodate employees being retained from the future Norwood closure previously discussed. The Company is entitled to a construction allowance of $400,000 to build normal tenant improvements in this space to its specifications. The Company began recording rent expense for this space during the quarter ending September 30, 2018, when it took control of the space for construction. 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 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 received $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 is actively seeking to sub-lease this space.

The Company also leases 43,850 square feet of manufacturing and office space at 333 Providence Highway, Norwood, MA under an agreement through February 28, 2019. 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 in 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 and the lease was terminated during 2018.

Facilities rent expense, net of sublease income, was $7.7, $6.8, $3.5, and $6.5 million during the years ended December 31, 2018 and 2017, the six months ended December 31, 2016, and fiscal year 2016, respectively.

As of December 31, 2018, the minimum rental commitments for the next five years and thereafter under the non-cancelable operating lease agreements discussed above are as follows (in thousands):

2019	$ 5,498
2020	5,419
2021	5,257
2022	5,323
2023	5,450
Thereafter	12,336
Total minimum lease payments	$ 39,283

In addition to the above table, the Company is responsible for variable operating costs and real estate taxes approximating $3.0 million per year through March 2026. There are no obligations under capital leases as of December 31, 2018, 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 December 31, 2018, the maximum amount that may be payable in the future under the Company's current collaborative agreements is $80 million.

Manufacturing Commitments

As of December 31, 2018, the Company has noncancelable obligations under several agreements related to in-process and future manufacturing of antibody and cytotoxic agents required for clinical supply of the Company's product candidates totaling $1.3 million, all of which will be paid in calendar 2019.

In the fourth quarter of 2018, the Company executed a commercial agreement, which superseded a previous letter agreement, with one of its manufacturers for future production of antibody through calendar 2022. Pursuant to the agreement, the Company's noncancelable commitment is approximately €22 million at December 31, 2018.

Litigation

The Company is not party to any material litigation.

K. 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 the years ended December 31, 2018 and 2017, the six months ended December 31, 2016, and fiscal year 2016, the Company's contributions to the 401(k) Plan totaled $1.0 million, $982,000, $536,000, and $1.1 million, respectively.

L. Quarterly Financial Information (Unaudited)

	Calendar Year 2018			
	First Quarter Ended March 31, 2018	Second Quarter Ended June 30, 2018	Third Quarter Ended September 30, 2018	Fourth Quarter Ended December 31, 2018
	(In thousands, except per share data)			
Revenues:				
License and milestone fees	$ 11,540	$ 1,321	$ 672	$ 1,747
Non-cash royalty revenue related to the sale of future royalties	7,190	7,242	8,441	9,281
Research and development support	383	388	388	218
Clinical materials revenue	702	336	1,427	2,170
Total revenues	19,815	9,287	10,928	13,416
Expenses:				
Research and development	44,831	38,701	47,243	43,681
General and administrative	9,995	8,652	8,347	9,752
Restructuring charge	1,731	686	870	406
Total expenses	56,557	48,039	56,460	53,839
Loss from operations	(36,742)	(38,752)	(45,532)	(40,423)
Non-cash interest expense on liability related to sale of future royalty	(3,046)	(2,611)	(2,546)	(2,428)
Interest expense on senior convertible notes	(24)	(23)	(23)	(25)
Other (expense) income, net	1,199	(238)	1,294	1,077
Net loss	$ (38,613)	$ (41,624)	$ (46,807)	$ (41,799)
Basic and diluted net loss per common share	$ (0.30)	$ (0.31)	$ (0.32)	$ (0.28)

	Calendar Year 2017			
	First Quarter Ended March 31, 2017	Second Quarter Ended June 30, 2017	Third Quarter Ended September 30, 2017	Fourth Quarter Ended December 31, 2017
	(In thousands, except per share data)			
Revenues:				
License and milestone fees	$ 18,730	$ 31,080	$ 79	$ 29,580
Royalty revenue	—	—	—	—
Non-cash royalty revenue related to the sale of future royalties	7,613	6,439	6,503	7,587
Research and development support	1,478	902	650	452
Clinical materials revenue	678	599	1,248	1,829
Total revenues	28,499	39,020	8,480	39,448
Expenses:				
Research and development	32,888	35,319	31,689	39,843
General and administrative	8,119	8,836	7,908	9,048
Restructuring charge	386	—	—	393
Total expenses	41,393	44,155	39,597	49,284
Loss from operations	(12,894)	(5,135)	(31,117)	(9,836)
Non-cash interest expense on liability related to sale of future royalty and convertible senior notes	(3,575)	(3,501)	(3,385)	(3,221)
Interest expense on senior convertible notes	(1,125)	(1,125)	(762)	(28)
Non-cash debt conversion expense	—	—	(22,191)	(724)
Other income, net	249	894	773	691
Net loss	$ (17,345)	$ (8,867)	$ (56,682)	$ (13,118)
Basic and diluted net loss per common share	$ (0.20)	$ (0.10)	$ (0.61)	$ (0.11)

	Six Month Transition Period	
	First Quarter Ended September 30, 2016	Second Quarter Ended December 31, 2016
	(In thousands, except per share data)	
Revenues:		
License and milestone fees	$ 76	$ 5,076
Royalty revenue	—	—
Non-cash royalty revenue related to the sale of future royalties	6,184	6,710
Research and development support	1,354	1,427
Clinical materials revenue	46	633
Total revenues	7,660	13,846
Expenses:		
Research and development	32,909	33,657
General and administrative	9,459	8,536
Restructuring charge	4,130	301
Total expenses	46,498	42,494
Loss from operations	(38,838)	(28,648)
Non-cash interest expense on liability related to sale of future royalty and convertible senior notes	(5,018)	(3,647)
Interest expense on senior convertible notes	(1,150)	(1,099)
Other income (expense), net	275	(758)
Net loss	$ (44,731)	$ (34,152)
Basic and diluted net loss per common share	$ (0.51)	$ (0.39)

	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	(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)

M. Stub Period Comparative Data (Unaudited)

The unaudited, condensed consolidated statements of earnings for the year ended December 31, 2016 and the six months ended December 31, 2015 is as follows:

	Year Ended December 31, 2016	Six Months Ended December 31, 2015
Revenues:		
License and milestone fees	$ 15,305	$ 16,762
Royalty revenue	—	195
Non-cash royalty revenue related to the sale of future royalties	26,218	11,975
Research and development support	5,175	1,620
Clinical materials revenue	1,930	2,328
Total revenues	48,628	32,880
Operating Expenses:		
Research and development	141,312	73,331
General and administrative	38,528	16,383
Restructuring charge	4,431	—
Total operating expenses	184,271	89,714
Loss from operations	(135,643)	(56,834)
Investment income, net	473	111
Non-cash interest expense on liability related to the sale of future royalties and convertible senior notes	(18,593)	(10,202)
Interest expense on convertible senior notes	(2,387)	—
Other expense, net	(583)	(42)
Net loss	$ (156,733)	$ (66,967)
Basic and diluted net loss per common share	$ (1.80)	$ (0.77)

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, or the Exchange Act) 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 December 31, 2018. 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 December 31, 2018 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 December 31, 2018. This report appears immediately below.

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

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of ImmunoGen Inc.

Opinion on Internal Control over Financial Reporting

We have audited ImmunoGen, Inc.'s internal control over financial reporting as of December 31, 2018, 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). In our opinion, ImmunoGen, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, shareholders' (deficit) equity and cash flows for each of the two years in the period ended December 31, 2018, the six-month transition period ended December 31, 2016 and the year ended June 30, 2016, and the related notes and our report dated March 1, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company'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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

Definition and Limitations of Internal Control Over Financial Reporting

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.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 1, 2019

(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 December 31, 2018 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.

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 2019 annual meeting of shareholders, which will be filed with the Securities and Exchange Commission not later than April 30, 2019 (120 days after the end of the year covered by this report), except that information required by Item 10 concerning our executive officers appears in Part I, Item 3.1 of this report.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules***

(a) Financial Statements:

(1) See "Index to Consolidated Financial Statements" at Item 8 of this report. 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) Exhibit Index follows.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Filed with this Form 10-K	Incorporated by Reference		
			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
3.1(b)	Articles of Amendment		10-Q	August 4, 2017	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

Exhibit Number	Exhibit Description	Filed with this Form 10-K	Incorporated by Reference		
			Form	Filing Date with SEC	Exhibit Number
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 Registrant		10-K	September 2, 2008	10.1(e)
10.1(f)	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)
10.1(i)	Ninth Amendment to Lease dated as of November 17, 2010 by and between Bobson 333 LLC, lessor, and the Registrant		8-K	November 18, 2010	10.1
10.1(j)	Tenth Amendment to Lease dated as of June 27, 2018 by and between Bobson Norwood Commercial, LLC and the Registrant		10-Q	August 3, 2018	10.1
10.1(k)	Eleventh Amendment to Lease dated as of February 27, 2019 by and between Bobson Norwood Commercial, LLC and the Registrant	X			
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
10.2(d)	Fourth Amendment to Lease Agreement dated as of April 6, 2018 by and between CRP/King 830 Winter, L.L.C., landlord, and the Registrant		10-Q	May 9, 2018	10.2

Exhibit Number	Exhibit Description	Filed with this Form 10-K	Incorporated by Reference		
			Form	Filing Date with SEC	Exhibit Number
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
10.4(d)*	Amendment No. 4, dated as of May 26, 2017 to the Collaboration and License Agreement between the Registrant and sanofi-aventis U.S. LLC		10-Q	August 4, 2017	10.2
10.5*	Collaborative Development and License Agreement dated as of July 7, 2006 by and between the Registrant and Biotest AG		10-Q	November 4, 2016	10.1
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 4, 2016	10.1
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
10.5(c)	Amendment No. 3, dated October 26, 2017, to the Collaborative Development and License Agreement by and between the Registrant and Biotest AG		10-Q	November 9, 2017	10.2
10.6*	Development and License Agreement dated as of October 20, 2008 by and between the Registrant and Bayer HealthCare AG		10-Q	May 9, 2018	10.3
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

Exhibit Number	Exhibit Description	Filed with this Form 10-K	Incorporated by Reference		
			Form	Filing Date with SEC	Exhibit Number
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 March 20, 2015 by and between the Registrant and Millennium Pharmaceuticals, Inc.		10-Q	May 8, 2015	10.1
10.10	Sales Agreement dated as of March 3, 2017 between the Registrant and Cowen and Company, LLC		S-3	March 3, 2017 (File No. 333-216438)	1.2
10.11*	Exclusive License and Asset Purchase Agreement dated as of May 23, 2017 by and between the Registrant and Debiopharm International, S.A.		10-Q	August 4, 2017	10.1
10.12*	Collaboration and Option Agreement dated as of August 28, 2017 by and between the Registrant and Jazz Pharmaceuticals Ireland Limited		10-Q	November 9, 2017	10.1
10.13*	Royalty Purchase Agreement dated as of January 8, 2019 among the Registrant, Hurricane, LLC, Immunity Royalty Holdings, L.P., and OMERS IP Healthcare Holdings Limited	X			
10.14†	2006 Employee, Director and Consultant Equity Incentive Plan, as amended and restated through November 11, 2014		8-K	November 13, 2014	10.1
10.14(a)†	Form of Incentive Stock Option Agreement for Executives		S-8	November 15, 2006	99.4
10.14(b)†	Form of Non-Qualified Stock Option Agreement for Executives		S-8	November 15, 2006	99.5
10.14(c)†	Form of Non-Qualified Stock Option Agreement for Directors		10-Q	October 29, 2010	10.1
10.14(d)†	Form of Director Deferred Stock Unit Agreement		10-Q	October 29, 2010	10.1
10.14(e)†	Form of Incentive Stock Option Agreement for all employees (including executives)		10-K	August 29, 2012	10.14(g)
10.14(f)†	Form of Non-Qualified Stock Option Agreement for all employees (including executives)		10-K	August 29, 2012	10.14(h)
10.14(g)†	Form of Non-Qualified Stock Option Agreement for Directors		10-K	August 29, 2012	10.14(i)
10.14(h)†	Form of Restricted Stock Agreement for all employees (including executives)		S-8	November 21, 2012	99.1
10.14(i)†	Form of Incentive Stock Option for all employees (including executives)		8-K	April 26, 2016	10.1
10.14(j)†	Form of Non-Qualified Stock Option Agreement for all employees (including executives)		8-K	April 26, 2016	10.2
10.14(k)†	Form of Performance Based Restricted Stock Agreement dated August 12, 2016		8-K	August 17, 2016	10.1
10.15†	2016 Employee, Director and Consultant Equity Incentive Plan, as amended and restated through June 13, 2017		8-K	June 16, 2017	10.1
10.15(a)†	Form of Incentive Stock Option Agreement		8-K	December 13, 2016	10.2
10.15(b)†	Form of Non-Qualified Stock Option Agreement for employees		8-K	December 13, 2016	10.3
10.15(c)†	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors		8-K	December 13, 2016	10.4

Exhibit Number	Exhibit Description	Filed with this Form 10-K	Incorporated by Reference		
			Form	Filing Date with SEC	Exhibit Number
10.15(d)†	Form of Deferred Stock Unit Agreement for Non-Employee Directors		8-K	December 13, 2016	10.5
10.15(e)†	Form of Restricted Stock Agreement for employees		10-Q	August 4, 2017	10.3
10.15(f)†	Form of Performance-Based Restricted Stock Agreement dated February 21, 2017 and June 14, 2017		10-Q	August 4, 2017	10.4
10.16†	2018 Employee, Director and Consultant Equity Incentive Plan		8-K	June 22, 2018	10.1
10.16(a)†	Form of Incentive Stock Option Agreement		8-K	June 22, 2018	10.2
10.16(b)†	Form of Non-Qualified Stock Option Agreement for employees		8-K	June 22, 2018	10.3
10.16(c)†	Form of Restricted Stock Unit Agreement		8-K	June 22, 2018	10.4
10.16(d)†	Form of Non-Qualified Option Agreement for Non-Employee Directors		8-K	June 22, 2018	10.5
10.16(e)†	Form of Deferred Stock Unit Agreement for Non-Employee Directors		8-K	June 22, 2018	10.6
10.17†	Employee Stock Purchase Plan		8-K	June 22, 2018	10.7
10.18†	2004 Non-Employee Director Compensation and Deferred Stock Unit Plan, as amended on September16, 2009		10-Q	November 4, 2009	10.1
10.19†	Form of Proprietary Information, Inventions and Competition Agreement between the Registrant and each of its executive officers		10-Q	February 8, 2007	10.15
10.20†	Change in Control Severance Agreement dated as of March 31, 2017 between the Registrant and Craig Barrows		10-Q	May 5, 2017	10.2
10.21†	Change in Control Severance Agreement dated as of March 31, 2017 between the Registrant and Anna Berkenblit		10-Q	May 5, 2017	10.3
10.22†	Change in Control Severance Agreement dated as of March 31, 2017 between the Registrant and Mark J. Enyedy		10-Q	May 5, 2017	10.4
10.23†	Change in Control Severance Agreement dated as of March 31, 2017 between the Registrant and Richard J. Gregory		10-Q	May 5, 2017	10.5
10.24†	Change in Control Severance Agreement dated as of April 23, 2018 between the Registrant and Blaine H. McKee		10-Q	May 9, 2018	10.5
10.25†	Change in Control Severance Agreement dated as of March 31, 2017 between the Registrant and Thomas Ryll		10-Q	May 5, 2017	10.7
10.26†	Change in Control Severance Agreement dated as of March 31, 2017 between the Registrant and Theresa G. Wingrove		10-Q	May 5, 2015	10.9
10.27†	Compensation Policy for Non-Employee Directors, as amended through March 28, 2018		10-Q	May 9, 2018	10.1
10.28†	Severance Pay Plan for Vice Presidents and Higher, as amended through February 15, 2018		10-K	March 7, 2018	10.30
10.29†	Summary of ImmunoGen Incentive Bonus Plan		8-K	February 20, 2018	10.1
21	Subsidiaries of the Registrant	X			
23	Consent of Ernst & Young LLP	X			

Exhibit Number	Exhibit Description	Filed with this Form 10-K	Incorporated by Reference		
			Form	Filing Date with SEC	Exhibit Number
31.1	Certifications of the principal executive officer and principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32	Certifications of principal executive officer and principal 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			

* 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 this transition report on Form 10-K.

Item 16. Summary Page

None

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: March 1, 2019

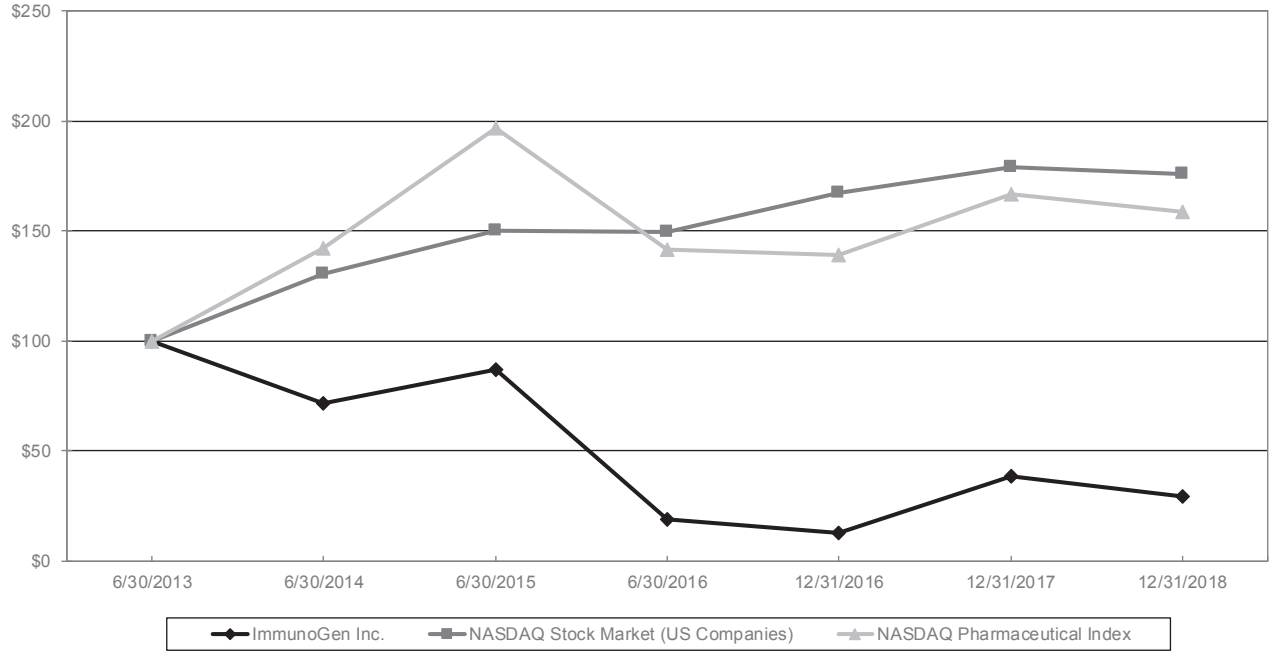
Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ MARK J. ENYEDY Mark J. Enyedy	President, Chief Executive Officer and Director (Principal Executive and Financial Officer)	March 1, 2019
/s/ DAVID G. FOSTER David G. Foster	Vice President - Finance (Principal Accounting Officer)	March 1, 2019
/s/ STEPHEN C. MCCLUSKI Stephen C. McCluski	Chairman of the Board of Directors	March 1, 2019
/s/ STUART A. ARBUCKLE Stuart Arbuckle	Director	March 1, 2019
/s/ MARK GOLDBERG, M.D. Mark Goldberg, M.D.	Director	March 1, 2019
/s/ DEAN J. MITCHELL Dean J. Mitchell	Director	March 1, 2019
/s/ KRISTINE PETERSON Kristine Peterson	Director	March 1, 2019
/s/ RICHARD J. WALLACE Richard J. Wallace	Director	March 1, 2019

(This page has been left blank intentionally.)

IMMUNOGEN, INC.
Stock Price Performance Graph

The graph and table below compare the annual percentage change in our cumulative total shareholder return on our common stock for the period from June 30, 2013 through December 31, 2018 (as measured by dividing (i) the sum of (A) the cumulative amount of dividends for the measurement period, assuming dividend reinvestment, and (B) the difference between our share price at the end and the beginning of the measurement period; by (ii) the share price at the beginning of the measurement period) with the total cumulative return of the NASDAQ Stock Market Index (U.S.) and the NASDAQ Pharmaceutical Stocks Total Return Index during such period. We have not paid any dividends on our common stock, and no dividends are included in the representation of our performance. The stock price performance on the graph below is not necessarily indicative of future price performance. This graph is not "soliciting material," is not deemed filed with the Commission and is not to be incorporated by reference in any of our filings under the Securities Act of 1933, or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing. Information used on the graph for the NASDAQ Pharmaceutical Stocks Total Return Index and the NASDAQ Stock Market Index (U.S.) was prepared by the Center for Research in Security Prices, a source believed to be reliable, but we are not responsible for any errors or omissions in such information.



	2013	2014	2015	2016	Dec 2016	Dec 2017	Dec 2018
IMMUNOGEN, INC.	$100.00	$ 71.43	$ 86.68	$ 18.57	$ 12.30	$ 38.64	$ 28.93
NASDAQ STOCK MARKET INDEX (U.S.)	$100.00	$130.62	$149.82	$149.63	$ 167.46	$ 178.99	$ 176.07
NASDAQ PHARMACEUTICAL STOCKS TOTAL RETURN INDEX (U.S.)	$100.00	$141.95	$196.77	$141.57	$ 139.31	$ 166.64	$ 158.71

* This index represents a group of peer issuers compiled by the Center for Research in Security Prices.

The above graph and table assume $100 invested on June 30, 2013 with all dividends reinvested, in each of our common stock, the NASDAQ Stock Market Index (U.S.) and the NASDAQ Pharmaceutical Stocks Total Return Index. Upon written request by any shareholder, we will promptly provide a list of the companies comprising the NASDAQ Pharmaceutical Stocks Total Return Index.

(This page has been left blank intentionally.)

CORPORATE INFORMATION

ImmunoGen, Inc.
830 Winter Street | Waltham, MA 02451
781-895-0600 | www.immunogen.com

EXECUTIVES

Mark J. Enyedy
President and Chief Executive Officer

Craig Barrows
Executive Vice President, General Counsel and Secretary

Richard J. Gregory, PhD
Executive Vice President, Chief Scientific Officer

Blaine H. McKee, PhD
Executive Vice President, Chief Business Officer

Anna Berkenblit, MD
Senior Vice President, Chief Medical Officer

Theresa G. Wingrove, PhD
Senior Vice President, Regulatory Affairs and Quality

Audrey Bergan
Vice President, Chief Human Resources Officer

Thomas Ryll, PhD
Vice President, Technical Operations

SHAREHOLDER INQUIRIES

Information about ImmunoGen can be found at www.immunogen.com. Inquiries related to the Company may be directed to the Investor Relations department at our headquarters. Communications related to stock and transfer requirements, including lost stock certificates and change of name or address, should be directed to the Transfer Agent.

DIRECTORS

CHAIRMAN OF THE BOARD
Stephen C. McCluski
Former Senior Vice President and Chief Financial Officer, Bausch & Lomb, Inc.

Stuart A. Arbuckle
Executive Vice President and Chief Commercial Officer, Vertex Pharmaceuticals, Inc.

Mark J. Enyedy
President and Chief Executive Officer, ImmunoGen, Inc.

Mark Goldberg, MD
Former Executive Vice President, Medical and Regulatory Strategy, Synageva BioPharma Corp.

Dean J. Mitchell
Executive Chairman of the Board, Covis Pharma Holdings S.a.r.l.

Kristine Peterson
Former Chief Executive Officer, Valeritas, Inc.

Richard J. Wallace
Former Senior Vice President Research and Development, GlaxoSmithKline plc

AUDITORS

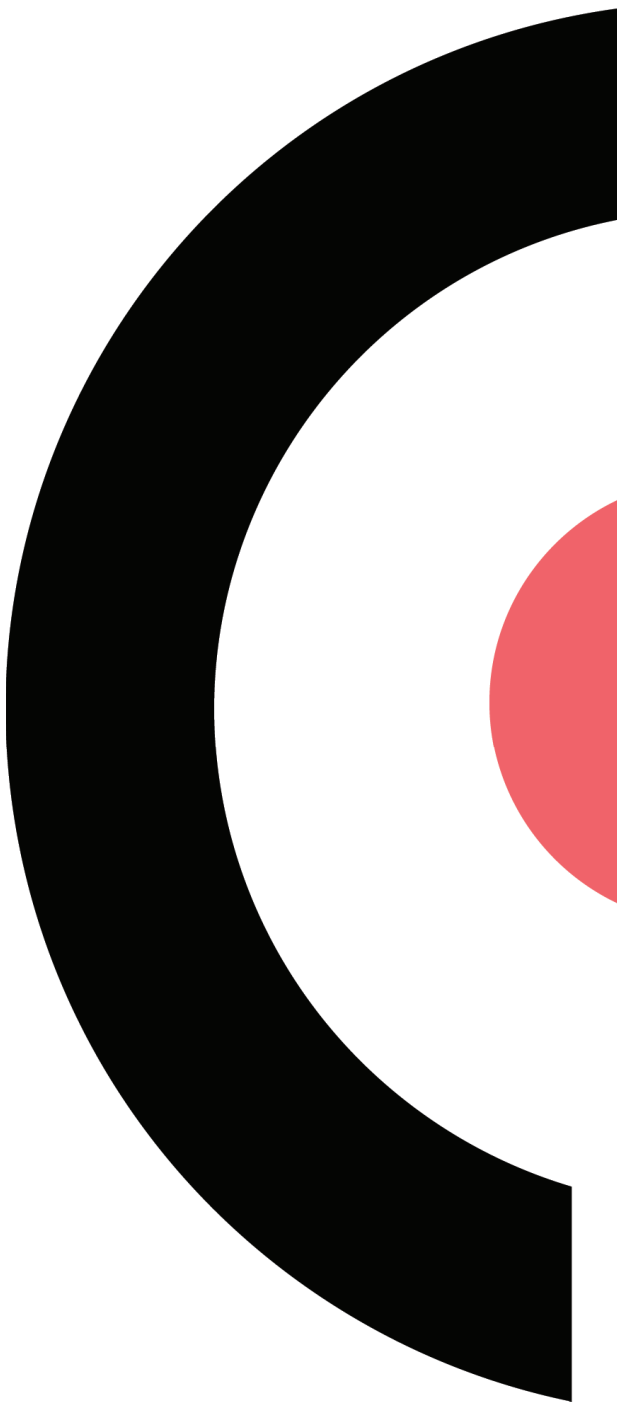
Ernst & Young LLP
Boston, MA

ANNUAL MEETING

9:00 AM on June 20, 2019
The University of Massachusetts Club
One Beacon Street, 32nd Floor
Boston, MA 02108

STOCK TRANSFER AGENT AND REGISTRAR

Broadridge Corporate Issuer Solutions, Inc.
P.O. Box 1342
Brentwood, NY 11717
Phone: 855-697-4961
Fax: 215-553-5402
Email: shareholder@broadridge.com



We extend our sincere gratitude to the patients, families and medical professionals who participate in our clinical trials as we work to meaningfully improve the lives of people with cancer.

immunogen

830 Winter Street
Waltham, MA 02451
781-895-0600
www.immunogen.com

NASDAQ: IMGN