SEATTLE GENETICS INC /WA
Form 424B5
September 11, 2015
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Filed pursuant to Rule 424(b)(5)
Registration No.: 333-206846

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Unit	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, par value $0.001 per share	13,463,415	$41.00	$552,000,015	$64,142.40

(1) Includes 1,756,097 shares that may be purchased by the underwriters upon exercise of the underwriters overallotment option.
(2) The filing fee is calculated and being paid pursuant to Rule 457(r) under the Securities Act of 1933, as amended, and relates to the Registration Statement on Form S-3 (File No. 333-206846) filed by the Registrant on September 9, 2015.

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Prospectus supplement

(To prospectus dated September 9, 2015)

11,707,318 shares

Common stock

We are offering 11,707,318 shares of our common stock.

Our common stock is listed on The NASDAQ Global Select Market under the symbol SGEN. On September 10, 2015, the last reported sale price of our common stock on The NASDAQ Global Select Market was $41.58 per share.

	Per share	Total
Public offering price	$ 41.000	$ 480,000,038
Underwriting discounts and commissions	$ 1.845	$ 21,600,002
Proceeds to Seattle Genetics, Inc. before expenses	$ 39.155	$ 458,400,036

We have granted the underwriters an option for a period of 30 days to purchase up to 1,756,097 additional shares of our common stock, solely to cover overallotments.

Investing in our common stock involves a high degree of risk. See Risk factors beginning on page S-10 of this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

Entities affiliated with one of our directors, Felix Baker, and which together are our largest stockholders, have agreed to purchase an aggregate of 3,338,927 of the shares of common stock offered hereby at the public offering price of $41.00 per share.

The underwriters expect to deliver the shares to purchasers on or about September 16, 2015.

J.P. Morgan **Leerink Partners**

UBS Investment Bank **Barclays** **RBC Capital Markets**

Needham & Company **William Blair**

September 10, 2015

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We have not, and the underwriters have not, authorized anyone to provide you with information different than or inconsistent with the information contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we have authorized for use in connection with this offering. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering, is accurate only as of the date of those respective documents, regardless of the time of delivery of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement entitled Where you can find more information and Incorporation of certain information by reference.

About this prospectus supplement

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus dated September 9, 2015, including the documents incorporated by reference therein, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission, or SEC, before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement.

All references in this prospectus supplement and the accompanying prospectus to Seattle Genetics, the Company, we, us, our, or similar references refer to Seattle Genetics, Inc., a Delaware corporation, and its subsidiaries on a consolidated basis, except where the context otherwise requires or as otherwise indicated.

This prospectus supplement, the accompanying prospectus, and the information incorporated herein and therein by reference include trademarks, trade names and service marks owned by us or other companies. Seattle Genetics®, and ADCETRIS® are our registered trademarks in the United States. All other trademarks or trade names referred to in this prospectus supplement, the accompanying prospectus and the information incorporated herein and therein by reference are the property of their respective owners.

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Prospectus supplement summary

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, you should read and consider carefully the more detailed information included or incorporated by reference in this prospectus supplement and the accompanying prospectus, including the factors described under the heading Risk factors beginning on page S-10 of this prospectus supplement, as well as the information included in any free writing prospectus that we have authorized for use in connection with this offering.

Our business

Seattle Genetics is a biotechnology company focused on the development and commercialization of targeted therapies for the treatment of cancer. Our marketed product ADCETRIS, or brentuximab vedotin, is an antibody-drug conjugate, or ADC, comprised of an anti-CD30 monoclonal antibody attached by a protease-cleavable linker utilizing our proprietary technology to a microtubule disrupting agent, monomethyl auristatin E (MMAE). ADCETRIS received accelerated approval in the United States in August 2011, conditional marketing authorization in the European Union in October 2012 and approval with conditions in Canada in February 2013 for administration to patients with relapsed classical Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL. On August 17, 2015, the U.S. Food and Drug Administration, or FDA, approved ADCETRIS for the treatment of patients with classical Hodgkin lymphoma at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation, or auto-HSCT, consolidation. We are collaborating with Takeda Pharmaceutical Company Limited, or Takeda, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Seattle Genetics retains commercial rights for ADCETRIS in the United States and its territories and in Canada, and Takeda has commercial rights in the rest of the world. ADCETRIS is now approved in over 55 countries and Takeda continues to pursue marketing authorizations in multiple other countries. Beyond our current labeled indications, we and Takeda have a broad development strategy for ADCETRIS evaluating its potential application in earlier lines of therapy for patients with Hodgkin lymphoma or mature T-cell lymphoma, or MTCL, including sALCL, and in other CD30-positive malignancies.

We and Takeda are conducting three additional phase 3 clinical trials of ADCETRIS, one in relapsed CD30-positive cutaneous T-cell lymphoma, or CTCL, called the ALCANZA trial, one in frontline advanced stage classical Hodgkin lymphoma, called the ECHELON-1 trial, and one in frontline CD30-positive MTCL, called the ECHELON-2 trial. We have entered into Special Protocol Assessment, or SPA, agreements with the FDA for the ALCANZA, ECHELON-1 and ECHELON-2 trials and Takeda also received scientific advice from the European Medicines Agency with respect to these trials. An SPA is an agreement with the FDA regarding the design of the clinical trial, including size and clinical endpoints, to support an efficacy claim in a Biologics License Application submission to the FDA if the trial achieves its primary endpoints. The ECHELON-2 trial would fulfill post-approval commitment obligations for ADCETRIS regarding drug efficacy, and positive results from this trial would form the basis for a submission to potentially convert the approval of ADCETRIS in the United States from accelerated approval to regular approval in its currently approved sALCL indication. The primary endpoint in the ALCANZA trial is an overall response rate lasting at least four months in patients treated with ADCETRIS compared to that achieved with therapy in the control arm. The primary endpoint in both of the ECHELON-1 and ECHELON-2 trials is progression-free survival, or PFS, per independent review facility assessment in patients treated with ADCETRIS compared to that achieved with therapy in the control arm. We expect to complete

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enrollment in ECHELON-1 later in 2015 and to complete enrollment in ECHELON-2 in 2016, and we expect to report data from both trials in the 2017 to 2018 timeframe.

In addition to ADCETRIS, our clinical-stage pipeline includes six ADC programs consisting of SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME, as well as SEA-CD40, which is based on our sugar-engineered antibody, or SEA, technology. In addition, we have multiple pre-clinical and research-stage programs that employ our proprietary technologies. We also have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd., Bayer Pharma AG, Celldex Therapeutics, Inc., Genentech, Inc., a member of the Roche Group, GlaxoSmithKline LLC, Pfizer, Inc., PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., and Takeda; as well as ADC co-development agreements with Agensys, Inc., an affiliate of Astellas Pharma, Inc., Genmab A/S and Oxford BioTherapeutics Ltd. We also recently entered into a collaboration agreement with Unum Therapeutics, Inc., or Unum, to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies incorporating our antibodies for the treatment of cancer.

Patents and proprietary technology

Our owned and licensed patents and patent applications are directed to ADCETRIS, our product candidates, monoclonal antibodies, our ADC and SEA technologies and other antibody-based and/or enabling technologies. We commonly seek patent claims directed to compositions of matter, including antibodies, ADCs, and drug-linkers containing highly potent cell-killing agents, as well as methods of using such compositions. When appropriate, we also seek claims to related technologies, such as methods of using certain sugar analogs utilized in our SEA technology. For ADCETRIS and each of our product candidates, we have filed or expect to file multiple patent applications. We maintain patents and prosecute applications worldwide for technologies that we have out-licensed, such as our ADC technology. Similarly, for partnered products and product candidates, such as ADCETRIS, ASG-22ME, and ASG-15ME, we seek to work closely with our development partners to coordinate patent efforts, including patent application filings, prosecution, term extension, defense and enforcement. As ADCETRIS and our development product candidates advance through research and development, we seek to diligently identify and protect new inventions, such as combinations, improvements to methods of manufacturing, and methods of treatment. We also work closely with our scientific personnel to identify and protect new inventions that could eventually add to our development pipeline. In addition to our patented intellectual property, we also rely on trade secrets and other proprietary information, especially when we do not believe that patent protection is appropriate or can be obtained.

For ADCETRIS and our related ADC technology, we own eight patents in the United States and Europe that will expire between 2020 and 2031. For SGN-CD33A and our related ADC technology, we own, co-own or have licensed rights to four patents in the United States and Europe that will expire between 2027 and 2030. Of these four patents, we own or co-own three patents and have licensed rights to one patent. For SGN-CD19A and our related ADC technology, we own nine patents in the United States and Europe that will expire between 2024 and 2029. For SGN-LIV1A and our related ADC technology, we own or have licensed rights to six patents in the United States and Europe that will expire between 2020 and 2026. Of these six patents, we own rights to four patents and have licensed rights to two patents. For SGN-70A and our related ADC technology, we own, co-own or have licensed rights to eleven patents in the United States and Europe that will expire between 2024 and 2030. Of these eleven patents, we own or co-own ten patents and have licensed rights to one patent. For SEA-CD40 and our related SEA technology, we own or have licensed rights to eleven patents in the United States and Europe that will expire between 2020 and 2030. Of these eleven patents, we own eight patents and have licensed rights to three patents. For ASG-22ME and our related ADC technology, we own, co-own or have

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licensed rights to eight patents in the United States and Europe that will expire between 2022 and 2031. Of these eight patents, we own or co-own six patents and have licensed rights to two patents. For ASG-15ME and our related ADC technology, we own or have licensed five patents in the United States and Europe that will expire between 2022 and 2033. Of these five patents, we own four patents and co-own one patent. In some cases, our U.S. patents may be eligible for patent term extension, and our European patents may be eligible for supplemental protection in one or more countries. The length of any such extension would vary by country.

Patents expire, on a country by country basis, at various times depending on various factors, including the filing date of the corresponding patent application(s), the availability of patent term extension and supplemental protection certificates and requirements for terminal disclaimers. Although we believe our owned and licensed patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We and our corporate collaborators may not be able to develop patentable products or processes or obtain patents from pending patent applications. Even if patent claims are allowed, the claims may not issue. In the event of issuance, the patents may not be sufficient to protect the proprietary technology owned by or licensed to us or our corporate collaborators. Our or our collaborators current patents, or patents that issue on pending applications, may be challenged, invalidated, infringed or circumvented. Our patents have been and may in the future be challenged by third parties in post-issuance administrative proceedings or in litigation as invalid or unenforceable under U.S. or foreign laws, or they may be infringed by third parties. As a result, we are from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law, U.S. Patent and Trademark Office inter partes review or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the United States and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings or litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our proprietary technologies without a license from us or our collaborators. Our and our collaborators patents may also be circumvented, which may allow third parties to use similar technologies without a license from us or our collaborators.

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. A number of pharmaceutical and biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover technologies similar to the technologies owned, optioned by or licensed to us or to our collaborators. In addition, we are monitoring the progress of multiple pending patent applications of other organizations that, if granted, may require us to license or challenge their enforceability in order to continue commercializing ADCETRIS or to commercialize our product candidates. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our or our collaborators ability to make, use or sell ADCETRIS or any other products.

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Recent developments

ADCETRIS Label Expansion. On August 17, 2015, the FDA approved ADCETRIS for the treatment of patients with classical Hodgkin lymphoma at high risk of relapse or progression as post-auto-HSCT consolidation. The approval was based on a phase 3 clinical trial, called the AETHERA trial, that was designed to compare one year of ADCETRIS therapy following auto-HSCT to placebo. In addition, data from the AETHERA trial converted the U.S. accelerated approval for ADCETRIS in the relapsed classical Hodgkin lymphoma indication to regular approval. We expect only modest, incremental sales growth, if any, at least in the near term as a result of the recent FDA approval of ADCETRIS for post-auto-HSCT consolidation treatment in classical Hodgkin lymphoma patients with high risk of relapse or progression subject to our ability to effectively commercialize ADCETRIS in this indication. For this reason and others, we expect that our ability to accelerate ADCETRIS sales growth, if at all, will depend primarily on our ability to continue to expand ADCETRIS labeled indications of use. Accordingly, we are exploring the use of ADCETRIS as a single agent and in combination therapy regimens earlier in the treatment of Hodgkin lymphoma and MTCL, including sALCL, and in a range of CD30-positive hematologic malignancies, including relapsed CTCL. This will continue to require additional time and investment in clinical trials and there can be no assurance that we and/or Takeda will obtain and maintain the necessary regulatory approvals to market ADCETRIS for any additional indications.

ALCANZA Enrollment Completion and Recent CTCL Data. On September 9, 2015, we announced that we and Takeda completed patient enrollment in the ALCANZA trial. ALCANZA is a randomized trial evaluating ADCETRIS versus investigator s choice of methotrexate or bexarotene in 132 patients with CD30-expressing CTCL who received prior systemic therapy. In 2012, the FDA granted ADCETRIS orphan drug designation for the treatment of mycosis fungoides, or MF, which is the most common type of CTCL. ADCETRIS is currently not approved for the treatment of CTCL. We expect to report data from this trial in the second half of 2016.

In addition, data from two investigator-sponsored phase 2 clinical trials evaluating ADCETRIS in relapsed CTCL were recently published in the Journal of Clinical Oncology, or JCO, by physicians at Stanford University and the University of Texas MD Anderson Cancer Center. The results of these two clinical trials demonstrated objective response rates of 70 and 73 percent, respectively, in relapsed CTCL patients having variable levels of CD30 expression treated with ADCETRIS. This compares to objective response rates of 30 to 45 percent from published trials utilizing standard of care treatments in this disease setting. The most common adverse events reported in these trials were peripheral neuropathy, fatigue, nausea, skin rash, hair loss, diarrhea, muscle pain and neutropenia. The following highlights data summaries from the JCO publications:

Phase II Investigator-Initiated Study of Brentuximab Vedotin in Mycosis Fungoides and Sézary Syndrome With Variable CD30 Expression Level: A Multi-Institution Collaborative Project (Published on July 20, 2015)

The phase 2 investigator-sponsored trial enrolled CTCL patients with MF or Sézary syndrome, which are types of CTCL. Of the 32 patients enrolled in the study, 30 were evaluable for efficacy and more than half had received three or more prior systemic therapies. The primary endpoint of the trial was objective clinical response rate. The study was led by principle investigator Dr. Youn H. Kim from Stanford University School of Medicine in Stanford, California. Key findings include:

- Twenty-one of 30 patients (70 percent) achieved an objective response across all stages of disease, including Stage IB, Stage IIB and Stage IV/SS. Overall, one patient had a complete response, 20 patients had a partial response, four patients had stable disease and five patients had progressive disease. Two patients were not evaluable for response. Of the patients who had partial responses, seven had near complete responses with over 90 percent skin improvement as measured by modified Severity-Weighted Assessment Tool, or mSWAT, scores and eight were still responding to therapy.

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Responses appeared to be durable; six- and 12-month Kaplan-Meier estimates indicated continuing responses in 90 percent and 79 percent of patients, respectively.

The most common related adverse events of any grade were peripheral neuropathy (66 percent), fatigue (47 percent), nausea (28 percent), hair loss (22 percent) and neutropenia (19 percent).

The most common Grade 3 or 4 related adverse events were neutropenia (four patients), rash (three patients) and peripheral neuropathy (one patient).

Results of a Phase II Trial of Brentuximab Vedotin (SGN-35) for CD30+ Cutaneous T-Cell Lymphomas and Lymphoproliferative Disorders (Published on August 10, 2015)

Data were published from a phase 2 investigator-sponsored trial evaluating the use of ADCETRIS in CD30-positive CTCL patients, including lymphomatoid papulosis, or LyP, primary cutaneous anaplastic large cell lymphoma, or pcALCL, or MF. The study was conducted by Dr. Madeleine Duvic from the University of Texas MD Anderson Cancer Center in Houston, Texas. Among 54 patients enrolled, 48 patients were evaluable at the time of analysis. The primary endpoint of the trial was to evaluate the safety and efficacy of ADCETRIS in CD30-positive CTCL. The key findings include:

Thirty-five of 48 patients (73 percent) achieved an objective response, including 20 of 20 (100 percent) with LyP and/or pcALCL and 15 of 28 (54 percent) with MF. Seventeen patients (35 percent) achieved a complete response.

The most common adverse events were peripheral neuropathy (67 percent), fatigue (35 percent), skin rash (24 percent), diarrhea (15 percent), muscle pain (17 percent), localized skin infection (15 percent), neutropenia (15 percent) and hair loss (11 percent).

The most common Grade 3 or 4 adverse events were neutropenia (three patients), nausea (two patients), unstable angina or myocardial infarction (two patients), infection (two patients), joint pain (two patients), fatigue (one patient), deep vein thrombosis (one patient), pulmonary embolism (one patient), aminotransferase elevation (one patient) and dehydration (one patient).

Company information

We were incorporated in Delaware on July 15, 1997. Our principal executive offices are located at 21823 30th Drive SE, Bothell, Washington 98021. Our telephone number is (425) 527-4000. Our website address is *www.seattlegenetics.com*. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this prospectus supplement or the accompanying prospectus, and you should not consider it part of this prospectus supplement or the accompanying prospectus. Our website address is included in this document as an inactive textual reference only.

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The offering

Common stock offering by us	11,707,318 shares
Common stock to be outstanding immediately after this offering	137,008,963 shares
Option to purchase additional shares	The underwriters have a 30-day option to purchase up to an additional 1,756,097 shares of common stock, solely to cover overallotments.
Use of proceeds	We intend to use the net proceeds from this offering to fund the ongoing commercialization of ADCETRIS in the United States and Canada, to fund our research and development efforts designed to further expand the ADCETRIS label and to advance our pipeline of product candidates, as well as for general corporate purposes, including working capital. See Use of proceeds.
Risk factors	Investing in our common stock involves a high degree of risk. See Risk factors.
NASDAQ Global Select Market symbol	SGEN

The number of shares of our common stock to be outstanding immediately after this offering is based on 125,301,645 shares outstanding as of June 30, 2015 and excludes:

- 9,498,949 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2015, having a weighted-average exercise price of $22.63 per share;
- 1,676,496 shares of our common stock issuable upon the vesting of restricted stock unit awards outstanding as of June 30, 2015;
- 4,957,720 shares of our common stock reserved for future issuance under our Amended and Restated 2007 Equity Incentive Plan as of June 30, 2015; and
- 1,050,206 additional shares of our common stock reserved for future issuance under our Amended and Restated 2000 Employee Stock Purchase Plan as of June 30, 2015.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise of the underwriters overallotment option.

Entities affiliated with one of our directors, Felix Baker, and which together are our largest stockholders, have agreed to purchase an aggregate of 3,338,927 of the shares of common stock offered hereby at the public offering price of $41.00 per share. In addition, in connection with this offering, we entered into a registration rights agreement with these entities, or the Baker Entities. Based on information available to us, the Baker Entities collectively beneficially owned approximately 25% of our common stock as of June 30, 2015. Under the registration rights agreement, we agreed that, if at any time and from time to time after the expiration of the 90-day lock-up period applicable to us and described under the heading Underwriting, the Baker Entities demand that we register their shares of our common stock for resale under the Securities Act of 1933,

as amended, or the Securities Act, we would be obligated to effect such registration. Our registration obligations

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under this registration rights agreement cover all shares now held or hereafter acquired (including the shares acquired in this offering) by the Baker Entities, will continue in effect for up to ten years, and include our obligation to facilitate certain underwritten public offerings of our common stock by the Baker Entities in the future.

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Summary consolidated financial data

The tables below present our summary consolidated financial data. The summary consolidated financial data as of December 31, 2014 and 2013 and for the years ended December 31, 2014, 2013 and 2012 are derived from the audited consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2014 that is incorporated by reference in this prospectus supplement and the accompanying prospectus. The summary consolidated financial data as of June 30, 2014 and for the six months ended June 30, 2015 and 2014 are derived from the unaudited consolidated financial statements included in our quarterly report on Form 10-Q for the quarterly period ended June 30, 2015 that is incorporated by reference in this prospectus supplement and the accompanying prospectus.

The foregoing information is only a summary and is not necessarily indicative of the results of our future operations. You should read this data together with the consolidated financial statements and related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included in our periodic reports on file with the SEC and incorporated by reference in this prospectus supplement and the accompanying prospectus. For details on how you can obtain the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, see Where you can find more information and Incorporation of certain information by reference.

	Years ended December 31,			Six months ended June 30,	
(In thousands, except per share amounts)	**2014**	**2013**	**2012**	**2015**	**2014**
Consolidated statements of comprehensive loss data:					
Revenues:					
Net product sales	$ 178,198	$ 144,665	$ 138,200	$ 103,981	$ 83,498
Collaboration and license agreement revenues	68,556	106,781	67,547	36,607	33,074
Royalty revenues	40,004	17,818	5,065	18,665	20,007
Total revenues	286,758	269,264	210,812	159,253	136,579
Costs and expenses:					
Cost of sales	17,513	13,759	11,546	11,150	7,752
Cost of royalty revenues	11,545	7,385	1,923	5,813	5,108
Research and development	230,743	218,627	170,297	149,132	108,190
Selling, general and administrative	104,320	92,354	84,300	62,464	49,543
Loss from operations	(77,363)	(62,861)	(57,254)	(69,306)	(34,014)
Investment and other income, net	1,222	341	3,472	114	123
Net loss	$ (76,141)	$ (62,520)	$ (53,782)	$ (69,192)	$ (33,891)
Net loss per share basic and diluted	$ (0.62)	$ (0.51)	$ (0.46)	$ (0.55)	$ (0.28)
Shares used in computation of net loss per share basic and diluted	123,408	121,575	117,851	124,690	123,053

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(In thousands)	2014	As of December 31, 2013	As of June 30, 2015
Consolidated balance sheet data:			
Cash, cash equivalents and short-term investments	$ 313,413	$ 374,267	$ 249,536
Working capital	282,093	338,058	220,362
Total assets	458,965	483,898	407,815
Stockholders equity	210,834	230,185	179,618

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Risk factors

Investing in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below and all other information in this prospectus supplement, the accompanying prospectus, and the documents incorporated by reference, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occur, our business, financial condition, results of operations or cash flows could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

Risks related to our business

Our near-term prospects are substantially dependent on ADCETRIS. If we and/or Takeda are unable to effectively commercialize ADCETRIS for the treatment of patients in its approved indications and to continue to expand its labeled indications of use, our ability to generate significant revenue or achieve profitability will be adversely affected.

ADCETRIS received accelerated approval in the United States in August 2011 and approval with conditions in Canada in February 2013 for patients with relapsed classical Hodgkin lymphoma or relapsed sALCL. On August 17, 2015, the FDA approved ADCETRIS for the treatment of patients with classical Hodgkin lymphoma at high risk of relapse or progression as post-auto-HSCT consolidation. ADCETRIS is our only product approved for marketing and our ability to generate revenue from product sales and achieve profitability is substantially dependent on our continued ability to effectively commercialize ADCETRIS for the treatment of patients in its approved indications and our ability to continue to expand its labeled indications of use. We may not be able to fully realize the commercial potential of ADCETRIS for a number of reasons, including:

- we may not be able to obtain and maintain regulatory approvals to market ADCETRIS for any additional indications, including for frontline Hodgkin lymphoma or MTCL, or to otherwise continue to expand its labeled indications of use;
- as a result of increased target enrollments in the ECHELON-1 and ECHELON-2 trials, our ability to successfully complete these trials on a timely basis could be adversely affected, which in turn could adversely affect our ability to continue to expand ADCETRIS labeled indications of use;
- the market penetration rate of ADCETRIS may be lower, or the duration of therapy in patients in ADCETRIS approved indications may be shorter, than our projections;
- we may be unable to effectively commercialize ADCETRIS in any new indications for which we receive marketing approval, including in the newly-approved indication for post-auto-HSCT consolidation treatment in classical Hodgkin lymphoma patients with high risk of relapse or progression;
- results from our required post-approval studies may fail to verify the clinical benefit of ADCETRIS in relapsed sALCL, which could result in the withdrawal of approval of ADCETRIS in the sALCL indication;
- there may be additional changes to the label for ADCETRIS, including ADCETRIS boxed warning, that further restrict how we market and sell ADCETRIS, including as a result of data collected from required post-approval studies such as our ECHELON-1 and ECHELON-2 clinical trials, or as the result of adverse events observed in these or other studies, including in investigator-sponsored studies;
- we may not be able to establish or demonstrate in the medical community the safety and efficacy of ADCETRIS and its potential advantages over and side effects compared to existing and future therapeutics;

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physicians may be reluctant to prescribe ADCETRIS until results from our required post-approval studies are available or other long term efficacy and safety data exists;

the estimated incidence rate of new patients in ADCETRIS approved indications may be lower than our projections;

there may be adverse results or events reported in any of the clinical trials that we and/or Takeda are conducting or may in the future conduct for ADCETRIS;

new competitive therapies may be approved for marketing by regulatory authorities in ADCETRIS labeled indications;

we may be unable to continue to effectively market, sell and distribute ADCETRIS;

ADCETRIS may receive adverse reimbursement and coverage policies from government and private payers such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators or may be subject to pricing pressures enacted by industry organizations;

the relative price of ADCETRIS may be higher than alternative treatment options;

there may be changed or increased regulatory restrictions;

we may not have adequate financial or other resources to effectively commercialize ADCETRIS; and

we may not be able to obtain adequate commercial supplies of ADCETRIS to meet demand or at an acceptable cost.

In December 2009, we entered into an agreement with Takeda to develop and commercialize ADCETRIS, under which we have commercial rights in the United States and its territories and Canada, and Takeda has commercial rights in the rest of the world. The success of this collaboration and the activities of Takeda will significantly impact the commercialization of ADCETRIS in countries other than the United States and in Canada. In October 2012, Takeda announced that it had received conditional marketing authorization for ADCETRIS from the European Commission for patients with relapsed Hodgkin lymphoma or relapsed sALCL, and has since obtained marketing approvals for ADCETRIS in many other countries. Conditional marketing authorization by the European Commission includes obligations to provide additional clinical data at a later stage to confirm the positive benefit-risk balance. Although Takeda received conditional marketing authorization from the European Commission and other countries, we cannot control the amount and timing of resources that Takeda dedicates to the commercialization of ADCETRIS, or to its marketing and distribution, and our ability to generate revenues from ADCETRIS product sales by Takeda depends on Takeda s ability to achieve market acceptance of, and to otherwise effectively market, ADCETRIS for its approved indications in its territory.

We believe that the level of our ongoing ADCETRIS sales in the United States is largely attributable to the incidence flow of patients eligible for treatment with ADCETRIS. We also believe that the incidence rate of new patients in ADCETRIS approved indications is relatively low, particularly when compared to many other oncology indications. In addition, we expect only modest, incremental sales growth, if any, in the near term as a result of the recent FDA approval of ADCETRIS for post-auto-HSCT consolidation treatment in classical Hodgkin lymphoma patients with high risk of relapse or progression subject to our ability to effectively commercialize ADCETRIS in this indication. For these and other reasons, we expect that our ability to accelerate ADCETRIS sales growth, if at all, will depend primarily on our ability to continue to expand ADCETRIS labeled indications of use. Accordingly, we are exploring the use of ADCETRIS as a single agent and in combination therapy regimens earlier in the treatment of Hodgkin lymphoma and MTCL, including sALCL, and in a range of CD30-positive hematologic malignancies, including relapsed CTCL. This will continue to require additional time

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and investment in clinical trials and there can be no assurance that we and/or Takeda will obtain and maintain the necessary regulatory approvals to market ADCETRIS for any additional indications. In addition, while ADCETRIS product sales grew from 2012 to 2013 and from 2013 to 2014, and our future plans assume that sales of ADCETRIS will increase, we cannot assure you that, even with the recent expansion to the prescribing label for ADCETRIS, which now includes post-auto-HSCT consolidation treatment in classical Hodgkin lymphoma patients with high risk of relapse or progression, we can maintain sales of ADCETRIS at or near current levels, or that ADCETRIS sales will continue to grow. We and Takeda have formed a collaboration with Ventana Medical Systems, Inc., or Ventana, under which Ventana is working to develop, manufacture and commercialize a molecular companion diagnostic test with the goal of identifying patients who might respond to treatment with ADCETRIS based on CD30 expression levels in their tissue specimens. However, Ventana may not be able to successfully develop and obtain regulatory approval for a molecular companion diagnostic that may be required by regulatory authorities to support regulatory approval of ADCETRIS in other CD30-positive malignancies in a timely manner or at all. Even if we and Takeda receive the required regulatory approvals to market ADCETRIS for any additional indications or in additional jurisdictions, we and Takeda may not be able to effectively commercialize ADCETRIS, including for the reasons set forth above. Our ability to grow ADCETRIS product sales in future periods is also dependent on price increases and we have periodically increased the price of ADCETRIS, most recently in July 2015. We cannot assure you that price increases we have taken or may take in the future will not in the future negatively affect ADCETRIS sales volumes.

Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

Our operating results are difficult to predict and may fluctuate significantly from quarter to quarter and year to year. We have only been commercializing ADCETRIS since August 2011 and although we provide sales guidance for ADCETRIS from time to time, you should not rely on ADCETRIS sales results in any period as being indicative of future performance. Such guidance is based on assumptions that may be incorrect or that may change from quarter to quarter. Sales of ADCETRIS have in the past been below the expectations of securities analysts and investors and have been below prior period sales, and sales of ADCETRIS in the future may also be below prior period sales, our own guidance and/or the expectations of securities analysts and investors. To the extent that we do not meet our guidance or the expectations of analysts or investors, our stock price may be adversely impacted, perhaps significantly. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- customer ordering patterns for ADCETRIS, which may vary significantly from period to period;
- the overall level of demand for ADCETRIS and the duration of therapy for patients receiving ADCETRIS;
- the extent to which coverage and reimbursement for ADCETRIS is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers;
- changes in the amount of deductions from gross sales, including government-mandated rebates, chargebacks and discounts that can vary because of changes to the government discount percentage, including increases in the government discount percentage resulting from price increases we have taken or may take in the future, or due to different levels of utilization by entities entitled to government rebates and discounts and changes in patient demographics;
- increases in the scope of eligibility for customers to purchase ADCETRIS at the discounted government price or to obtain government-mandated rebates on purchases of ADCETRIS;
- changes in our cost of sales, including but not limited to an increase in our cost of sales as a percentage of sales in future periods as product manufactured prior to FDA approval, and therefore fully expensed, is consumed;

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- the incidence rate of new patients in ADCETRIS approved indications;
- the timing, cost and level of investment in our sales and marketing efforts to support ADCETRIS sales;
- the timing, cost and level of investment in our research and development activities involving ADCETRIS and our product candidates, including possible future in-licensing activities; and
- expenditures we will or may incur to conduct required post-approval studies for ADCETRIS and acquire or develop additional technologies, product candidates and products.

In addition, from time to time, we enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments, and we expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues. Accordingly, our revenues will also depend on development funding and the achievement of development and clinical milestones under our existing collaboration and license agreements, including, in particular, our ADCETRIS collaboration with Takeda, as well as entering into new collaboration and license agreements. These upfront and milestone payments may vary significantly from quarter to quarter and any such variance could cause a significant fluctuation in our operating results from one quarter to the next. Further, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee s requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price, the magnitude of the expense that we must recognize may vary significantly.

For these and other reasons, it is difficult for us to accurately forecast future sales of ADCETRIS, collaboration and license agreement revenues, royalty revenues, or future profits or losses. As a result, our operating results in future periods could be below our guidance or the expectations of securities analysts or investors, which could cause the trading price of our common stock to decline, perhaps substantially.

Reports of adverse events or safety concerns involving ADCETRIS could delay or prevent us from obtaining or maintaining regulatory approval, or could negatively impact sales of ADCETRIS.

Reports of adverse events or safety concerns involving ADCETRIS could interrupt, delay or halt clinical trials of ADCETRIS, including the ongoing FDA-required ADCETRIS post-approval confirmatory studies as well as the post-approval confirmatory studies that Takeda is required to conduct as a condition to the conditional marketing authorization of ADCETRIS by the European Commission. For example, during 2013 concerns regarding pancreatitis caused an investigator conducting an independent study involving ADCETRIS to temporarily halt enrollment in the trial and to amend the eligibility criteria and monitoring for the trial. Subsequently, we have revised our prescribing information to add pancreatitis as a known adverse event. In addition, reports of adverse events or safety concerns involving ADCETRIS could result in regulatory authorities denying or withdrawing approval of ADCETRIS for any or all indications, including the use of ADCETRIS for the treatment of patients in its approved indications. There are no assurances that patients receiving ADCETRIS will not experience serious adverse events in the future. Further, there are no assurances that patients receiving ADCETRIS with co-morbid diseases not previously studied, such as autoimmune diseases, will not experience new or different serious adverse events in the future.

Adverse events may also negatively impact the sales of ADCETRIS. We may also be required to further update the ADCETRIS prescribing information based on reports of adverse events or safety concerns or implement a Risk Evaluation and Mitigation Strategy, which could adversely affect ADCETRIS acceptance in the market, make competition easier or make it more difficult or expensive for us to distribute ADCETRIS. For example, we have revised the prescribing information for ADCETRIS to add pancreatitis, impaired hepatic function and impaired renal function as known adverse events as well as to include a boxed warning related to the risk that

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JC virus infection resulting in progressive multifocal leukoencephalopathy, or PML, and death can occur in patients receiving ADCETRIS. In addition, we are currently in discussion with the FDA to update the prescribing information with respect to patients who may experience pulmonary toxicity. Further, based on the identification of future adverse events, we may be required to further revise the prescribing information, including ADCETRIS boxed warning, which could negatively impact sales of ADCETRIS or adversely affect ADCETRIS acceptance in the market.

Even though we have obtained approval to market ADCETRIS in three indications, we are subject to ongoing regulatory obligations and review, including post-approval requirements that could result in the withdrawal of ADCETRIS from the market for certain indications if such requirements are not met.

Given the recent conversion of U.S. accelerated approval of ADCETRIS in the relapsed classical Hodgkin lymphoma indication to regular approval, ADCETRIS is now approved for treating patients in one indication under accelerated approval regulations in the U.S. and approval with conditions in two indications in Canada, which allow for approval of products for cancer or other serious or life threatening illnesses based on a surrogate endpoint or on a clinical endpoint other than survival or irreversible morbidity. Under these types of approvals, we are subject to certain post-approval requirements pursuant to which we are conducting additional confirmatory and safety phase 3 trials to verify and describe the clinical benefit of ADCETRIS. Our failure to complete these required post-approval studies, or to confirm a clinical benefit during these post-approval studies, could result in the withdrawal of approval of ADCETRIS in those indications, which would seriously harm our business. In addition, we are subject to extensive ongoing obligations and continued regulatory review from applicable regulatory agencies, such as continued adverse event reporting requirements and the requirement to have our promotional materials pre-cleared by the FDA. There may also be additional post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize ADCETRIS in the United States, Canada or potentially other jurisdictions. Similarly, the conditional marketing authorization of ADCETRIS for two indications by the European Commission includes obligations to provide additional clinical data at a later stage to confirm the results of the two pivotal studies. Takeda s failure to provide these additional clinical data or to confirm the results of the pivotal studies, could result in the European Commission withdrawing approval of ADCETRIS in the European Union, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda in the European Union and could adversely affect our results of operations.

Under the FDA s accelerated approval regulations, the labeling, packaging, adverse event reporting, storage, advertising and promotion of ADCETRIS for the treatment of patients with sALCL, the indication that has received accelerated approval and not yet converted to full approval, is subject to extensive regulatory requirements all of which may result in significant expense and limit our ability to commercialize ADCETRIS for the sALCL indication. We and the manufacturers of ADCETRIS are also required to comply with current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture ADCETRIS, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject an approved product, its manufacturer and the manufacturer s facilities to continual review and inspections. The subsequent discovery of previously unknown problems with ADCETRIS, including adverse events of unanticipated severity or frequency, or problems with the facilities where ADCETRIS is manufactured, may result in restrictions on the marketing of ADCETRIS, up to and including withdrawal of ADCETRIS from the market. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, such noncompliance could result in regulatory action and additional costs to us. Failure to comply with applicable FDA and other regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

issuance of Form 483 notices or Warning Letters by the FDA or other regulatory agencies;

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imposition of fines and other civil penalties;

criminal prosecutions;

injunctions, suspensions or revocations of regulatory approvals;

suspension of any ongoing clinical trials;

total or partial suspension of manufacturing;

delays in commercialization;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us or Takeda;

refusals to permit drugs to be imported into or exported from the United States;

restrictions on operations, including costly new manufacturing requirements; and

product recalls or seizures.

The policies of the FDA and other regulatory agencies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of ADCETRIS in any additional indications or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we or Takeda might not be permitted to market ADCETRIS and our business would suffer.

Clinical trials are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcome is uncertain.

We are currently conducting multiple clinical trials for ADCETRIS and our product candidates and we plan to commence additional trials of ADCETRIS and our product candidates in the future. Each of our clinical trials requires the investment of substantial expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delays in accumulating the required number of clinical events for data analyses, delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site, and shortages of available drug supply. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In addition, many of our future and ongoing ADCETRIS clinical trials are being or will be coordinated with Takeda, which may delay the commencement or affect the continuation or completion of these trials. We have experienced enrollment-related delays in certain of our current and previous clinical trials and will likely experience similar delays in our future trials, particularly as we attempt to enroll larger numbers of patients required for phase 3 studies of ADCETRIS that we are required to conduct, and are currently conducting, to satisfy the FDA s post-approval requirements. We depend on medical institutions and clinical research organizations, or CROs, to conduct some of our clinical trials in compliance with Good Clinical Practice, or GCP, and to the extent they fail to enroll patients for our clinical trials, fail to conduct our trials in accordance with GCP, or are delayed for a significant time in achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a

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result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, different standards of medical care, and foreign currency transactions insofar as changes in the relative value of the U.S. dollar to the foreign currency where the trial is being conducted may impact our actual costs.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP and other requirements in foreign countries, and may require large numbers of test patients. We, the FDA or other foreign governmental agencies could delay, suspend, halt or modify our clinical trials of ADCETRIS or any of our product candidates, as well as any related special protocol assessment, or SPA, agreements, for numerous reasons, including:

- ADCETRIS or the applicable product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements, GCP or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- the time required to determine whether ADCETRIS or the applicable product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- ADCETRIS or the applicable product candidate may not appear to be more effective than current therapies;
- the quality or stability of ADCETRIS or the applicable product candidate may fall below acceptable standards;
- our inability to produce or obtain sufficient quantities of ADCETRIS or the applicable product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- our inability to recruit and enroll patients to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or

our inability to retain patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies, which often occur in later- stage clinical trials. For example, it is currently unknown if

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ADCETRIS may be safely and effectively combined with human programmed death receptor-1, or PD-1, inhibitors, including nivolumab. As a further example, during 2011 we announced that, based on a phase 1 trial combining ADCETRIS with ABVD chemotherapy, ADCETRIS should not be combined with bleomycin, one of the drugs in ABVD chemotherapy, due to increased incidence of pulmonary toxicity in the combination arm of the trial. As a result, we added a contraindication warning relating to the concomitant use of ADCETRIS and bleomycin due to pulmonary toxicity. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive clinical trial results could negatively affect our ability to market ADCETRIS or expand into other indications. Further, given the progression-free survival, or PFS, trends in our phase 1 data combining ADCETRIS with standard chemotherapy regimens and the positive PFS outcome in the AETHERA trial, we and Takeda have evaluated the potential that event rates may be slower than expected in both the ECHELON-1 and ECHELON-2 trials and have discussed with regulatory agencies proposed trial modifications. In April 2015, the FDA approved proposed amendments to the ECHELON-1 and ECHELON-2 SPAs for both trials to increase target enrollment from 1,040 to 1,240 patients in ECHELON-1 and from 300 to 450 patients in ECHELON- 2. These increases in our target enrollment for these clinical trials will also extend the patient treatment phase of the trials. Although we continue to expect the timeline for reporting data from these clinical trials to be in the 2017 to 2018 timeframe, it is possible that these trial modifications could adversely impact our ability to successfully complete the ECHELON-1 and ECHELON-2 trials on a timely basis, which in turn could adversely affect our ability to continue to expand ADCETRIS labeled indications of use. Adverse medical events, including patient fatalities that may be attributable to ADCETRIS during a clinical trial, could cause a trial to be redone or terminated. Further, some of our clinical trials may be overseen by an independent data monitoring committee, or IDMC, and an IDMC may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial.

We face intense competition and rapid technological change, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

With respect to ADCETRIS, there are currently no FDA-approved drugs other than ADCETRIS for the treatment of classical Hodgkin lymphoma or sALCL in its approved indications; however, Celgene s Istodax and Spectrum Pharmaceuticals Folotyn are both approved for relapsed or refractory peripheral T-cell lymphoma. Compelling data have been presented involving several developing technologies, including antibody therapies that target PD-1 and CAR modified T-cell therapies, that may compete with ADCETRIS in the future. For example, the FDA recently granted breakthrough therapy designation for Bristol-Myers Squibb s nivolumab therapy to treat patients with Hodgkin lymphoma after failure of auto-HSCT and ADCETRIS therapy. In addition, we are aware of multiple investigational agents that are currently being studied, including Pfizer s crizotinib, Takeda s alistertib, AbbVie s ibrutinib, and Gilead s idelalisib, which, if successful, may compete with ADCETRIS in the future. In addition, there are many existing approaches used in the treatment of patients in ADCETRIS three approved indications, including auto-HSCT, combination chemotherapy, clinical trials with experimental agents and single agent regimens, which represent competition for ADCETRIS.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. We are aware of many pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapy or that are otherwise developing various approaches to cancer and autoimmune disease therapy. Some of these competitors have successfully commercialized antibody products or are developing or testing product candidates that do or may in the future compete directly with our product candidates. For example, we believe that companies including AbbVie, Amgen, Bayer, Biogen, Bristol-Myers Squibb, Celgene, Eisai, Genentech, Gilead, GSK, ImmunoGen, Infinity, Merck, Novartis, Pfizer, Sanofi-Aventis, Spectrum Pharmaceuticals, Takeda, Teva and Xencor are developing and/or marketing products or technologies that may compete with ours, and some of these companies,

including AstraZeneca, Bristol-Myers Squibb, ImmunoGen and Pfizer, have ADC technology. Other potential competitors include large, fully integrated pharmaceutical companies and more established biotechnology companies that have significant resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals and marketing. Also, academic institutions, government agencies and other public and private research organizations conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing. It is possible that these competitors will succeed in developing technologies that are more effective than ADCETRIS or our product candidates or that would render our technology obsolete or noncompetitive. We anticipate that we will face increased competition in the future as new companies enter our market and scientific developments surrounding other cancer therapies continue to accelerate.

We are subject to various state and federal healthcare related laws and regulations that may impact our business and could subject us to significant fines and penalties.

Our operations may be directly or indirectly subject to various state and federal healthcare laws, including, without limitation, the federal Anti-Kickback Statute, federal civil and criminal false claims laws, HIPAA/HITECH, the federal civil monetary penalties statute, and the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA. These laws may impact, among other things, the sales, marketing and education programs for ADCETRIS.

The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. Additionally, PPACA amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs.

The federal civil and criminal false claims laws prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false claim to, or the knowing use of false statements to obtain payment from or approval by the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease, or conceal an obligation to pay money to the federal government. PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Suits filed under the civil False Claims Act, known as qui tam actions, can be brought by any individual on behalf of the government and such individuals, commonly known as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. The filing of qui tam actions has caused a number of pharmaceutical, medical device and other healthcare companies to have to defend a civil False Claims Act action. When an entity is determined to have violated the civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute,

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a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the Anti-Kickback Statute, PPACA amended the intent requirement of the criminal healthcare fraud statutes such that a person or entity no longer needs to have actual knowledge of the statute or intent to violate it.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information.

The federal civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal transparency requirements under PPACA require certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals, and physician ownership and investment interests.

There are foreign and state law equivalents of these laws, such as anti-kickback, false claims, and data privacy and security laws, to which we are currently and may in the future, be subject. We may also be subject to state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Many of these state laws differ from each other in significant ways, thus complicating compliance efforts.

The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits companies and individuals from engaging in specified activities to obtain or retain business or to influence a person working in an official capacity. Under the FCPA, it is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, governmental staff members, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

The FDA and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. If we are found to have promoted an approved product, including ADCETRIS, for off-label uses we may be subject to significant liability, including civil and administrative financial penalties and other remedies as well as criminal financial penalties and other sanctions. Even when a company is not determined to have engaged in off-label promotion, the allegation from government authorities or market participants that a company has engaged in such activities could have a significant impact on the company s sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies.

In order to comply with these laws, we have implemented a comprehensive compliance program to actively identify, prevent and mitigate risk through the implementation of compliance policies and systems and by promoting a culture of compliance. Although we take our obligation to maintain our compliance with these various laws and regulations seriously and our compliance program is designed to prevent the violation of

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these laws and regulations, if we are found to be in violation of any of the laws and regulations described above or other applicable state and federal healthcare fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from government healthcare reimbursement programs and/or the curtailment or restructuring of our operations, any of which could have a material adverse effect on our business, results of operations and growth prospects. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal, state and foreign healthcare laws is costly and time- consuming for our management.

As we expand our operations internationally, we will be subject to an increased risk of conducting activities in a manner that violates applicable anti-bribery or anti-corruption laws. We are also subject to foreign laws and regulations covering data privacy and the protection of health-related and other personal information. These laws and regulations could create liability for us or increase our cost of doing business, any of which could have a material adverse effect on our business, results of operations and growth prospects.

We recently have begun to expand our operations internationally. Though we are at an early stage with our international expansion, our business activities outside of the United States are subject to the FCPA, which is described above, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we currently and may in the future operate, including the U.K. Bribery Act. The U.K. Bribery Act prohibits giving, offering, or promising bribes to any person, including non-U.K. government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the U.K. Bribery Act, companies which carry on a business or part of a business in the U.K. may be held liable for bribes given, offered or promised to any person, including non-U.K. government officials and private persons, by employees and persons associated with such company in order to obtain or retain business or a business advantage for such company. In the course of expanding our operations internationally, we will need to establish and expand business relationships with various third parties, such as independent contractors, distributors, vendors, advocacy groups and physicians, and we will interact more frequently with foreign officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA, U.K. Bribery Act or similar laws of other countries that may govern our activities. Any interactions with any such parties or individuals where compensation is provided that are found to be in violation of such laws could result in substantial fines and penalties and could materially harm our business. Furthermore, any finding of a violation under one country s laws may increase the likelihood that we will be prosecuted and be found to have violated another country s laws. If our business practices outside the United States are found to be in violation of the FCPA, U.K. Bribery Act or other similar laws, we may be subject to significant civil and criminal penalties which could have a material adverse effect on our business, results of operations and growth prospects. We are also subject to foreign laws and regulations covering data privacy and the protection of health-related and other personal information. In this regard, European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Failure to comply with these laws could lead to government enforcement actions and significant penalties against us, which could have a material adverse effect on our business, results of operations and growth prospects.

We have a history of net losses. We expect to continue to incur net losses and may not achieve profitability for some time, if at all.

We have incurred substantial net losses in each of our years of operation. We have incurred these losses principally from costs incurred in our research and development programs and from our selling, general and administrative expenses. We expect to continue to spend substantial amounts on research and development, including amounts for conducting required post-approval and other clinical trials of, and seeking additional

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regulatory approvals for, ADCETRIS as well as commercializing ADCETRIS for the treatment of patients in its three approved indications. In addition, we expect to make substantial expenditures to further develop and potentially commercialize our product candidates. Accordingly, we expect to continue to incur net losses and may not achieve profitability for some time, if at all. Although we recognize revenue from ADCETRIS product sales and we continue to earn amounts under our collaboration agreements, our revenue and profit potential is unproven and our limited operating and commercialization history makes our future operating results difficult to predict. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

If we or our collaborators are not able to obtain or maintain required regulatory approvals, we or our collaborators will not be able to commercialize our product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaborators are permitted to market our product candidates in the United States or foreign countries until we obtain marketing approval from the FDA or other foreign regulatory authorities, and we or our collaborators may never receive regulatory approval for the commercial sale of any of our product candidates. In addition, part of our strategy is to continue to explore the use of ADCETRIS earlier in the treatment of Hodgkin lymphoma and MTCL and in other CD30-positive malignancies, including CTCL, and we are currently conducting multiple clinical trials for ADCETRIS. However, we and/or Takeda may be unable to obtain or maintain any regulatory approvals for the commercial sale of ADCETRIS for any additional indications. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured, and we have only limited experience in preparing and submitting the applications necessary to gain regulatory approvals. Further, the FDA and other foreign regulatory agencies have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate we develop, including any regulatory approvals for the potential commercial sale of ADCETRIS in additional indications or in any additional territories. In this regard, even if we believe the data collected from clinical trials of ADCETRIS and our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other foreign regulatory authority. In addition, the FDA or their advisors may disagree with our interpretations of data from pre-clinical studies and clinical trials. Moreover, even though three of our phase 3 clinical trials of ADCETRIS that we are conducting with Takeda are being conducted under SPA agreements with the FDA, this is not a guarantee or indication of approval, and we cannot be certain that the design of, or data collected from, any of our current or potential future clinical trials that are being conducted under SPAs with the FDA will be sufficient to support FDA approval. Further, a SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise, new drugs are approved in the same indication, or if we have failed to comply with the agreed upon trial protocols. In addition, a SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of a SPA agreement and the data and results from the applicable clinical trial. Regulatory agencies also may approve a product candidate for fewer indications than requested or may grant approval subject to the performance of post-approval studies or risk evaluation and mitigation strategies for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of ADCETRIS in additional indications.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols and/or related SPA agreements to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful

completion of a clinical trial. In addition, as part of the U.S. Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all regulatory submissions in a given time frame. However, the FDA does not always meet its PDUFA targeted action dates and if the FDA were to fail to meet a PDUFA targeted action date in the future for ADCETRIS, the commercialization of ADCETRIS in any additional indications could be delayed or impaired. Due to these and other factors, ADCETRIS could take a significantly longer time to gain regulatory approvals in any additional indications than we expect or may never gain additional regulatory approvals, which could delay or eliminate any potential product revenue from sales of ADCETRIS in any additional indications, which could significantly delay or prevent us from achieving profitability.

We depend on collaborative relationships with other companies to assist in the research and development of ADCETRIS and, in other situations, for the development and commercialization of product candidates utilizing or incorporating our technologies. If we are not able to locate suitable collaborators or if our collaborators do not perform as expected, this may negatively affect our ability to commercialize ADCETRIS and/or generate revenues through technology licensing, or may otherwise negatively affect our business.

We have established and intend to continue to establish collaborations with third parties to develop and market ADCETRIS and some of our current and future product candidates. For example, we entered into a collaboration agreement with Takeda in December 2009 that granted Takeda rights to develop and commercialize ADCETRIS outside of the United States and Canada. We also have ADC collaborations with AbbVie, Bayer, Celldex, Genentech, GSK, Pfizer, Progenics and Takeda, and ADC co-development agreements with Agensys, Genmab and OBT. In addition, in June 2015, we entered into a collaboration agreement with Unum to develop and commercialize novel ACTR therapies incorporating our antibodies for cancer.

Under certain conditions, our collaborators may terminate their agreements with us and discontinue use of our technologies. In addition, we cannot control the amount and timing of resources our collaborators may devote to products utilizing or incorporating our technology. Moreover, our relationships with our collaborators may divert significant time and effort of our scientific staff and management team and require effective allocation of our resources to multiple internal and collaborative projects. Our collaborators may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborators. Even if our collaborators continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Our collaborators may fail to perform their obligations under the collaboration agreements or may be slow in performing their obligations. If Takeda or any of our ADC collaborators terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, it may have a detrimental effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, reimbursement of development costs, as well as possibly requiring us to devote additional efforts and incur costs associated with pursuing internal development of product candidates. In particular, if Takeda were to terminate the ADCETRIS collaboration, we would not receive milestone payments, co-funded development payments or royalties for the sale of ADCETRIS outside the United States and Canada. As a result of such termination, we may have to engage another collaborator to complete the ADCETRIS development process and to commercialize ADCETRIS outside the United States and Canada, or to complete the development process and undertake commercializing ADCETRIS outside the United States and Canada ourselves, either of which could significantly delay the continued development and commercialization of ADCETRIS and increase our costs. In turn, this could significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing ADCETRIS, which are now being co-funded by Takeda. In addition, under our collaboration agreement with Unum, we will rely solely on Unum to conduct preclinical research and clinical development activities with respect to the initial two ACTR product candidates that combine Unum s ACTR technology with our antibodies through phase 1 with funding from us. Any failure on the part of Unum to initiate or complete these research

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and clinical development activities, or negative or inclusive results arising from such activities, could adversely affect the development of the ACTR product candidates under the collaboration, and we could otherwise fail to receive any future return on our investment in the collaboration. Furthermore, if our collaborators do not prioritize and commit substantial resources to programs associated with our product candidates or collaboration product candidates, we and/or our collaborators may be unable to commercialize these product candidates, which would limit our ability to generate revenue and become profitable. In the future, we may not be able to locate third-party collaborators to develop and market our product candidates and we may lack the capital and resources necessary to develop all our product candidates alone.

Healthcare law and policy changes, based on recently enacted legislation, may have a material adverse effect on us.

In March 2010, the PPACA became law in the United States. PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of PPACA of greatest importance to the pharmaceutical industry include increased Medicaid rebates, expanded Medicaid eligibility, extension of Public Health Service eligibility, annual fees payable by manufacturers and importers of branded prescription drugs, annual reporting of financial relationships with physicians and teaching hospitals, and a new Patient-Centered Outcomes Research Institute. Many of these provisions have had the effect of reducing the revenue generated by our sales of ADCETRIS and will have the effect of reducing any revenue generated by sales of any future commercial products we may have. In addition, we anticipate that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for any approved product, which may harm our business. For example, increased discounts, rebates or chargebacks may be mandated by governmental or private insurers or fee caps and pricing pressures enacted by industry organizations or state and federal governments, any of which could significantly affect the revenue generated by sales of our products, including ADCETRIS. Insurers may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. In addition, although ADCETRIS is approved in two indications in the European Union, Japan and other countries outside of the United States, government austerity measures or further healthcare reform measures in other countries could adversely affect demand and pricing for ADCETRIS, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda.

To date, we have depended on a small number of collaborators for a substantial portion of our revenue. The loss of any one of these collaborators could result in a material decline in our revenue.

We have collaborations with a limited number of companies. To date, a substantial portion of our revenue has resulted from payments made under agreements with our corporate collaborators, and although ADCETRIS sales currently comprise a greater proportion of our revenue, we expect that a portion of our revenue will continue to come from corporate collaborations. Even though ADCETRIS received regulatory approval in the United States, our revenues will still depend in part on Takeda s ability and willingness to market the approved product outside of the United States and Canada. The loss of our collaborators, especially Takeda, or the failure of our collaborators to perform their obligations under their agreements with us, including paying license or technology fees, milestone payments, royalties or reimbursements, could have a material adverse effect on our financial performance. Payments under our existing and future collaboration agreements are also subject to significant fluctuations in both timing and amount, which could cause our revenue to fall below the expectations of securities analysts and investors and cause a decrease in our stock price.

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We are dependent upon a small number of distributors for a significant portion of our net sales, and the loss of, or significant reduction or cancellation in sales to, any one of these distributors could adversely affect our operations and financial condition.

In the United States and Canada, we sell ADCETRIS through a limited number of pharmaceutical distributors. Customers order ADCETRIS through these distributors. We generally receive orders from distributors and ship product directly to the customer. We do not promote ADCETRIS to these distributors and they do not set or determine demand for ADCETRIS; however, our ability to effectively commercialize ADCETRIS will depend, in part, on the performance of these distributors. Although we believe we can find alternative distributors on relatively short notice, the loss of a major distributor could materially and adversely affect our results of operations and financial condition.

We currently rely on third-party manufacturers and other third parties for production of our drug products and our dependence on these manufacturers may impair the continued development and commercialization of ADCETRIS.

We do not currently have the internal ability to manufacture the drug products that we sell or need to conduct our clinical trials, and we therefore rely on corporate collaborators and contract manufacturing organizations to supply drug product for commercial supply and our IND-enabling studies and clinical trials. For the monoclonal antibody used in ADCETRIS, we have contracted with AbbVie for clinical and commercial supplies. For the drug linker used in ADCETRIS, we have contracted with Sigma Aldrich Fine Chemicals, or SAFC, for clinical and commercial supplies. We have multiple contract manufacturers for conjugating the drug linker to the antibody and producing the ADCETRIS product. For our ADC product candidates, multiple contract manufacturers, including AbbVie and SAFC, perform antibody and drug-linker manufacturing and several other contract manufacturers perform conjugation of the drug-linker to the antibody and fill/finish of the drug product. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including shipping and storage of ADCETRIS and our product candidates. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, vial and store sufficient quantities of ADCETRIS for use in our clinical trials and for commercial sale. If our contract manufacturers or other third parties fail to deliver ADCETRIS for clinical use or sale on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or otherwise discontinue development, production and sale of ADCETRIS. Moreover, contract manufacturers have a limited number of facilities in which ADCETRIS can be produced and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters or as the result of regulatory actions could result in the cancellation of shipments, loss of product in the manufacturing process, a shortfall in ADCETRIS supply, or the inability to sell our products in the U.S. or abroad. In addition, we have committed to provide Takeda with their needs of certain parts of the ADCETRIS supply chain for a limited period of time, which may require us to arrange for additional manufacturing supply. Moreover, we depend on outside vendors for the supply of raw materials used to produce ADCETRIS. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have ADCETRIS manufactured to meet commercial and clinical requirements would be adversely affected.

Any failures or setbacks in our ADC development program would negatively affect our business and financial position.

ADCETRIS and our SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME product candidates are all based on our ADC technology, which utilizes proprietary stable linkers and potent cell-killing synthetic agents. Our ADC technology is also the basis of our collaborations with AbbVie, Agensys, Bayer,

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Celldex, Genentech, GSK, Pfizer, Progenics and Takeda, and our co-development agreements with Agensys, Genmab and OBT. Although ADCETRIS has received marketing approval in the United States, Canada, the European Union, Japan and other countries, ADCETRIS is our first and only ADC product that has been approved for commercial sale in any jurisdiction. Any failures or setbacks in our ADC development program, including adverse effects resulting from the use of this technology in human clinical trials, could have a detrimental impact on the continued commercialization of ADCETRIS in its current or any potential future approved indications and on our internal product candidate pipeline, as well as our ability to maintain and/or enter into new corporate collaborations regarding our ADC technology, which would negatively affect our business and financial position.

Our current product candidates are in relatively early stages of development, and it is possible that none of these product candidates will ever become commercial products.

Our current product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all. Currently, our clinical-stage product candidates include six ADC programs, which consist of SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME, and SEA-CD40, which is based on our sugar-engineered antibody, or SEA, technology. If a product candidate fails at any stage of development or we otherwise determine to discontinue development of that product candidate, we will not have the anticipated revenues from that product candidate to fund our operations, and we may not receive any return on our investment in that product candidate. In this regard, we previously determined to discontinue the development of SGN-75 and we will not receive any return on our investment in that product candidate. Moreover, we still have only limited data from our phase 1 trials of our product candidates. As a result, we may conduct lengthy and expensive clinical trials of our product candidates only to learn that a product candidate is not an effective treatment or is not superior to existing approved therapies, or has an unacceptable safety profile, which could prevent or significantly delay regulatory approval for such product candidate. Due to the uncertain and time-consuming clinical development and regulatory approval process, we may not successfully develop any of our product candidates and it is possible that none of our current product candidates will ever become commercial products. In addition, we expect that much of our effort and many of our expenditures over the next few years will be devoted to the additional clinical development of and commercialization activities associated with ADCETRIS, which may restrict or delay our ability to develop our clinical and pre-clinical product candidates.

We may need to raise significant amounts of additional capital following this offering that may not be available to us.

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees and support our pre-clinical development, manufacturing and clinical trial activities, as well as commercialize ADCETRIS and conduct required post-approval, and other clinical studies of ADCETRIS. Although some of these expenditures related to ADCETRIS are expected to be shared with Takeda, and we expect to offset some of these costs with sales proceeds of ADCETRIS, we may need to raise significant amounts of additional capital following this offering. In addition, we may require significant additional capital in order to acquire additional technologies, products or companies. We may seek additional funding through public or private financings and we do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If adequate funds are not available to us when we need them, we will be required to delay, reduce the scope of or eliminate one or more of our development programs, which may adversely affect our business and operations. Our future capital requirements will depend upon a number of factors, including:

- the level of sales and market acceptance of ADCETRIS;

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- the rate of progress and cost of the confirmatory post-approval studies that we are required to conduct as a condition to the FDA s accelerated approval of ADCETRIS;
- the time and costs involved in obtaining regulatory approvals of ADCETRIS in additional indications, if any;
- the size, complexity, timing, progress and number of our clinical programs;
- the timing, receipt and amount of milestone-based payments or other revenue from our collaborations or license arrangements, including royalty revenue generated from commercial sales of ADCETRIS by Takeda;
- the cost of establishing and maintaining clinical and commercial supplies of ADCETRIS;
- the costs associated with acquisitions or licenses of additional technologies, products, or companies, including licenses we may need to commercialize our products;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the potential costs associated with international, state and federal taxes; and
- competing technological and market developments.

In addition, changes in our business may occur that would consume available capital resources sooner than we expect. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

We rely on license agreements for certain aspects of ADCETRIS and our ADC technology. Failure to maintain these license agreements or to secure any required new licenses could prevent us from continuing to develop and commercialize ADCETRIS and our product candidates.

We have entered into agreements with third-party commercial and academic institutions to license technology for use in ADCETRIS and our ADC technology. Currently, we have license agreements with Bristol-Myers Squibb and the University of Miami, among others. Some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon diligence requirements or milestones may allow the licensor to terminate the agreement. Many of our license agreements grant us exclusive licenses to the underlying technologies. If our licensors terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize ADCETRIS or our product candidates. Further, we may have disputes with our licensors, which may impact our ability to develop and commercialize ADCETRIS or our product candidates or require us to enter into additional licenses. For example, Arizona State University and related entities, or Arizona State, have filed patent infringement lawsuits against us in the United States and Italy and against our collaborator Takeda and our contract manufacturer for ADCETRIS in France concerning certain patents owned by Arizona State. The lawsuit against us in the United Stated has been dismissed, but the proceedings are pending in Italy and France. An adverse result in this dispute, or current or potential future disputes with our licensors, may impact our ability to develop and commercialize ADCETRIS and our product candidates, or may require us to enter into additional licenses or to incur additional costs in litigation or settlement. In addition, continued development and commercialization of ADCETRIS and our product candidates will likely require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

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If we are unable to enforce our intellectual property rights or if we fail to sustain and further build our intellectual property rights, we may not be able to commercialize ADCETRIS and competitors may be able to develop competing therapies.

Our success depends, in part, on obtaining and maintaining patent protection and successfully enforcing these patents and defending them against third-party challenges in the United States and other countries. We own multiple U.S. and foreign patents and pending patent applications for our technologies. We also have rights to issued U.S. patents, patent applications, and their foreign counterparts, relating to our monoclonal antibody, linker and drug-based technologies. Our rights to these patents and patent applications are derived in part from worldwide licenses from the University of Miami and Bristol-Myers Squibb, among others. In addition, we have licensed certain of our U.S. and foreign patents and patent applications to third parties.

The standards that the U.S. Patent and Trademark Office and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may not contain claims that will permit us to stop competitors from using similar technology. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. For example, the U.S. Supreme Court has recently modified some legal standards applied by the U.S. Patent and Trademark Office in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license. In addition, changes to the U.S. patent system have come into force under the Leahy-Smith America Invents Act, or the America Invents Act, including changes from a first-to-invent system to a first to file system, changes to examination of U.S. patent applications and changes to the processes for challenging issued patents. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, covered business method reviews and other post-grant reviews. These proceedings are conducted before the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, or USPTO. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. As a result, entities associated with hedge funds have recently begun challenging valuable pharmaceutical patents based on prior art through the IPR process. A decision in such a proceeding adverse to our interests could result in the loss of valuable patent rights which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any event, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We rely on trade secrets and other proprietary information where we believe patent protection is not appropriate or obtainable. However, trade secrets and other proprietary information are difficult to protect. We have taken measures to protect our unpatented trade secrets and know-how, including the use of confidentiality and assignment of inventions agreements with our employees, consultants and certain contractors. It is possible, however, that these persons may breach the agreements or that our competitors may independently develop or otherwise discover our trade secrets or other proprietary information. Our research collaborators may publish confidential data or other restricted information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

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We may incur substantial costs and lose important rights or may not be able to continue to commercialize ADCETRIS or to commercialize any of our product candidates that may be approved for commercial sale as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be required to obtain patent and other intellectual property rights from others.

We may face potential lawsuits by companies, academic institutions or others alleging infringement of their intellectual property. In this regard, Arizona State has filed patent infringement lawsuits against us in the United States and Italy and against our collaborator Takeda and our contract manufacturer for ADCETRIS in France concerning certain patents owned by Arizona State. The lawsuit in the United Stated has been dismissed against us, but the proceedings are pending in Italy and France. Because patent applications can take a few years to publish, there may be currently pending applications of which we are unaware that may later result in issued patents that adversely affect the continued commercialization of ADCETRIS or future commercialization of our product candidates in development. In addition, we are monitoring the progress of multiple pending patent applications of other organizations that, if granted, may require us to license or challenge their enforceability in order to continue commercializing ADCETRIS or to commercialize our product candidates that may be approved for commercial sale. As a result of the patent infringement lawsuits that have been filed or may be filed against us in the future by third parties alleging infringement by us of patent or other intellectual property rights, we may be required to pay substantial damages, including but not limited to treble damages, attorneys fees and costs, for past infringement if it is ultimately determined that our products infringe a third party s intellectual property rights. Even if infringement claims against us are without merit, the results may be unpredictable. In addition, defending lawsuits takes significant time, may be expensive and may divert management s attention from other business concerns. Further, we may be stopped from developing, manufacturing or selling our products until we obtain a license from the owner of the relevant technology or other intellectual property rights, or be forced to undertake costly design-arounds, if feasible. If such a license is available at all, it may require us to pay substantial royalties or other fees.

We are from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law, USPTO interference or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the United States and elsewhere. In addition, if we choose to go to court to stop a third party from infringing our patents, that third party has the right to ask the court to rule that these patents are invalid and/or should not be enforced. Under the America Invents Act, a third party may also have the option to challenge the validity of certain patents with the PTAB, whether they are accused of infringing our patents or not, and certain entities associated with hedge funds have recently begun challenging valuable pharmaceutical patents through the IPR process. These lawsuits and administrative proceedings are expensive and consume time and other resources, and we may not be successful in these proceedings or in stopping infringement. In addition, there is a risk that a court will decide that these patents are not valid or infringed, or that the PTAB will decide that certain patents are not valid, and that we do not have the right to stop a third party from using the patented subject matter. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary technologies without a license from us or our collaborators, which may also result in loss of future royalty payments. Furthermore, if such challenges to our rights are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing potential products, which could adversely affect our business and results of operations. In addition, we may challenge the patent or other intellectual property rights of third parties and if we are unsuccessful in actions we bring against the rights of such parties, through litigation or otherwise, and it is determined that we infringe the intellectual property rights of such parties, we may be prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those rights or develop or obtain alternative technologies, any of which could harm our business.

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If we lose our key personnel or are unable to attract and retain additional qualified personnel, our future growth and ability to compete would suffer.

We are highly dependent on the efforts and abilities of the principal members of our senior management. Additionally, we have scientific personnel with significant and unique expertise in monoclonal antibodies, ADCs and related technologies. The loss of the services of any one of the principal members of our managerial or scientific staff may prevent us from achieving our business objectives.

In addition, the competition for qualified personnel in the biotechnology field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. In order to commercialize ADCETRIS, we have been required to expand our workforce, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, sales and marketing. These activities required the addition of new personnel, including sales and marketing management, and the development of additional expertise by existing management personnel. We continue to face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, as well as academic and other research institutions. To the extent we are not able to retain these individuals on favorable terms or attract any additional personnel that may be required, our business may be harmed.

Product liability and product recalls could harm our business, and we may not be able to obtain adequate insurance to protect us against product liability losses.

The current and future use of ADCETRIS by us and our corporate collaborators in clinical trials and the sale of ADCETRIS, expose us to product liability claims. These claims might be made directly by consumers or healthcare providers or indirectly by pharmaceutical companies, our corporate collaborators or others selling such products. We may experience financial losses in the future due to product liability claims. We have obtained limited general commercial liability insurance coverage for our clinical trials. We expanded our insurance coverage to include the sale of commercial products upon approval of ADCETRIS. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against all losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Product recalls may be issued at our discretion, or at the discretion of government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of ADCETRIS could materially adversely affect our business by rendering us unable to sell ADCETRIS for some time and by adversely affecting our reputation.

Risks associated with operating in foreign countries could materially adversely affect our business.

We recently have begun to expand our operations internationally, and we currently have subsidiaries in the U.K., Switzerland and Canada. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- diverse regulatory, financial and legal requirements, and any future changes to such requirements, in one or more countries where we are located or do business;
- applicable trade laws, tariffs, export quotas, custom duties or other trade restrictions and any changes to them;
- economic weakness, including inflation, or political or economic instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

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foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;

liabilities for activities of, or related to, our international operations;

workforce uncertainty in countries where labor unrest is more common than in the United States; and

laws and regulations relating to data security and the unauthorized use of, or access to, commercial and personal information.

These and other risks described elsewhere in these risk factors associated with expanding our international operations could materially adversely affect our business.

Our operations involve hazardous materials and are subject to environmental, health and safety controls and regulations.

We are subject to environmental, health and safety laws and regulations, including those governing the use of hazardous materials, and we spend considerable time complying with such laws and regulations. Our business activities involve the controlled use of hazardous materials and although we take precautions to prevent accidental contamination or injury from these materials, we cannot completely eliminate the risk of using these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may materially harm our business, financial condition and results of operations.

If any of our facilities are damaged or our clinical, research and development or other business processes are interrupted, our business could be seriously harmed.

We conduct most of our business in a limited number of facilities in a single geographical location in Bothell, Washington. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates or interrupt the sales process for ADCETRIS. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

If we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.

We rely on information technology systems to keep financial records, maintain laboratory, patient and corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses. If we were to experience a prolonged system disruption in the information technology systems, it could result in the delay of development of our product candidates or the coordination of our sales activities, which could adversely affect our business. In addition, in order to maximize our information technology efficiency, we have physically consolidated our primary corporate data and computer operations. This concentration, however, exposes us to a greater risk of disruption to our internal information technology systems. Although we maintain offsite back-ups of our data, if operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable timeframe.