SEATTLE GENETICS INC /WA
Form 10-Q
November 06, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

OR

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

For the transition period from _____ to _____

Commission file number 0-32405

SEATTLE GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**91-1874389**
(State or other jurisdiction of	**(I.R.S. Employer**
incorporation or organization)	**Identification No.)**

21823 30th Drive SE

Bothell, Washington 98021

(Address of principal executive offices, including zip code)

(Registrant s telephone number, including area code): (425) 527-4000

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

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

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

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

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

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

As of November 1, 2017, there were 143,928,341 shares of the registrant s common stock outstanding.

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Seattle Genetics, Inc. Quarterly

Report on Form 10-Q

For the Quarter Ended September 30, 2017

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Seattle Genetics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands, except par value)

	September 30, 2017	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 128,140	$ 108,673
Short-term investments	322,258	480,313
Accounts receivable, net	90,432	61,928
Inventories	60,837	68,124
Prepaid expenses and other current assets	18,905	15,610
Total current assets	620,572	734,648
Property and equipment, net	82,769	62,870
Long-term investments	19,967	29,988
Other non-current assets	129,775	10,890
Total assets	$ 853,083	$ 838,396
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 119,978	$ 120,669
Current portion of deferred revenue	32,811	27,847
Total current liabilities	152,789	148,516
Long-term liabilities		
Deferred revenue, less current portion	37,901	53,006
Deferred rent and other long-term liabilities	2,685	2,787
Total long-term liabilities	40,586	55,793
Commitments and contingencies		
Stockholders equity		
Preferred stock, $0.001 par value, 5,000 shares authorized; none issued	0	0

Common stock, $0.001 par value, 250,000 shares authorized; 143,803 shares issued and outstanding at September 30, 2017 and 142,193 shares issued and outstanding at December 31, 2016	144	142
Additional paid-in capital	1,774,936	1,701,048
Accumulated other comprehensive income (loss)	17,997	(63)
Accumulated deficit	(1,133,369)	(1,067,040)
Total stockholders equity	659,708	634,087
Total liabilities and stockholders equity	$ 853,083	$ 838,396

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

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Seattle Genetics, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Revenues				
Net product sales	$ 79,177	$ 70,117	$ 223,841	$ 194,981
Collaboration and license agreement revenues	39,444	23,974	82,779	64,148
Royalty revenues	16,670	12,224	46,025	53,743
Total revenues	135,291	106,315	352,645	312,872
Costs and expenses				
Cost of sales	9,019	7,427	24,555	20,272
Cost of royalty revenues	5,196	3,748	13,900	10,470
Research and development	113,606	92,711	346,196	271,136
Selling, general and administrative	39,667	34,841	118,783	97,870
Total costs and expenses	167,488	138,727	503,434	399,748
Loss from operations	(32,197)	(32,412)	(150,789)	(86,876)
Investment and other income, net	82,218	660	84,460	1,903
Net income (loss)	$ 50,021	$ (31,752)	$ (66,329)	$ (84,973)
Net income (loss) per share basic	$ 0.35	$ (0.23)	$ (0.46)	$ (0.61)
Net income (loss) per share diluted	$ 0.34	$ (0.23)	$ (0.46)	$ (0.61)
Shares used in computation of net income (loss) per share basic	143,357	140,928	142,876	140,369
Shares used in computation of net income (loss) per share diluted	148,068	140,928	142,876	140,369
Comprehensive income (loss):				
Net income (loss)	$ 50,021	$ (31,752)	$ (66,329)	$ (84,973)
Other comprehensive income:				
Unrealized gain (loss) on securities available-for-sale, net of tax of $5,915, $0, 11,087, and $0, respectively	9,627	(146)	18,044	891
Foreign currency translation gain (loss)	14	(7)	16	7

Comprehensive income (loss)	$ 59,662	$ (31,905)	$ (48,269)	$ (84,075)

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

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Seattle Genetics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine months ended September 30,	
	2017	2016
Operating activities		
Net loss	$ (66,329)	$ (84,973)
Adjustments to reconcile net loss to net cash used in operating activities		
Share-based compensation	47,899	37,045
Depreciation and amortization	16,393	13,270
Amortization of premiums, accretion of discounts and loss on investments	653	4,318
Gain on Immunomedics warrant derivative	(76,699)	0
Income tax benefit on unrealized gain on available-for-sale securities	(5,415)	0
Deferred income taxes	(5,672)	0
Deferred rent and other long-term liabilities	(102)	(855)
Changes in operating assets and liabilities		
Accounts receivable, net	(28,504)	(12,191)
Inventories	7,287	(14,682)
Prepaid expenses and other assets	(2,084)	(4,219)
Accounts payable and accrued liabilities	6,208	8,367
Deferred revenue	(10,141)	(27,997)
Net cash used in operating activities	(116,506)	(81,917)
Investing activities		
Purchases of securities available-for-sale	(445,659)	(443,333)
Proceeds from maturities of securities available-for-sale	538,200	549,500
Proceeds from sales of securities available-for-sale	60,056	0
Purchases of property and equipment	(42,615)	(18,885)
Net cash provided by investing activities	109,982	87,282
Financing activities		
Proceeds from exercise of stock options and employee stock purchase plan	25,991	23,409
Net cash provided by financing activities	25,991	23,409
Net increase in cash and cash equivalents	19,467	28,774
Cash and cash equivalents at beginning of period	108,673	102,255

Cash and cash equivalents at end of period	$ 128,140	$ 131,029

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

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Seattle Genetics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements reflect the accounts of Seattle Genetics, Inc. and its wholly-owned subsidiaries (collectively Seattle Genetics or the Company). All intercompany transactions and balances have been eliminated. Management has determined that the Company operates in one segment: the development and sale of pharmaceutical products on its own behalf or in collaboration with others. Substantially all of the Company s assets and revenues are related to operations in the United States; however, the Company also has subsidiaries in Canada, Switzerland and the United Kingdom.

The condensed consolidated balance sheet data as of December 31, 2016 were derived from audited financial statements not included in this quarterly report on Form 10-Q. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and generally accepted accounting principles in the United States of America, or GAAP, for unaudited condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements reflect all adjustments consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair statement of the Company s financial position and results of its operations, as of and for the periods presented.

Unless indicated otherwise, all amounts presented in financial tables are presented in thousands, except for per share and par value amounts.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company s Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the SEC.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The results of the Company s operations for the three and nine month periods ended September 30, 2017 are not necessarily indicative of the results to be expected for the full year.

Non-cash investing activities

The Company had $1.2 million and $8.1 million of accrued capital expenditures as of September 30, 2017 and December 31, 2016, respectively. Accrued capital expenditures have been treated as a non-cash investing activity and, accordingly, have not been included in the statement of cash flows until such amounts have been paid in cash.

Investments

The Company invests cash resources primarily in debt securities. In addition, as of September 30, 2017, the Company held an equity investment in the common stock of Immunomedics, Inc., or Immunomedics, as further described in Note 7. These debt and equity securities are classified as available-for-sale, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive income (loss) in stockholders equity. Realized gains, realized losses and declines in the value of securities judged to be other-than-temporary, are included in investment and other income, net. The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Amortization of premiums and accretion of discounts on debt securities are included in investment and other income, net. Interest and dividends earned on all securities are included in investment and other income, net. The Company classifies investments in debt securities maturing within one year of the reporting date, or where management s intent is to use the investments to fund current operations or to make them available for current operations, as short-term investments. The Company classifies its equity investment in Immunomedics in other non-current assets.

If the estimated fair value of a security is below its carrying value, the Company evaluates whether it is more likely than not that it will sell the security before its anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. The Company also evaluates whether or not it intends to sell the investment. If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value. In addition, the Company considers whether credit losses exist for any securities. A credit loss exists if the present value of cash flows expected to be collected is less than the amortized cost basis of the security. Other-than-temporary declines in estimated fair value and credit losses are charged against investment and other income, net.

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Derivative financial instruments

The Company holds a warrant to purchase 8.7 million shares of Immunomedics common stock, which is accounted for as a derivative. The Company does not hold derivative instruments for trading or speculative purposes. The Company accounts for financial instruments as derivatives when the instrument includes an underlying and notional amount or payment provision, an initial net investment, and a net settlement. Derivative financial instruments are measured at fair value on the issuance date and are revalued on each subsequent balance sheet date. The Company uses the Black-Scholes model using observable market inputs to estimate the fair value of derivatives. The changes in estimated fair value are recognized as current period income or loss.

Other non-current assets

Other non-current assets included a $5.0 million non-controlling investment in a privately-held company that is accounted for under the cost method of accounting. The Company periodically evaluates the carrying value of the investment if significant adverse events or circumstances indicate an impairment in value. As of September 30, 2017, no impairment in value had been observed.

Long-term incentive plans

The Company has established Long-Term Incentive Plans, or LTIPs. The LTIPs provide eligible employees with the opportunity to receive performance-based incentives, which may be comprised of a cash payment, stock options, and/or restricted stock units. As of September 30, 2017, the estimated unrecognized compensation expense related to the LTIPs was $36.0 million. The total estimate of unrecognized compensation expense is expected to change in the future for several reasons, including the addition of more eligible employees, or the addition, termination, or modification of an LTIP.

Revenue recognition

The Company s revenues are comprised of ADCETRIS® net product sales, amounts earned under its collaboration and licensing agreements and royalties. Revenue recognition is predicated upon persuasive evidence of an agreement existing, delivery of products or services being rendered, amounts payable being fixed or determinable, and collectibility being reasonably assured.

Net product sales

The Company sells ADCETRIS through a limited number of pharmaceutical distributors in the U.S. and Canada. Customers order ADCETRIS through these distributors and the Company typically ships product directly to the customer. The Company records product sales when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. Accruals are established for these deductions and actual amounts incurred are offset against applicable accruals. The Company reflects these accruals as either a reduction in the related account receivable from the distributor, or as an accrued liability depending on the nature of the sales deduction. Sales deductions are based on management s estimates that consider payer mix in target markets and experience to date. These estimates involve a substantial degree of judgment.

Government-mandated rebates and chargebacks: The Company has entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate based on covered purchases of ADCETRIS. Medicaid rebates are invoiced to the Company by the various state

Medicaid programs. The Company estimates Medicaid rebates based on a variety of factors, including its experience to date. The Company has also completed a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. The Company has entered into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services, which enables certain entities that qualify for government pricing under the Public Health Services Act, or PHS, to receive discounts on their qualified purchases of ADCETRIS. Under these agreements, distributors process a chargeback to the Company for the difference between wholesale acquisition cost and the applicable discounted price. As a result of the Company s direct-ship distribution model, it can determine the entities purchasing ADCETRIS and this information enables the Company to estimate expected chargebacks for FSS and PHS purchases based on each entity s eligibility for the FSS and PHS programs. The Company also reviews historical rebate and chargeback information to further refine these estimates.

Distribution fees, product returns and other deductions: The Company s distributors charge a volume-based fee for distribution services that they perform for the Company. The Company allows for the return of product that is within 30 days of its expiration date or that is damaged. The Company estimates product returns based on its experience to date. In addition, the Company considers its direct-ship distribution model, its belief that product is not typically held in the distribution channel, and the expected

rapid use of the product by healthcare providers. The Company provides financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance amounts through SeaGen Secure. SeaGen Secure is available to patients in the U.S. and its territories who meet various financial and treatment need criteria. Estimated contributions for commercial coinsurance under SeaGen Secure are deducted from gross sales and are based on an analysis of expected plan utilization. These estimates are adjusted as necessary to reflect the Company s actual experience.

Collaboration and license agreement revenues

The Company has developed a proprietary technology for linking cytotoxic agents to monoclonal antibodies called antibody-drug conjugates, or ADCs. This proprietary technology is the basis of ADC collaborations that the Company has entered into in the ordinary course of its business with a number of biotechnology and pharmaceutical companies. Under these ADC collaboration agreements, the Company grants its collaborators research and commercial licenses to the Company s technology and provides technology transfer services, technical advice, supplies and services for a period of time.

If there are continuing performance obligations, the Company uses a time-based proportional performance model to recognize revenue over the Company s performance period for the related agreement. Collaboration and license agreements are evaluated to determine whether the multiple elements and associated deliverables can be considered separate units of accounting. To date, the pre-commercial deliverables under the Company s collaboration and license agreements have not qualified as separate units of accounting. The assessment of multiple element arrangements requires judgment in order to determine the appropriate point in time, or period of time, that revenue should be recognized. The Company believes that the development period in each agreement is a reasonable estimate of the performance obligation period of such agreement. Accordingly, all amounts received or due, including any upfront payments, maintenance fees, development and regulatory milestone payments and reimbursement payments, are recognized as revenue over the performance obligation periods of each agreement. These performance obligation periods typically range from one to three years. The agreements with Takeda Pharmaceutical Company Limited, or Takeda, and Genentech, Inc., a member of the Roche Group, or Genentech, have performance obligation periods of ten and seventeen years, respectively. All of the remaining performance obligation periods for active collaborations are currently expected to be completed in three years or less. When no performance obligations are required of the Company, or following the completion of the performance obligation period, such amounts are recognized as revenue when collectibility is reasonably assured. Generally, all amounts received or due other than sales-based milestones and royalties are classified as collaboration and license agreement revenues as they are earned. Sales-based milestones and royalties are recognized as royalty revenue as they are reported to the Company.

The Company s collaboration and license agreements include contractual milestones. Generally, the milestone events contained in the Company s collaboration and license agreements coincide with the progression of the collaborators product candidates from development, to regulatory approval and then to commercialization and fall into the following categories.

Development milestones in the Company s collaborations may include the following types of events:

Designation of a product candidate or initiation of preclinical studies. The Company s collaborators must undertake significant preclinical research and studies to make a determination of the suitability of a product candidate and the time from those studies or designation to initiation of a clinical trial may take several years.

Initiation of a phase 1 clinical trial. Generally, phase 1 clinical trials may take one to two years to complete.

Initiation of a phase 2 clinical trial. Generally, phase 2 clinical trials may take one to three years to complete.

Initiation of a phase 3 clinical trial. Generally, phase 3 clinical trials may take two to six years to complete.

Regulatory milestones in the Company s collaborations may include the following types of events:

Filing of regulatory applications for marketing approval such as a Biologics License Application in the United States or a Marketing Authorization Application in Europe. Generally, it may take up to twelve months to prepare and submit regulatory filings.

Receiving marketing approval in a major market, such as in the United States, Europe, Japan or other significant countries. Generally, it may take up to three years after a marketing application is submitted to obtain approval for marketing and pricing from the applicable regulatory agency.

Commercialization milestones in the Company s collaborations may include the following types of events:

First commercial sale in a particular market, such as in the United States, Europe, Japan or other significant countries.

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Product sales in excess of a pre-specified threshold. The amount of time to achieve this type of milestone depends on several factors, including, but not limited to, the dollar amount of the threshold, the pricing of the product, market penetration of the product and the rate at which customers begin using the product.

The Company s ADC collaborators are solely responsible for the development of their product candidates and the achievement of milestones in any of the categories identified above is based solely on the collaborators efforts.

In the case of the Company s ADCETRIS collaboration with Takeda, the Company may be involved in certain development activities; however, the achievement of milestone events under the agreement is primarily based on activities undertaken by Takeda.

The process of successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing a product candidate is highly uncertain and the attainment of any milestones is therefore uncertain and difficult to predict. In addition, since the Company does not take a substantive role or control the research, development or commercialization of any products generated by its ADC collaborators, the Company is not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable to the Company by its ADC collaborators. As such, the milestone payments associated with its ADC collaborations involve a substantial degree of uncertainty and risk that they may never be received. Similarly, even in those collaborations where the Company may have an active role in the development of the product candidate, such as the Company s ADCETRIS collaboration with Takeda, the attainment of a milestone is based on the collaborator s activities and is generally outside the direction and control of the Company.

The Company generally invoices its collaborators and licensees on a monthly or quarterly basis, or upon the completion of the effort or achievement of a milestone, based on the terms of each agreement. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods when the applicable revenue recognition criteria have been met. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

Royalty revenues and cost of royalty revenues

Royalty revenues primarily reflect amounts earned under the ADCETRIS collaboration with Takeda. These royalties include sales royalties, which are based on a percentage of Takeda s net sales at rates that range from the mid-teens to the mid-twenties based on sales volume, and commercial sales-based milestones. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenue in the Company s consolidated financial statements. Cost of royalty revenues reflects amounts owed to the Company s third-party licensors related to Takeda s sales of ADCETRIS. These amounts are recognized in the quarter in which Takeda reports its sales activity to the Company, which is the quarter following the related sales. Royalty revenues also include amounts earned in connection with the Company s ADC collaborations.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued an Accounting Standards Update entitled ASU 2014-09, Revenue from Contracts with Customers. The standard requires entities to recognize revenue through an evaluation that includes identification of the contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. In August 2015, FASB issued an Accounting Standards Update entitled ASU 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date , which defers the effective date of ASU 2014-09 to the Company s fiscal year beginning January 1, 2018. The FASB has continued to issue accounting standards updates to clarify and provide implementation guidance related to Revenue from Contracts

with Customers, including ASU 2016-08, Revenue from Contract with Customers: Principal versus Agent Considerations , ASU 2016-10, Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing , ASU 2016-12, Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients and ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers. The Company s preliminary assessment of this new standard is that it will generally not change the way in which the Company recognizes product revenue from sales of ADCETRIS. However, the Company expects that sales-based royalties and commercial sales-based milestones will be recorded in the period of the related sale based on estimates, rather than recording them as reported by the customer. In addition, the Company expects that the achievement of development milestones under the Company s collaborations will be recorded in the period their achievement becomes probable, which may result in their recognition earlier than under current accounting principles. The new standard also requires more extensive disclosures related to revenue recognition, particularly in quarterly financial statements. The Company will adopt the standard on January 1, 2018 and intends to use the modified retrospective method of adoption. The Company is continuing to evaluate the impact of the standard on all of its revenues, including those mentioned above, and its assessments may change in the future based on its ongoing evaluation.

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In January 2016, FASB issued an Accounting Standards Update entitled ASU 2016-01, Financial Instruments: Overall. The standard addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The Company will adopt the standard on January 1, 2018 using a modified retrospective approach. The standard will require that the Company record changes in the fair value of equity securities in net income or loss. The implementation of this standard is expected to increase the volatility of net income or loss to the extent that the Company continues to hold equity securities.

In February 2016, FASB issued an Accounting Standards Update entitled ASU 2016-02, Leases. The standard requires entities to recognize in the consolidated balance sheet a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. The standard will become effective for the Company beginning January 1, 2019, with early adoption permitted. The Company is currently evaluating the guidance to determine the potential impact on its financial condition, results of operations and cash flows, and financial statement disclosures, and expects that the adoption of the standard will increase assets and liabilities related to the Company s operating leases in the consolidated balance sheets.

In March 2016, FASB issued an Accounting Standard Update entitled ASU 2016-09, Compensation Stock Compensation. The standard is intended to simplify certain elements of accounting for share-based payment transactions, including the income tax impact, classification of awards as either equity or liabilities, and classification on the statement of cash flows. In addition, the standard allows an entity-wide accounting policy election to either estimate the number of awards that are expected to vest, as currently required, or account for forfeitures when they occur. The Company has elected to continue estimating the number of awards that are expected to vest. The Company adopted the standard as of January 1, 2017. Since the Company has incurred annual net losses since its inception and maintains a full valuation allowance on its net deferred tax assets, the adoption did not have a material impact on the Company s financial condition, results of operations and cash flows.

In October 2016, FASB issued an Accounting Standard Update entitled ASU 2016-16, Accounting for Income Taxes: Intra-Entity Asset Transfers of Assets Other than Inventory. The standard is intended to simplify the accounting for intercompany sales of assets other than inventory. Under current GAAP, the tax effects of intra-entity asset transfers are deferred until the transferred asset is sold to a third party or otherwise recovered through use. Under the new guidance, a reporting entity would recognize the tax expense from the sale of the asset in the seller s jurisdiction when the transfer occurs, even though the pre-tax effects of that transaction are eliminated in consolidation. Any deferred tax asset that arises in the buyer s jurisdiction would also be recognized at the time of the transfer. The standard will become effective for the Company beginning on January 1, 2018. The Company is currently evaluating the new standard; however, since the Company has incurred annual net losses since its inception and maintains a full valuation allowance on its net deferred tax assets, the adoption is not expected to have a material impact on the Company s financial condition, results of operations and cash flows, or financial statement disclosures.

In June 2016, FASB issued an Accounting Standard Update entitled ASU 2016-13, Financial Instruments: Credit Losses. The objective of the standard is to provide information about expected credit losses on financial instruments at each reporting date, and to change how other than temporary impairments on investments securities are recorded. The standard will become effective for the Company beginning on January 1, 2020 with early adoption permitted. The Company is currently evaluating the guidance to determine the potential impact on its financial condition, results of operations and cash flows, and financial statement disclosures.

In January 2017, FASB issued an Accounting Standard Update entitled, ASU 2017-01, Business Combinations: Clarifying the Definition of a Business. The objective of the standard is to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions of assets or businesses. The Company adopted this standard on a prospective basis as of January 1, 2017.

The adoption of this standard did not have a material impact on the Company s financial condition, results of operations and cash flows, or financial statement disclosures.

In May 2017, FASB issued an Accounting Standard Update entitled, ASU 2017-09, Compensation Stock Compensation (Topic 718): Scope of Modification Accounting. The objective of the standard is to provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The standard is applied prospectively to awards modified on or after the adoption date. The Company early adopted this standard on April 1, 2017. The adoption did not have a material impact on the Company s financial condition, results of operations and cash flows.

2. Net income (loss) per share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of our common stock outstanding and other dilutive securities outstanding during the period. The potential dilutive shares resulting from the assumed exercise of outstanding stock options and the assumed vesting of restricted stock units were determined using the treasury stock method. The Company excluded certain restricted stock units and options to purchase common stock from the calculation of diluted net income per share that would have resulted in an anti-dilutive effect for the three months ended

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September 30, 2017. The Company excluded all restricted stock units and options to purchase common stock from the calculation of basic and diluted net loss per share as such securities were anti-dilutive for the three months ended September 30, 2016, and for the nine months ended September 30, 2017, and 2016. The weighted-average number of restricted stock units and options to purchase common stock that have been excluded from the number of shares used to calculate diluted net income (loss) per share totaled 3,460,000 and 13,272,000 for the three months ended September 30, 2017 and 2016, respectively, and 13,367,000 and 12,714,000 for the nine months ended September 30, 2017 and 2016, respectively.

The following table summarizes the computation of basic and diluted net income (loss) per share ($ in thousands, other than per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Net income (loss) basic and diluted	$ 50,021	$ (31,752)	$ (66,329)	$ (84,973)
Weighted average shares outstanding basic	143,357	140,928	142,876	140,369
Effect of dilutive securities:				
Dilutive effect of common shares from stock options	3,575	0	0	0
Dilutive effect of common shares from restricted stock units	1,136	0	0	0
Weighted average shares outstanding diluted	148,068	140,928	142,876	140,369
Basic net income (loss) per share	$ 0.35	$ (0.23)	$ (0.46)	$ (0.61)
Diluted net income (loss) per share	$ 0.34	$ (0.23)	$ (0.46)	$ (0.61)

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3. Investments

Investments consisted of available-for-sale securities as follows (in thousands):

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
September 30, 2017				
U.S. Treasury securities	$ 342,412	$ 1	$ (188)	$ 342,225
Common stock investment in Immunomedics	12,677	29,263	0	41,940
Total	$ 355,089	$ 29,264	$ (188)	$ 384,165
Contractual Maturities (at date of purchase)				
Due in one year or less	$ 201,836			$ 201,782
Due in one to two years	140,576			140,443
Total	$ 342,412			$ 342,225

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
December 31, 2016				
U.S. Treasury securities	$ 510,356	$ 68	$ (123)	$ 510,301
Contractual Maturities (at date of purchase)				
Due in one year or less	$ 229,856			$ 229,864
Due in one to two years	280,500			280,437
Total	$ 510,356			$ 510,301

Investments classified as available-for-sale securities are presented in the accompanying consolidated balance sheets as follows (in thousands):

	September 30, 2017	December 31, 2016
Short-term investments	$ 322,258	$ 480,313
Long-term investments	19,967	29,988
Other non-current assets Common stock investment in Immunomedics	41,940	0
Total	$ 384,165	$ 510,301

The aggregate estimated fair value of the Company s investments with unrealized losses was as follows (in thousands):

	Period of continuous unrealized loss			
	12 Months or less		Greater than 12 months	
	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses
September 30, 2017				
U.S. Treasury securities	$ 282,236	$ (174)	$ 19,993	$ (14)
December 31, 2016				
U.S. Treasury securities	$ 200,327	$ (123)	$ NA	$ NA

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4. Fair value

The Company holds short-term and long-term available-for-sale securities, and the Immunomedics common stock warrant that are measured at fair value, which is determined on a recurring basis according to a fair value hierarchy that prioritizes the inputs and assumptions used, and the valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described as follows:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.

Level 3: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The determination of a financial instrument s level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. The Company considers observable data to be market data which is readily available, regularly distributed or updated, reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

Level 1 investments are valued based on quoted market prices in active markets. The Company estimates the fair value of Level 2 instruments utilizing the Black-Scholes valuation model, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. The Company did not hold any Level 3 investments as of September 30, 2017 or December 31, 2016 and did not transfer any investments between Levels 1, 2 and 3 during the nine months ended September 30, 2017.

The following table presents the Company s debt and equity securities by level within the fair value hierarchy for the periods presented (in thousands):

	Fair value measurement using:			
	Quoted prices in active markets for identical assets (Level 1)	**Other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**	**Total**
As of September 30, 2017				
Short-term investments U.S. Treasury securities	$ 322,258	$ 0	$ 0	$ 322,258
	19,967	0	0	19,967

Long-term investments U.S. Treasury securities				
Other non-current assets Common stock warrant in Immunomedics	0	78,714	0	78,714
Other non-current assets Common stock investment in Immunomedics	41,940	0	0	41,940
Total	$ 384,165	$ 78,714	$ 0	$ 462,879

	Fair value measurement using:			
	Quoted prices in active markets for identical assets (Level 1)	**Other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**	**Total**
As of December 31, 2016				
Short-term investments U.S. Treasury securities	$ 480,313	$ 0	$ 0	$ 480,313
Long-term investments U.S. Treasury securities	29,988	0	0	29,988
Total	$ 510,301	$ 0	$ 0	$ 510,301

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5. Inventories

The following table presents the Company s inventories of ADCETRIS (in thousands):

	September 30, 2017	December 31, 2016
Raw materials	$ 51,656	$ 62,516
Work in process	0	8
Finished goods	9,181	5,600
Total	$ 60,837	$ 68,124

The Company capitalizes ADCETRIS inventory costs. ADCETRIS inventory that is deployed into clinical, research or development use is charged to research and development expense when it is no longer available for use in commercial sales. The Company does not capitalize manufacturing costs for any of its product candidates.

6. Income taxes

The Company has recorded income tax benefits in investment and other income, net, of $2.7 million and $5.4 million for the three and nine months ended September 30, 2017, respectively, in connection with unrealized gains on available-for-sale securities. The Company has not recorded a provision for income tax expense for the quarter ended September 30, 2017 as the Company expects to report a net loss for the full year ending December 31, 2017, and continues to maintain a full valuation allowance on the net deferred tax assets.

7. Immunomedics stock purchase agreement

In February 2017, the Company paid Immunomedics $14.7 million for 3.0 million shares of Immunomedics common stock and a warrant to purchase an additional 8.7 million shares of Immunomedics common stock at an exercise price of $4.90 per share, pursuant to a stock purchase agreement. The consideration was allocated between the common stock and the warrant based on the relative fair values as of the purchase date, or $12.7 million and $2.0 million, respectively. The shares of common stock were classified as available-for-sale securities and carried at estimated fair value with unrealized gains and losses included in accumulated other comprehensive income (loss) in stockholders equity. The common stock investment was included in other non-current assets as of September 30, 2017.

Based on management s assessment, the $2.0 million value allocated to the warrant was determined to be substantially impaired as of March 31, 2017, and therefore was charged to investment and other income, net, for the nine months ended September 30, 2017. In September 2017, Immunomedics registered the resale of the shares of Immunomedics common stock underlying the warrant under the Securities Act of 1933, as amended, and as a result, the warrant met the definition of a derivative under ASC 815 as of September 30, 2017. Consequently, the Company recorded a gain of $78.7 million and $76.7 million in investment and other income, net, resulting from the change in the fair value of the warrant derivative for the three and nine months ended September 30, 2017, respectively. The warrant was recorded at its fair value of $78.7 million in other non-current assets as of September 30, 2017, and is exercisable by the Company until December 31, 2017.

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8. Legal matters

On January 10, 2017, the Company became a named defendant in a securities class action complaint filed in the United States District Court for the Western District of Washington, or the Court, seeking compensatory damages of an undisclosed amount. On October 18, 2017, the Court granted the Company s motion to dismiss with leave for plaintiff to file a second consolidated amended complaint.

On March 29, 2017, a stockholder derivative lawsuit was filed in Washington Superior Court for the County of Snohomish, or the Snohomish County Superior Court, naming as defendants certain of the Company s current and former executive officers and members of its board of directors. The Company is named as a nominal defendant. On October 18, 2017, in light of the granting of the Company s motion to dismiss in the securities class action complaint, the parties in the stockholder derivative lawsuit filed a joint status report with the Snohomish County Superior Court stipulating to continue to stay the derivative lawsuit pending further developments in the securities class action.

The Company does not believe it is feasible to predict or determine the ultimate outcome or resolution of these proceedings, or to estimate the amount of, or potential range of, loss with respect to these proceedings. In addition, the timing of the final resolution of these proceedings is uncertain. As a result of these lawsuits, the Company will incur litigation expenses and may incur indemnification expenses, and potential resolutions of the lawsuits could include settlements requiring payments. Those expenses could have a material impact on the Company s financial position, results of operations, and cash flows.

On February 13, 2017, the Company was named a co-defendant in a lawsuit filed by venBio Select Advisors LLC, or venBio, in the Delaware Chancery Court against the members of the board of directors of Immunomedics. On May 4, 2017, the Company and Immunomedics agreed to terminate the license agreement between the parties and to amend the term of the Immunomedics common stock warrant to be exercisable by the Company only until December 31, 2017, and in connection therewith, Immunomedics and venBio agreed to fully settle, resolve and release the Company, and the Company agreed to fully settle, resolve and release Immunomedics and venBio, from all disputes, claims and liabilities arising from the license agreement and the transactions contemplated thereby, subject to the terms of the related termination agreement and settlement agreement. The termination agreement between Immunomedics and the Company and the settlement of the venBio lawsuit were effective August 25, 2017.

9. Subsequent event

Closing of Manufacturing Facility Acquisition

On July 30 and July 31, 2017, the Company entered into certain agreements to acquire a biologics manufacturing facility located in Bothell, Washington. As part of the transaction, the Company and Bristol Myers Squibb Company, or BMS, through BMS or its wholly-owned subsidiary, entered into an assignment and assumption agreement, or the Assignment Agreement, an asset purchase agreement, or the Asset Purchase Agreement, and agreed to enter into certain ancillary transitional service agreements effective upon the closing of the transactions contemplated by the Asset Purchase Agreement.

Under the Assignment Agreement, on July 30, 2017, BMS assigned to the Company all of its rights and obligations under a purchase agreement, or the Purchase Agreement, pursuant to which BMS agreed to purchase the manufacturing facility site location, which includes the underlying real estate and the manufacturing building, from BMR-3450 Monte Villa Parkway LLC, or BMR. The purchase price was $17.8 million, which the Company recorded in property and equipment, net as of September 30, 2017. Under the terms of the Purchase Agreement, the Company assumed BMR s obligations under a lease between BMS and BMR, or the Lease, under which BMS occupied the

manufacturing facility site location until October 1, 2017. The Lease terminated upon the closing of the transactions contemplated by the Asset Purchase Agreement on October 1, 2017.

On October 1, 2017, the Company completed the acquisition of certain equipment and improvements from BMS in exchange for a payment of approximately $25.5 million. In addition, the Company hired the employees who were employed by BMS at the manufacturing facility site location. The acquisition of the manufacturing facility and the related assets and liabilities will be accounted for as a business combination using the acquisition method. The purchase price will be allocated to the assets acquired and liabilities assumed, and the Company expects to include a preliminary determination in its consolidated financial statements for the year ending December 31, 2017.

The Company also entered into a clinical manufacturing services agreement on October 1, 2017, under which the Company agreed to manufacture certain BMS clinical product candidates in accordance with prescribed production schedules and quantities through the later of December 31, 2018 or when certain technical transfer activities have been completed, and to maintain personnel, equipment and expertise sufficient to perform the agreed upon services. BMS will compensate the Company for services rendered under the clinical manufacturing services agreement, based on an agreed upon rate for use of the facility and employees.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

The following discussion of our financial condition and results of operations contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as may, might, will, should, expect, plan, anticipate, project, believe, estimate, predict, potential, intend or continue, the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Quarterly Report on Form 10-Q are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements except as required by law. Any or all of our forward-looking statements in this document may turn out to be incorrect. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q in greater detail under the heading Item 1A Risk Factors. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

Seattle Genetics is a biotechnology company focused on the development and commercialization of targeted therapies for the treatment of cancer. Our antibody-drug conjugate, or ADC, technology utilizes the targeting ability of antibodies to deliver cell-killing agents directly to cancer cells. We are commercializing ADCETRIS®, or brentuximab vedotin, for the treatment of several types of CD30-expressing lymphomas. We are also advancing a pipeline of novel therapies for solid tumors and blood-related cancers designed to address unmet medical needs and improve treatment outcomes for patients.

ADCETRIS® (brentuximab vedotin)

Our marketed product ADCETRIS® is approved by the United States Food and Drug Administration, or FDA, and the European Commission for three indications encompassing several settings for the treatment of relapsed Hodgkin lymphoma and relapsed systemic anaplastic large cell lymphoma, or sALCL. ADCETRIS is commercially available in 68 countries around the world, including in the United States, Canada, members of the European Union and Japan. 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.

Beyond our current labeled indications, we have a broad development strategy for ADCETRIS evaluating its therapeutic potential in earlier lines of therapy for patients with Hodgkin lymphoma, mature T-cell lymphoma, or MTCL, also known as peripheral T-cell lymphoma, or PTCL, including sALCL, as well as in combination with checkpoint inhibitors. We and our partners are currently conducting four phase 3 clinical trials of ADCETRIS as described below:

ALCANZA: In 2016, we and Takeda reported that the ALCANZA phase 3 trial met its primary endpoint. We submitted a supplemental Biologics License Application, or sBLA, to the FDA in June 2017 to seek approval for a new indication in cutaneous T-cell lymphoma, or CTCL, for patients who require systemic therapy, based in part on data from the ALCANZA trial. The FDA granted Breakthrough Therapy Designation, or BTD, in November 2016 to ADCETRIS for the treatment of patients with CD30-expressing mycosis fungoides (MF) and primary cutaneous anaplastic large cell lymphoma (pcALCL) who require systemic therapy and have received one prior systemic therapy. In August 2017, the FDA granted Priority Review for the sBLA, and the Prescription Drug User Fee Act, or PDUFA, target action date is December 16, 2017.

ECHELON-1: In June 2017, we and Takeda announced positive top line data from the ECHELON-1 trial, a randomized, open-label, phase 3 trial investigating ADCETRIS plus AVD (adriamycin, vinblastine, dacarbazine) versus ABVD (adriamycin, bleomycin, vinblastine, dacarbazine) as frontline combination therapy in patients with previously untreated advanced classical Hodgkin lymphoma. The ECHELON-1 trial met its primary endpoint, demonstrating that treatment with ADCETRIS plus AVD resulted in a statistically significant improvement in modified progression-free survival, or PFS, versus the control arm as assessed by an independent review facility (hazard ratio=0.770; p-value=0.035). The two-year modified PFS rate for patients in the ADCETRIS plus AVD arm was 82.1 percent compared to 77.2 percent in the control arm. Interim analysis of overall survival, the key secondary endpoint, also trended in favor of the ADCETRIS plus AVD arm. The safety profile of ADCETRIS plus AVD in the ECHELON-1 trial was consistent with that known for the single-agent components of the regimen. There was an increased incidence of febrile neutropenia and peripheral

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neuropathy in the ADCETRIS plus AVD arm. Febrile neutropenia was reduced through the use of prophylactic growth factors in a subset of patients, and peripheral neuropathy was managed through dose modifications. The control arm had an increased rate and severity of pulmonary toxicity as compared to the ADCETRIS plus AVD arm. In September 2017, the FDA granted BTD to ADCETRIS in combination with chemotherapy for the frontline treatment of patients with advanced classical Hodgkin lymphoma. In November 2017, we submitted an sBLA to the FDA seeking approval of ADCETRIS as part of a frontline combination chemotherapy regimen in patients with previously untreated advanced classical Hodgkin lymphoma.

ECHELON-2: In November 2016, we and Takeda completed enrollment of 452 patients in our ECHELON-2 trial for frontline MTCL. The primary endpoint of the trial is PFS per independent review facility assessment. Based on reviews of pooled, blinded data, we have observed a lower rate of reported PFS events than anticipated. We plan to discuss with the FDA the potential to unblind the trial prior to achieving the target number of PFS events specified in our Special Protocol Assessment, or SPA, agreement. Based on the length of follow-up and the slow rate at which PFS events are occurring, we believe the primary endpoint data will be mature in 2018, and continue to expect to report top-line data next year.

CHECKMATE 812: We and Bristol-Myers Squibb Company, or BMS, are conducting a pivotal phase 3 clinical trial, or the CHECKMATE 812 trial, to evaluate the combination of BMS s immunotherapy Opdivo (nivolumab) with ADCETRIS for the treatment of relapsed/refractory or transplant-ineligible advanced classical Hodgkin lymphoma.

The ALCANZA, ECHELON-1 and ECHELON-2 trials are each being conducted under SPA agreements with the FDA and pursuant to scientific advice from the European Medicines Agency, or EMA. A SPA agreement 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 new drug application or a BLA submission to the FDA if the trial achieves its primary endpoint.

Clinical-stage product candidates

In collaboration with Astellas Pharma, Inc., or Astellas, we are developing enfortumab vedotin, formerly known as ASG-22ME. We and Astellas are conducting a pivotal phase 2 clinical trial for locally advanced or metastatic urothelial cancer patients who have been previously treated with checkpoint inhibitor, or CPI, therapy. We and Astellas also plan to initiate a phase 1b trial of enfortumab vedotin in combination with CPI therapy to begin late in 2017 for patients with metastatic urothelial cancer.

In collaboration with Genmab A/S, or Genmab, we are developing tisotumab vedotin, an ADC that targets tissue factor. We and Genmab plan to start a pivotal phase 2 clinical trial in patients with recurrent and/or metastatic cervical cancer.

Our clinical-stage pipeline also includes five other ADC programs consisting of SGN-LIV1A, SGN-CD19A, or denintuzumab mafodotin, SGN-CD19B, SGN-CD123A, and SGN-CD352A, as well as two immuno-oncology agents, SEA-CD40, which is based on our sugar-engineered antibody, or SEA, technology, and SGN-2FF, which is a novel small molecule. In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies, including SGN-CD48A.

In June 2017, we announced that we were discontinuing the phase 3 CASCADE clinical trial of SGN-CD33A in frontline older acute myeloid leukemia, or AML, patients, and suspending patient enrollment and treatment in all other

SGN-CD33A trials. We took this action following consultation with the Independent Data Monitoring Committee, or IDMC, and after reviewing unblinded data from the CASCADE trial which indicated a higher rate of deaths, including fatal infections, in the SGN-CD33A-containing arm versus the control arm of the trial. In addition, the Investigational New Drug application, or IND, for SGN-CD33A has been placed on hold, and no clinical trials may resume under the IND until the FDA lifts the clinical hold. We are continuing to review data for the SGN-CD33A program; however, at this time, we have no plans to initiate additional clinical trials of SGN-CD33A.

We have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd., or AbbVie; Bayer Pharma AG, or Bayer; Celldex Therapeutics, Inc., or Celldex; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; Pfizer, Inc., or Pfizer; and PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics. In addition, we have a collaboration 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.

Our ongoing research, development, manufacturing and commercial activities will require substantial amounts of capital and may not ultimately be successful. Over the next several years, we expect that we will incur substantial expenses, primarily as a result of activities related to the commercialization of ADCETRIS, and the continued development of ADCETRIS, enfortumab vedotin, and tisotumab vedotin. Our other product candidates are in relatively early stages of development. Enfortumab vedotin, tisotumab vedotin and our other product candidates will require significant further development, financial resources and personnel to pursue and obtain regulatory approval and develop into commercially viable products, if at all. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS, the research, continued development and manufacturing of our product candidates and expansion of our pipeline will likely require us to raise substantial amounts of additional capital and our operating expenses may fluctuate as a result of such activities. In addition, we may incur significant milestone payment obligations to certain of our licensors as our product candidates progress through clinical trials towards potential commercialization.

We recognize revenue from ADCETRIS product sales in the United States and Canada. Our future ADCETRIS product sales are difficult to accurately predict from period to period. In this regard, our product sales have varied, and may continue to vary, significantly from period to period and may be affected by a variety of factors. Such factors include the incidence rate of new patients in ADCETRIS approved indications, customer ordering patterns, the overall level of demand for ADCETRIS, the duration of therapy for patients receiving ADCETRIS, and the extent to which coverage and reimbursement for ADCETRIS is available from government and other third-party payers. Obtaining and maintaining appropriate coverage and reimbursement for ADCETRIS is increasingly challenging due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide, as well as increasing legislative and enforcement interest in the United States with respect to pharmaceutical drug pricing practices. We anticipate that 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 ADCETRIS. We also anticipate that Congress, state legislatures, and third-party payors may continue to review and assess alternative healthcare delivery and payment systems and may in the future propose and adopt legislation or policy changes or implementations effecting additional fundamental changes in the healthcare delivery system, any of which could negatively affect our revenue or sales of ADCETRIS (or any future approved products). In addition, the competition ADCETRIS faces from competing therapies is intensifying, and we anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other cancer therapies continue to accelerate. We also believe that the level of our current ADCETRIS sales in the United States has been attributable to the incidence flow of patients eligible for treatment with ADCETRIS, which can vary significantly from period to period. Moreover, we believe that the incidence rate in ADCETRIS approved indications is relatively low, particularly when compared to many other oncology indications. 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, particularly with respect to the frontline Hodgkin lymphoma and frontline MTCL indications. Our efforts to continue to expand ADCETRIS labeled indications of use will continue to require additional time and investment in clinical trials to complete and may not be successful. Our ability to successfully commercialize ADCETRIS and to continue to expand its labeled indications of use are subject to a number of risks and uncertainties, including those discussed in Part II, Item 1A of this Quarterly Report on Form 10-Q. In particular, although we reported positive top line data in both our ALCANZA and ECHELON-1 trials in August 2016 and June 2017, respectively, there can be no assurance that either we or Takeda will ultimately obtain regulatory approvals of ADCETRIS in either of the ALCANZA or ECHELON-1 treatment settings in our respective territories, which would limit our sales of, and the commercial potential of, ADCETRIS. In addition, negative or inconclusive results in our ECHELON-2 trial would negatively impact, or preclude altogether, our and Takeda s ability to obtain regulatory approvals in the frontline MTCL indication in our respective territories, which could also limit our sales of, and the commercial potential of, ADCETRIS. We also expect that amounts earned from our collaboration agreements, including royalties, will continue to be an important source of our revenues and cash flows. These revenues will be impacted by future development funding and the achievement of development, clinical and commercial success by our collaborators under our existing collaboration and license agreements, including our ADCETRIS collaboration with Takeda, as well as by entering into potential new collaboration and license agreements. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and should not be relied upon as being indicative of our future performance.

Financial summary

For the nine months ended September 30, 2017, total revenues increased to $352.6 million, compared to $312.9 million for the same period in 2016. This increase was driven primarily by higher ADCETRIS net product sales, offset in part by a decline in royalty revenues, which included a one-time $20.0 million milestone payment in the first quarter of 2016. Net product sales of ADCETRIS were $223.8 million for the nine months ended

September 30, 2017, compared to $195.0 million for the same period in 2016. For the nine months ended September 30, 2017, total costs and expenses increased to $503.4 million, compared to $399.7 million for the same period in 2016. This primarily reflected increased investment in enfortumab vedotin and increased drug product supply activities to Takeda, as well as investment in our growing pipeline of pre-clinical and clinical-stage programs. As of September 30, 2017, we had $470.4 million in cash, cash equivalents and short- and long-term investments, and $659.7 million in total stockholders equity. Net income (loss) for the three and nine month periods ended September 30, 2017 included a gain of $78.7 million and $76.7 million in investment and other income, net, resulting from the change in the fair value of the Immunomedics warrant derivative for the three and nine months ended September 30, 2017, respectively. Losses from operations were $32.2 million and $150.8 million for the three and nine months ended September 30, 2017, respectively, and we otherwise expect to continue to incur net losses in future periods.

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Results of operations

Three and nine months ended September 30, 2017 and 2016

Net product sales

We sell ADCETRIS in the U.S. and Canada. Our net product sales were as follows ($ in thousands):

	Three months ended September 30,			Nine months ended September 30,		
	2017	2016	% Change	2017	2016	% Change
Net product sales	$ 79,177	$ 70,117	13%	$ 223,841	$ 194,981	15%

The increase in net product sales for the three and nine months ended September 30, 2017 over the comparable periods in 2016 primarily resulted from an increase in sales volume, and to a lesser extent, from the effect of price increases instituted since the 2016 period. The increase in sales volume was primarily driven by increased use of ADCETRIS across multiple lines of therapy in Hodgkin lymphoma and for the treatment of other CD30-expressing malignancies.

We expect continued growth in ADCETRIS sales in 2017 as compared to 2016. Our ability to accelerate the rate of ADCETRIS sales growth in future periods, if at all, will be primarily dependent on our ability to continue to expand ADCETRIS labeled indications of use. Our efforts to expand ADCETRIS labeled indications of use will continue to require additional time and investment in clinical trials to complete and may not be successful.

We sell ADCETRIS through a limited number of pharmaceutical distributors. Customers order ADCETRIS through these distributors and we typically ship product directly to the customer. We record product sales when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. These are generally referred to as gross-to-net deductions. Accruals are established for these deductions and actual amounts incurred are offset against applicable accruals. We reflect these accruals as either a reduction in the related account receivable from the distributor, or as an accrued liability depending on the nature of the sales deduction. Sales deductions are based on our estimates that consider payer mix in target markets and our experience to date. These estimates involve a substantial degree of judgment.

Government-mandated rebates and chargebacks: We have entered into a Medicaid Drug Rebate Agreement with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate to participating states based on covered purchases of ADCETRIS. Medicaid rebates are invoiced to us by the various state Medicaid programs. We estimate Medicaid rebates based on a variety of factors, including our experience to date. We also have completed our Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. We have entered into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services which enables certain entities that qualify for government pricing under the Public Health Services Act, or PHS, to receive discounts on their qualified purchases of ADCETRIS. Under these agreements, distributors process a chargeback to us for the difference between wholesale acquisition cost and the applicable discounted price. As a result of our direct-ship distribution model, we can identify the entities purchasing ADCETRIS and this information enables us to estimate expected chargebacks for FSS and PHS purchases based on each entity s eligibility for the FSS and PHS programs. We also review actual rebate and chargeback information to further refine

these estimates.

Distribution fees, product returns and other deductions: Our distributors charge a volume-based fee for distribution services that they perform for us. We allow for the return of product that is within 30 days of its expiration date or that is damaged. We estimate product returns based on our experience to date. In addition, we consider our direct-ship distribution model, our belief that product is not typically held in the distribution channel, and the expected rapid use of the product by healthcare providers. We provide financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance amounts through SeaGen Secure. SeaGen Secure is available to patients in the U.S. and its territories who meet various financial and treatment need criteria. Estimated contributions for commercial coinsurance under SeaGen Secure are deducted from gross sales and are based on an analysis of expected plan utilization. These estimates are adjusted as necessary to reflect our actual experience.

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Gross-to-net deduction accruals, net of related payments and credits, are summarized as follows (in thousands):

	Rebates and chargebacks	Distribution fees, product returns and other	Total
Balance as of December 31, 2016	$ 9,500	$ 3,198	$ 12,698
Provision related to current period sales	75,006	5,605	80,611
Adjustment for prior period sales	1,156	(212)	944
Payments/credits for current period sales	(64,756)	(3,993)	(68,749)
Payments/credits for prior period sales	(9,306)	(1,223)	(10,529)
Balance as of September 30, 2017	$ 11,600	$ 3,375	$ 14,975

Mandatory government discounts are the most significant component of our total gross-to-net deductions and the discount percentage has been increasing. These discount percentages increased during the three and nine months ended September 30, 2017 over the comparable periods in 2016 as a result of price increases we instituted that exceeded the rate of inflation, and to a lesser extent, as a result of an increase in sales eligible for government mandated rebates or chargebacks. Generally, the change in government prices is limited to the rate of inflation. We expect future gross-to-net deductions to fluctuate based on the volume of purchases eligible for government mandated discounts and rebates, as well as changes in the discount percentage, which is impacted by potential future price increases, the rate of inflation, and other factors.

As a result of price increases and a continued increase in the percentage of our gross sales that are eligible for government mandated rebates and chargebacks, we expect gross-to-net deductions to increase in 2017 as compared to 2016. In recent months there has been extensive discussion in the United States about expanding government discount programs, including allowing Medicare to negotiate drug prices, and pressure on pharmaceutical drug pricing is expected to increase. If government discounted programs are expanded or discounts increased as a result of changes in regulations in the United States, our gross to net deductions will increase and our net sales will be negatively impacted.

Collaboration and license agreement revenues

Our proprietary ADC technologies are the basis of our ADC collaborations that we have entered into in the ordinary course of business with a number of biotechnology and pharmaceutical companies. Under these ADC collaboration agreements, we grant our collaborators research and commercial licenses to our technology and typically provide technology transfer services, technical advice, supplies and services for a period of time.

If there are continuing performance obligations, we use a time-based proportional performance model to recognize revenue over our performance period for the related agreement. Collaboration and license agreements are evaluated to determine whether the multiple elements and associated deliverables can be considered separate units of accounting. To date, the pre-commercial deliverables under our collaboration and license agreements have not qualified as separate units of accounting. The assessment of multiple element arrangements requires judgment in order to determine the appropriate point in time, or period of time, that revenue should be recognized. We believe that the development period in each agreement is a reasonable estimate of the performance obligation period of such agreement. Accordingly, all amounts received or due, including any upfront payments, maintenance fees, development and regulatory milestone payments and reimbursement payments, are recognized as revenue over the

performance obligation periods of each agreement. These performance obligation periods typically range from one to three years. The agreements with Takeda and Genentech have performance obligation periods of ten and seventeen years, respectively. All of the remaining performance obligation periods for our active collaborations are currently expected to be completed in three years or less. When no performance obligations are required of us, or following the completion of the performance obligation period, such amounts are recognized as revenue when collectibility is reasonably assured. Generally, all amounts received or due other than sales-based milestones and royalties are classified as collaboration and license agreement revenues as they are earned. Sales-based milestones and royalties are recognized as royalty revenue as they are reported to us.

Our collaboration and license agreements include contractual milestones. Generally, the milestone events contained in our collaboration and license agreements coincide with the progression of the collaborators product candidates from development to regulatory approval and then to commercialization.

Development milestones in our collaborations may include the following types of events:

Designation of a product candidate or initiation of pre-clinical studies. Our collaborators must undertake significant pre-clinical research and studies to make a determination of the suitability of a product candidate and the time from those studies or designation to initiation of a clinical trial may take several years.

Initiation of a phase 1 clinical trial. Generally, phase 1 clinical trials may take one to two years to complete.

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Initiation of a phase 2 clinical trial. Generally, phase 2 clinical trials may take one to three years to complete.

Initiation of a phase 3 clinical trial. Generally, phase 3 clinical trials may take two to six years to complete.

Regulatory milestones in our collaborations may include the following types of events:

Filing of regulatory applications for marketing approval such as a BLA in the United States or a Marketing Authorization Application in Europe. Generally, it may take up to twelve months to prepare and submit regulatory filings.

Receiving marketing approval in a major market, such as in the United States, Europe, Japan or other significant countries. Generally it may take up to three years after a marketing application is submitted to obtain approval for marketing and pricing from the applicable regulatory agency.

Commercialization milestones in our collaborations may include the following types of events:

First commercial sale in a particular market, such as in the United States, Europe, Japan or other significant countries.

Product sales in excess of a pre-specified threshold. The amount of time to achieve this type of milestone depends on several factors, including, but not limited to, the dollar amount of the threshold, the pricing of the product, market penetration of the product and the rate at which customers begin using the product.

Our ADC collaborators are solely responsible for the development of their product candidates and the achievement of milestones in any of the categories identified above is based solely on the collaborators efforts.

In the case of our ADCETRIS collaboration with Takeda, we may be involved in certain development activities; however, the achievement of development, regulatory and commercial milestone events under the agreement is primarily based on activities undertaken by Takeda.

The process of successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing a product candidate is highly uncertain and the attainment of any milestones is therefore uncertain and difficult to predict. In addition, since we do not take a substantive role or control the research, development or commercialization of any products generated by our ADC collaborators, we are not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable to us by our ADC collaborators. As such, the milestone payments associated with our ADC collaborations involve a substantial degree of uncertainty and risk that they may never be received. Similarly, even in those collaborations where we may have an active role in the development of the product candidate, such as our ADCETRIS collaboration with Takeda, the attainment of a milestone is based on the collaborator s activities and is generally outside our direction and control.

We generally invoice our collaborators and licensees on a monthly or quarterly basis, or upon the completion of the effort or achievement of a milestone, based on the terms of each agreement. Any deferred revenue arising from amounts received in advance of the culmination of the earnings process is recognized as revenue in future periods when the applicable revenue recognition criteria have been met. Deferred revenue expected to be recognized within

the next twelve months is classified as a current liability.

Collaboration and license agreement revenues by collaborator are summarized as follows ($ in thousands):

	Three months ended September 30,			Nine months ended September 30,		
	2017	2016	% Change	2017	2016	% Change
Takeda	$ 21,665	$ 12,087	79%	$ 59,158	$ 34,530	71%
AbbVie	17,350	8,780	98%	21,394	19,274	11%
Other	429	3,107	(86)%	2,227	10,344	(78)%
Total	$ 39,444	$ 23,974	65%	$ 82,779	$ 64,148	29%

Collaboration revenues from Takeda fluctuate based on changes in the earned portion of reimbursement funding under the ADCETRIS collaboration, which are influenced by the activities each party is performing under the collaboration agreement at a given time. Collaboration revenues from Takeda increased during the three and nine months ended September 30, 2017 from the comparable periods in 2016, primarily driven by an increase in drug product supply activities.

Changes in revenues recognized from AbbVie and from our other collaboration agreements, which include our ADC collaborations and our co-development collaborations, reflect the timing of development milestones and licensing fees.

Our collaboration and license agreement revenues are impacted by the term and duration of our collaboration and license agreements and by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services. Collaboration and license agreement revenues may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their product candidates, the level of support we provide to our collaborators, specifically to Takeda under our ADCETRIS collaboration, the timing of milestones achieved and our ability to enter into additional collaboration and co-development agreements. We expect our collaboration and license agreement revenues in 2017 to increase as compared with 2016 due to the timing of progress-dependent milestones achieved. We have a significant balance of deferred revenue, representing prior payments from our collaborators that have not yet been recognized as revenue. This deferred revenue will be recognized as revenue in future periods using a time-based approach as we fulfill our performance obligations.

Collaboration agreements

Takeda

Our ADCETRIS collaboration with Takeda provides for the global co-development of ADCETRIS by the companies and the commercialization of ADCETRIS by Takeda in its territory. We received an upfront payment and have received and are entitled to receive progress-dependent milestone payments based on Takeda s achievement of significant events under the collaboration, in addition to tiered royalties with percentages starting in the mid-teens and escalating to the mid-twenties based on net sales of ADCETRIS within Takeda s licensed territories. Additionally, the companies equally co-fund the cost of selected development activities conducted under the collaboration. We recognize as collaboration revenue the upfront payment, progress-dependent milestone payments, and net development cost reimbursement payments from Takeda over the ten-year development period of the collaboration, which began in December 2009. When the performance of development activities under the collaboration results in us making a reimbursement payment to Takeda, the effect is to reduce the amount of collaboration revenue that we record. We also receive reimbursement for the cost of drug product supplied to Takeda for its use and, in some cases, pay Takeda for drug product they supply to us. The earned portion of net collaboration payments is reflected as a component of collaboration and license agreement revenues.

As of September 30, 2017, total future potential milestone payments to us under the ADCETRIS collaboration could total approximately $165 million. Of the remaining amount, up to approximately $7 million relates to the achievement of development milestones, up to approximately $118 million relates to the achievement of regulatory milestones and up to approximately $40 million relates to the achievement of commercial milestones. As of September 30, 2017, $70 million in milestones had been achieved as a result of regulatory and commercial progress by Takeda.

Astellas

We entered into an agreement with Agensys, subsequently acquired by Astellas, to jointly research, develop and commercialize ADCs for the treatment of several types of cancer. The collaboration encompasses combinations of our ADC technology with fully-human antibodies developed by Astellas to proprietary cancer targets.

Under the collaboration agreement, we and Astellas are co-funding all development and commercialization costs for enfortumab vedotin, and will share in any profits that may come from this product candidate if successfully commercialized on a 50/50 basis. Costs associated with co-development activities are included in research and development expense.

Astellas is developing another ADC product candidate on its own, subject to paying us annual maintenance fees, milestones, royalties and support fees for research and development services and material provided under the

collaboration agreement. Amounts received for this product candidate being developed solely by Astellas are recognized as revenue.

Genmab

We entered into an agreement with Genmab for the development and commercialization of ADCs for the treatment of several types of cancer. Under the agreement, we had the right to exercise a co-development option for tisotumab vedotin and in August 2017, we exercised our option. We and Genmab will share all future costs and profits for development and commercialization of tisotumab vedotin on a 50/50 basis. We will be responsible for tisotumab vedotin commercialization activities in the U.S., Canada, and Mexico, while Genmab will be responsible for commercialization activities in all other territories. Each party has the option to co-promote up to a specified percentage of the sales effort in the other party s territories. Costs associated with co-development activities following the exercise of our co-development option are included in research and development expense.

Genmab is developing another ADC product candidate on its own, subject to paying us annual maintenance fees, milestones, royalties and support fees for research and development services and material provided under the agreement. Amounts received for this product candidate being developed solely by Genmab are recognized as revenue.

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Unum Therapeutics

We have a strategic collaboration and license agreement with Unum to develop and commercialize novel ACTR therapies incorporating our antibodies for cancer. We and Unum are developing two ACTR product candidates that combine Unum s ACTR technology with our antibodies. Unum is obligated to conduct preclinical research and clinical development activities through phase 1 clinical trials and we are obligated to provide funding for these activities. The agreement calls for us to work together to co-develop and jointly fund programs after phase 1 clinical trials unless either company opts out. Costs associated with co-development activities are included in research and development expense.

We and Unum would co-commercialize any successfully developed product candidates and share any profits 50/50 on any co- developed programs in the United States. We retain exclusive commercial rights outside of the United States, paying Unum a royalty that is a high single digit to mid-teens percentage of ex-U.S. sales, if any. The potential future licensing and progress-dependent milestone payments to Unum under the collaboration may total up to $400 million between the two ACTR programs, payment of which is triggered by the achievement of development, regulatory and commercial milestones.

ADC Collaboration Agreements

We have other active collaborations with a number of companies to allow them to use our proprietary ADC technology. Under our ADC collaborations, which we have entered into in the ordinary course of business, we typically receive or are entitled to receive upfront cash payments, progress-dependent milestones and royalties on net sales of products incorporating our ADC technology, as well as annual maintenance fees and support fees for research and development services and materials provided under the agreements. These amounts are recognized as revenue as they are realized, or over the performance obligation period of the agreements during which we provide limited support to the collaborator. Our ADC collaborators are responsible for development, manufacturing and commercialization of any ADC product candidates that result from the collaborations and are solely responsible for the achievement of the potential milestones under these collaborations.

As of September 30, 2017, our ADC collaborations and co-development agreements had generated cash of more than $375 million, primarily in the form of upfront payments. Total milestone payments to us under our current ADC collaboration and co-development agreements could total up to approximately $2.9 billion if all potential product candidates achieved all of their milestone events. Of this amount, approximately $0.4 billion relates to the achievement of development milestones, approximately $1.1 billion relates to the achievement of regulatory milestones and approximately $1.4 billion relates to the achievement of commercial milestones. Since we do not control the research, development or commercialization of any of the products that would generate these milestones, we are not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable by our collaborators. Successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing it is a significantly lengthy and highly uncertain process which entails a significant risk of failure. In addition, business combinations, changes in a collaborator s business strategy and financial difficulties or other factors could result and have resulted in a collaborator abandoning or delaying development of its product candidates. As such, the milestone payments associated with our ADC collaborations and co-development agreements involve a substantial degree of risk and may never be received. Accordingly, we do not expect, and investors should not assume, that we will receive all of the potential milestone payments described above and it is possible that we may never receive any additional significant milestone payments under these agreements.

Royalty revenues and cost of royalty revenues

Royalty revenues primarily reflect royalties paid to us by Takeda under the ADCETRIS collaboration. These royalties include commercial sales-based milestones and sales royalties. The royalty rate paid by Takeda is calculated as a percentage of Takeda s net sales of ADCETRIS, ranges from the mid-teens to the mid-twenties depending on sales volumes, and resets annually. Takeda bears a portion of third-party royalty costs owed on sales of ADCETRIS in its territory. This amount is included in our royalty revenues. Cost of royalty revenues reflect amounts owed to our third-party licensors related to the sale of ADCETRIS in Takeda s territory.

Our royalty revenues and cost of royalty revenues were as follows ($ in thousands):

	Three months ended September 30,			Nine months ended September 30,		
	2017	2016	% Change	2017	2016	% Change
Royalty revenues	$ 16,670	$ 12,224	36%	$ 46,025	$ 53,743	(14)%
Cost of royalty revenues	$ 5,196	$ 3,748	39%	$ 13,900	$ 10,470	33%

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Royalty revenues increased for the three months ended September 30, 2017 as compared to 2016, driven by higher sales volumes by Takeda in its territories, as well as increases in the royalty rate which is based on sales volumes. Royalty revenues for the nine months ended September 30, 2017 decreased from the comparable period in 2016 as the nine months ended September 30, 2016 included a one-time $20.0 million milestone payment triggered by Takeda s exceeding $200 million in annual sales for the first time. The decrease driven by the milestone payment in the 2016 period was partially offset by increases in sales volume in the 2017 period.

Cost of royalty revenues fluctuates based on the amount of net sales of ADCETRIS by Takeda in its territories.

We expect that royalty revenues will decrease slightly in 2017 as compared to 2016 primarily as a result of the 2016 royalty revenues including the one-time $20 million sales milestone payment. We expect cost of royalty revenues to increase in 2017 primarily due to anticipated increases in sales volumes in Takeda s territories, and to a lesser extent, increases in the applicable royalty rate.

Cost of sales

ADCETRIS cost of sales includes manufacturing costs of product sold, third-party royalty costs, amortization of technology license costs, and distribution and other costs. Our cost of sales was as follows ($ in thousands):

	Three months ended September 30,			Nine months ended September 30,		
	2017	2016	% Change	2017	2016	% Change
Cost of sales	$ 9,019	$ 7,427	21%	$ 24,555	$ 20,272	21%

Cost of sales increased during the three and nine months ended September 30, 2017 as compared to 2016 primarily due to increased sales volumes, and to a lesser extent, due to increases in the royalty rate payable which is based on sales volumes. We expect cost of sales to increase in 2017, primarily due to anticipated increases in sales volumes.

Research and development

Our research and development expenses are summarized as follows ($ in thousands):

	Three months ended September 30,			Nine months ended September 30,		
	2017	2016	% Change	2017	2016	% Change
Research	$ 20,492	$ 14,509	41%	$ 55,095	$ 45,368	21%
Development and contract manufacturing	41,263	39,184	5%	133,689	106,150	26%
Clinical	51,851	39,018	33%	157,412	119,618	32%
Total research and development expenses	$ 113,606	$ 92,711	23%	$ 346,196	$ 271,136	28%

Research expenses include, among other things, personnel, occupancy and laboratory expenses, technology access fees associated with the discovery and identification of new monoclonal antibodies and related technologies, and the development of novel classes of stable linkers and cell-killing agents for our ADC technology. Research expenses also

include research activities associated with our product candidates, such as preclinical translational biology and *in vitro* and *in vivo* studies, and IND-enabling pharmacology and toxicology studies. The increase in research expenses during the three and nine months ended September 30, 2017 as compared to the same periods in 2016 primarily reflects increases in both internal and co-development costs to support our growing pipeline of product candidates, and to a lesser extent, increases in staffing and related occupancy costs.

Development and contract manufacturing expenses include personnel and occupancy expenses, external contract manufacturing costs for the scale up and pre-approval manufacturing of drug product used in research and our clinical trials, and costs for drug product supplied to our collaborators. Development and contract manufacturing expenses also include quality control and assurance activities, and storage and shipment of our product candidates. The increase in development and contract manufacturing expenses during the three months ended September 30, 2017 as compared to the same period in 2016 primarily reflects increases in staffing and related occupancy costs. The increase in development and contract manufacturing expenses during the nine months ended September 30, 2017 as compared to the same period in 2016 primarily reflects increased drug product supplied to Takeda, and to a lesser extent, increases in staffing and other costs to support our growing pipeline of product candidates.

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Clinical expenses include personnel, travel, occupancy costs, and external clinical trial costs including costs for clinical sites, clinical research organizations, contractors and regulatory activities associated with conducting human clinical trials. The increase in clinical expenses during the three months ended September 30, 2017 as compared to the same period in 2016 reflects increased clinical trial activity related to our product candidates, primarily SGN-CD48A as it advances into clinical trials, enfortumab vedotin and 2FF, and related increases in staffing. The increase in clinical expenses during the nine months ended September 30, 2017 as compared to the same period in 2016 reflects increased clinical trial activity related to our product candidates, primarily SGN-CD33A and enfortumab vedotin, and related increases in staffing.

We utilize our employee and infrastructure resources across multiple development projects as well as our discovery and research programs directed towards identifying monoclonal antibodies and new classes of stable linkers and cell-killing agents for our ADC program. We track human resource efforts expended on many of our programs for purposes of billing our collaborators for time incurred at agreed upon rates and for resource planning. We do not account for actual costs on a project-by-project basis as it relates to our infrastructure, facility, employee and other indirect costs. We do, however, separately track significant third-party costs including clinical trial costs, manufacturing costs and other contracted service costs on a project-by-project basis.

The following table shows expenses incurred for research, contract manufacturing of our product candidates and clinical and regulatory services provided by third parties as well as pre-commercial milestone payments for in-licensed technology for ADCETRIS and each of our clinical-stage product candidates. The table also presents other third-party costs and overhead consisting of personnel, facilities and other indirect costs not directly charged to these development programs.

	Three months ended September 30,		Nine months ended September 30,		Five years ended September 30, 2017
Development program ($ in thousands)	**2017**	**2016**	**2017**	**2016**	
ADCETRIS (brentuximab vedotin)	$ 23,698	$ 18,438	$ 65,626	$ 55,216	$ 326,292
SGN-CD33A (vadastuximab talirine)	1,440	9,416	31,003	31,422	111,537
ASG-22ME (enfortumab vedotin)	3,703	1,053	15,399	3,345	28,990
SGN-LIV1A	4,523	1,147	8,179	3,163	22,995
Other clinical stage programs	8,012	7,078	20,966	19,828	104,806
Total third-party costs	41,376	37,132	141,173	112,974	594,620
Other costs and overhead	72,230	55,579	205,023	158,162	922,446
Total research and development	$ 113,606	$ 92,711	$ 346,196	$ 271,136	$ 1,517,066

Third-party costs for ADCETRIS increased during the three and nine months ended September 30, 2017 from the comparable periods in 2016, primarily due to an increase in drug product supplied to Takeda, offset partially by a decrease in clinical trial activities. The cost of drug product supplied to Takeda is charged to research and development expense. We are reimbursed for the drug product, which is included as a component of collaboration revenue.

Third-party costs for SGN-CD33A decreased during the three and nine months ended September 30, 2017 from the comparable periods in 2016 due to the discontinuation of our phase 3 CASCADE and other SGN-CD33A clinical trials.

Third-party costs for enfortumab vedotin and SGN-LIV1A increased during the three and nine months ended September 30, 2017 from the comparable periods in 2016 primarily due to an increase in drug supply activities and, to a lesser extent, clinical trial costs as we prepare to initiate additional clinical trials in 2017.

Other costs and overhead include third-party costs of our other preclinical programs, including our strategic collaboration with Unum, and costs associated with personnel and facilities. These costs increased during the three and nine months ended September 30, 2017 from the comparable periods in 2016 due to development activities to expand our product pipeline, including increases in staffing levels and the expansion of our facilities to accommodate our growth.

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Our expenditures on our ADCETRIS clinical development program and on our current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. In order to advance our product candidates toward commercialization, the product candidates are tested in numerous preclinical safety, toxicology and efficacy studies. We then conduct clinical trials for those product candidates that take several years or more to complete. The length of time varies substantially based upon the type, complexity, novelty and intended use of a product candidate. Likewise, in order to expand ADCETRIS labeled indications of use, we are required to conduct additional extensive clinical trials. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

- the number of patients required in our clinical trials;
- the length of time required to enroll trial participants;
- the number and location of sites included in the trials;
- the costs of producing supplies of the product candidates needed for clinical trials and regulatory submissions;
- the safety and efficacy profile of the product candidate;
- the use of clinical research organizations to assist with the management of the trials; and
- the costs and timing of, and the ability to secure, regulatory approvals.

We anticipate that our total research and development expenses in 2017 will increase compared to 2016 due to an increase in ADCETRIS costs related to drug product supplied to Takeda, as well as increased costs for the development of our product candidates, primarily enfortumab vedotin and SGN-LIV1A, and the purchase of the BMS manufacturing facility. Certain ADCETRIS development activities, including some clinical studies, will be conducted by Takeda, the costs of which are not reflected in our research and development expenses. Because of these and other factors, expenses will fluctuate based upon many factors, including the degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial event.

The risks and uncertainties associated with our research and development projects are discussed more fully in Part II, Item 1A Risk Factors. As a result of the uncertainties discussed above, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, anticipated completion dates or when and to what extent we will receive cash inflows from the commercialization and sale of ADCETRIS in any additional approved indications or of any of our product candidates.

Selling, general and administrative

Selling, general and administrative ($ in thousands)	Three months ended September 30, 2017	2016	% Change	Nine months ended September 30, 2017	2016	% Change
Selling, general and administrative	$ 39,667	$ 34,841	14%	$ 118,783	$ 97,870	21%

Selling, general and administrative expenses increased during the three and nine months ended September 30, 2017 from the comparable periods in 2016 primarily due to increases in staffing to support our continued growth. For the nine months ended September 30, 2017 as compared to the comparable period in 2016, the increase in expenses was also driven by increases in expenses for legal matters.

We anticipate that selling, general and administrative expenses will increase in 2017 compared to 2016 as we continue our commercial activities in support of the commercialization of ADCETRIS, as well as our support of general operations.

Investment and other income, net

Investment and other income, net ($ in thousands)	Three months ended September 30, 2017	2016	% Change	Nine months ended September 30, 2017	2016	% Change
Investment and other income, net	$ 82,218	$ 660	*	$ 84,460	$ 1,903	*

* *Not meaningful*

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The components of investment and other income, net are summarized as follows ($ in thousands):

Investment and other income, net ($ in thousands)	Three months ended September 30, 2017	2016	% Change	Nine months ended September 30, 2017	2016	% Change
Gain on Immunomedics warrant derivative	$ 78,714	$ 0	N/A	$ 76,699	$ 0	N/A
Income tax benefit on unrealized gain on available-for-sale securities	2,739	0	N/A	5,415	0	N/A
Investment income, net	765	660	16%	2,346	1,903	23%
Total investment and other income, net	$ 82,218	$ 660	N/A	$ 84,460	$ 1,903	N/A

N/A: No amount in comparable period or not a meaningful comparison.

The gain on the Immunomedics warrant derivative for both the three and nine months ended September 30, 2017, was driven by the change in fair value of the warrant derivative. For the nine months ended September 30, 2017, this gain was offset by the cost-basis impairment recorded in the first quarter of 2017. The income tax benefit for both the three and nine months ended September 30, 2017 was due to unrealized gains on available-for-sale securities, primarily driven by our common stock investment in Immunomedics. Investment income, net increased for both the three and nine month periods ended September 30, 2017 as compared to the prior year periods due to an increase in the effective yield of our portfolio.

The fair value of both the Immunomedics common stock and the warrant derivative fluctuate based on changes in the stock price of Immunomedics. Furthermore, upon our adoption of ASU 2016-01 on January 1, 2018, we are required to record changes in the fair value of equity securities in net income or loss. To the extent that we continue to hold Immunomedics common stock or other equity securities, our operating results may fluctuate significantly.

Liquidity and capital resources

Selected balance sheet and cash flow data ($ in thousands)	September 30, 2017	December 31, 2016
Cash, cash equivalents, and short- and long-term investments	$ 470,365	$ 618,974
Working capital	467,783	586,132
Stockholders equity	659,708	634,087

	Nine months ended September 30, 2017	2016
Cash provided by (used in):		
Operating activities	$ (116,506)	$ (81,917)
Investing activities	109,982	87,282
Financing activities	25,991	23,409

Our combined cash, cash equivalents and investment securities decreased during the nine months ended September 30, 2017 from the balance at December 31, 2016, primarily reflecting our net loss for the period, as well as

purchases of property and equipment as we expand our facilities to support our growth.

The changes in net cash used in operating activities are primarily related to our net loss, working capital fluctuations and changes in our non-cash expenses, all of which are highly variable. The changes in cash provided by investing activities primarily reflect differences between the proceeds received from sale and maturity of our investments and amounts reinvested, and to a lesser extent, increases in our purchases of property and equipment as we initiated a purchase of a manufacturing facility and continued to expand our facilities to support our growth. Net cash provided by financing activities resulted from the proceeds of stock option exercises and our employee stock purchase plan.

We have primarily financed our operations through the issuance of equity securities, collections from commercial sales of ADCETRIS, and by amounts received pursuant to product collaborations and our ADC collaborations. To a lesser degree, we have also financed our operations through royalty revenues and interest earned on cash, cash equivalents and investment securities. These financing and revenue sources have historically allowed us to maintain adequate levels of cash and investments.

Our cash, cash equivalents, and investments in debt securities are held in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate securities, taxable municipal bonds, commercial paper and money market accounts. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs. However, if our liquidity needs

should be accelerated for any reason in the near term, or investments do not pay at maturity, we may be required to sell investments in debt securities in our portfolio prior to their scheduled maturities, which may result in a loss. As of September 30, 2017, we had $450.4 million held in cash and cash equivalents, or short-term investments scheduled to mature within the next twelve months.

At our currently planned spending rates we believe that our financial resources, together with product and royalty revenues from sales of ADCETRIS and the fees, milestone payments and reimbursements we expect to receive under our existing collaboration and license agreements, will be sufficient to fund our operations for at least the next twelve months. Changes in our spending rate may occur that would consume available capital resources sooner, such as increased development, manufacturing and clinical trial expenses in connection with our expanding pipeline programs, or our undertaking of additional programs, business activities, or entry into strategic transactions, including potential additional acquisitions of products, technologies or businesses. Accordingly, we may be required to, or may otherwise determine to, raise additional capital to fund those obligations. Further, in the event of a termination of the ADCETRIS collaboration agreement with Takeda, we would not receive development cost sharing payments or milestone payments or royalties for the development or sale of ADCETRIS in Takeda s territory, and we would be required to fund all ADCETRIS development and commercial activities. Any of these factors could lead to a need for us to raise additional capital.

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees, support our preclinical development, manufacturing and clinical trial activities for ADCETRIS and our other pipeline programs, and expand internationally, as well as commercialize ADCETRIS and position ADCETRIS for potential additional regulatory approvals. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS, and the research, continued development and manufacturing of our product candidates will likely require us to raise substantial amounts of additional capital. Further, we actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses, and we may require significant additional capital in order to complete or otherwise provide funding for any additional acquisitions. We may seek additional funding through some or all of the following methods: corporate collaborations, licensing arrangements and public or private debt or equity financings. We do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may 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.

Commitments

Our future minimum contractual commitments were reported in our Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the SEC.

On October 1, 2017, we completed the acquisition of certain plant equipment and improvements from BMS in exchange for a payment of approximately $25.5 million. We completed the acquisition of the manufacturing facility site location in July 2017 for a purchase price of $17.8 million, which was recorded in property and equipment as of September 30, 2017.

In August 2017, we entered into a 36 month lease extension for approximately 50,000 square feet of facilities, which is used primarily for office space. The additional aggregate based rent due over the extended lease term is approximately $2.7 million. The lease has one remaining seven-year renewal option.

In September 2017, we entered into an operating lease for approximately 18,000 square feet of facilities, to be used primarily for office space. The additional aggregate base rent due over the 18 month lease term is approximately $0.5 million. The lease has two approximately five-year renewal options.

In October 2017, we entered into two, 72 month lease extensions for approximately 145,000 square feet of facilities which are used for laboratory and general office purposes. The lease extensions will commence on July 1, 2018. The additional aggregate base rent due over the extended lease terms is approximately $20.7 million. Each lease contains one additional five-year renewal option.

Except with respect to the foregoing, our future minimum contractual commitments have not changed materially from the amounts previously reported.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued an Accounting Standards Update entitled ASU 2014-09, Revenue from Contracts with Customers. The standard requires entities to recognize revenue through an evaluation that includes identification of the contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. In August 2015, FASB issued an Accounting Standards Update entitled ASU 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date, which defers the effective date of ASU 2014-09 to our fiscal year beginning January 1, 2018. The FASB has continued to issue accounting standards updates to clarify and provide implementation guidance related to Revenue from Contracts with Customers, including ASU 2016-08, Revenue from Contract with Customers: Principal versus Agent Considerations, ASU 2016-10, Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing , ASU 2016-12, Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients and ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers. Our preliminary assessment of this new standard is that it will generally not change the way in which we recognize product revenue from sales of ADCETRIS. However, we expect that sales-based royalties and commercial sales-based milestones will be recorded in the period of the related sale based on

estimates, rather than recording them as reported by the customer. In addition, we expect that the achievement of development milestones under our collaborations will be recorded in the period their achievement becomes probable, which may result in their recognition earlier than under current accounting principles. The new standard also requires more extensive disclosures related to revenue recognition, particularly in quarterly financial statements. We will adopt the standard on January 1, 2018 and intend to use the modified retrospective method of adoption. We are continuing to evaluate the impact of the standard on all of our revenues, including those mentioned above, and our assessments may change in the future based on our ongoing evaluation.

In January 2016, FASB issued an Accounting Standards Update entitled ASU 2016-01, Financial Instruments: Overall. The standard addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. We will adopt the standard on January 1, 2018 using a modified retrospective approach. The standard will require us to record changes in the fair value of equity securities in net income or loss. The implementation of this standard is expected to increase the volatility of net income or loss to the extent that we continue to hold equity securities.

In February 2016, FASB issued an Accounting Standards Update entitled ASU 2016-02, Leases. The standard requires entities to recognize in the consolidated balance sheet a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. The standard will become effective for us beginning January 1, 2019, with early adoption permitted. We are currently evaluating the guidance to determine the potential impact on our financial condition, results of operations and cash flows, and financial statement disclosures, and expect that the adoption of the standard will increase assets and liabilities related to our operating leases in our consolidated balance sheets.

In March 2016, FASB issued an Accounting Standard Update entitled ASU 2016-09, Compensation Stock Compensation. The standard is intended to simplify certain elements of accounting for share-based payment transactions, including the income tax impact, classification of awards as either equity or liabilities, and classification on the statement of cash flows. In addition, the standard allows an entity-wide accounting policy election to either estimate the number of awards that are expected to vest, as currently required, or account for forfeitures when they occur. We have elected to continue estimating the number of awards that are expected to vest. We adopted the standard as of January 1, 2017. Since we have incurred annual net losses since our inception and maintain a full valuation allowance on our net deferred tax assets, the adoption did not have a material impact on our financial condition, results of operations and cash flows.

In October 2016, FASB issued an Accounting Standard Update entitled ASU 2016-16, Accounting for Income Taxes: Intra-Entity Asset Transfers of Assets Other than Inventory. The standard is intended to simplify the accounting for intercompany sales of assets other than inventory. Under current GAAP, the tax effects of intra-entity asset transfers are deferred until the transferred asset is sold to a third party or otherwise recovered through use. Under the new guidance, a reporting entity would recognize the tax expense from the sale of the asset in the seller s jurisdiction when the transfer occurs, even though the pre-tax effects of that transaction are eliminated in consolidation. Any deferred tax asset that arises in the buyer s jurisdiction would also be recognized at the time of the transfer. The standard will become effective for us beginning on January 1, 2018. We are currently evaluating the new standard; however, since we have incurred annual net losses since our inception and maintain a full valuation allowance on our net deferred tax assets, the adoption is not expected to have a material impact on our financial condition, results of operations and cash flows, or financial statement disclosures.

In June 2016, FASB issued an Accounting Standard Update entitled ASU 2016-13, Financial Instruments: Credit Losses. The objective of the standard is to provide information about expected credit losses on financial instruments at each reporting date, and to change how other than temporary impairments on investments securities are recorded. The

standard will become effective for us beginning on January 1, 2020 with early adoption permitted. We are currently evaluating the guidance to determine the potential impact on our financial condition, results of operations and cash flows, and financial statement disclosures.

In January 2017, FASB issued an Accounting Standard Update entitled ASU 2017-01, Business Combinations: Clarifying the Definition of a Business. The objective of the standard is to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions of assets or businesses. We adopted this standard on a prospective basis as of January 1, 2017. The adoption of this standard did not have a material impact on our financial condition, results of operations and cash flows, or financial statement disclosures.

In May 2017, FASB issued an Accounting Standard Update entitled ASU 2017-09, Compensation Stock Compensation (Topic 718): Scope of Modification Accounting. The objective of the standard is to provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The standard should be applied prospectively to awards modified on or after the adoption date. The Company early adopted this standard on April 1, 2017. The adoption did not have a material impact on the Company s financial condition, results of operations and cash flows.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risks include interest rate risk, equity price risk, and foreign currency exchange rate risk. Of these risks, equity price risk could have a significant impact on our results of operations.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We currently have holdings in U.S. Treasury securities. A summary of our investment in debt securities subject to interest rate risk are as follows (in thousands):

	September 30, 2017	December 31, 2016
Short-term investments	$ 322,258	$ 480,313
Long-term investments	19,967	29,988
Total	$ 342,225	$ 510,301

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of $1.4 million in the fair value of our available-for-sale debt securities as of September 30, 2017. In addition, a hypothetical decrease of 10% in the effective yield of our available-for-sale debt securities would reduce our expected investment income by approximately $0.4 million over the next twelve months based on our investment balance at September 30, 2017.

Equity Price Risk

As of September 30, 2017, we held 3.0 million shares of Immunomedics common stock and a warrant to purchase an additional 8.7 million shares of Immunomedics common stock at an exercise price of $4.90 per share. The fair value of both the common stock and warrant fluctuate based on changes in the stock price of Immunomedics. Additionally, as of September 30, 2017, the warrant met the definition of a derivative. Because the warrant is accounted for as a derivative, we record the changes in fair value in our consolidated statement of operations. We recorded a gain of $78.7 million and $76.7 million in investment and other income, net, resulting from the change in the fair value of the warrant derivative for the three and nine months ended September 30, 2017, respectively. A hypothetical decrease of 10% in the price of Immunomedics common stock would reduce the fair value of the warrant derivative by approximately $12.1 million, thereby reducing our net income by approximately $12.1 million for the three months ended September 30, 2017, and increasing our net loss by approximately $12.1 million for the three months ended September 30, 2017.

Furthermore, upon our adoption of ASU 2016-01 on January 1, 2018, we are required to record changes in the fair value of equity securities in net income or loss. To the extent that we continue to hold Immunomedics common stock or other equity securities, our operating results may fluctuate significantly.

Foreign Currency Risk

Most of our revenues and expenses are denominated in U.S. dollars and as a result, we have not experienced significant foreign currency transaction gains and losses to date. Our commercial sales in Canada are denominated in Canadian Dollars. We also had other transactions denominated in foreign currencies during the nine months ended

September 30, 2017, primarily related to contract manufacturing and ex-U.S. clinical trial activities, and we expect to continue to do so. Our royalties from Takeda are derived from their sales of ADCETRIS in multiple countries and in multiple currencies that are converted into U.S. dollars for purposes of determining the royalty owed to us. Our primary exposure is to fluctuations in the Euro, British Pound, Canadian Dollar and Swiss Franc. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. However, transaction gains or losses may become significant in the future as we continue to expand our operations internationally. We have not engaged in foreign currency hedging to date; however, we may do so in the future.

Item 4. Controls and Procedures

(a) *Evaluation of disclosure controls and procedures.* Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this quarterly report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were, in design and operation, effective.

(b) *Changes in internal control over financial reporting.* There have not been any changes in our internal control over financial reporting during the quarter ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Part II. Other Information

Item 1. Legal Proceedings

Stockholder Class Action. On January 10, 2017, a purported securities class action lawsuit was commenced in the United States District Court for the Western District of Washington, naming as defendants us and certain of our officers. A consolidated amended complaint was filed on June 6, 2017, following the court s appointment of a lead plaintiff and its approval of lead plaintiff s counsel. The lawsuit alleges material misrepresentations and omissions in public statements regarding our business, operational and compliance policies, violations by all named defendants of Section 10(b) of the Exchange Act, and Rule 10b-5 thereunder, as well as violations of Section 20(a) of the Exchange Act. The complaint seeks compensatory damages of an undisclosed amount. The plaintiff alleges, among other things, that we made false and/or misleading statements and/or failed to disclose that SGN-CD33A presents a significant risk of fatal hepatotoxicity and that we had therefore overstated the viability of SGN-CD33A as a treatment for AML. It is possible that additional suits will be filed, or allegations received from stockholders, with respect to these same matters and also naming us and/or our officers and directors as defendants. We filed a motion to dismiss this complaint on July 28, 2017. On October 18, 2017, the Court granted our motion to dismiss with leave for plaintiff to file a second consolidated amended complaint. We do not believe it is feasible to predict or determine the ultimate outcome or resolution of this litigation, or to estimate the amount of, or potential range of, loss with respect to this proceeding. In addition, the timing of the final resolution of this proceeding is uncertain. As a result of the lawsuit, we will incur litigation expenses and may incur indemnification expenses, and potential resolutions of the lawsuit could include a settlement requiring payments. Those expenses could have a material impact on our financial position, results of operations, and cash flows.

Stockholder Derivative Action. On March 29, 2017, a stockholder derivative lawsuit was filed in Washington Superior Court for the County of Snohomish, or the Snohomish Count Superior Court. The complaint names as defendants certain of our current and former executives and members of our board of directors. We are named as a nominal defendant. The complaint generally makes the same allegations as the securities class action, claiming that the individual defendants breached their duties to us. The complaint seeks unspecified damages, disgorgement of compensation, corporate governance changes, and attorneys fees and costs. Because the complaint is derivative in nature, it does not seek monetary damages from us. On June 8, 2017, the Snohomish County Superior Court entered an order staying the Stockholder Derivative Action until resolution of the motion to dismiss the Stockholder Class Action. On October 18, 2017, in light of the granting of our motion to dismiss in the Stockholder Class Action, the parties in the Stockholder Derivative Action filed a joint status report with the Snohomish County Superior Court stipulating to continue to stay the Stockholder Derivative Action pending further developments in the Stockholder Class Action. As a result of the lawsuit, we may incur litigation and indemnification expenses.

venBio Action. On February 13, 2017, we were named a co-defendant in a lawsuit filed by venBio Select Advisors LLC, or venBio, in the Delaware Chancery Court, against the members of the board of directors of Immunomedics, Inc., or Immunomedics. The lawsuit, or the venBio lawsuit, alleged that the members of the Immunomedics board breached their fiduciary duties toward their stockholders by hastily licensing IMMU-132 to us. We were alleged to have aided and abetted the breach of fiduciary duties. Among other things, venBio sought to enjoin the closing of the transactions contemplated by the development and license agreement, or the Immunomedics License, we entered into with Immunomedics in February 2017 that provided for the grant to us of exclusive worldwide rights to IMMU-132, and a related stock purchase agreement. On May 4, 2017, we and Immunomedics agreed to terminate the Immunomedics License and to amend the term of the warrant Immunomedics issued to us under the stock purchase agreement to be exercisable by us only until December 31, 2017. In connection therewith, Immunomedics and venBio agreed to fully settle, resolve and release us, and we agreed to fully settle, resolve and release Immunomedics and

venBio, from all disputes, claims and liabilities arising from the Immunomedics License, the stock purchase agreement and the transactions contemplated thereby, subject of the terms of the related termination agreement and settlement agreement. The termination agreement between Immunomedics and us and the settlement of the venBio lawsuit were effective August 25, 2017.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report on Form 10-Q.

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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 and our prospects for profitability will be adversely affected.

ADCETRIS®, or brentuximab vedotin, is now approved by the United States Food and Drug Administration, or FDA, and the European Commission for three indications, encompassing several settings for the treatment of relapsed Hodgkin lymphoma and relapsed systemic anaplastic large cell lymphoma, or sALCL. ADCETRIS is our only product approved for marketing and our ability to generate revenue from product sales and our prospects for profitability are 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 and/or Takeda may not be able to obtain and maintain regulatory approvals to market ADCETRIS for any additional indications in our respective territories, including for cutaneous T-cell lymphoma, or CTCL, frontline Hodgkin lymphoma or frontline mature T-cell lymphoma, or MTCL, or to otherwise continue to expand its labeled indications of use;

- we and/or Takeda may fail to obtain regulatory approval and may fail to commercialize ADCETRIS in either the ALCANZA and the ECHELON-1 treatment settings in our respective territories notwithstanding the positive data we reported from those trials, which would limit our sales of, and the commercial potential of, ADCETRIS;

- negative or inconclusive results in, or delays in, our ECHELON-2 phase 3 trial would negatively impact, or preclude altogether, our and Takeda s ability to obtain regulatory approvals and commercialize ADCETRIS in the frontline MTCL indication in our respective territories which would also limit our sales of, and the commercial potential of, ADCETRIS;

- results from the ECHELON-1 trial or the ECHELON-2 trial, either of which could be considered confirmatory by the FDA for the relapsed sALCL indication, may fail to sufficiently confirm the clinical benefit of ADCETRIS in relapsed sALCL, which could result in the withdrawal of approval of ADCETRIS in the relapsed sALCL indication and negatively impact our potential future product sales for the relapsed sALCL indication;

- new competitive therapies, including immuno-oncology agents such as PD-1 inhibitors (e.g., nivolumab and pembrolizumab), have been approved by regulatory authorities or may be submitted in the near term to regulatory authorities for approval in ADCETRIS labeled indications, and these competitive products could negatively impact our commercial sales of ADCETRIS;

our commercial sales of ADCETRIS could be lower than our projections due to a lower market penetration rate, increased competition by alternative products or biosimilars, or a shorter duration of therapy in patients in ADCETRIS approved indications;

we may be unable to effectively commercialize ADCETRIS in any new indications for which we receive marketing approval;

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 our required post-approval study, or as the result of adverse events observed in that study or in other studies, including in the post-approval confirmatory studies that Takeda is required to conduct as a condition to the conditional marketing authorization of ADCETRIS granted by the European Commission or in investigator-sponsored studies;

we may not be able to establish or demonstrate in the medical community the safety, efficacy, or value of ADCETRIS and its potential advantages compared to existing and future therapeutics in the frontline Hodgkin lymphoma setting and other settings;

physicians may be reluctant to prescribe ADCETRIS due to side effects associated with its use or until results from our required post-approval study are available or other long term efficacy and safety data exist;

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;

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

ADCETRIS may be impacted by 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 or state and federal governments, including as a result of increased scrutiny over pharmaceutical pricing or otherwise;

- the relative price of ADCETRIS may be higher than alternative treatment options, and therefore its reimbursement may be limited by private and governmental insurers;
- 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. In July 2016, Takeda announced that it had received marketing authorization for ADCETRIS from the European Commission for the treatment of adult patients with CD30-positive Hodgkin lymphoma at increased risk of relapse or progression following autologous stem cell transplant. 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 Takeda s territory.

While ADCETRIS product sales grew from 2014 to 2015 and from 2015 to 2016, and our future plans assume that sales of ADCETRIS will increase, we cannot assure you that ADCETRIS sales will continue to grow or that we can maintain sales of ADCETRIS at or near current levels. 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. 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-expressing hematologic malignancies, including 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.

In particular, although we reported positive top line data in both our ALCANZA and ECHELON-1 trials in August 2016 and June 2017, respectively, there can be no assurance that either we or Takeda will ultimately obtain regulatory approvals of ADCETRIS in either of the ALCANZA or ECHELON-1 treatment settings in our respective territories, which would limit our sales of, and the commercial potential of, ADCETRIS. In addition, negative or inconclusive results in our ECHELON-2 trial would negatively impact, or preclude altogether, our and Takeda s ability to obtain regulatory approvals in the frontline MTCL indication in our respective territories, which would also limit our sales of, and the commercial potential of, ADCETRIS. Moreover, the SPA agreement for the ECHELON-2 trial requires that the trial continue until a specified number of progression-free survival, or PFS, events designated for the trial

occurs. Based on reviews of pooled, blinded data, we have observed a lower rate of reported PFS events in the ECHELON-2 trial than anticipated. We plan to discuss with the FDA the potential to unblind the trial prior to achieving the target number of PFS events specified in the SPA agreement. We cannot predict the outcome of those discussions or whether we would be able to reach agreement with the FDA. If we are unable to reach agreement with the FDA and determine to unblind the trial prior to achieving the target number of PFS events as specified in the SPA agreement, the FDA could treat the SPA agreement for ECHELON-2 trial as rescinded. In that event, we would no longer have commitments from the FDA regarding the appropriate design, size and endpoints of the study for regulatory approval, making our ability to successfully obtain regulatory approval of ADCETRIS in the ECHELON-2 treatment setting more uncertain. In addition, earlier unblinding in the ECHELON-2 trial could also negatively impact the likelihood of achieving positive results in the trial sufficient to support regulatory approval. Alternatively, if we are unable to reach agreement with the FDA, we could determine to continue the ECHELON-2 trial until the target number of PFS events specified in the SPA agreement is achieved, which could result in a substantial delay in our ability to conduct the final data analysis from the ECHELON-2 trial.

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-expressing malignancies in a timely manner or at all. Further, if a companion diagnostic requirement were included in the ADCETRIS label, such a requirement may limit our ability to commercialize ADCETRIS in the applicable setting due to potential label requirements, prescriber practices, constraints on availability of the diagnostic, or other factors.

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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 periodically increase the price of ADCETRIS. Price increases on ADCETRIS and negative publicity regarding drug pricing and price increases generally, whether on ADCETRIS or products distributed by other pharmaceutical companies, could negatively affect market acceptance of, and sales of, ADCETRIS. In any event, 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.

Reports of adverse events or safety concerns involving ADCETRIS or our product candidates could delay or prevent us from obtaining or maintaining regulatory approvals, or could negatively impact sales of ADCETRIS or the prospects for our product candidates.

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 study 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 limiting, 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. For example, there was an increased incidence of febrile neutropenia and peripheral neuropathy in the ADCETRIS plus AVD arm of the ECHELON-1 trial, which could limit or narrow any approval by the FDA, or could limit prescribing of ADCETRIS in the ECHELON-1 treatment setting if approved by the FDA, both of which could negatively impact sales of ADCETRIS or adversely affect ADCETRIS acceptance in the market. 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 negatively impact the sales of ADCETRIS. We may be required to further update the ADCETRIS prescribing information, including boxed warnings, based on reports of adverse events or safety concerns or implement a Risk Evaluation and Mitigation Strategy, or REMS, 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, the prescribing information for ADCETRIS includes pancreatitis, impaired hepatic function, impaired renal function, pulmonary toxicity, and gastrointestinal complications as known adverse events as well as a boxed warning related to the risk that JC virus infection resulting in progressive multifocal leukoencephalopathy, or PML, and death can occur in patients receiving ADCETRIS. 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.

Likewise, reports of adverse events or safety concerns involving ADCETRIS or our product candidates could interrupt, delay or halt clinical trials of such product candidates, or could result in our inability to obtain regulatory approvals for any of our product candidates. For example, we discontinued the phase 3 CASCADE clinical trial of SGN-CD33A based on unexpected adverse events following a higher rate of deaths in the SGN-CD33A containing arm versus the control arm of this trial, and the Investigational New Drug application, or IND, for SGN-CD33A was subsequently placed on hold by the FDA. At this time, we have no plans to initiate additional clinical trials of

SGN-CD33A. In the future, we may determine to discontinue our SGN-CD33A program altogether, in which case we will not receive any return on our investment in SGN-CD33A. In addition, we are planning or conducting pivotal trials for enfortumab vedotin and tisotumab vedotin based on only limited phase 1 clinical data, and unexpected safety concerns could be observed in these pivotal or other later stage trials which could delay or prevent us from advancing the clinical development of enfortumab vedotin or tisotumab vedotin and may adversely affect our business, results of operations and prospects.

Concerns regarding the safety of ADCETRIS or our product candidates as a result of undesirable side effects identified during clinical testing or otherwise could cause the FDA to order us to cease further development or commercialization of ADCETRIS or the applicable product candidate. Undesirable side effects caused by ADCETRIS or our product candidates could also result in denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, the requirement of additional trials or the inclusion of unfavorable information in our product labeling, and in turn delay or prevent us from commercializing ADCETRIS or the applicable product candidate. In addition, actual or potential drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial for ADCETRIS or our product candidates or result in potential product liability claims. Any of these events could prevent us from developing or commercializing ADCETRIS or the particular product candidate, and could significantly harm our business, results of operations and prospects.

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

ADCETRIS is approved for treating patients in the relapsed sALCL indication under accelerated approval regulations in the U.S., approved with conditions in relapsed HL and sALCL in Canada, and approved under conditional marketing authorization in relapsed HL and sALCL in Europe, in each case under regulations 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, including clinical trials to confirm clinical benefit. In the U.S., either the ECHELON-1 trial or the ECHELON-2 trial results may be sufficient to confirm the clinical benefit of ADCETRIS in relapsed sALCL and thereby convert the relapsed sALCL to regular approval. In Canada and Europe, the ECHELON-1 results may be sufficient to confirm the clinical benefit of ADCETRIS in relapsed HL, and the ECHELON-2 results may be sufficient to confirm the clinical benefit of ADCETRIS in relapsed sALCL. Our failure to complete a required post-approval study, or to confirm a clinical benefit could result in the withdrawal of approval of ADCETRIS in the indications for which approval is conditional in certain geographical markets which would seriously harm our business. Similarly, Takeda s failure to provide these additional clinical data from confirmatory studies could result in the European Commission withdrawing approval of ADCETRIS in the European Union for certain indications, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda in the European Union and could adversely affect our results of operations. In addition, 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 relapsed sALCL is subject to extensive regulatory requirements all of which entails significant expense and may limit our ability to commercialize ADCETRIS for the relapsed sALCL indication.

In addition, we are subject to extensive ongoing obligations and continued regulatory review from applicable regulatory agencies with respect to any product for which we have obtained regulatory approval, including ADCETRIS in each of its approved indications, such as continued adverse event reporting requirements and the requirement to have some of 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.

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, including periodic unannounced 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 FDA 483 notices or Warning Letters by the FDA or other regulatory agencies;
- 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 submitted by us;
- 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.

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If we or our collaborators are not able to obtain or maintain required regulatory approvals, we or our collaborators will not be able to successfully commercialize ADCETRIS or 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-expressing 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 preclinical studies and clinical trials. For example, based in part on the positive data we reported from the ALCANZA trial, we have submitted an sBLA to the FDA to seek approval of ADCETRIS for a new indication in CTCL patients who require systemic therapy and the FDA has granted Breakthrough Therapy Designation to ADCETRIS for the treatment of patients with CD30-expressing mycosis fungoides (MF) and primary cutaneous anaplastic large cell lymphoma (pcALCL) who require systemic therapy and have received one prior systemic therapy. In addition, based on the positive data we reported from the ECHELON-1 trial, in November 2017, we submitted an sBLA to the FDA for approval of ADCETRIS as part of a frontline combination chemotherapy regimen in patients with previously untreated advanced classical Hodgkin lymphoma. However, the FDA may disagree with our interpretations of the data from the ALCANZA and/or ECHELON-1 trials and/or may otherwise determine not to approve our sBLA submissions in a timely manner or at all. Moreover, even though our ALCANZA, ECHELON-1 and ECHELON-2 trials 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 were or are being conducted under SPA agreements 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, including as a result of completing a clinical trial with fewer events than planned. 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. For example, even though we believe that the data from the ALCANZA and ECHELON-1 trials are supportive of approval of ADCETRIS in the ALCANZA and ECHELON-1 treatment settings, respectively, our SPA agreements with the FDA covering the ALCANZA and ECHELON-1 trials are not a guarantee or indication of approval of ADCETRIS in either the ALCANZA or ECHELON-1 treatment settings (or in any other indications). Regulatory agencies also may approve a product candidate for fewer indications or a narrower label than requested or may grant approval subject to the performance of post-approval studies or REMS for a product candidate. In addition, the breakthrough therapy and priority review designations granted to ADCETRIS may not result in a faster review or approval process and such designations do not reflect commitments that ADCETRIS will be approved in either of the ALCANZA or ECHELON-1 treatment settings, or with any particular label. Similarly, regulatory agencies may not approve the

labeling claims that are necessary or desirable for the successful commercialization of ADCETRIS in additional indications, including any indications in the ALCANZA or ECHELON-1 treatment settings.

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 institutional review boards, or 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. In this regard, the sBLA that we submitted to the FDA to seek approval of ADCETRIS for a new indication in CTCL patients who require systemic therapy was accepted for filing and designated for priority review with a PDUFA targeted action date of December 16, 2017. However, the FDA does not always meet its PDUFA targeted action dates and if the FDA were to fail to meet the PDUFA targeted action date for our filed sBLA or fail to meet future PDUFA targeted action dates established for ADCETRIS or any of our product candidates, if any, the commercialization of the affected product candidate or of ADCETRIS in any additional indications could be delayed or impaired. Due to these and other factors, ADCETRIS and our product candidates could take a significantly longer time to gain regulatory approvals than we expect or may never gain new regulatory approvals, which could delay or eliminate any potential product revenue from sales of our product candidates or of ADCETRIS in any additional indications, which could significantly delay or prevent us from achieving profitability.

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The successful commercialization of ADCETRIS and our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.

Successful sales of ADCETRIS and any future products will depend, in part, on the extent to which coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new products and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. In light of such challenges to prices, we cannot be sure that we will achieve and continue to have coverage available for ADCETRIS and any other product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. If we are unable to obtain adequate levels of coverage and reimbursement for our product candidates, their marketability will be negatively and materially impacted. For example, even if we are able to obtain approval of our sBLA submission to the FDA to expand the labeled indications of use for ADCETRIS to the frontline advanced Hodgkin lymphoma setting based on our recent ECHELON-1 trial data, we cannot be certain that third-party payors will provide reimbursement for ADCETRIS in that indication based on the relative price or perceived benefit of ADCETRIS as compared to alternative treatment options, which may materially harm our ability to maintain or increase sales of ADCETRIS or may otherwise negatively affect future ADCETRIS sales.

Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. In addition, obtaining and maintaining adequate coverage and reimbursement status is time-consuming and costly. Third-party payors may deny coverage and reimbursement status altogether of a given drug product, or cover the product but may also establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development. Further, one payor s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Because the rules and regulations regarding coverage and reimbursement change frequently, in some cases at short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact the favorable status.

The unavailability or inadequacy of third-party coverage and reimbursement could have a material adverse effect on the market acceptance of ADCETRIS and any of our future products and the future revenues we may expect to receive from those products. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business. Continuing negative publicity regarding pharmaceutical pricing practices and ongoing presidential and congressional focus on this issue create significant uncertainty regarding regulation of the healthcare industry and third-party coverage and reimbursement. If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of ADCETRIS or the pricing of pharmaceutical products generally, the prices that we charge for ADCETRIS and any future approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of ADCETRIS and any future approved products may be negatively impacted.

Healthcare law and policy changes may have a material adverse effect on us.

In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively 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. 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.

Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. For example, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In Congress, the U.S. House of Representatives passed PPACA replacement legislation known as the American Health Care Act of 2017 in May 2017, which was not introduced in the Senate. More recently, the Senate

Republicans have proposed multiple bills to repeal or repeal and replace portions of the PPACA. Although none of these measures have been enacted, Congress may consider other legislation to repeal or replace certain elements of the PPACA. On October 12, 2017, President Trump signed another Executive Order directing certain federal agencies to propose regulations or guidelines to permit small businesses to form association health plans, expand the availability of short-term, limited duration insurance, and expand the use of health reimbursement arrangements, which may circumvent some of the requirements for health insurance mandated by the PPACA. In addition, citing legal guidance from the U.S. Department of Justice, the U.S. Department of Health and Human Services, has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the PPACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until such appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. While Congress is considering legislation to appropriate funds for CSR payments the future of that legislation is uncertain. We continue to evaluate the effect that the PPCCA and its possible repeal and replacement has on our business.

In addition, we anticipate that the 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 ADCETRIS or any future 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 could be 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. In addition, drug-pricing by pharmaceutical companies has come under increased scrutiny. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing by requiring drug companies to notify insurers and government regulators of price increases and to provide an explanation the reasons for the increase, reduce the out-of-pocket cost of prescription drugs, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. We expect further federal and state legislation and healthcare reforms to continue to be proposed to control increasing healthcare costs and to control the rising cost of prescription drugs. These proposals, if implemented, could limit the price for ADCETRIS or any future approved products. Commercial opportunity could be negatively impacted by legislative action that controls pricing, mandates price negotiations, or increases government discounts and rebates.

Also, price increases on ADCETRIS and negative publicity regarding drug pricing and price increases generally, whether on ADCETRIS or products distributed by other pharmaceutical companies, could negatively affect market acceptance of, and sales of, ADCETRIS. In addition, although ADCETRIS is approved in the European Union, Japan and other countries outside of the United States, government austerity measures or further healthcare reform measures and pricing pressures in other countries could adversely affect demand and pricing for ADCETRIS, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda.

Other legislative changes have also been proposed and adopted since PPACA was enacted. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reduction to several government programs. This includes a 2% reduction in Medicare provider payments paid under Medicare Part B to physicians for physician-administered drugs, such as certain oral oncology drugs, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, legislation has been proposed to shorten the period of

biologic data and market exclusivity granted by the FDA. If such legislation is enacted, we may face competition from biosimilars of ADCETRIS or any future approved products earlier than otherwise would have occurred. Increased competition may negatively impact coverage and pricing of ADCETRIS, which could negatively affect our financial condition or results of operations.

We expect to experience pricing pressures in connection with the sale of ADCETRIS due to the trend toward managed healthcare, and additional legislative proposals. For example, the PPACA increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization and increased the types of entities eligible for the federal 340B drug discount program. On January 30, 2017, the White House Office of Management and Budget withdrew the draft August 2015 Omnibus Guidance document that was issued by the Department of Health and Human Services Health Resources and Services Administration, or HRSA, that addressed a broad range of topics including, among other items, the definition of a patient s eligibility for 340B drug pricing. However, as concerns continue to grow over the need for tighter oversight, there remains the possibility that HRSA or other agency under the Department of Health and Human Services, or HHS, will propose a similar regulation or that Congress will explore changes to the 340B program through legislation. For example, the Centers for Medicare & Medicaid Services has issued a proposed rule that would revise the Medicare hospital outpatient prospective payment system, including a new reimbursement methodology for drugs purchased under the 340B program for Medicare patients. In addition, HHS has currently set July 1, 2018 for implementation of the

final rule setting forth the calculation of the ceiling price and application of civil monetary penalties under the 340B program. A significant portion of ADCETRIS purchases are eligible for 340B drug pricing, therefore an expansion of the 340B program or reduction in 340B pricing, whether in the form of the final rule or otherwise would likely have a negative impact on our net sales of ADCETRIS.

We cannot predict what healthcare reform initiatives may be adopted in the future. However, we anticipate that Congress, state legislatures, and third-party payors may continue to review and assess alternative healthcare delivery and payment systems and may in the future propose and adopt legislation or policy changes or implementations effecting additional fundamental changes in the healthcare delivery system. We also expect ongoing initiatives to increase pressure on drug pricing. We cannot assure you as to the ultimate content, timing, or effect of changes, nor is it possible at this time to estimate the impact of any such potential legislation; however, such changes or the ultimate impact of changes could negatively affect our revenue or sales of ADCETRIS or any potential future approved products.

Enhanced governmental scrutiny, private litigation scrutiny and private litigation involving pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations may require us to modify our programs.

To help patients afford our products, we have a patient assistance program and also occasionally make donations to independent charitable foundations that help financially needy patients. These types of programs designed to assist patients afford pharmaceuticals have become the subject of scrutiny. In recent years, some pharmaceutical manufacturers were named in class action lawsuits challenging the legality of their patient assistance programs and support of independent charitable patient support foundations under a variety of federal and state laws. At least one insurer also has directed its network pharmacies to no longer accept manufacturer co- payment coupons for certain specialty drugs the insurer identified. Our patient assistance program and support of independent charitable foundations could become the target of similar litigation.

In addition, there has been regulatory review and enhance government scrutiny of donations by pharmaceutical companies to patient assistance programs operated by charitable foundations. For example, the Office of Inspector General of the U.S. Department of Health & Human Services, or OIG, has established specific guidelines permitting pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor s product. If we or our vendors or donation recipients are deemed to fail to comply with laws or regulations in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Further, numerous organizations, including pharmaceutical manufacturers, have received subpoenas from the OIG and other enforcement authorities seeking information related to their patient assistance programs and support. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

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. We are also conducting a pivotal phase 2 trial of enfortumab vedotin with Astellas for locally advanced or metastatic urothelial cancer patients who have been previously treated with checkpoint inhibitor therapy, and plan to conduct a pivotal phase 2 trial of tisotumab vedotin with Genmab in patients with recurrent and/or metastatic cervical cancer, in each case based on only limited phase 1 clinical data. Neither enfortumab vedotin nor tisotumab vedotin have previously been evaluated in later stage clinical trials and we cannot be certain that the design of, or data collected from, these trials will be adequate to demonstrate the safety and efficacy of enfortumab vedotin or tisotumab vedotin, or will otherwise be sufficient to support FDA or any foreign regulatory approvals.

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 IRB approval to conduct a clinical trial at a prospective site, and shortages of available drug supply. For example, the SPA agreement for the ECHELON-2 trial requires that the trial continue until a specified number of PFS events designated for the trial occurs. Based on reviews of pooled, blinded data, we have observed a lower rate of reported PFS events than anticipated. We plan to discuss with the FDA the potential to unblind the trial prior to achieving the target number of PFS events specified in the SPA agreement. We cannot predict the outcome of those discussions or whether we would be able to reach agreement with the FDA. If we are unable to reach agreement with the FDA and determine to unblind the trial prior to achieving the target number of PFS events as specified in the SPA agreement, the FDA could treat the SPA agreement for ECHELON-2 trial as rescinded. In that event, we would no longer have commitments from the FDA regarding the appropriate design, size and endpoints of the study for regulatory approval, making our ability to successfully obtain regulatory approval of ADCETRIS in the ECHELON-2 treatment setting more uncertain. In addition, earlier unblinding in the ECHELON-2 trial could also negatively impact the likelihood of achieving positive results in the trial sufficient to support regulatory approval. Alternatively, if we are unable to reach agreement with the FDA, we could determine to continue the ECHELON-2 trial until the target number of PFS events specified in the SPA agreement is achieved, which could result in a substantial delay in our ability to conduct the final

data analysis from the ECHELON-2 trial.

Additionally, 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, perceived side effects and the availability of alternative or new treatments. Many of our future and ongoing clinical trials are being or will be coordinated or conducted with Takeda, Astellas, Genmab and other collaborators, which may delay the commencement or affect the continuation or completion of these trials. From time to time, we have experienced enrollment-related delays in clinical trials and we will likely continue to experience similar delays in our current and future trials. 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 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.

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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, the data safety monitoring boards for such trials and the IRBs or Ethics Committees for the institutions in which such trials are being conducted. In addition, clinical trials must be conducted with supplies of ADCETRIS or our product candidates produced under cGMP and other requirements in foreign countries, and may require large numbers of test patients. We or our collaborators, the FDA, other foreign governmental agencies or the applicable data safety monitoring boards, IRBs and Ethics Committees could delay, suspend, halt or modify our clinical trials of ADCETRIS or any of our product candidates, and we, our collaborators and/or the FDA could terminate or modify any related SPA agreements, for numerous reasons, including:

- ADCETRIS or the applicable product candidate may have unforeseen safety issues or 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 and the inability of our collaborators to produce or obtain sufficient quantities of ADCETRIS or the applicable product candidate to complete the trials;
- our inability and the inability of our collaborators 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 and the inability of our collaborators to obtain IRB or Ethics Committee approval to conduct a clinical trial at a prospective site;

- changes in governmental regulations or administrative actions that adversely affect our ability and the ability of our collaborators to continue to conduct or to complete clinical trials;

- 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 and the inability of our collaborators 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;

- our inability and the inability of our collaborators 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; or

- our inability and the inability of our collaborators to ensure adequate statistical power to detect statistically significant treatment effects, whether through our inability to enroll or retain patients in trials or because the specified number of events designated for a completed trial have not occurred.

In addition, we or our collaborators may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, including unexpected adverse events that may occur when our product candidates are combined with other therapies. For example, in June 2017, we suspended patient enrollment and treatment in all SGN-CD33A trials and discontinued the phase 3 CASCADE clinical trial of SGN-CD33A in frontline older AML patients, following a higher rate of deaths in the SGN-CD33A containing arm versus the control arm of this trial, and the IND for SGN-CD33A was subsequently placed on hold by the FDA. At this time, we have no plans to initiate additional clinical trials of SGN-CD33A. In the future, we may determine to discontinue our SGN-CD33A program altogether, in which case we will not receive any return on our investment in SGN-CD33A.

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Negative or inconclusive clinical trial results could adversely affect our ability and the ability of our collaborators to obtain regulatory approvals of our product candidates or to market ADCETRIS and/or expand ADCETRIS into other indications. In particular, negative or inconclusive results in our ECHELON-2 trial would negatively impact or preclude altogether, our and Takeda s ability to obtain regulatory approvals in the frontline MTCL indication in our respective territories, which would limit our sales of, and the commercial potential of, ADCETRIS. In addition, clinical trial results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. For example, although we reported positive top line data in both our ALCANZA and ECHELON-1 trials, regulatory agencies, including the FDA, or their advisors, may disagree with our interpretations of data from the ALCANZA and/or ECHELON-1 trial and may not approve the expansion of ADCETRIS labeled indications of use based on the results of those trials or any other of our clinical trials. Adverse medical events during a clinical trial, including patient fatalities, could cause a trial to be redone or terminated, curtail or end the development of a product candidate, and may result in other negative consequences to us. Further, some of our clinical trials are overseen by an 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. In addition, we may be required to implement additional risk mitigation measures that could require us to suspend our clinical trials if certain safety events occur.

We depend on collaborative relationships with other companies to assist in the research and development of ADCETRIS and 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, develop other product candidates and/or generate revenues through technology licensing, or may otherwise negatively affect our business.

We have established 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. In addition, we have entered into 50/50 co-development agreements with Astellas for the development of enfortumab vedotin, and with Genmab for the development of tisotumab vedotin. We are also collaborating with BMS with respect to the CHECKMATE 812 pivotal phase 3 clinical trial evaluating the combination of Opdivo (nivolumab) with ADCETRIS for the treatment of relapsed/refractory or transplant-ineligible advanced classical Hodgkin lymphoma. In addition, we have ADC collaborations with AbbVie, Bayer, Celldex, Genentech, GSK, Pfizer and Progenics, and we have entered into a collaboration agreement with Unum to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies incorporating our antibodies for cancer. Our dependence on collaborative arrangements to assist in the development and commercialization of ADCETRIS and for the development and commercialization of product candidates utilizing or incorporating our technologies subjects us to a number of risks, including:

- we are not able to control the amount and timing of resources that our collaborators devote to the development or commercialization of products and product candidates utilizing or incorporating our technologies, or to their marketing and distribution;

- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of the applicable products and product candidates or that result in costly litigation or arbitration that diverts management s attention and resources;

with respect to collaborations under which we have an active role, such as our ADCETRIS collaboration and our 50/50 co-development agreements with Astellas and Genmab, we may have differing opinions or priorities than our collaborators, or we may encounter challenges in joint decision making, which may result in the delay or termination of the research, development or commercialization of the applicable products and product candidates, including ADCETRIS, enfortumab vedotin, and tisotumab vedotin;

our current and potential future collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

significant delays in the development of product candidates by current and potential collaborators could allow competitors to bring products to market before product candidates utilizing or incorporating our technologies are approved and impair the ability of current and potential future collaborators to effectively commercialize these product candidates;

our relationships with our collaborators may divert significant time and effort of our scientific staff and management team and require the effective allocation of our resources to multiple internal collaborative projects;

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- our current and potential future collaborators may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;
- our current and potential future collaborators may receive regulatory sanctions relating to other aspects of their business that could adversely affect the development, approval or commercialization of the applicable products or product candidates;
- our current and potential future collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a collaborator s business strategy may adversely affect such party s willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborators that are developed by such collaborator either independently or in collaboration with others, including our competitors;
- our current and potential collaborators may experience financial difficulties; and
- our collaborations may be terminated, breached or allowed to expire, or our collaborators may reduce the scope of our agreements with them, which could have a material adverse effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, and/or reimbursement of development costs, and which could require us to devote additional efforts and to incur the additional costs associated with pursuing internal development and commercialization of the applicable products and product candidates.

If our collaborative arrangements are not successful as a result of any of the above factors, or any other factors, then our ability to advance the development and commercialization of the applicable products and product candidates and to otherwise generate revenue from these arrangements and to become profitable will be adversely affected, and our business and business prospects may be materially harmed. In particular, if Takeda were to terminate the ADCETRIS collaboration, which it may do for any reason upon prior written notice to us, 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. Similarly, both Astellas and Genmab have the right to opt-out of their co-development obligations relating to enfortumab vedotin and tisotumab vedotin, respectively. If either Astellas or Genmab were to opt-out of their co-development agreements with us, this would significantly delay the development of the impacted product candidate and increase our costs. Any of these events could significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing ADCETRIS, enfortumab vedotin or tisotumab vedotin, which are now being co-funded by our collaboration partners. In the future, we may not

be able to locate third-party collaborators to develop and market products and product candidates utilizing or incorporating our technologies, and we may lack the capital and resources necessary to develop and market these products and product candidates alone.

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.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many third parties compete with us in developing various approaches to treating cancer. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to our programs.

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With respect to ADCETRIS, there are several other FDA-approved drugs for its approved indications. Bristol-Myers Squibb s Opdivo (nivolumab) and Merck s Keytruda (pembrolizumab) are approved for the treatment of certain patients with relapsed or refractory classical Hodgkin lymphoma, and Celgene s Istodax (romidepsin) and Spectrum Pharmaceuticals Folotyn (pralatrexate) and Beleodaq (belinostat) are approved for relapsed or refractory sALCL among other T-cell lymphomas. The competition ADCETRIS faces from these and other therapies is intensifying. Additionally, Merck is conducting a phase 3 clinical trial in relapsed or refractory classical Hodgkin lymphoma comparing Keytruda (pembrolizumab) with ADCETRIS. If this clinical trial demonstrates that pembrolizumab is more effective than ADCETRIS in that treatment setting, our sales of ADCETRIS would be negatively impacted. We are also aware of multiple investigational agents that are currently being studied, including Roche s atezolizumab, Pfizer s avelumab, and Kyowa s mogamulizumab, which, if successful, may compete with ADCETRIS in the future. Data have also been presented on several developing technologies, including bispecific antibodies and CAR modified T-cell therapies that may compete with ADCETRIS in the future. Further, there are many competing approaches used in the treatment of patients in ADCETRIS three approved indications, including auto-HSCT, allogeneic stem cell transplant, combination chemotherapy, clinical trials with experimental agents and single-agent regimens.

With respect to enfortumab vedotin, treatment in second line metastatic urothelial cancer is limited to CPI monotherapy or generic chemotherapy. There are other investigational agents that, if approved, could be competitive with enfortumab vedotin, including Immunomedics sacituzumab govitecan and Lilly s ramucirumab.

With respect to tisotumab vedotin, we are aware of other companies that currently have products in development for the treatment of late-stage cervical cancer which could be competitive with tisotumab vedotin, including Agenus, Astrazeneca, Bristol-Myers Squibb, Immunomedics, Innovent Biologics, Merck, and Roche. In addition, several CPIs that are FDA-approved in other treatment settings are being explored for the treatment of late-stage cervical cancer in ongoing phase 2 clinical trials.

Many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same types of cancer that our product candidates are designed and being developed to treat. For example, we believe that companies including AbbVie, ADC Therapeutics, Affimed, Agios, Amgen, Astellas, Bayer, Biogen, Bristol-Myers Squibb, Celgene, Eisai, Genentech, GSK, Gilead, ImmunoGen, Immunomedics, Infinity, Karyopharm, MedImmune, MEI Pharma, Merck, Novartis, Pfizer, Sanofi-Aventis, Spectrum Pharmaceuticals, Takeda, Teva, and Xencor are developing and/or marketing products or technologies that may compete with ours. In addition, our ADC collaborators may develop compounds utilizing our technology that may compete with product candidates that we are developing.

We are aware of other companies that have technologies that may be competitive with ours, including Astellas, AstraZeneca, Bristol-Myers Squibb, ImmunoGen, Immunomedics, MedImmune, Mersana and Pfizer, all of which have ADC technology. ImmunoGen has several ADCs in development that may compete with our product candidates. ImmunoGen has also established partnerships with other pharmaceutical and biotechnology companies to allow those other companies to utilize ImmunoGen s technology, including Sanofi-Aventis, Genentech, Novartis, Takeda and Lilly. We are also aware of a number of companies developing monoclonal antibodies directed at the same antigen targets or for the treatment of the same diseases as our product candidates. For example, we believe Amgen and Xencor have anti-CD19 programs that may be competitive with our product candidates.

In addition, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be highly similar or biosimilar to or interchangeable with an FDA-approved biological product. This pathway allows competitors to reference the FDA s prior approvals regarding innovative biological products and data submitted with a BLA to obtain approval of a biosimilar application 12 years after the time of approval of the innovative biological product. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the 12-year

exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another company cannot rely on the FDA s prior approvals in approving a BLA for an innovator s biological product to support the biosimilar product s approval. Further, under the FDA s current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. The FDA approved the first biosimilar product in the United States in May 2015. In the European Union, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued since 2005. We are aware of many pharmaceutical and biotechnology and other companies that are actively engaged in research and development of biosimilars or interchangeable products.

It is possible that our competitors will succeed in developing technologies that are more effective than ADCETRIS, enfortumab vedotin, tisotumab vedotin or our product candidates or that would render our technology obsolete or noncompetitive, or will succeed in developing biosimilar or interchangeable products for ADCETRIS, enfortumab vedotin, tisotumab vedotin or our product

candidates. We anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other cancer therapies continue to accelerate. We cannot predict to what extent the entry of biosimilars or other competing products will impact potential future sales of ADCETRIS, enfortumab vedotin, tisotumab vedotin or our product candidates.

Our operating results are difficult to predict 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. In addition, 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, on occasion, 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 including the impact of any competitive or biosimilar products 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;
- 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 and other activities involving ADCETRIS, enfortumab vedotin, tisotumab vedotin and our product candidates by us or our collaborators;

- changes in the price of Immunomedics common stock that affect the valuation of the Immunomedics common stock and the warrant we hold; and

- expenditures we will or may incur to develop and/or commercialize any additional products, product candidates, or technologies that we may develop, in-license, or acquire.

In addition, we have entered into licensing and collaboration agreements with other companies that include development funding and milestone payments to us, 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 potential 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, changes in our operations, such as increased development, manufacturing and clinical trial expenses in connection with our expanding pipeline programs, or our undertaking of additional programs, business activities or entry into strategic transactions, including potential additional acquisitions of products, technologies or businesses may also cause significant fluctuations in our expenses. In addition, 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. Additionally, we have implemented long-term incentive plans for our employees, and the incentives provided under these plans are contingent upon the achievement of certain regulatory

milestones. Costs of performance-based compensation under our long-term incentive plans are not recorded as an expense until the achievement of the applicable milestones is deemed probable of being met, which may result in large fluctuations to the expense we must recognize in any particular period.

Additionally, as of September 30, 2017, we held 3.0 million shares of Immunomedics common stock and a warrant to purchase an additional 8.7 million shares of common stock. The change in fair value of the warrant derivative from period to period is recorded to earnings and can significantly affect our operating results. For example, due to the gain of $78.7 million we recorded in investment and other income, net, during the three months ended September 30, 2017 resulting from the change in the fair value of the Immunomedics warrant derivative, we recorded net income of $50.0 million for the three months ended September 30, 2017 while our operating loss during the same period was $32.2 million. In addition, beginning in 2018, we will adopt ASU 2016-01 Financial Instruments: Overall, and as a result, we will record changes in the fair value of equity securities, including any Immunomedics common stock, in net income or loss, which is expected to increase the volatility of net income or loss to the extent that we continue to hold significant equity securities.

For these and other reasons, it is difficult for us to accurately forecast future sales of ADCETRIS, collaboration and license agreement revenues, royalty revenues, operating expenses 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.

We have a history of net losses. We expect to continue to incur net losses and may not achieve future 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. Although we reported net income of $50.0 million for the three months ended September 30, 2017, this was due to the gain of $78.7 million we recorded in investment and other income, net, resulting from the change in the fair value of the Immunomedics warrant derivative for the three months ended September 30, 2017, and we otherwise expect to continue to incur net losses in future periods. We have also incurred net losses in each of our years since inception. 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 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 enfortumab vedotin, tisotumab vedotin and our product candidates. Accordingly, we expect to continue to incur net losses and may not achieve profitability in the future 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 commercialization history makes our future operating results difficult to predict. Even if we do achieve profitability in the future, 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.

We have engaged in, and may in the future engage in strategic transactions that increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses. Any potential acquisitions or in-licensing transactions may entail numerous risks, including but not limited to:

risks associated with satisfying the closing conditions relating to such transactions and realizing their anticipated benefits;

increased operating expenses and cash requirements;

difficulty integrating acquired technologies, products, operations, and personnel with our existing business;

diversion of management s attention in connection with both negotiating the acquisition or license and integrating the business, technology or product;

retention of key employees;

uncertainties in our ability to maintain key business relationships of any acquired entities;

strain on managerial and operational resources;

- difficulty implementing and maintaining effective internal control over financial reporting at businesses that we acquire, particularly if they are not located near our existing operations;

- exposure to unforeseen liabilities of acquired companies or companies in which we invest; and

- potential costly and time-consuming litigation, including stockholder lawsuits.

As a result of these or other problems and risks, businesses, technologies or products we acquire or invest in or obtain licenses to may not produce the revenues, earnings or business synergies that we anticipated, acquired or licensed technologies may not result in regulatory approvals, and acquired or licensed products may not perform as expected. As a result, we may incur higher costs and realize lower revenues than we had anticipated. We cannot assure you that any acquisitions or investments we have made or may make in the future will be completed or that, if completed, the acquired business, licenses, investments, products, or technologies will generate sufficient revenue to offset the negative costs or other negative effects on our business. Failure to manage effectively our growth through acquisition or in-licensing transactions could adversely affect our growth prospects, business, results of operations, financial condition, and cash flow.

In addition, we may spend significant amounts, issue dilutive securities, assume or incur significant debt obligations, incur large one-time expenses and acquire intangible assets in connection with acquisitions and in-licensing transactions that could result in significant future amortization expense and write-offs. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Other pharmaceutical companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for these opportunities. Even if appropriate opportunities are available, we may not be able to successfully identify them or we may not have the financial resources necessary to pursue them, and if pursued, we may be unable to structure and execute transactions in the anticipated timeframe, or at all.

Even if we are able to successfully identify and acquire complementary products, technologies or businesses, we cannot assure you that we will be able to successfully manage the risks associated with integrating acquired products, technologies or businesses or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing transaction. Further, while we seek to mitigate risks and liabilities of potential acquisitions and in-licensing transactions through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business. Additionally, we may not realize the anticipated benefits of such transactions, including the possibility that expected synergies and accretion will not be realized or will not be realized within the expected time frame.

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

Our clinical-stage product candidates include seven ADC programs, which consist of enfortumab vedotin, tisotumab vedotin, SGN-LIV1A, SGN-CD19A, SGN-CD19B, SGN-CD123A, and SGN-352A, as well as two immuno-oncology agents, SEA-CD40, which is based on our sugar-engineered antibody, or SEA, technology, and SGN-2FF, which is a novel small molecule. Other than enfortumab vedotin and tisotumab vedotin, which are in or expected to enter pivotal trials based on only limited phase 1 clinical data, our current product candidates are in relatively early stages of development. All of our product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all.

If a product candidate fails at any stage of development or we or our collaborators 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. Moreover, we still have only limited data from our early trials of our product candidates. In this regard, preclinical studies and any encouraging or positive preliminary and interim data from our clinical trials of our product candidates may not be predictive of the results of ongoing or later clinical trials. Even if we or our collaborators are able to complete our planned clinical trials of our product candidates according to our current development timeline, the encouraging or positive results from clinical trials of our product candidates in earlier stage trials may not be replicated in subsequent clinical trial results. As a result, we and our collaborators 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 or could cause us to discontinue the development of such product candidate. Also, later-stage clinical trials could differ in significant ways from earlier stage clinical trials, which could cause the outcome of the later-stage trials to differ from earlier stage clinical trials. For example, we are conducting a pivotal phase 2 trial of enfortumab vedotin with Astellas for locally advanced or metastatic urothelial cancer patients who have been previously treated with checkpoint inhibitor therapy, and plan to conduct a pivotal phase 2 trial of tisotumab vedotin with Genmab in patients with recurrent and/or metastatic cervical cancer, in each case based on only limited phase 1 clinical data. Neither enfortumab vedotin nor tisotumab vedotin have previously been evaluated in later stage clinical trials

and we cannot be certain that the design of, or data collected from, these trials will be adequate to demonstrate the safety and efficacy of enfortumab vedotin or tisotumab vedotin, or will otherwise be sufficient to support FDA or any foreign regulatory approvals. Differences in earlier and later stage clinical trials may include changes to inclusion and exclusion criteria, efficacy endpoints and statistical design. Many companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in late-stage clinical trials after achieving encouraging or positive results in early-stage development. We cannot be certain that we will not face similar setbacks in our ongoing or planned clinical trials, including the ongoing and planned pivotal phase 2 trials for enfortumab vedotin and tisotumab vedotin. We have not yet completed any late-stage clinical trials for our current product candidates, and if we or our collaborators fail to produce positive results in our ongoing or planned clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

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 preclinical product candidates.

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 or changes in their product development or business strategy 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 we market ADCETRIS in the United States and Canada, our revenues still depend in part on Takeda s ability and willingness to market ADCETRIS outside of the United States and Canada. The loss of our collaborators, especially Takeda, changes in product development or business strategies of our collaborators, or the failure of our collaborators to perform their obligations under their agreements with us for any reason, 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 potential 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.

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

and our product candidates.

Although we recently acquired a biologics manufacturing facility located in Bothell, Washington, we rely and expect to continue to rely on corporate collaborators and contract manufacturing organizations to supply drug product or intermediates 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.

We are planning to use our own manufacturing facility to support our growing pipeline. As an organization, we have no prior experience operating a manufacturing facility.

In October 2017, we acquired a biologics manufacturing facility located in Bothell, Washington, which facility we intend to use to support our clinical supply needs. Under the terms of this acquisition, we are required to operate the facility and produce certain clinical drug product components for BMS under a transitional services agreement for a period of time. As an organization, we have no prior experience manufacturing for ourselves or other parties, and operating this facility requires us to comply with complex regulations and to continue to hire and retain experienced scientific, quality control, quality assurance and manufacturing personnel. We could encounter challenges in operating the manufacturing facility in compliance with cGMP, regulatory or other applicable requirements, resulting in potential negative consequences, including regulatory actions, which could undermine our ability to utilize this facility for our own manufacturing needs and/or result in a breach of our contractual manufacturing obligations to BMS. Any of these risks, if actualized, could materially and adversely affect our business and financial position. In addition, despite the acquisition of this facility, we nonetheless expect to continue to rely on corporate collaborators and contract manufacturing organizations to supply drug product and intermediates for commercial supply and our IND-enabling studies and clinical trials. Our continuing dependence on these manufacturers may impair the continued development and commercialization of ADCETRIS and our product candidates.

We are subject to various state and federal laws and regulations, including healthcare laws and regulations, that may impact our business and could subject us to significant fines and penalties or other negative consequences.

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 PPACA. These laws may impact, among other things, the sales, marketing and education programs for ADCETRIS.

The federal Anti-Kickback Statute prohibits persons and entities 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, including the civil False Claims Act, 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. Many pharmaceutical and other healthcare companies have recently been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing or other activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company s products; and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs.

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, 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, and its implementing regulations, governs certain types of individuals and entities with respect to the conduct of certain electronic healthcare transactions and imposes certain obligations with respect to 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, the Physician Payments Sunshine Act, require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children s Health Insurance Program to annually report to the U.S. Department of Health and Human Services Centers for Medicare & Medicaid 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 and regulations, such as anti-kickback, false claims, and data privacy and security laws, to which we are currently and/or 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 FDA and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. In recent years, private whistleblowers have also pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of off-label promotion. 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.

We are also subject to numerous other laws and regulations that are not specific to the healthcare industry. For instance, 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 number and complexity of both U.S. federal and state laws continue to increase. In addition to enforcement by governmental agencies, we also expect a continuation of the trend of private plaintiff lawsuits against pharmaceutical manufacturers under the whistleblower provisions of the False Claims Act and state equivalents or other laws and regulations such as securities rules and the evolution of new theories of liability under those statutes. Government agencies will likely continue to intervene in such private whistleblower lawsuits and such intervention typically raises the company s cost significantly. For example, federal enforcement agencies have recently scrutinized product and patient assistance programs, including manufacturer reimbursement support services as well as relationships with specialty pharmacies. Several investigations have resulted in government enforcement authorities intervening in related whistleblower lawsuits and obtaining significant civil and criminal settlements.

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 these laws and regulations, we cannot guarantee that our compliance program will be sufficient or effective, that our employees will comply with our policies and that our employees will notify us of any violation of our policies, that

we will have the ability to take appropriate and timely corrective action in response to any such violation, or that we will make decisions and take actions that will necessarily limit or avoid liability for whistleblower claims that individuals, such as employees or former employees, may bring against us or that governmental authorities may prosecute against us based on information provided by individuals. If we are found to be in violation of any of the laws and regulations described above or other applicable state and federal healthcare laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, imprisonment, diminished profits and future earnings, exclusion from government healthcare reimbursement programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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 are 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 are expanding our operations internationally, and we currently have subsidiaries in the U.K., Switzerland and Canada. 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.

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

ADCETRIS and our enfortumab vedotin, tisotumab vedotin, SGN-LIV1A, SGN-CD19A, SGN-CD19B, SGN-CD123A, and SGN-CD352A 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, Astellas, Bayer, Celldex, Genentech, GSK, Pfizer, and Progenics, and our collaboration agreements with Takeda, Astellas, and Genmab. 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. In addition, certain of our ADC product candidates include additional proprietary technologies that have not yet been proven in late stage clinical development. Any failures or further setbacks in our ADC development program or with respect to our additional proprietary technologies, including adverse effects resulting from the use of this technology in human clinical trials and/or the imposition of additional clinical holds on our trials of any of our other product candidates, 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.

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We have been named a defendant in a purported securities class action lawsuit and a stockholder derivative lawsuit. These, and potential similar or related lawsuits, could result in substantial damages and may divert management s time and attention from our business.

On January 10, 2017, a purported securities class action lawsuit was commenced in the United States District Court for the Western District of Washington, naming as defendants us and certain of our officers. The lawsuit alleges material misrepresentations and omissions in public statements regarding our business, operational and compliance policies, violations by all named defendants of Section 10(b) of the Exchange Act, and Rule 10b-5 thereunder, as well as violations of Section 20(a) of the Exchange Act. The complaint seeks compensatory damages of an undisclosed amount. The plaintiff alleges, among other things, that we made false and/or misleading statements and/or failed to disclose that SGN-CD33A presents a significant risk of fatal hepatotoxicity and that we had therefore overstated the viability of SGN-CD33A as a treatment for AML. It is possible that additional suits will be filed, or allegations received from stockholders, with respect to these same matters and also naming us and/or our officers and directors as defendants.

On March 29, 2017, a stockholder derivative lawsuit was filed in Washington Superior Court for the County of Snohomish. The complaint names as defendants certain of our current and former executives and members of our board of directors. We are named as a nominal defendant. The complaint generally makes the same allegations as the securities class action, claiming that the individual defendants breached their duties to us. The complaint seeks unspecified damages, disgorgement of compensation, corporate governance changes, and attorneys fees and costs. Because the complaint is derivative in nature, it does not seek monetary damages from us.

These lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual costs to be incurred relating to the lawsuits will depend upon many unknown factors. The outcome of these lawsuits is necessarily uncertain, and we could be forced to expend significant resources in the defense of these lawsuits, and we may not prevail. Monitoring and defending against legal actions is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities, which could result in delays of our clinical trials or our development and commercialization efforts. In addition, we may incur substantial legal fees and costs in connection with these lawsuits. We are also generally obligated, to the extent permitted by law, to indemnify our current and former directors and officers who are named as defendants in these and similar lawsuits. We are not currently able to estimate the possible cost to us from these matters, as these lawsuits are currently at an early stage and we cannot be certain how long it may take to resolve these matters or the possible amount of any damages that we may be required to pay. We have not established any reserves for any potential liability relating to these lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. Decisions adverse to our interests in these lawsuits could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our cash flow, results of operations and financial position. In addition, the uncertainty of the currently pending litigation could lead to increased volatility in our stock price.

We may need to raise significant amounts of additional capital 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, support our preclinical development, manufacturing and clinical trial activities for ADCETRIS and our other pipeline programs, and expand internationally, as well as commercialize ADCETRIS and position ADCETRIS for potential additional regulatory approvals. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS, and the research, continued development and manufacturing of our product candidates will likely require us to raise substantial amounts of additional capital. Further, we actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses, and we may require significant additional capital in

order to complete or otherwise provide funding for any additional acquisitions. We may seek additional funding through some or all of the following methods: corporate collaborations, licensing arrangements and public or private debt or equity financings. We do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may 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;
- the rate of progress and cost of the confirmatory post-approval study that we are required to conduct as a condition to the FDA s accelerated approval of ADCETRIS in the relapsed sALCL indication;
- 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 and our collaborations;

- 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, as well as licenses we may need to commercialize our products;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- expenses associated with the pending and potential additional related purported securities class action or derivative lawsuits, as well as any other potential litigation;
- the potential costs associated with international, state and federal taxes; and
- competing technological and market developments.

In addition, changes in our spending rate may occur that would consume available capital resources sooner, such as increased development, manufacturing and clinical trial expenses in connection with our expanding pipeline programs, or our undertaking of additional programs, business activities or entry into strategic transactions, including potential additional acquisitions of products, technologies or businesses. 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.

During the past several years, domestic and international financial markets have experienced extreme disruption from time to time, including, among other things, high volatility and significant declines in stock prices and severely diminished liquidity and credit availability for both borrowers and investors. Such adverse capital and credit market conditions could make it more difficult to obtain additional capital on favorable terms, or at all, which could have a material adverse effect on our business and growth prospects.

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 BMS and the University of Miami, among others. In addition to royalty provisions, some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon royalty or 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 have had in the past, and may in the future 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. An adverse result in 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.

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 successfully commercialize ADCETRIS or future products 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 third parties. 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, or USPTO, 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 have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our products. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the United States or other countries may be applied retroactively to affect the validation enforceability, or term of our patent. For example, the U.S. Supreme Court has recently modified some legal standards applied by the USPTO 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, and post-grant review and covered business methods. These proceedings are conducted before the Patent Trial and Appeal Board, or PTAB, of the 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 some patents on the grounds that it was anticipated or made obvious by prior art. As a result, non-practicing entities associated with hedge funds, pharmaceutical companies who may be our competitors and others have challenged certain valuable pharmaceutical U.S. 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 any other potential future changes to the U.S. patent system 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.

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. 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. Our challenges to patents of other

organizations may not be successful, which may affect our ability to commercialize ADCETRIS or our product candidates. 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 lost profits, royalties, 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 or may be 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, IPR, post-grant review 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, not infringed 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 at the PTAB, whether they are accused of infringing our patents or not, and certain entities associated with hedge funds,

pharmaceutical companies and other entities have challenged 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 not infringed or otherwise not enforceable, or that the PTAB will decide that certain patents are not valid or should have a shorter term, 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.

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 continue to commercialize ADCETRIS and advance our pipeline, we have been required to expand our workforce, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, sales and marketing. 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. For example, we may not be successful in attracting or retaining key personnel necessary to support our strategy to develop and commercialize ADCETRIS in earlier lines of therapy, including potentially in the ECHELON-1 treatment setting.

If we are unable to manage our growth, our business, financial condition, results of operations and prospects may be adversely affected.

We have experienced and expect to continue to experience significant growth in the number of our employees and in the scope of our operations, including in connection with our recent acquisition of, and planned operation of, a manufacturing facility. This growth places significant demands on our management, operational and financial resources, and our current and planned personnel, systems, procedures and controls may not be adequate to support our growth. To effectively manage our growth, we must continue to improve existing, and implement new, operational and financial systems, procedures and controls and must expand, train and manage our growing employee base, and there can be no assurance that we will effectively manage our growth without experiencing operating inefficiencies or control deficiencies. We expect that we may need to increase our management personnel to oversee our expanding operations, and recruiting and retaining qualified individuals is difficult. In addition, the physical

expansion of our operations may lead to significant costs and may divert our management and capital resources. If we are unable to manage our growth effectively, or are unsuccessful in recruiting qualified management personnel, our business, financial condition, results of operations and prospects may be adversely affected.

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 have and may in the future be made directly by patients or healthcare providers or indirectly by pharmaceutical companies, our corporate collaborators or others selling such products. Additionally, in connection with our acquisition of the manufacturing facility from BMS, we have agreed to enter into certain transitional services agreements under which we expect to manufacture certain clinical drug product components for BMS for a period of time. As a result, it is possible that we may be named as a defendant in product liability suits that may allege that drug products we manufacture for BMS have resulted in injury to patients. We may experience substantial financial losses in the future due to product liability claims. We have obtained product liability coverage, including coverage for human clinical trials and product sold commercially. 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 amounts, 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 are expanding 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;
- adverse tax consequences, including changes in applicable tax laws and regulations;
- 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;
- 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.

For example, since a significant proportion of the regulatory framework in the U.K. is derived from European Union directives and regulations, Brexit could materially change the regulatory regime applicable to our operations and those

of our collaborators, including with respect to marketing authorizations for ADCETRIS and our product candidates. We may also face new regulatory costs and challenges as result of Brexit that could have a material adverse effect on our operations. Depending on the terms of Brexit, the U.K. could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers which could make our doing business in Europe more difficult. In addition, currency exchange rates for the British Pound and the Euro with respect to each other and the U.S. dollar have already been affected by Brexit. Should this foreign exchange volatility continue, it could cause volatility in our quarterly financial results. In any event, we cannot predict to what extent these changes will impact our business or results of operations, or our ability to conduct operations in Europe.

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 addition, with respect to our recently-acquired manufacturing facility, we may incur substantial costs to comply with environmental laws and regulations and may become subject to the risk of accidental contamination or injury from the use of hazardous materials in our manufacturing process. It is also possible that our recently-acquired manufacturing facility may expose us to environmental liabilities associated with historical site conditions that we are not currently aware of and did not cause. In this regard, some environmental laws impose liability for contamination on current owners and operators of affected sites, regardless of fault. In the event of an accident or environmental discharge, or new or previously unknown contamination is discovered or new cleanup obligations are otherwise imposed in connection with any of our currently or previously owned or operated facilities, we may be held liable for any resulting damages, which may materially harm our business, financial condition and results of operations.

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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, capture laboratory data, maintain clinical trial data 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 or other disruptive events including but not limited to natural disaster. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors, it could delay or negatively impact the development and commercialization of ADCETRIS and our product candidates, which could adversely impact our business. 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. In addition, our information technology systems are potentially vulnerable to data security breaches whether by employees or others which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, customers and others, any of which could have a material adverse effect on our business, financial condition and results of operations. Moreover, a security breach or privacy violation that leads to disclosure or modification of, personally identifiable information, could harm our reputation, compel us to comply with federal and/or state breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. In addition, a data security breach could result in loss of clinical trial data or damage to the integrity of that data. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other negative consequences because of lost or misappropriated information. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Increasing use of social media could give rise to liability.

We are increasingly relying on social media tools as a means of communications. To the extent that we continue to use these tools as a means to communicate about ADCETRIS and our product candidates or about the diseases that ADCETRIS and our product candidates are intended to treat, there are significant uncertainties as to either the rules that apply to such communications, or as to the interpretations that health authorities will apply to the rules that exist. As a result, despite our efforts to comply with applicable rules, there is a significant risk that our use of social media for such purposes may cause us to nonetheless be found in violation of them. Such uses of social media could have a material adverse effect on our business, financial condition and results of operations.

Legislative actions and new accounting pronouncements are likely to impact our future financial position or results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future and as a result we may be required to make changes in our accounting policies. Those changes could adversely affect our reported revenues and expenses, future profitability or financial position. Compliance with new regulations regarding corporate governance and public disclosure may result in additional expenses.

For example, in May 2014, the Financial Accounting Standards Board, or FASB, issued an Accounting Standards Update entitled ASU 2014-09, Revenue from Contracts with Customers which will replace the existing revenue recognition guidance in U.S. GAAP when it becomes effective for us on January 1, 2018. Our preliminary assessment of this new standard is that it will generally not change the way in which we recognize product revenue from sales of ADCETRIS. However, we expect that sales-based royalties and commercial sales-based milestones will be recorded in the period of the related sale based on estimates, rather than recording them as reported by the customer. In addition, the achievement of development milestones under our collaborations will be recorded in the period their achievement becomes probable, which may result in their recognition earlier than under current accounting principles. We are continuing to evaluate the impact of the new standard on all of our revenues, including those mentioned above, and our assessments may change in the future based on our continuing evaluation. Additionally, beginning in 2018, we will

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adopt ASU 2016-01 Financial Instruments: Overall, and as a result, we will record changes in the fair value of equity securities, including our investments in Immunomedics securities, in net income or loss. In any event, the application of existing or future financial accounting standards, particularly those relating to the way we account for revenues and costs, could have a significant impact on our reported results. In addition, compliance with new regulations regarding corporate governance and public disclosure may result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from science and business activities to compliance activities.

Risks Related to Our Common Stock

Our stock price is volatile and our shares may suffer a decline in value.

The market price of our stock has in the past been, and is likely to continue in the future to be, very volatile. During the third quarter of 2017, our closing stock price fluctuated between $45.92 and $55.02 per share. As a result of fluctuations in the price of our common stock, you may be unable to sell your shares at or above the price you paid for them. The market price of our common stock may be subject to substantial volatility in response to many risk factors listed in this section, and others beyond our control, including:

- the level of ADCETRIS sales in the United States, Canada, the European Union, Japan and other countries in which Takeda has received approval by relevant regulatory authorities;
- announcements regarding the results of discovery efforts and preclinical, clinical and commercial activities by us, or those of our competitors;
- announcements of FDA or foreign regulatory approval or non-approval of ADCETRIS, or specific label indications for or restrictions, warnings or limitations in its use, or delays in the regulatory review or approval process, including in connection with our sBLA submissions to the FDA to seek approval of ADCETRIS in the ALCANZA and ECHELON-1 treatment settings;
- announcements regarding the results of the clinical trials we, Takeda and/or BMS are conducting or may in the future conduct for ADCETRIS, including the ECHELON-2 phase 3 trial and the CHECKMATE 812 trial;
- announcements regarding the results of the clinical trials we and our collaborators are conducting for enfortumab vedotin and tisotumab vedotin;
- announcements regarding, or negative publicity concerning, adverse events or safety concerns associated with the use of ADCETRIS or our product candidates;

- issuance of new or changed analysts reports and recommendations regarding us or our competitors;
- termination of or changes in our existing collaborations or licensing arrangements, especially our ADCETRIS collaboration with Takeda, our enfortumab vedotin collaboration with Astellas, and our tisotumab vedotin collaboration with Genmab, or establishment of new collaborations or licensing arrangements;
- our entry into additional material strategic transactions including licensing or acquisition of products, businesses or technologies;
- actions taken by regulatory authorities with respect to our product candidates, our clinical trials or our regulatory filings;
- our raising of additional capital and the terms upon which we may raise any additional capital;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- developments or disputes concerning our proprietary rights;
- developments regarding the pending and potential additional related purported securities class action lawsuits, as well as any other potential litigation;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- changes in government regulations; and
- economic or other external factors.

The stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, as a result of

Brexit and/or significant changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade and health care spending and delivery, including the possible repeal and/or replacement of all or portions of PPACA or greater restrictions on free trade stemming from Trump Administration policies, the financial markets could experience significant volatility that could also negatively impact the markets for biotechnology and pharmaceutical stocks. These broad market fluctuations have adversely affected and may in the future adversely affect the trading price of our common stock.

In the past, class action or derivative litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. In this regard, we have become, and may in the future again become, subject to claims and litigation alleging violations of the securities laws or other related claims, which could harm our business and require us to incur significant costs. The pending purported securities class action lawsuit and any additional lawsuits brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management s attention and resources, which could result in delays of our clinical trials or our development and commercialization efforts.

Substantial future sales of shares of our common stock or equity-related securities could cause the market price of our common stock to decline.

Sales of a substantial number of shares of our common stock into the public market, including sales by members of our management or board of directors or entities affiliated with such members, could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-related securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of November 1, 2017, we had 143,928,341 shares of common stock outstanding, all of which shares are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144. In addition, we may issue a substantial number of shares of our common stock or equity- related securities, including convertible debt, to meet our capital needs, including in connection with funding acquisition or licensing opportunities, capital expenditures or product development costs, which issuances could be substantially dilutive and could adversely affect the market price of our common stock. Likewise, future issuances by us of our common stock upon the exercise, conversion or settlement of equity-based awards or other equity-related securities would dilute existing stockholders ownership interest in our company and any sales in the public market of these shares, or the perception that these sales might occur, could also adversely affect the market price of our common stock.

Moreover, we have in the past and may in the future grant rights to some of our stockholders that require us to register the resale of our common stock or other securities on behalf of these stockholders and/or facilitate public offerings of our securities held by these stockholders, including in connection with potential future acquisition or capital-raising transactions. For example, in connection with our September 2015 public offering of common stock, we entered into a registration rights agreement with entities affiliated with Baker Bros. Advisors LP, or the Baker Entities, that together, based on information available to us, collectively beneficially owned approximately 32.0% of our common stock as of November 1, 2017. Under the registration rights agreement, if at any time and from time to time the Baker Entities demand that we register their shares of our common stock for resale under the Securities Act of 1933, we would be obligated to effect such registration. On October 12, 2016, pursuant to the registration rights agreement, we registered for resale, from time to time, up to 44,059,594 shares of our common stock held by the Baker Entities. Our registration obligations under the registration rights agreement cover all shares now held or hereafter acquired 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. If the Baker Entities, by its exercise of these registration and/or underwriting rights in the future, or otherwise, sell a large number of our shares, or the market

perceives that the Baker Entities intend to sell a large number of our shares, including in connection with our October 2016 registration of shares held by the Baker Entities for resale, this could adversely affect the market price of our common stock. We have also filed registration statements to register the sale of our common stock reserved for issuance under our equity incentive and employee stock purchase plans. Accordingly, these shares will be able to be freely sold in the public market upon issuance as permitted by any applicable vesting requirements.

Our existing stockholders have significant control of our management and affairs.

Our executive officers and directors and holders of greater than five percent of our outstanding voting stock, together with entities that may be deemed affiliates of, or related to, such persons or entities, beneficially owned approximately 69.5% of our voting power as of November 1, 2017. As a result, these stockholders, acting together, are able to control our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, including a merger, consolidation, takeover or other business combination involving us or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control, which might affect the market price of our common stock.

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Anti-takeover provisions could make it more difficult for a third party to acquire us.

Our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders, which authority could be used to adopt a poison pill that could act to prevent a change of control of Seattle Genetics that has not been approved by our Board of Directors. The rights of the holders of common stock may be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control of Seattle Genetics without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. Further, certain provisions of our charter documents, including provisions eliminating the ability of stockholders to take action by written consent and limiting the ability of stockholders to raise matters at a meeting of stockholders without giving advance notice, may have the effect of delaying or preventing changes in control or management of Seattle Genetics, which could have an adverse effect on the market price of our stock. In addition, our charter documents provide for a classified board, which may make it more difficult for a third party to gain control of our Board of Directors. Similarly, state anti-takeover laws in Delaware and Washington related to corporate takeovers may prevent or delay a change of control of Seattle Genetics.

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Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation By Reference Form	SEC File No.	Exhibit	Filing Date
2.1+ **	Asset Purchase Agreement, dated July 31, 2017, between Bristol-Myers Squibb Company and Seattle Genetics, Inc.				
3.1	Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.	10-Q	000-32405	3.1	11/07/2008
3.2	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.	8-K	000-32405	3.3	05/26/2011
3.3	Amended and Restated Bylaws of Seattle Genetics, Inc.	8-K	000-32405	3.1	11/25/2015
4.1	Specimen Stock Certificate.	S-1/A	333-50266	4.1	02/08/2001
4.2	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.	10-Q	000-32405	4.3	11/07/2008
4.3	Registration Rights Agreement, dated September 10, 2015, between Seattle Genetics, Inc. and the persons listed on Schedule A attached thereto.	8-K	000-32405	10.1	9/11/2015
10.1+	Purchase Agreement, dated June 16, 2017, between BMR-3450 Monte Villa Parkway, LLC and ZymoGenetics, Inc.				
10.2+	Assignment and Assumption of Purchase Agreement, dated July 30, 2017, between ZymoGenetics, Inc. and Seattle Genetics, Inc.				
10.3+	License and Collaboration Agreement, effective October 7, 2011, between Genmab A/S and Seattle Genetics, Inc.				
10.4*+	Seattle Genetics, Inc. Long Term Incentive Plan for TV and EV				
10.5*+	Form of Stock Unit Grant Notice for Long Term Incentive Plan for TV and EV				
10.6*+	Form Stock Unit Grant Notice for Non-US Participants Long Term Incentive Plan for TV and EV				
31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).				
31.2+					

	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS+	XBRL Instance Document.
101.SCH+	XBRL Taxonomy Extension Schema Document.
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document.

\+ Filed herewith.
Pursuant to a request for confidential treatment, portions of this Exhibit have been redacted from the publicly filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934.

* Indicates a management contract or compensatory plan or arrangement.

** Schedules to the Asset Purchase Agreement, dated July 31, 2017, between Bristol-Myers Squibb Company and Seattle Genetics, Inc. have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The registrant will furnish copies of any such schedules to the Securities and Exchange Commission upon request.

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SIGNATURE

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

SEATTLE GENETICS, INC.

By: **/s/ TODD E. SIMPSON**
Todd E. Simpson
Duly Authorized and Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: November 6, 2017