SEATTLE GENETICS INC /WA
Form 10-Q
April 26, 2019
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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 March 31, 2019
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 incorporation or organization)	(I.R.S. Employer 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 every Interactive Data File required to be submitted 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 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	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 April 22, 2019, there were 161,314,623 shares of the registrant's common stock outstanding.

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For the Quarter Ended March 31, 2019
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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)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$84,270	$78,186
Short-term investments	334,025	332,486
Accounts receivable, net	156,955	146,281
Inventories	67,236	53,239
Prepaid expenses and other current assets	37,306	43,403
Total current assets	679,792	653,595
Property and equipment, net	114,604	103,820
Operating lease right-of-use assets	59,341	—
Long-term investments	—	49,194
In-process research and development	300,000	300,000
Goodwill	274,671	274,671
Other non-current assets	164,196	122,049
Total assets	$1,592,604	$1,503,329
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$38,772	$44,179
Accrued liabilities and other	142,187	147,293
Current portion of deferred revenue	26,910	33,600
Total current liabilities	207,869	225,072
Long-term liabilities:		
Operating lease liabilities, long-term	61,026	—
Other long-term liabilities	10,298	4,314
Total long-term liabilities	71,324	4,314
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000 shares authorized; none issued	—	—
Common stock, $0.001 par value, 250,000 shares authorized; 161,141 shares issued and outstanding at March 31, 2019 and 160,262 shares issued and outstanding at December 31, 2018	161	160
Additional paid-in capital	2,650,951	2,598,411
Accumulated other comprehensive income (loss)	216	(40)
Accumulated deficit	(1,337,917)	(1,324,588)
Total stockholders' equity	1,313,411	1,273,943
Total liabilities and stockholders' equity	$1,592,604	$1,503,329

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 March 31,	
	2019	2018
Revenues:		
Net product sales	$135,001	$95,357
Collaboration and license agreement revenues	44,578	29,559
Royalty revenues	15,620	15,674
Total revenues	195,199	140,590
Costs and expenses:		
Cost of sales	7,911	10,358
Cost of royalty revenues	2,389	5,377
Research and development	158,265	152,502
Selling, general and administrative	80,271	66,182
Total costs and expenses	248,836	234,419
Loss from operations	(53,637)	(93,829)
Investment and other income (loss), net	40,308	(17,886)
Net loss	$(13,329)	$(111,715)
Net loss per share - basic and diluted	$(0.08)	$(0.73)
Shares used in computation of per share amounts - basic and diluted	160,657	152,049
Comprehensive loss:		
Net loss	$(13,329)	$(111,715)
Other comprehensive income:		
Unrealized gain on securities available-for-sale, net of tax	222	27
Foreign currency translation gain (loss)	34	(8)
Total other comprehensive income	256	19
Comprehensive loss	$(13,073)	$(111,696)

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

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Seattle Genetics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands)

	Common stock					
	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
Balances as of December 31, 2017	144,395	$ 144	$1,806,159	$ 63,836	$(1,192,570)	$677,569
Net loss	—	—	—	—	(111,715)	(111,715)
Other comprehensive income	—	—	—	19	—	19
Cumulative effects of accounting changes	—	—	—	(64,119)	90,675	26,556
Issuance of common stock for employee stock purchase plan	106	—	4,424	—	—	4,424
Stock option exercises	375	1	7,480	—	—	7,481
Restricted stock vested during the period, net	24	—	—	—	—	—
Issuance of common stock	13,269	13	658,152	—	—	658,165
Share-based compensation	—	—	16,838	—	—	16,838
Balances as of March 31, 2018	158,169	$ 158	$2,493,053	$ (264)	$(1,213,610)	$1,279,337
Balances as of December 31, 2018	160,262	$ 160	$2,598,411	$ (40)	$(1,324,588)	$1,273,943
Net loss	—	—	—	—	(13,329)	(13,329)
Other comprehensive income	—	—	—	256	—	256
Issuance of common stock for employee stock purchase plan	104	—	6,147	—	—	6,147
Stock option exercises	719	1	20,678	—	—	20,679
Restricted stock vested during the period, net	56	—	—	—	—	—
Share-based compensation	—	—	25,715	—	—	25,715
Balances as of March 31, 2019	161,141	$ 161	$2,650,951	$ 216	$(1,337,917)	$1,313,411

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)

	Three Months Ended March 31,	
	2019	2018
Operating activities:		
Net loss	$(13,329)	$(111,715)
Adjustments to reconcile net loss to net cash used by operating activities		
Share-based compensation	25,715	16,838
Depreciation and amortization	4,944	6,864
Amortization of right-of-use assets	2,421	—
(Gains) losses on equity securities	(38,125)	18,825
Changes in operating assets and liabilities		
Accounts receivable, net	(10,674)	(17,531)
Inventories	(13,997)	(11,937)
Prepaid expenses and other assets	7,402	(11,529)
Lease liability	(2,484)	—
Deferred revenue	(6,690)	(8,350)
Other liabilities	(12,410)	(28,629)
Net cash used by operating activities	(57,227)	(147,164)
Investing activities:		
Purchases of securities	(78,481)	(62,628)
Proceeds from maturities of securities	127,500	120,022
Proceeds from sales of securities	—	48,469
Purchases of property and equipment	(12,534)	(4,673)
Acquisition of Cascadian Therapeutics, Inc., net of cash acquired	—	(598,151)
Net cash provided (used) by investing activities	36,485	(496,961)
Financing activities:		
Net proceeds from issuance of common stock	—	658,165
Proceeds from exercise of stock options and employee stock purchase plan	26,826	11,905
Net cash provided by financing activities	26,826	670,070
Net increase in cash and cash equivalents	6,084	25,945
Cash and cash equivalents at beginning of period	78,186	160,945
Cash and cash equivalents at end of period	$84,270	$186,890

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," "we," "our," or "us"). All intercompany transactions and balances have been eliminated. We acquired Cascadian Therapeutics, Inc., or Cascadian, in March 2018, as further described in Note 4. Management has determined that we operate in one segment: the development and sale of pharmaceutical products on our own behalf or in collaboration with others. Substantially all of our assets and revenues are related to operations in the U.S.; however, we also have subsidiaries in Australia, Canada, Ireland, Luxembourg, the Netherlands, Switzerland, and the United Kingdom.

The condensed consolidated balance sheet data as of December 31, 2018 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 that, in the opinion of management, are necessary for a fair statement of our financial position and results of our operations as of and for the periods presented.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC.

The preparation of financial statements in accordance with GAAP requires us to make estimates, assumptions, and judgments that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The results of our operations for the three month period ended March 31, 2019 are not necessarily indicative of the results to be expected for the full year or any other interim period.

Non-cash financing and investing activities

We had $8.9 million and $4.6 million of accrued capital expenditures as of March 31, 2019 and December 31, 2018, 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. During the three months ended March 31, 2019, the Company acquired $27.1 million right-of-use assets in exchange for lease liabilities. Refer to Note 3.

Investments

We hold certain equity securities that we acquired in connection with strategic agreements, which are reported at estimated fair value. Changes in the fair value of equity securities are recorded in income or loss. The cost of equity securities for purposes of computing gains and losses is based on the specific identification method.

We invest our available cash primarily in debt securities. These debt 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 and loss in stockholders' equity. Realized gains, realized losses and declines in the value of debt securities judged to be other-than-temporary are included in investment and other income, net. The cost of debt securities 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 are included in investment and other income, net. We classify 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.

If the estimated fair value of a debt security is below its carrying value, we evaluate whether it is more likely than not that we 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. We also evaluate whether or not we intend 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, we consider 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 included in investment and other income, net.

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Leases

We adopted Accounting Standards Update, or "ASU 2016-02, Leases" on January 1, 2019. As a result of this standard, we recorded a liability to make lease payments and a right-of-use, asset representing its right to use the underlying asset for the lease term in our condensed consolidated balance sheet. We elected the modified retrospective method transition option, which permitted us not to restate the comparative period presented.

We elected the "package of practical expedients", which permitted us not to reassess under the standard our prior conclusion about lease identification, lease classification and initial direct cost. We also elected the practical expedient to not separate lease and non-lease components for our real estate leases, and elected the short-term lease recognition exemption for our short-term leases, which allows us not to recognize lease liabilities and right-of-use assets on our consolidated balance sheet for leases with an original term of twelve months or less.

The standard had a material impact on our condensed consolidated balance sheet, did not have an impact on our condensed consolidated statement of comprehensive loss, and there was no cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Refer to Note 3 for additional information.

We determine if an arrangement is a lease at inception date. All of our leases are classified as operating leases. Operating lease liabilities and the corresponding right-of-use assets are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The operating lease right-of-use asset also excludes lease incentives and initial direct costs incurred. As our existing leases do not contain an implicit interest rate, we estimate our incremental borrowing rate based on information available at commencement date in determining the present value of future payments. We include options to extend the lease in our lease liability and right-of-use asset when it is reasonably certain that we will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. For our short-term leases, we recognize lease payments as an expense on a straight-line base over the lease term.

Business combinations, including acquired in-process research and development and goodwill

We account for business combinations using the acquisition method, recording the acquisition-date fair value of total consideration over the acquisition-date fair value of net assets acquired as goodwill.

Fair value is typically estimated using an income approach based on the present value of future discounted cash flows. The significant estimates in the discounted cash flow model primarily include the discount rate, and rates of future revenue and expense growth and/or profitability of the acquired business. The discount rate considers the relevant risk associated with business-specific characteristics and the uncertainty related to the ability to achieve the projected cash flows. We may record adjustments to the fair values of assets acquired and liabilities assumed within the measurement period (up to one year from the acquisition date).

In-process research and development assets are accounted for as indefinite-lived intangible assets and maintained on the balance sheet until either the underlying project is completed or the asset becomes impaired. If the project is completed, the carrying value of the related intangible asset is amortized to cost of sales over the remaining estimated life of the asset beginning in the period in which the project is completed. If the asset becomes impaired or is abandoned, the carrying value of the related intangible asset is written down to its fair value and an impairment charge is recorded in the period in which the impairment occurs.

We evaluate indefinite-lived intangible assets and goodwill for impairment annually, as of October 1, or more frequently when events or circumstances indicate that impairment may have occurred. As part of the impairment evaluation, we may elect to perform an assessment of qualitative factors. If this qualitative assessment indicates that it is more likely than not that the fair value of the indefinite-lived intangible asset or the reporting unit (for goodwill) is less than its carrying value, we then would proceed with the quantitative impairment test to compare the fair value to the carrying value and record an impairment charge if the carrying value exceeds the fair value.

Acquisition-related costs, including banking, legal, accounting, valuation, and other similar costs, are expensed in the periods in which the costs are incurred and included in loss from operations in the consolidated financial statements. The results of operations of the acquired business are included in the consolidated financial statements from the acquisition date.

Long-term incentive plans

We have established Long-Term Incentive Plans, or LTIPs. The LTIPs provide eligible employees with the opportunity to receive performance-based incentive compensation, which may be comprised of cash, stock options, and/or RSUs. The payment of cash and the grant and/or vesting of equity are contingent upon the achievement of pre-determined regulatory milestones. We record compensation expense over the estimated service period for each milestone subject to the achievement of the milestone being considered probable in accordance with the provisions of Accounting Standards Codification Topic 450, Contingencies. At each reporting date, we assess whether achievement of a milestone is considered probable and, if so, record compensation expense based on the portion of the service period elapsed to date with respect to that milestone, with a

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cumulative catch-up, net of estimated forfeitures. We recognize compensation expense with respect to a milestone over the remaining estimated service period. As of March 31, 2019, the estimated unrecognized compensation expense related to all LTIPs was $54.0 million.

The total estimate of unrecognized compensation expense could change in the future for several reasons, including the addition or termination of employees, the recognition of LTIP compensation expense, or the addition, termination, or modification of an LTIP.

Revenue recognition

Our revenues are comprised of ADCETRIS net product sales, amounts earned under our collaboration and licensing agreements, and royalties. Revenue recognition occurs when a customer obtains control of promised goods or services in an amount that reflects the consideration we expect to receive in exchange for those goods or services. The period between when we transfer control of promised goods or services and when we receive payment is expected to be one year or less, and that expectation is consistent with our historical experience. As such, we do not adjust our revenues for the effects of a significant financing component.

Net product sales

We sell ADCETRIS through a limited number of pharmaceutical distributors in the U.S. and Canada. Customers order ADCETRIS through these distributors, and we typically ship product directly to the customer. The delivery of ADCETRIS to the end-user site represents a single performance obligation for these transactions. We record product sales at the point in time when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. The transaction price for product sales represents the amount we expect to receive, which is 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. 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 management’s estimates that consider payor mix in target markets and experience to-date. These estimates involve a substantial degree of judgment. We have applied a portfolio approach as a practical expedient for estimating net product sales from ADCETRIS.

Government-mandated rebates and chargebacks: We have 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 us by the various state Medicaid programs. We estimate Medicaid rebates using the expected value approach, based on a variety of factors, including our experience to-date. We have also completed a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. In addition, 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 the expected value of each entity’s eligibility for the FSS and PHS programs. We also review historical 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 using the expected value approach. 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.

Collaboration and license agreement revenues

We have collaboration and license agreements with a number of biotechnology and pharmaceutical companies. Our proprietary technology for linking cytotoxic agents to monoclonal antibodies called antibody-drug conjugates, or ADCs, is the basis for many of these collaboration and license agreements, including the ADC collaborations that we have entered into in the ordinary course of business, under which we granted 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.

Our collaboration and license agreements include contractual milestones. Generally, the milestone events coincide with the progression of the collaborators' product candidates. These consist of development milestones (such as designation of a

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product candidate or initiation of preclinical studies and the initiation of phase 1, phase 2, or phase 3 clinical trials), regulatory milestones (such as the filing of regulatory applications for marketing approval), and commercialization milestones (such as first commercial sale in a particular market and product sales in excess of a pre-specified threshold). 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. 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 potential future milestone payments or royalties may be payable to us by our ADC collaborators. As such, the potential future milestone payments associated with our ADC collaborations involve a substantial degree of uncertainty and risk that they may never be received. In the case of our ADCETRIS collaboration with Takeda Pharmaceutical Company Limited, or Takeda, we may be involved in certain development activities; however, the achievement of milestone events under the agreement is primarily based on activities undertaken by Takeda.

ADC collaborations are initially evaluated as to whether the intellectual property licenses granted by us represent distinct performance obligations. If they are determined to be distinct, the value of the intellectual property licenses would be recognized up-front while the research and development service fees would be recognized as the performance obligations are satisfied. Variable consideration is assessed at each reporting period as to whether it is not subject to significant future reversal and, therefore, should be included in the transaction price at the inception of the contract. Assessing the recognition of variable consideration requires significant judgment. If a contract includes a fixed or minimum amount of research and development support, this also would be included in the transaction price. Changes to ADC collaborations, such as the extensions of the research term or increasing the number of targets or technology covered under an existing agreement, are assessed for whether they represent a modification or should be accounted for as a new contract.

We have concluded that the license of intellectual property in our current ADC collaborations is not distinct from the perspective of our customers at the time of initial transfer, since we do not license intellectual property without related technology transfer and research and development support services. Such evaluation requires significant judgment since it is made from the customer's perspective. Our performance obligations under our collaborations include such things as providing intellectual property licenses, performing technology transfer, performing research and development consulting services, providing reagents, ADCs, and other materials, and notifying the customer of any enhancements to licensed technology or new technology that we discover, among others. We determined our performance obligations under our current ADC collaborations as evaluated at contract inception were not distinct and represented a single performance obligation. Revenue is recognized using a proportional performance model, representing the transfer of goods or services as activities are performed over the term of the agreement. Upfront payments are also amortized to revenue over the performance period. Upfront payment contract liabilities resulting from our collaborations do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the licenses granted reflects research and development expenses already incurred by us.

When no performance obligations are required of us, or following the completion of the performance obligation period, such amounts are recognized as revenue upon transfer of control of the goods or services to the customer. Generally, all amounts received or due other than sales-based milestones and royalties are classified as collaboration and license agreement revenues. Sales-based milestones and royalties are recognized as royalty revenue in the period the related sale occurred.

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. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. 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 commercial sales-based milestones and sales royalties that relate predominantly to the license of intellectual property. Sales royalties are based on a percentage of Takeda's net sales of ADCETRIS, with rates that range from the mid-teens to the mid-twenties based on sales volume. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenues. Cost of royalty revenues reflects amounts owed to our third-party licensors related to Takeda's sales of ADCETRIS. These amounts are recognized in the period in which the related sales by Takeda occur.

Recent accounting pronouncements not yet adopted

In June 2016, Financial Accounting Standards Board, or FASB, issued "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 investment 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, cash flows, and financial statement disclosures.

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In August 2018, FASB issued "ASU 2018-15, Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract." The objective of the standard is to align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. 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, cash flows, and financial statement disclosures.

In November 2018, FASB issued "ASU 2018-18, Clarifying the Interaction between Topic 808 and Topic 606." The objective of the standard is to clarify the interaction between Topic 808, Collaborative Arrangements, and Topic 606, Revenue from Contracts with Customers. Currently, Topic 808 does not provide comprehensive recognition or measurement guidance for collaborative arrangements, and the accounting for those arrangements is often based on an analogy to other accounting literature or an accounting policy election. Similarly, aspects of Topic 606 have resulted in uncertainty in practice about the effect of the revenue standard on the accounting for collaborative arrangements. 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, cash flows, and financial statement disclosures.

2. Revenue from contracts with customers

We have one marketed product, ADCETRIS. Substantially all of our product revenues are recorded in the U.S. Substantially all of our royalty revenues are from our collaboration with Takeda. Collaboration and license agreement revenues by collaborator are summarized as follows:

(dollars in thousands)	Three months ended March 31, 2019	Three months ended March 31, 2018
Takeda	$43,379	$13,572
AbbVie	325	8,000
Other	874	7,987
Collaboration and license agreement revenues	$44,578	$29,559

Contract liabilities consist of deferred revenue primarily related to our remaining performance obligations under the Takeda ADCETRIS collaboration and are presented as line items on the condensed consolidated balance sheets. Deferred revenue will be recognized as the remaining performance obligations are satisfied through November 2019. We recognized collaboration and license agreement revenues of $9.3 million during the three months ended March 31, 2019 that were included in the deferred revenue balance as of December 31, 2018. For the three months ended March 31, 2019, collaboration and license agreement revenues from Takeda also included substantially all of a $30.0 million regulatory milestone, which was related to European Commission approval of ADCETRIS for patients with previously untreated CD30-expressing stage IV classical Hodgkin lymphoma, received by Takeda during the quarter.

3. Operating leases

We have operating leases for our office and laboratory facilities with terms that expire from 2021 through 2029. Upon adoption of Topic 842 on January 1, 2019, we recognized $35.2 million of operating lease liabilities and $34.7 million of operating lease right-of-use assets for our existing leases on our condensed consolidated balance sheet. As of March 31, 2019, our operating lease liabilities and operating lease right-of-use assets were $67.0 million and $59.3 million, respectively. The increases in operating lease liabilities and operating lease right-of-use assets during the three months ended March 31, 2019 reflected new facilities leases that commenced during the period. All of our significant leases include options for us to extend the lease term. None of our options to extend the rental term of any existing leases were considered reasonably certain as of March 31, 2019.

Supplemental operating lease information were as follows:

(dollars in thousands)	Three months ended March 31, 2019
Operating lease cost	$ 3,186
Variable lease cost	$ 678

As of March 31, 2019, the weighted average remaining lease term for our operating leases was 7.3 years, and the weighted average discount rate for our operating leases was 5.4%.

Future minimum lease payments under the lease agreements as of March 31, 2019 were as follows:

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Years ending December 31,	(dollars in thousands)
2019 (remaining nine months)	$ 6,850
2020	11,173
2021	12,059
2022	11,555
2023	11,388
Thereafter	30,455
Total future minimum lease payments	$ 83,480
Less: imputed interest	(16,436)
Total	$ 67,044

Operating lease liabilities were recorded in the following captions of our condensed consolidated balance sheet were as follows:

(dollars in thousands)	March 31, 2019
Accrued liabilities and other	$6,018
Operating lease liabilities, long-term	61,026
Total	$67,044

We have also entered into additional lease obligations of $16.9 million for office space that have not commenced as of March 31, 2019, and we expect to commence in the second quarter of 2019.

As of December 31, 2018, our future obligations related to building leases were as follows:

Years ending December 31,	(dollars in thousands)
2019	$ 10,332
2020	11,863
2021	12,770
2022	12,288
2023	12,142
Thereafter	30,517
Total future minimum lease payments	$ 89,912

4. Acquisition of Cascadian

In March 2018, we acquired all issued and outstanding shares of Cascadian, a clinical-stage biopharmaceutical company based in Seattle, Washington, for $10.00 per share in cash, or approximately $614.1 million, which was funded by an underwritten public offering as further described in Note 6. The acquisition of Cascadian expanded our late-stage pipeline, providing global rights to tucatinib, an investigational oral tyrosine kinase inhibitor, or TKI, that was being evaluated in a phase 2 trial called HER2CLIMB for patients with HER2 positive metastatic breast cancer who have been previously treated with HER2-targeted agents, including patients with or without brain metastases.

The acquisition of Cascadian was accounted for as a business combination. During the three months ended March 31, 2018, we incurred $8.5 million in acquisition-related costs, which were recorded in selling, general and administrative expenses.

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The purchase price allocation of the assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date was as follows:

(dollars in thousands)	
Cash and cash equivalents	$15,919
Short-term and long-term investments	66,491
Prepaid expenses and other assets	2,215
Property and equipment	566
In-process research and development	300,000
Goodwill	274,671
Accounts payable and accrued liabilities	(22,139)
Deferred tax liability	(23,653)
Total purchase price	$614,070

The amount allocated to in-process research and development was based on the present value of future discounted cash flows, which was based on significant estimates. These estimates included the number of potential patients and market price of a future tucatinib-based regimen, costs required to conduct clinical trials and potentially commercialize tucatinib, as well as estimates for probability of success and the discount rate. Goodwill primarily was attributed to tucatinib's potential application in other treatment settings, intangible assets that do not qualify for separate recognition, and synergies with our existing pipeline and capabilities. Goodwill is not expected to be deductible for tax purposes.

The financial information in the table below summarizes the combined results of operations of Seattle Genetics and Cascadian on a pro forma basis for the 2018 comparative period:

(dollars in thousands)	Three months ended March 31, 2018
Revenues	$140,590
Net loss	(140,649)

5. Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares and dilutive potential common shares outstanding during the period. Dilutive potential common shares include incremental common shares issuable upon the vesting of unvested restricted stock units and the exercise of outstanding stock options, calculated using the treasury stock method.

For the three months ended March 31, 2019 and 2018, we excluded all restricted stock units and stock options from the per share calculations as such securities were anti-dilutive. The weighted average number of restricted stock units and stock options that were excluded totaled approximately 13,202,000 and 13,506,000 for the three months ended March 31, 2019 and 2018, respectively.

6. Common stock

In February 2018, we completed an underwritten public offering of 13,269,230 shares of our common stock at a public offering price of $52.00 per share. The offering resulted in net proceeds to us of $658.2 million, after deducting underwriting discounts, commissions, and other offering expenses. The primary use of the net proceeds was to fund the acquisition of Cascadian.

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7. Fair value

We have certain assets that are measured at fair value on a recurring basis according to a fair value hierarchy that prioritizes the inputs, assumptions and valuation techniques used to measure fair value. The three levels of the fair value hierarchy are:

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. We consider 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.

The fair value hierarchy of assets carried at fair value and measured on a recurring basis was as follows:

	Fair value measurement using:			
(dollars in thousands)	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
March 31, 2019				
Short-term investments—U.S. Treasury securities	$334,025	$ —	$ —	$334,025
Other non-current assets—equity securities	151,937	—	—	151,937
Total	$485,962	$ —	$ —	$485,962
December 31, 2018				
Short-term investments—U.S. Treasury securities	$332,486	$ —	$ —	$332,486
Long-term investments—U.S. Treasury securities	49,194	—	—	49,194
Other non-current assets—equity securities	113,812	—	—	113,812
Total	$495,492	$ —	$ —	$495,492

Our equity securities primarily consisted of holdings in common stock of Immunomedics, Inc., purchased in connection with a strategic collaboration with the company in 2017. The collaboration agreement with Immunomedics was subsequently terminated in 2017.

Our debt securities consisted of the following:

(dollars in thousands)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
March 31, 2019				
U.S. Treasury securities	$333,796	$ 263	$ (34)	$334,025
Contractual maturities (at date of purchase):				
Due in one year or less	$198,093			$198,126
Due in one to two years	135,703			135,899
Total	$333,796			$334,025
December 31, 2018				
U.S. Treasury securities	$381,673	$ 133	$ (126)	$381,680
Contractual maturities (at date of purchase):				

Due in one year or less	$ 246,440	$ 246,402
Due in one to two years	135,233	135,278
Total	$ 381,673	$ 381,680

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8. Investment and other income (loss), net

Investment and other income (loss), net consisted of the following:

	Three months ended March 31,	
(dollars in thousands)	2019	2018
Gain (loss) on equity securities	$38,125	$(18,825)
Investment income, net	2,183	939
Total investment and other income (loss), net	$40,308	$(17,886)

Gain (loss) on equity securities includes the realized and unrealized holding gains and losses on our equity securities. Our equity securities are described in more detail in Note 7.

9. Inventories

The following table presents our inventories of ADCETRIS:

(dollars in thousands)	March 31, 2019	December 31, 2018
Raw materials	$56,963	$ 43,986
Finished goods	10,273	9,253
Total	$67,236	$ 53,239

We capitalize 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. We do not capitalize manufacturing costs for any of our product candidates.

10. Legal matters

On March 8, 2018, three purported stockholders of Cascadian filed a Verified Complaint to Compel Inspection of Books and Records under 8 Del. C. §220 in the Delaware Court of Chancery against Cascadian, seeking to inspect books and records in order to determine whether wrongdoing or mismanagement has taken place such that it would be appropriate to file claims for breach of fiduciary duty, and to investigate the independence and disinterestedness of the former Cascadian directors with respect to the Cascadian Acquisition. We filed our answer to this complaint on March 28, 2018. On February 20, 2019, we entered into an agreement regarding production and confidentiality of books and records with plaintiffs, pursuant to which we produced relevant books and records on April 22, 2019. As a result of this lawsuit, we may incur litigation and indemnification expenses.

In addition, from time to time in the ordinary course of business we become involved in various lawsuits, claims and proceedings relating to the conduct of our business, including those pertaining to the defense and enforcement of our patent or other intellectual property rights. These proceedings are costly and time consuming. Additionally, 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.

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

This Quarterly Report on Form 10-Q, including 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," "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 wrong. 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 "Part II. 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 that develops and commercializes therapies targeting cancer. We are commercializing ADCETRIS®, or brentuximab vedotin, for the treatment of several types of lymphoma. 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. Many of our programs, including ADCETRIS, are based on our antibody-drug conjugate, or ADC, technology that utilizes the targeting ability of monoclonal antibodies to deliver cell-killing agents directly to cancer cells.

Our marketed product ADCETRIS is commercially available in 72 countries, including in the U.S., Canada, members of the European Union and Japan. We commercialize ADCETRIS in the U.S. and its territories and in Canada, and we are collaborating with Takeda Pharmaceutical Company Limited, or Takeda, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Takeda has commercial rights in the rest of the world and pays us a royalty. ADCETRIS is approved by the U.S. Food and Drug Administration, or FDA, in six indications. For patients with Hodgkin lymphoma, ADCETRIS is approved as monotherapy for patients whose disease has relapsed and as consolidation therapy following prior treatment, and in combination with chemotherapy for the treatment of patients with previously untreated disease. For patients with T-cell lymphomas, ADCETRIS is approved as monotherapy in patients with relapsed or refractory systemic anaplastic large cell lymphoma, or sALCL, or certain types of cutaneous T-cell lymphoma, or CTCL, or in combination with chemotherapy in patients with previously untreated CD30-expressing peripheral T-cell lymphoma, or PTCL.

Beyond our current labeled indications, we are evaluating ADCETRIS in several clinical trials in combination with nivolumab (Opdivo®) under a clinical collaboration with Bristol-Myers Squibb Company, or BMS. Nivolumab is a programmed death-1, or PD-1, immune checkpoint inhibitor. The trials are evaluating the combination in several settings for Hodgkin and non-Hodgkin lymphoma.

Our late-stage pipeline includes two ADCs and an oral tyrosine kinase inhibitor, or TKI, for solid tumors that are in clinical trials designed to support applications for potential regulatory approvals.

In collaboration with Astellas Pharma, Inc., or Astellas, we are developing enfortumab vedotin, which is an ADC targeting Nectin-4. We and Astellas are conducting a pivotal phase 2 trial, called EV-201, evaluating single-agent enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who were previously treated with a PD-1 or PD-L1 inhibitor, including those who have also been treated with a platinum-containing chemotherapy, or the first cohort, and those who have not received a platinum-containing chemotherapy and who are ineligible for cisplatin, or the second cohort. In March 2018, the FDA granted Breakthrough Therapy designation to

enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who were previously treated with a checkpoint inhibitor. In March 2019, we announced positive top-line results from the first cohort of EV-201 that enrolled 128 patients who previously received both platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor. Results from the first cohort showed a 44 percent objective response rate, or ORR, per blinded independent central review. The duration of response was consistent with that recently reported in the previous phase 1 study, or EV-101. The most common treatment-related adverse events included fatigue, alopecia, decreased appetite, rash and peripheral neuropathy. Based on these results, we and Astellas plan to submit a Biologics License Application to the FDA in 2019 under the FDA's accelerated approval pathway. The second cohort of the EV-201 trial continues to enroll patients. We and Astellas are also conducting a global, randomized phase 3 trial, called EV-301, for patients with metastatic urothelial cancer who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor. EV-301 is intended to

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support global regulatory applications for potential approvals in regions where EV-201 does not support approval and potentially serve as a confirmatory trial in the U.S. if we are able to obtain accelerated approval based on the data from the first cohort in the EV-201 trial. Additionally, we and Astellas are conducting a phase 1b trial of enfortumab vedotin, called EV-103, in combination with either pembrolizumab and/or other anticancer agents as first- or second-line treatment for patients with locally advanced or metastatic urothelial cancer.

We are also developing tucatinib, an oral TKI targeting HER2, a growth factor receptor overexpressed in many cancers. Tucatinib is currently being evaluated as part of a combination regimen in a global randomized (2:1) pivotal trial, called HER2CLIMB, comparing tucatinib vs. placebo, each in combination with capecitabine and trastuzumab. The trial is evaluating patients with HER2-positive metastatic breast cancer who have been previously treated with trastuzumab, pertuzumab (Perjeta®) and ado-trastuzumab emtansine, or T-DM1, (Kadcyla®), including patients with or without brain metastases. In early 2019, we announced that we achieved enrollment of 480 patients in the trial to enable analysis of the primary endpoint of progression-free survival, or PFS, with top-line data expected to be reported in 2019. In April 2019, we reached the target enrollment of 600 patients in HER2CLIMB to support the analyses of key secondary endpoints, including overall survival, or OS, as well as PFS in patients with brain metastases.

In collaboration with Genmab A/S, or Genmab, we are developing tisotumab vedotin, which is an ADC targeting tissue factor, or TF. We and Genmab are conducting a pivotal phase 2 trial, called the innovaTV 204 trial, evaluating single-agent tisotumab vedotin for patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment. The trial is intended to support potential regulatory submission under the FDA's accelerated approval pathway. In March 2019, we completed enrollment in the innovaTV 204 trial. Additionally in March 2019, updated results from the phase 1/2 dose-escalation trial, called innovaTV 201, of tisotumab vedotin were presented at the Society of Gynecologic Oncology, or SGO, 50th annual meeting. The data showed a 22 percent confirmed objective response rate by independent review committee and median duration of response of six months in recurrent or metastatic cervical cancer. The most common adverse events of any grade were epistaxis (51 percent), fatigue (51 percent), nausea (49 percent), conjunctivitis (42 percent) and alopecia (40 percent). We are also conducting a phase 2 clinical trial called innovaTV 207, for patients with other solid tumors including colorectal, non-small cell lung, pancreatic or head and neck cancers. The trial is intended to inform a potential future broad development program. In addition, we are conducting a phase 2 clinical trial, called innovaTV 208, for patients with platinum-resistant ovarian cancer.

We are developing ladiratuzumab vedotin, an ADC targeting LIV-1, which is currently being evaluated in phase 1 and phase 2 clinical trials both as monotherapy and in combination with other agents for patients with metastatic triple-negative breast cancer.

Our early-stage clinical pipeline includes SGN-CD48A, which utilizes our ADC technology, and SEA-BCMA, a monoclonal antibody utilizing our sugar-engineered antibody, or SEA, technology. In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies, and we plan to submit several investigational new drug applications to the FDA in 2019. As a result of recent portfolio prioritization decisions, we are no longer developing SGN-2FF.

We have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd., or AbbVie; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; and Progenics Pharmaceuticals Inc., or Progenics. Of these collaborators, Genentech, GSK and AbbVie each have ADCs using our technology in late-stage clinical trials. In December 2018, Roche submitted regulatory applications in the U.S. and the European Union, or EU, for approval of polatuzumab vedotin, an ADC that uses our technology, to treat patients with relapsed or refractory diffuse large B-cell lymphoma. In February 2019, the FDA granted polatuzumab vedotin priority review with a Prescription Drug User Fee Act, or PDUFA, date of August 19, 2019. 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. Unum is conducting a phase 1 trial evaluating Unum's ACTR087 drug candidate in combination with SEA-BCMA in patients with relapsed/refractory multiple myeloma.

Outlook

Our ongoing research, development, manufacturing and commercial activities will require substantial amounts of capital and may not ultimately be successful. 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, tucatinib, and tisotumab vedotin. Enfortumab vedotin, tucatinib, tisotumab vedotin, and our other product candidates will require significant further development, financial resources and personnel to pursue, obtain and maintain regulatory approvals and to develop them into commercially viable products, if at all. Our other product candidates are in relatively early stages of development. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to our plans to build a commercial infrastructure in Europe and to otherwise continue to expand our operations internationally. Our commitment of resources to the continuing development, regulatory and commercialization activities for

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ADCETRIS, the research, continued development and manufacturing of our product candidates, launch and commercialization activities for potential new products, and the anticipated expansion of our pipeline and operations will likely require us to raise substantial amounts of additional capital, and our operating expenses may fluctuate as a result of such activities. We may also 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 U.S. and Canada. Our future ADCETRIS product sales are difficult to accurately predict from period to period and are dependent on, among other things, the incidence flow of patients eligible for treatment with ADCETRIS. 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 approval of ADCETRIS in additional indications, the extent to which coverage and reimbursement for ADCETRIS is available from government and other third-party payors, competition, the incidence rate of new patients in ADCETRIS' approved indications, customer ordering patterns, physicians' perception and adoption of ADCETRIS, the overall level of demand for ADCETRIS, and the duration of therapy for patients receiving ADCETRIS. In particular:

- 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 U.S. 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.
- 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.

While we expect continued growth in ADCETRIS sales in 2019 as compared to 2018, we expect that our ability to grow ADCETRIS sales, if at all, will depend primarily on our ability to establish or demonstrate in the medical community the value of ADCETRIS and its potential advantages compared to existing and future therapeutics in the newly-diagnosed, previously untreated Stage III and IV classical Hodgkin lymphoma indication approved in March 2018 based on the results of the ECHELON-1 trial, or the frontline Hodgkin lymphoma indication, and the newly diagnosed, previously untreated sALCL, or other CD30-expressing PTCL, including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, indication approved in November 2018 based on the results of the ECHELON-2 trial, or the frontline PTCL indication, and the extent to which physicians make prescribing decisions with respect to ADCETRIS in these indications. Further, our ability to grow ADCETRIS sales will be affected by our ability to continue to expand ADCETRIS' utilization across all labeled indications of use. In addition, Takeda may be unable to obtain regulatory approvals of ADCETRIS in the ECHELON-1 treatment setting in its territories (other than in jurisdictions like Japan and the European Union where ADCETRIS is approved in combination with doxorubicin (Adriamycin®), vinblastine and dacarbazine, or AVD, as a frontline treatment option for CD30-positive Hodgkin lymphoma patients), and of ADCETRIS in the ECHELON-2 treatment setting in its territories, which also would limit their sales of, and the commercial potential of, ADCETRIS.

We 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 three months ended March 31, 2019, total revenues increased to $195.2 million, compared to $140.6 million for the same period in 2018. This increase was driven primarily by 42% higher ADCETRIS net product sales. Net product sales of ADCETRIS were $135.0 million for the three months ended March 31, 2019, compared to $95.4 million for the same period in 2018, which increased primarily driven by recent ADCETRIS label expansions.
For the three months ended March 31, 2019, total costs and expenses increased to $248.8 million, compared to $234.4 million for the same period in 2018. This primarily reflected higher sales and marketing costs to support recent ADCETRIS launches, as well as higher research and development expenses for our continued investment in our late-stage pipeline, offset in part by upfront payments for in-license agreements in the comparable period of 2018. Net loss for the three months ended

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March 31, 2019 was favorably impacted by a net gain of $38.1 million resulting from the change in the fair value of our equity securities.

As of March 31, 2019, we had $418.3 million in cash, cash equivalents and investments and $1.3 billion in total stockholders' equity.

Results of operations

Net product sales

We sell ADCETRIS in the U.S. and Canada.

	Three months ended March 31,		
(dollars in thousands)	2019	2018	% Change
Net product sales	$135,001	$95,357	42 %

The increase in net product sales for the three months ended March 31, 2019 from the comparable period in 2018 primarily resulted from higher sales volume during 2019 and, to a lesser extent, from the effect of price increases. Higher sales volume during the 2019 period was driven by label expansions of ADCETRIS; in particular, for the frontline Hodgkin lymphoma indication in March 2018, and for the frontline PTCL indication in November 2018.

We sell ADCETRIS through a limited number of pharmaceutical distributors in the U.S. and Canada. Customers order ADCETRIS through these distributors, and we typically ship product directly to the customer. The delivery of ADCETRIS to the end-user site represents a single performance obligation for these transactions. We record product sales at the point in time when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. The transaction price for product sales represents the amount we expect to receive, which is 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. 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 management's estimates that consider payor mix in target markets and experience to date. These estimates involve a substantial degree of judgment. We have applied a portfolio approach as a practical expedient for estimating net product sales from ADCETRIS.

Gross-to-net deductions, net of related payments and credits, were as follows:

(in thousands)	Rebates and chargebacks	Distribution fees, product returns and other	Total
Balance as of December 31, 2018	$ 26,968	$ 5,604	$32,572
Provision related to current period sales	57,105	3,293	60,398
Adjustment for prior period sales	160	(188)	(28)
Payments/credits for current period sales	(39,899)	(1,426)	(41,325)
Payments/credits for prior period sales	(13,332)	(678)	(14,010)
Balance as of March 31, 2019	$ 31,002	$ 6,605	$37,607

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 months ended March 31, 2019 as a result of price increases we instituted that exceeded the rate of inflation. 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. We expect gross-to-net deductions to increase in 2019 as compared to 2018, driven by growth in ADCETRIS gross sales.

Collaboration and license agreement revenues

We have collaboration and license agreements with a number of biotechnology and pharmaceutical companies. Our proprietary ADC technology is the basis of many of these collaboration and license agreements, including the ADC collaborations that we have entered into in the ordinary course of our business, under which 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. Our collaboration and license agreements include contractual milestones. Generally, the milestone events coincide with the progression of the collaborators' product candidates. These consist of development milestones (such as designation of a product candidate or initiation of preclinical studies and the initiation of phase 1, phase 2, or phase 3 clinical

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trials), regulatory milestones (such as the filing of regulatory applications for marketing approval), and commercialization milestones (such as first commercial sale in a particular market and product sales in excess of a pre-specified threshold).

Collaboration and license agreement revenues by collaborator were as follows:

	Three months ended March 31,		
(dollars in thousands)	2019	2018	% Change
Takeda	$43,379	$13,572	220 %
AbbVie	325	8,000	(96)%
Other	874	7,987	(89)%
Total collaboration and license agreement revenues	$44,578	$29,559	51 %

Collaboration revenues from Takeda fluctuate based on changes in the recognized portion of reimbursement funding under the ADCETRIS collaboration, which are impacted by the activities each party is performing under the collaboration agreement at a given time. For example, when Takeda's level of spending on clinical collaboration activities increases above our own, our earned portion of reimbursement funding generally decreases. Additionally, we receive reimbursement for the cost of drug product supplied to Takeda for its use, the timing of which fluctuates based on Takeda's product supply needs. Collaboration revenues from Takeda can also fluctuate based on the achievement of milestones by Takeda. The increase in collaboration revenues from Takeda for the three months ended March 31, 2019 reflects the earned portion of a $30.0 million milestone related to European Commission approval of ADCETRIS for patients with previously untreated CD30-expressing stage IV classical Hodgkin lymphoma. As of March 31, 2019, $26.5 million of deferred revenue was related to our collaboration with Takeda, which we will recognize as the remaining performance obligations are satisfied through November 2019.

Collaboration revenues from AbbVie decreased for the three months ended March 31, 2019 from the comparable period in 2018 due to the recognition of a development milestone from our ADC collaboration in 2018.

Other collaboration revenues decreased for the three months ended March 31, 2019 from the comparable period in 2018, primarily due to clinical manufacturing services performed for BMS during the three months ended March 31, 2018, under a transitional services agreement related to our acquisition of a manufacturing facility. These activities concluded as of March 31, 2018.

Our collaboration and license agreement revenues are impacted by the term and duration of those 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 potential additional collaboration and license agreements. We expect our collaboration and license agreement revenues in 2019 to be higher than 2018, driven by the timing of milestones.

Collaboration agreements

Takeda

Our ADCETRIS collaboration with Takeda provides for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. We received an upfront payment and have received and are entitled to receive progress- and sales-dependent milestone payments based on Takeda's achievement of significant events under the collaboration, in addition to tiered royalties with percentages ranging from the mid-teens to the mid-twenties based on net sales of ADCETRIS within Takeda's licensed territories. Additionally, we and Takeda equally co-fund the cost of selected development activities conducted under the collaboration. We recognize as collaboration revenue the upfront payment, progress-dependent development and regulatory milestone payments, and net development cost reimbursement payments from Takeda over the ten-year development period of the collaboration, which ends in November 2019. 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 in collaboration and license agreement revenues.

As of March 31, 2019, total future potential milestone payments to us under the ADCETRIS collaboration could total approximately $125.0 million. Of that amount, up to approximately $7.0 million relates to the achievement of development milestones, up to approximately $78.0 million relates to the achievement of regulatory milestones and up to approximately $40.0 million relates to the achievement of commercial milestones. As of March 31, 2019, $110.0 million in milestones had been achieved as a result of regulatory and commercial progress by Takeda.

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Astellas

We have an agreement with Agensys, which subsequently became an affiliate of 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 this collaboration, we and Astellas are co-funding all development costs for enfortumab vedotin. Costs associated with co-development activities are included in research and development expense.

In 2018, we and Astellas entered into a joint commercialization agreement to govern the global commercialization of enfortumab vedotin, if approved for commercial sale:

- In the U.S., we and Astellas will jointly promote enfortumab vedotin. We will record sales of enfortumab vedotin in the U.S. and be responsible for all U.S. distribution activities. The companies will share equally in costs incurred, and any profits realized, in the U.S.
- Outside the U.S., we will commercialize in all countries in North and South America, and Astellas will commercialize in rest of the world, including Europe, Asia, Australia and Africa. The agreement is intended to provide that we and Astellas will effectively share equally in costs incurred and any profits realized in all of these markets. Cost and profit sharing in Canada, the United Kingdom, Germany, France, Spain and Italy will be based on product sales and costs of commercialization. In the remaining markets, the commercializing party will bear costs and will pay the other party a royalty rate applied to net sales of the product based on a rate intended to approximate an equal cost and profit share for both parties.

Genmab

We have an agreement with Genmab to develop and commercialize ADCs for the treatment of several types of cancer, under which we previously exercised a co-development option for tisotumab vedotin. We and Genmab will share all future costs and profits for development and commercialization of tisotumab vedotin on an equal basis. Costs associated with co-development activities are included in research and development expense. 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.

Unum

We have an agreement with Unum to develop and commercialize novel ACTR therapies for cancer. We and Unum are developing two ACTR product candidates that combine Unum’s ACTR technology with our antibodies. Unum is conducting preclinical research and clinical development activities through phase 1 clinical trials, and we are providing 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 equally on any co-developed programs in the U.S. We retain exclusive commercial rights outside of the U.S., paying Unum a royalty that is a high single digit to mid-teens percentage of ex-U.S. sales. The potential future licensing and progress-dependent milestone payments to Unum under the collaboration may total up to $400.0 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 these 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- and sales-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 over the performance obligation period or, if there is no performance obligation, upon transfer of control of the goods or services to the customer. Our ADC collaborators are solely responsible for research, product development, manufacturing and commercialization of any product candidates under these collaborations, which includes achievement of the potential milestones.

As of March 31, 2019, our ADC collaborations had generated approximately $400.0 million, primarily in the form of upfront and milestone payments. Remaining milestone payments to us under our current ADC collaborations could total approximately $2.3 billion if all potential product candidates achieved all of their milestone events. Of this amount, approximately $0.3 billion relates to the achievement of development milestones, approximately $1.0 billion relates to the achievement of regulatory milestones and approximately $1.0 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 potential future milestone payments or royalties may be

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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 potential future milestone payments associated with our ADC collaboration 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 in the future.

Royalty revenues and cost of royalty revenues

Royalty revenues primarily reflect royalties earned under the ADCETRIS collaboration with Takeda. These royalties include commercial sales-based milestones and sales royalties. Sales royalties are based on a percentage of Takeda's net sales of ADCETRIS, with rates that range from the mid-teens to the mid-twenties based on sales volume. Takeda bears third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenues. Cost of royalty revenues reflects amounts owed to our third-party licensors related to Takeda's sales of ADCETRIS.

	Three months ended March 31,		
(dollars in thousands)	2019	2018	% Change
Royalty revenues	$15,620	$15,674	— %
Cost of royalty revenues	$2,389	$5,377	(56)%

Royalty revenues for the three months ended March 31, 2019 were consistent with the comparable period in 2018. Takeda net sales of ADCETRIS in its territories increased during the 2019 period; however, royalty revenue for the comparable period in 2018 included additional royalty revenue attributable to Takeda's portion of certain third-party royalty obligations which expired at the end of 2018. We expect that royalty revenues will increase in 2019 as compared to 2018, primarily due to anticipated increases in sales volume by Takeda.

Cost of royalty revenues fluctuates based on the amount of net sales of ADCETRIS by Takeda in its territories. Cost of royalty revenues decreased for the three months ended March 31, 2019 from the comparable period in 2018 due to lower amounts owed to certain third-party licensors.

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.

	Three months ended March 31,		
(dollars in thousands)	2019	2018	% Change
Cost of sales	$7,911	$10,358	(24)%

Cost of sales decreased for the three months ended March 31, 2019 from the comparable period in 2018 primarily due to a reduction in amounts owed to certain third-party licensors, offset in part by increased ADCETRIS sales volumes. We expect cost of sales to decrease in 2019 as compared to 2018, primarily due to a reduction in royalties owed under technology license agreements.

Research and development

	Three months ended March 31,		
(dollars in thousands)	2019	2018	% Change
Research and clinical development	$106,202	$116,540	(9)%
Process sciences and manufacturing	52,063	35,962	45 %
Total research and development	$158,265	$152,502	4 %

Certain prior year balances have been reclassified within research and development expenses to conform to current year presentation.

Research and clinical development expenses include, among other things, personnel, occupancy and laboratory expenses, technology access fees, preclinical translational biology and in vitro and in vivo studies, IND-enabling

pharmacology and toxicology studies, and external clinical trial costs including costs for clinical sites, clinical research organizations, contractors and regulatory activities associated with conducting human clinical trials. The decrease for the three months ended March 31, 2019 from the comparable period in 2018 reflected $35.0 million of upfront in-licensing payments made during the first quarter of 2018, offset in part by increases in employee-related costs and co-development costs to support our late stage pipeline of product candidates.

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Process sciences and 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. Process sciences and manufacturing expenses also include quality control and assurance activities, and storage and shipment of our product candidates. The increase for the three months ended March 31, 2019 from the comparable period in 2018 primarily reflected increases in staffing and other costs to support our late-stage pipeline of product candidates.

We utilize our employee and infrastructure resources across multiple research and development projects. 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 basis as it relates to our infrastructure, facility, employee and other indirect costs; however, we do separately track significant third-party costs including clinical trial costs, manufacturing costs and other contracted service costs on a project basis. To that end, the following table shows third-party costs incurred for research, contract manufacturing of our product candidates and clinical and regulatory services, as well as pre-commercial milestone payments for in-licensed technology for ADCETRIS and certain of our clinical-stage product candidates. The table also presents other costs and overhead consisting of third-party costs for our preclinical stage programs, personnel, facilities and other indirect costs not directly charged to development programs.

	Three months ended March 31,		Five years ended
(dollars in thousands)	2019	2018	March 31, 2019
ADCETRIS (brentuximab vedotin)	$6,981	$7,531	$ 294,372
Enfortumab vedotin	6,451	4,163	61,933
Tucatinib	20,413	2,874	61,152
Tisotumab vedotin	7,580	7,368	35,855
Ladiratuzumab vedotin	5,559	7,255	57,817
Other clinical stage programs	5,179	7,247	256,903
Total third-party costs for clinical stage programs	52,163	36,438	768,032
Other costs and overhead	106,102	116,064	1,262,326
Total research and development	$158,265	$152,502	$ 2,030,358

Third-party costs for ADCETRIS decreased for the three months ended March 31, 2019 from the comparable period in 2018 primarily due to a reduction in clinical trial activities, as well as less drug product supplied to Takeda. 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 in collaboration and license agreement revenues.

Third-party costs for enfortumab vedotin increased for the three months ended March 31, 2019 from the comparable period in 2018 primarily due to increases in clinical trial and manufacturing expenses.

Third-party costs for tucatinib increased for the three months ended March 31, 2019 from the comparable period in 2018 due to higher clinical trial expenses for the phase 2 pivotal trial called HER2CLIMB, and higher manufacturing expenses.

Third-party costs for tisotumab vedotin for the three months ended March 31, 2019 were consistent with the comparable period in 2018.

Third-party costs for ladiratuzumab vedotin decreased for the three months ended March 31, 2019 from the comparable period in 2018 primarily due to lower drug supply expenses.

Other costs and overhead include third-party costs of our preclinical programs and costs associated with personnel and facilities. These costs decreased for the three months ended March 31, 2019 from the comparable period in 2018, due primarily to $35.0 million of upfront in-licensing payments made in the first quarter of 2018, offset in part by higher expenses associated with our preclinical programs.

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 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;

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- 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 2019 will increase compared to 2018 due primarily to higher costs for the development of our product candidates, primarily enfortumab vedotin, tucatinib, tisotumab vedotin, and ladiratuzumab vedotin. 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

	Three months ended March 31,		
(dollars in thousands)	2019	2018	% Change
Selling, general and administrative	$80,271	$66,182	21 %

Selling, general and administrative expenses increased for the three months ended March 31, 2019 from the comparable period in 2018 primarily due to increases in staffing, external spend related to our late-stage product candidates and ADCETRIS commercialization efforts related to the frontline Hodgkin lymphoma and frontline PTCL indications, as well as higher infrastructure costs to support our continued growth. The three months ended March 31, 2018 included costs associated with the Cascadian Acquisition.

We anticipate that selling, general and administrative expenses will increase in 2019 compared to 2018 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 (loss), net

	Three months ended March 31,		
(dollars in thousands)	2019	2018	% Change
Gain (loss) on equity securities	$38,125	$(18,825)	(303)%
Investment income, net	2,183	939	132 %
Total investment and other income (loss), net	$40,308	$(17,886)	(325)%

Investment and other income (loss), net includes other non-operating income and loss, such as unrealized holding gains and losses on equity securities (which primarily include common stock holdings in Immunomedics), realized gains and losses on equity and debt securities, and amounts earned on our investments in U.S. Treasury securities.

The increase in investment and other income (loss), net for the three months ended March 31, 2019 from the comparable period in 2018 was driven by a $38.1 million net gain from changes in the fair value of our equity securities. As of March 31, 2019, our shares held of Immunomedics common stock had a fair value of $148.3 million, which are included in other non-current assets.

Liquidity and capital resources

(dollars in thousands)	March 31, 2019	December 31, 2018
Cash, cash equivalents, and investments	$418,295	$459,866
Working capital	471,923	428,523

Stockholders' equity	1,313,411	1,273,943

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	Three months ended March 31,	
(dollars in thousands)	2019	2018
Cash provided (used) by:		
Operating activities	$(57,227)	$(147,164)
Investing activities	36,485	(496,961)
Financing activities	26,826	670,070

The change in net cash from operating activities primarily was related to the change in our net loss, working capital fluctuations and changes in our non-cash expenses, all of which are highly variable.

The change in net cash from investing activities reflected differences between the proceeds received from sale and maturity of our investments and amounts reinvested, as well as payments for business combinations. Cash used for investing activities during the three months ended March 31, 2018 included $614.1 million cash paid (or $598.2 million net of the cash acquired) for the Cascadian Acquisition in 2018.

The change in net cash from financing activities included proceeds from stock option exercises and our employee stock purchase plan for all periods presented. Cash provided by financing activities during the three months ended March 31, 2018 included $658.2 million in net proceeds from our public offering in 2018.

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

Our cash, cash equivalents, and investments 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 investment securities in our portfolio prior to their scheduled maturities, which may result in a loss. As of March 31, 2019, we had $418.3 million held in cash, cash equivalents and investments scheduled to mature within the next twelve months.

At our currently planned spending rates, we believe that our existing 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.

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees, support our development, manufacturing and clinical trial activities for ADCETRIS and our other pipeline programs, as well as commercialize ADCETRIS and prepare to potentially launch and commercialize additional products. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to our plans to build a commercial infrastructure in Europe and to otherwise continue to expand our operations internationally. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS, the research, continued development and manufacturing of our product candidates, our pursuit of regulatory approvals for and preparing to potentially launch and commercialize our product candidates, and the anticipated expansion of our pipeline and operations 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 such transactions. Moreover, 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, which could lead to a need for us to raise additional capital. In addition, we may choose to raise additional

capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. We may seek additional capital 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 capital when we need it, 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, 2018. In April 2019, we entered into a 10-year lease extension for one of our facilities being used for office

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space, which contains 5-year accelerated termination date options. The lease extension will commence in June 2019. Aggregate base rent due over the extended 10-year lease term is approximately $13.5 million.

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

Critical accounting policies

The preparation of financial statements in accordance with generally accepted accounting principles requires us to make estimates, assumptions, and judgments that affect the amounts reported in the financial statements and accompanying notes. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from those estimates. Our critical accounting policies, those with the more significant judgments and estimates, used in the preparation of our financial statements for the three months ended March 31, 2019 were consistent with those in Part II Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2018.

Recent accounting pronouncements

Refer to “Part I. Item 1. Note 1–-Summary of significant accounting policies” for a discussion on recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes to our market risk disclosures as set forth in Part II Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2018.

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 at the reasonable assurance level.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

(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 March 31, 2019 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

The information required to be set forth under this Item 1 is incorporated by reference to "Note 10. Legal matters" of the Notes to Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q.

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.

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 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 ability to effectively commercialize ADCETRIS for the treatment of patients in its approved indications and our ability to continue to expand its labeled indications of use. We may not be able to fully realize the commercial potential of ADCETRIS for a number of reasons, including:

- we may be unable to effectively commercialize ADCETRIS in any new indications for which we receive marketing approval, including in the newly diagnosed, previously untreated Stage III and IV classical Hodgkin lymphoma indication approved in March 2018 based on the results of the ECHELON-1 trial, or the frontline Hodgkin lymphoma indication, and the newly diagnosed, previously untreated systemic anaplastic large-cell lymphoma, or sALCL or other CD30-expressing peripheral T-cell lymphomas, or PTCL, including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified indication approved in November 2018 based on the results of the ECHELON-2 trial, or the frontline PTCL indication;
- we and/or Takeda Pharmaceutical Company Limited, or Takeda, our collaborator in the development and commercialization of ADCETRIS, may not be able to obtain and maintain regulatory approvals to market ADCETRIS in its currently approved indications or for any additional indications in our respective territories, including in the frontline Hodgkin lymphoma and frontline PTCL indications outside the U.S., which would limit sales of, and the commercial potential of, ADCETRIS;
- 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 and frontline PTCL indications as well as other approved indications;
- 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, a shorter duration of therapy in patients in ADCETRIS' approved indications, or for other reasons;
- 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 any of the clinical trials that we and/or Takeda are conducting or may in the future conduct for ADCETRIS, including investigator-sponsored

studies and 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 the EC;

- 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, Takeda and/or Bristol-Myers Squibb Company, or BMS, are conducting or may in the future conduct for ADCETRIS;
- we may be unable to continue to effectively market, sell and distribute ADCETRIS;

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- ADCETRIS may be impacted by adverse reimbursement and coverage policies from government and private payors 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;
- physicians may be reluctant to prescribe ADCETRIS due to side effects associated with its use or until long term efficacy and safety data exist;
- 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 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 EC for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL, and has since obtained marketing approvals for ADCETRIS in many other countries. Conditional marketing authorization by the EC includes obligations to provide additional clinical data at a later stage to confirm the positive benefit-risk balance. 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. Further, foreign sales of ADCETRIS could be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions or barriers and changes in tariffs, including as a result of the United Kingdom's planned separation from the European Union, commonly referred to as Brexit, escalating global trade and political tensions, or otherwise.

While ADCETRIS product sales have grown over time, and our future plans assume that sales of ADCETRIS will increase, we cannot assure you that, even with the recent expansions to the prescribing label for ADCETRIS in the United States, which now includes, the frontline Hodgkin lymphoma and frontline PTCL indications, ADCETRIS sales will continue to grow or that we can maintain sales of ADCETRIS at or near current levels. We also expect that our ability to grow ADCETRIS sales, if at all, will depend primarily on our ability to establish or demonstrate in the medical community the value of ADCETRIS and its potential advantages compared to existing and future therapeutics in the frontline Hodgkin lymphoma and frontline PTCL indications, and the extent to which physicians make prescribing decisions with respect to ADCETRIS in these indications. Further, our ability to grow ADCETRIS sales will be affected by our ability to continue to expand ADCETRIS' utilization across all labeled indications of use. In addition, Takeda may be unable to obtain regulatory approvals of ADCETRIS in the ECHELON-1 treatment setting in its territories (other than in jurisdictions like Japan and the European Union where ADCETRIS is approved in combination with doxorubicin (Adriamycin®), vinblastine and dacarbazine, or AVD, as a frontline treatment option for CD30-positive Hodgkin lymphoma patients), and of ADCETRIS in the ECHELON-2 treatment setting in its territories, which also would limit their sales of, and the commercial potential of, ADCETRIS.

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 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. The Food and Drug Administration, or FDA, and similar regulatory authorities outside the United States regulate companion diagnostics. Companion diagnostics may require separate or coordinated regulatory approval prior to or in association with commercialization of the related therapeutic product. While the FDA did not require the concurrent approval of a CD30 companion diagnostic for approval of ADCETRIS in the frontline PTCL indication or in any other of its approved indications, the FDA's approval of ADCETRIS in the frontline PTCL indication included a

post-marketing commitment to develop a clinically validated in-vitro diagnostic device for the selection of patients with CD30-expressing PTCL, not including sALCL, for treatment with ADCETRIS in this indication. If Ventana develops an in-vitro diagnostic device that we are able to clinically validate, the FDA may revise our label for the frontline PTCL indication to require the use of the in-vitro test as a companion diagnostic or to include additional clinical data regarding the use of the in-vitro test as a complementary diagnostic. If the FDA or another regulatory authority requires a companion diagnostic in the ADCETRIS label for the frontline PTCL indication or in connection with or as a condition of future regulatory approvals, such a requirement may limit our ability to commercialize ADCETRIS in the applicable treatment setting due to potential label requirements, prescriber practices, constraints on availability of the diagnostic, or other factors. If Ventana is unable to successfully develop the CD30 in-vitro diagnostic, or

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experiences delays in doing so, or we experience delays in clinical validation of the diagnostic, we will likely need to renegotiate the timing or content of our post-marketing commitment regarding the in-vitro diagnostic device with the FDA.

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.

Our success also depends on our ability to obtain regulatory approvals of our product candidates and, if approved, to successfully launch and commercialize those product candidates. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In furtherance of our growth strategy, we have made significant investments in a number of product candidates, including our later-stage product candidates enfortumab vedotin, tucatinib and tisotumab vedotin. In March 2019, we announced positive top-line results from the first cohort of patients enrolled in a pivotal phase 2 trial of enfortumab vedotin, or the EV-201 trial, who previously received both platinum chemotherapy and a checkpoint inhibitor (PD-1 or PD-L1) that is being conducted by us and Astellas Pharma Inc., or Astellas. Based on the results from the first cohort, we and Astellas plan to submit a Biologics License Application, or BLA, to the FDA in 2019 under the FDA's accelerated approval pathway. Our and Astellas' ability to complete the planned BLA submission on the anticipated timing remains subject to our and Astellas' ability to complete necessary pre-filing activities, including chemistry, manufacturing and controls, or CMC, activities. Moreover, 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 foreign regulatory agencies have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for enfortumab vedotin or any of our other product candidates. In addition, although enfortumab vedotin was granted Breakthrough Therapy designation by the FDA for patients with locally advanced or metastatic urothelial cancer whose disease has progressed during or following treatment with a PD-1 or PD-L1 inhibitor, Breakthrough Therapy designation does not guarantee that we will be able to take advantage of the expedited review procedures and does not increase the likelihood that enfortumab vedotin will receive any marketing approvals. In any event, we cannot predict whether our planned BLA submission, if submitted, will be approved in a timely manner, if at all, and we cannot otherwise assure you that any of our product candidates will receive any marketing approvals. In fact, it is possible that none of our product candidates will ever become commercial products. Even if approved for commercial sale, our ability to realize the anticipated benefits from our product candidates is subject to a number of risks and uncertainties, including our and our collaborators' ability to successfully launch, market and commercialize any approved products, our reliance, in the case of enfortumab vedotin and tisotumab vedotin, on Astellas and Genmab A/S, or Genmab, respectively, to effectively jointly commercialize any new approved products with us, the acceptance of any new approved products by the medical community and patients, and the extent to which coverage and reimbursement for any new approved products will be available from government and health administration authorities, private health insurers and other third-party payors.

If we are unable to obtain and maintain regulatory approval for our product candidates, including enfortumab vedotin, in a timely manner, or at all, or if sales of an approved product do not reach the levels we expect, our anticipated revenue from our product candidates and our prospects for profitability would be adversely affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 post-approval confirmatory studies that Takeda is required to conduct as a condition of the marketing authorization of ADCETRIS by the EC. 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. The ADCETRIS label provides for use of prophylactic growth factors for Stage III or IV classical Hodgkin lymphoma patients receiving ADCETRIS plus AVD to mitigate events of neutropenia and febrile neutropenia, but despite this, these product safety concerns could limit prescribing of ADCETRIS for newly diagnosed patients with previously untreated Stage III and IV classical Hodgkin lymphoma and 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.

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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 also 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 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.

In particular, we are conducting pivotal trials for enfortumab vedotin, tucatinib and tisotumab vedotin based on only limited clinical data. Although data continues to be generated in our pivotal trials and we recently announced positive top-line results from the first cohort in the EV-201 trial, there may still be important facts about the safety, efficacy, and risk versus benefit of these product candidates that are not known to us at this time which may negatively impact our ability to develop and commercialize these product candidates. In addition, in response to safety events observed in our clinical trials of enfortumab vedotin and tisotumab vedotin, including patient deaths, we have in the past, and may in the future, institute additional precautionary safety measures such as dosing caps and delays, enhanced monitoring for side effects, and modified patient inclusion and exclusion criteria. Additional and/or unexpected safety events could be observed in these pivotal or other later-stage trials that could delay or prevent us from advancing the clinical development of, or obtaining regulatory approvals for, enfortumab vedotin, tucatinib 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.

Even though we and Takeda have obtained regulatory approvals to market ADCETRIS, we and Takeda 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 in certain indications if such requirements are not met. ADCETRIS is approved for treating patients in the relapsed sALCL and relapsed Hodgkin lymphoma indications with conditions in Canada, and approved under conditional marketing authorization in relapsed Hodgkin lymphoma and sALCL in the European Union, 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. For the European Union indications, Takeda is subject to certain post-approval requirements, including the requirement to conduct clinical trials to confirm clinical benefit. In Canada, the ECHELON-1 results may be sufficient to confirm the clinical benefit of ADCETRIS in relapsed Hodgkin lymphoma, and the ECHELON-2 results may be sufficient to confirm the clinical benefit of ADCETRIS in relapsed sALCL. In the European Union,

there are other post approval requirements to convert the conditional marketing authorization for ADCETRIS in relapsed Hodgkin lymphoma and relapsed sALCL into a standard marketing authorization. Takeda's failure to provide these additional clinical data from confirmatory studies could result in the EC 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, 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 and our collaborators' ability to commercialize ADCETRIS and any future-approved

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product. For example, we and Astellas are conducting the EV-201 trial. In March 2019, we announced positive top-line results from the first cohort of patients enrolled in the EV-201 trial who previously received both platinum chemotherapy and a checkpoint inhibitor (PD-1 or PD-L1). Based on the results from the first cohort, we and Astellas plan to submit a BLA to the FDA in 2019 under the FDA's accelerated approval pathway. As a condition of any potential approval under the FDA's accelerated approval pathway, the FDA may require that we and/or Astellas perform confirmatory post-marketing studies to verify and describe the clinical benefit of enfortumab vedotin. Moreover, in connection with any such accelerated approval, the labeling and advertising and promotion of enfortumab vedotin would be subject to additional regulatory requirements, which could entail significant expense and could negatively impact the potential future launch and commercialization of enfortumab vedotin.

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 our product candidates, 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 or any new approved product, including adverse events of unanticipated severity or frequency, or problems with the facilities where ADCETRIS or any new approved product is manufactured, may result in restrictions on the marketing of ADCETRIS or any such new approved product, up to and including withdrawal of the affected product 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 our product candidates or 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 our collaborators might not be permitted to market ADCETRIS or any products that might be approved in the future, and our business would suffer.

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

We are currently conducting multiple clinical trials for ADCETRIS and our product candidates and we plan to commence additional trials of ADCETRIS and our product candidates in the future. In this regard, we and Astellas are conducting the EV-201 trial and a phase 3 clinical trial of enfortumab vedotin, called the EV-301 trial, in metastatic urothelial cancer patients who previously received both platinum chemotherapy and a checkpoint inhibitor (PD-1 or PD-L1). Additionally, we are conducting a pivotal phase 2 trial of tucatinib for patients with HER2-positive metastatic breast cancer who have been previously treated with HER2-targeted agents, including patients with or without brain

metastases, which we refer to as the HER2CLIMB trial, and a pivotal phase 2 trial of tisotumab vedotin with Genmab in patients with recurrent and/or metastatic cervical cancer, which we refer to as the innovaTV 204 trial. Each of these trials was initiated based on only limited phase 1 clinical data. In particular, enfortumab vedotin, tucatinib and tisotumab vedotin have not 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

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sufficient to support FDA or any foreign regulatory approvals. In this regard, while we reported positive top-line results from the first cohort in the EV-201 trial and we and Astellas plan to submit a BLA to the FDA in 2019 under the FDA's accelerated approval pathway based on the results from the first cohort, the FDA may disagree with our interpretation of the data from the first cohort in the EV-201 trial and/or may otherwise determine not to approve our planned BLA submission in a timely manner or at all. In addition, we do not have Special Protocol Assessment agreements with the FDA for any of these trials.

Each of our clinical trials requires the investment of substantial expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delays in accumulating the required number of clinical events for data analyses, delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site, and shortages of available drug supply. 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 adversely 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.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, foreign governmental agencies, including data protection authorities, 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, 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, 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, clinical protocols or regulations relating to data protection;
- problems, errors or other deficiencies with respect to data collection, data processing and analysis;
- 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;

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- 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.

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 additional indications. In particular, negative or inconclusive results in our HER2CLIMB trial would negatively impact or preclude altogether our ability to obtain any regulatory approvals of tucatinib, which could result in our failure to realize the anticipated benefits of our acquisition of Cascadian Therapeutics, Inc., or Cascadian, referred to as the Cascadian Acquisition, and negatively impact our plans to build a commercial infrastructure in Europe. 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 results from the first cohort in the EV-201 trial, regulatory agencies, including the FDA, or its advisors, may disagree with our interpretations of the data from the first cohort in the EV-201 trial and may not approve our planned BLA submission. Moreover, although we reported positive top-line results in both our ECHELON-1 and ECHELON-2 trials, regulatory agencies outside of the U.S., or their advisors, may disagree with Takeda's interpretations of data from the ECHELON-1 and ECHELON-2 trials. Based upon those interpretations, regulatory agencies outside of the U.S. may not approve the expansion of ADCETRIS' labeled indications of use to the ECHELON-1 treatment setting (beyond jurisdictions like Japan and the European Union where ADCETRIS is approved in combination with AVD as a frontline treatment option for CD30-positive Hodgkin lymphoma patients), and may not approve the expansion of the ADCETRIS labeled indications of use to the ECHELON-2 treatment setting. Adverse medical events during a clinical trial, including patient fatalities, could cause a trial to be redone or terminated, require us to cease development of a product candidate or the further development or commercialization of ADCETRIS, result in our failure to expand ADCETRIS into additional indications, adversely affect our ability to market ADCETRIS, and may result in other negative consequences to us, including the inclusion of unfavorable information in our product labeling. Further, some of our clinical trials are overseen by an independent data monitoring committee, or IDMC, and an IDMC may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial. 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.

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

Our late-stage product candidates are enfortumab vedotin, tucatinib, and tisotumab vedotin, which are in pivotal trials based on only limited clinical data. Our earlier-stage clinical pipeline includes ladiratuzumab vedotin, which is in phase 2 clinical development, and SGN-CD48A, and SEA-BCMA, which are in phase 1 clinical development. As a result of recent portfolio prioritization decisions, we are no longer developing SGN-2FF. In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies. Enfortumab vedotin, tucatinib,

tisotumab vedotin, and our other product candidates will require significant further development, financial resources and personnel to pursue, obtain and maintain regulatory approvals and to develop them 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. In this regard, if we are unable to successfully complete the development of, obtain regulatory approvals for and commercialize tucatinib, we will not realize the anticipated benefits of the Cascadian Acquisition. Moreover, with the exception of data from the first cohort of EV-201, we have reported only limited data from early trials of our product candidates. Preclinical studies and any encouraging or positive

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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 later-stage trials. In addition, we are developing product candidates in indications in which competition is intense, and it is possible that a clinical trial we run may meet its safety and efficacy endpoints but we may choose not to advance the development and commercialization of the product candidate due to changes in the competitive environment and the rapid evolution of the standard of care. 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. Differences in earlier- and later-stage clinical trials may include changes to inclusion and exclusion criteria, efficacy endpoints and statistical design. In this regard, we are conducting the EV-201 and EV-301 trials of enfortumab vedotin with Astellas, the HER2CLIMB trial of tucatinib and the innovaTV 204 trial of tisotumab vedotin with Genmab in each case based on only limited clinical data. Enfortumab vedotin, tucatinib and tisotumab vedotin have not 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 support FDA or any foreign regulatory approvals. Moreover, tucatinib and tisotumab vedotin may fail to demonstrate sufficient efficacy in our pivotal trials despite the results observed in earlier-stage trials, and despite the positive top-line results we reported for the first cohort in the EV-201 trial, we cannot be certain that enfortumab vedotin will demonstrate sufficient efficacy in other trials, including in the EV-301 and EV-103 trials. In addition, there may still be important facts about the safety, efficacy, and risk versus benefit of these product candidates that are not known to us at this time which may negatively impact our ability to develop and commercialize these product candidates. In particular, in response to safety events observed in our clinical trials of enfortumab vedotin and tisotumab vedotin, including patient deaths, we have in the past, and may in the future, institute additional precautionary safety measures such as dosing caps and delays, enhanced monitoring for side effects, and modified patient inclusion and exclusion criteria. Additional and/or unexpected safety events or our failure to generate additional efficacy data in our clinical trials that support registration could significantly impact the value of enfortumab vedotin, tucatinib and tisotumab vedotin to our business. 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 in the ongoing pivotal trials for enfortumab vedotin, tucatinib and tisotumab vedotin. We have not yet completed any late-stage clinical trials for our 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, financial condition, results of operations and growth 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, or we may choose to discontinue the development of product candidates for a variety of reasons such as due to safety, risk versus benefit profile, exclusivity, competitive landscape, or prioritization of our resources. It is possible that none of our product candidates will ever become commercial products. In addition, we have to make decisions about which clinical stage and pre-clinical product candidates to develop and advance, and we may not have the resources to invest in certain product candidates, or clinical data and other development considerations may not support the advancement of one or more product candidates. Decision-making about which product candidates to prioritize involves inherent uncertainty, and our development program decision-making and resource prioritization decisions may not improve our results of operations or prospects or enhance the value of our common stock. Our failure to effectively advance our development programs could have a material adverse effect on our business and prospects, and cause the price of our common stock to decline.

If we or our collaborators are not able to obtain or maintain required regulatory approvals, we or our collaborators will not be able to 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 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 in CD30-expressing lymphomas, 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

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submitting the applications necessary to gain regulatory approvals. Further, the FDA and 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 foreign regulatory authority. In addition, the FDA or any foreign regulatory authority or their respective advisors may disagree with our interpretations of data from preclinical studies and clinical trials. For example, based on the positive top-line results we reported from the first cohort in the EV-201 trial, we and Astellas plan to submit a BLA to the FDA in 2019 under the FDA's accelerated approval pathway. However, the FDA may disagree with our interpretation of the data from the first cohort in the EV-201 trial and/or may otherwise determine not to approve our planned BLA in a timely manner or at all. Regulatory agencies also may approve a product candidate for fewer or narrower indications than requested, or with a label that includes only subtypes of a particular indication rather than a more general disease classification. For example, the label approved by the FDA based on our phase 3 ALCANZA trial covered only primary cutaneous anaplastic large cell lymphoma, or pcALCL, and CD30-expressing mycosis fungoides, or MF, which are two subtypes of cutaneous T-cell lymphoma, or CTCL. Additionally, the FDA or foreign regulatory authorities may grant approval subject to the performance of post-approval studies or REMS for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of ADCETRIS in any additional indications.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs, for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In addition, as part of the U.S. Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all regulatory submissions in a given time frame. However, the FDA does not always meet its PDUFA targeted action dates and if the FDA were to fail to meet a PDUFA targeted action date in the future for ADCETRIS or any of our product candidates, 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.

The successful commercialization of ADCETRIS and our product candidates will depend on a variety of factors, including the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies, and the acceptance of our products by the medical community and patients.

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 increasing levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. In light of this pricing scrutiny, 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 coverage and adequate levels of reimbursement for ADCETRIS and any other product candidates that we commercialize, their marketability will be negatively and materially impacted. For example, we cannot be certain that third-party payors will provide coverage and adequate reimbursement for ADCETRIS in the frontline Hodgkin lymphoma indication based on the relative price and 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. Similarly, even if we and Astellas are able to obtain approval of our planned BLA submission to the FDA for enfortumab vedotin, we cannot be certain that third party payors will provide coverage and adequate

reimbursement for enfortumab vedotin based on its relative price and perceived benefit as compared to alternative treatment options, which may materially harm our and Astellas' ability to commercialize enfortumab vedotin, if approved.

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, in the United States, there is no uniform policy of coverage and reimbursement among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided is made on a payor-by-payor basis. 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

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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.

The degree of market acceptance among patients, physicians, and third-party payors is also important to our ability to successfully commercialize ADCETRIS. The degree of acceptance will depend on a number of factors including the effectiveness of our marketing, sales and distribution strategy and operations, the acceptance of our product by patients, physicians and third party payors, the perceived advantages and relative cost, safety and efficacy of alternative treatments, as well as the acceptance and degree of adoption of our products and future products by institutional pathways and institutional, local, and national guidelines such as the National Comprehensive Cancer Networks® Clinical Practice Guidelines in Oncology, or the NCCN Guidelines. Many oncology practices and healthcare providers rely on the NCCN Guidelines or other institutional practice pathways in decisions related to treatment of patients and utilization of medicines. To the extent that approved regimens including ADCETRIS or our future products are not included or positioned favorably in such treatment guidelines and pathways, the full utilization potential of our products may not be reached, which may harm our ability to successfully commercialize ADCETRIS or our potential future products. For example, in the ADCETRIS frontline Hodgkin lymphoma indication, the NCCN Guidelines are more restrictive than our labeled indication and these guidelines have been translated into treatment pathways for many institutions, which may harm our ability to successfully commercialize ADCETRIS.

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.

Certain provisions of the PPACA 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, since January 20, 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provision of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the

so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the “individual mandate” was repealed. While the Texas U.S. District Court Judge, as well as the Trump administration and the Centers for Medicare & Medicaid Services, or CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and our business. 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

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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 PPACA and its possible repeal and replacement has on our business.

Further, on March 23, 2018, CMS finalized updates to the National Drug Rebate Agreement, or the Rebate Agreement, for the first time in 27 years, to incorporate legislative and regulatory changes that have occurred since the Rebate Agreement was first published. These updates align the Rebate Agreement with certain provisions of PPACA and contain additional changes incorporating CMS policies adopted over the years. In order to have ADCETRIS, or any future approved product, covered under Medicaid, and Medicare Part B, we were required to enter into the revised Rebate Agreement with CMS. If we fail to comply with the terms of the revised Rebate Agreement, we will be unable to obtain, and maintain, Medicaid and Medicare Part B coverage and reimbursement, which could negatively affect our financial condition and results of operations.

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 and rebates may be mandated by governmental entities, or requested by 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 and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing by requiring drug companies to notify insurers, purchasers and government regulators of price increases and to provide an explanation as to the reasons for the increase, reduce the out-of-pocket costs to patients for prescription drugs, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. Moreover, in May 2018, the Trump administration released its "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," or the Blueprint. The Blueprint contains several potential regulatory actions and legislative recommendations aimed at lowering prescription drug prices, including measures to promote innovation and competition for biologics, changes to Medicare Part D to give plan sponsors more leverage when negotiating prices with manufacturers, and updating the Medicare drug-pricing dashboard to make price increases and generic competition more transparent. Recently on February 6, 2019, the Office of Inspector General, or OIG, of the Department of Health and Human Services, or HHS, published a Proposed Rule that would eliminate the current safe harbor protection under the Anti-Kickback Statute for pharmaceutical manufacturer rebates to Medicare Part D plans, Medicaid managed care organizations and the Pharmacy Benefit Managers, or PBMs, that they contract. The proposal would also create two new safe harbors. The first would protect certain point-of sale price reductions to certain Federal Health Care Program enrollees and the second would protect certain fixed fees paid by drug manufacturers directly to PBMs for services provided to PBMs. In addition, HHS released a Request for Information, or RFI, soliciting public input on ways to lower drug pricing. Together, the recommendations in the Blueprint and RFI, if enacted by Congress and HHS, could lead to changes to Medicare Parts B and D, including the transition of certain drugs covered under Part B to Part D or the offering of alternative purchasing options under the Competitive Acquisition Program that currently applies to selected drugs and biologics covered under Part B. While many of the proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative, administrative and/or additional measures to control drug costs. For example, in November 2018, CMS issued a proposed regulation that would, require Part D plans to include drug pricing information and lower cost therapeutic alternatives as well as allow “step therapy” in Medicare Advantage for Part B drugs. The rule also proposes exceptions to the current Part D coverage requirements for six “protected classes” of drugs (immunosuppressants , antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics) by allowing Part D sponsors to use certain formulary management, exclude certain new formulations of protected class drugs from the formulary and

exclude a protected class drug from formulary if the price of the drug increased beyond a certain threshold over a specified look-back period. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing, cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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

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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 oncology drugs, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 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 also expect to experience pricing pressures in connection with the sale of ADCETRIS due to certain managed healthcare initiatives. For example, the PPACA increased the mandated Medicaid rebate from 15.1% to 23.1% of Average Manufacturer Price, expanded the rebate to Medicaid managed care utilization and increased the types of entities eligible for the federal 340B drug discount program. As concerns continue to grow over the need for tighter oversight, there remains the possibility that the Heath Resources and Services Administration or another agency under the HHS will propose a similar regulation or that Congress will explore changes to the 340B program through legislation. For example, a bill was recently introduced in 2018 that would require hospitals to report their low-income utilization of the program. Further, the Centers for Medicare & Medicaid Services issued a final rule that would revise the Medicare hospital outpatient prospective payment system for calendar year 2019, including a new reimbursement methodology for drugs purchased under the 340B program for Medicare patients at the hospital setting and recently announced the same change for physician-based practices under 340B in 2019. In addition, HHS has set January 1, 2019, as the effective date of the final rule setting forth the calculation of the ceiling price and application of civil monetary penalties. Pursuant to the final rule, after January 1, 2019, manufacturers must calculate 340B program ceiling prices on a quarterly basis. Moreover, manufacturers could be subject to a $5,000 penalty for each instance where they knowingly and intentionally overcharge a covered entity under the 340B program. A significant portion of ADCETRIS purchases are eligible for 340B drug pricing, and 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 these 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 and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations may require us to modify our programs and could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

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 in affording 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. Our patient assistance program and support of independent charitable foundations could become the target of similar litigation. 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. In addition, certain state and federal enforcement authorities and members of Congress have initiated inquiries about co-pay assistance programs. Some state legislatures have also been considering proposals that would restrict or ban co-pay coupons.

In addition, there has been regulatory review and enhanced government scrutiny of donations by pharmaceutical companies to patient assistance programs operated by charitable foundations. For example, the 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

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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 U.S. Department of Justice and other enforcement authorities seeking information related to their patient assistance programs and support, and certain of these organizations have entered into, or have otherwise agreed to, significant civil settlements with applicable enforcement authorities. In connection with these civil settlements, the U.S. government has and may in the future require the affected companies to enter into complex corporate integrity agreements that impose significant reporting and other requirements on those companies. 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 negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

We depend on collaborative relationships with other companies to assist in the development and commercialization 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 and commercialize 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 collaborations 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 or refractory, or transplant-ineligible, advanced classical Hodgkin lymphoma. In addition, we have antibody-drug conjugate, or ADC, collaborations with AbbVie Biotechnology Ltd., or AbbVie; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; and Progenics Pharmaceuticals Inc., or Progenics, and we have entered into a collaboration agreement with Unum Therapeutics, Inc., or Unum, to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies incorporating our antibodies for the treatment of cancer. 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, including enfortumab vedotin and tisotumab vedotin, and because control of development and commercialization is shared with our collaborators, we do not have sole discretion and control over the development and commercialization of these product candidates;
- 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 with Takeda and our 50:50 co-development and related agreements with Astellas and Genmab, we may have differing opinions, processes or priorities than our collaborators, or we may encounter challenges in joint decision making and joint execution, including with respect to any joint commercialization plans, 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;
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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 collaborations 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. Moreover, 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.

With respect to ADCETRIS, there are several other FDA-approved drugs for its approved indications. BMS's nivolumab (Opdivo®) and Merck's pembrolizumab (Keytruda®) are approved for the treatment of certain patients with relapsed or refractory classical Hodgkin lymphoma, and Celgene's romidepsin (Istodax®) and Spectrum Pharmaceuticals' pralatrexate

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(Folotyn®) and belinostat (Beleodaq®) are approved for relapsed or refractory sALCL among other T-cell lymphomas. Kyowa Kirin's mogamulizumab (Poteligeo®) is approved for adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome. 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 pembrolizumab (Keytruda®) 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 and Pfizer's avelumab, 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' approved indications, including autologous hematopoietic stem cell transplant, allogeneic stem cell transplant, combination chemotherapy, clinical trials with experimental agents and single-agent regimens.

With respect to enfortumab vedotin, treatment in pre-treated metastatic urothelial cancer is limited to checkpoint inhibitor monotherapy, generic chemotherapy or, for patients with select fibroblast growth factor receptor genetic alterations, Janssen's erdafitinib (Balversa®). There are other investigational agents that, if approved, could be competitive with enfortumab vedotin, such as Immunomedics' sacituzumab govitecan. Treatment in front line metastatic urothelial cancer is evolving and includes two approved checkpoint inhibitor therapies with several trials of investigational agents in combination with chemotherapy or other novel agents potentially reporting data in 2019.

With respect to tucatinib, there are multiple marketed products which target HER2, including the antibodies trastuzumab (Herceptin®) and pertuzumab (Perjeta®) and the antibody drug conjugate ado-trastuzumab emtansine or T-DM1 (Kadcyla®). In addition, lapatinib (Tykerb®) is a dual EGFR/HER2 oral kinase inhibitor for the treatment of metastatic breast cancer and neratinib (Nerlynx®) is an EGFR/HER2/HER4 inhibitor indicated for extended adjuvant use that is also being studied for use in pre-treated HER2-positive metastatic breast cancer. In addition, Daiichi Sankyo and Synthon each have an antibody drug conjugate in a pivotal study in this patient population and MacroGenics has a HER2 targeted, Fc-optimized antibody, margetuximab, also in a pivotal study.

With respect to tisotumab vedotin, in June 2018, Merck's pembrolizumab (Keytruda®) was approved for the treatment of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy in patients whose tumors express PD-L1. We are also 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, BMS, Iovance Biotherapeutics, Merck, Regeneron Pharmaceuticals and Roche.

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, BMS, Celgene, Daiichi Sankyo, Eisai, Genentech, GSK, Gilead, ImmunoGen, Immunomedics, Infinity, Janssen, Karyopharm, MacroGenics, MedImmune, MEI Pharma, Merck, Novartis, Pfizer, Puma Biotech, 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 AbbVie, ADC Therapeutics, Astellas, AstraZeneca, BMS, Daiichi Sankyo, ImmunoGen, Immunomedics, MedImmune, Mersana, Pfizer, and Roche, 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.

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. In the European Union, the EC has granted marketing authorizations for biosimilars pursuant to a set of general and

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product class-specific guidelines. 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, tucatinib, tisotumab vedotin or our other product candidates or that would render our technology obsolete or noncompetitive, or will succeed in developing biosimilar, interchangeable or generic products for ADCETRIS, enfortumab vedotin, tucatinib, tisotumab vedotin or our other 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, tucatinib, tisotumab vedotin or our other 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. As a result, 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. In addition, such guidance is based on assumptions that may be incorrect or that may change from quarter to quarter, and it may be particularly difficult to correctly forecast sales in indications for which we have recently received marketing approval. Moreover, 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 again 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 payors;
- our ability to establish or demonstrate in the medical community the safety, efficacy or value of ADCETRIS and its potential advantages compared to existing and future therapies in the frontline Hodgkin lymphoma and frontline PTCL indications and ADCETRIS' other approved indications;
- 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, tucatinib, tisotumab vedotin and our other product candidates by us or our collaborators;
- changes in the prices of the Immunomedics, Inc., or Immunomedics, and Unum common stock that affect the valuation of the common stock of those companies that 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

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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, or business activities, or entry into strategic transactions, including potential future 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 March 31, 2019, we held shares of Immunomedics common stock with a fair value of $148.3 million. We record changes in the fair value of our equity securities, including the Immunomedics and Unum common stock that we hold, in net income or loss, which can lead to volatility of net income or loss to the extent that we continue to hold common stock or other 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. We expect to continue to spend substantial amounts on research and development, including amounts for conducting clinical trials of ADCETRIS as well as commercializing ADCETRIS for the treatment of patients in its approved indications. In addition, we expect to make substantial expenditures to further develop and potentially commercialize enfortumab vedotin, tucatinib, tisotumab vedotin and our other product candidates. We may also pursue new operations or continue the expansion of our existing operations, including with respect to our plans to build a commercial infrastructure in Europe and to otherwise continue to expand our operations internationally. Accordingly, we expect to continue to incur net losses in future periods 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. For example, in March 2018, we made significant investment in tucatinib through the Cascadian Acquisition. The Cascadian Acquisition and any potential future acquisitions or in-licensing transactions 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;

- the potential disruption of our historical core 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;
- difficulties in assimilating employees and corporate cultures of any acquired companies;

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- uncertainties in our ability to maintain key business relationships of any acquired companies;
- 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 unanticipated liabilities of acquired companies or companies in which we invest;
- the potential need to write down assets or recognize impairment charges; 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 product candidates or technologies, including tucatinib, 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 acquisitions 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 or goodwill 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, liabilities and uncertainties effectively, including in connection with the Cascadian Acquisition, could have a material adverse effect on our business and adversely affect our results of operations and financial condition. 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.

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.

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

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

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

Although we own 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 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 Millipore Sigma, an affiliate of Merck KGaA, for clinical and commercial supplies. We have multiple contract manufacturers for conjugating the drug linker to the antibody and producing the ADCETRIS product. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce 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 bear costly losses or 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 or contractual disputes could result in the cancellation of shipments, loss of product in the manufacturing process, a shortfall in ADCETRIS supply, or limit our ability to sell our products in the U.S. and Canada or for Takeda to sell ADCETRIS in its territories. Moreover, we and Takeda 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 clinical and commercial requirements would be adversely affected.

For the clinical supply of our product candidates, which include ADCs as well as antibodies and small molecules such as tucatinib, we rely on multiple contract manufacturers and other third parties to perform manufacturing services for us. With respect to enfortumab vedotin and tisotumab vedotin specifically, we rely on drug product supply provided by our collaborators and have little control over their supply chains or the contract manufacturers they utilize. For the foreseeable future, we expect to continue to rely on contract manufacturers and, in the case of enfortumab vedotin and tisotumab vedotin, on our collaborators, for manufacturing of clinical supplies. If our third-party manufacturers and collaborators cease or interrupt production, fail to supply satisfactory materials, products or services for any reason or experience performance delays or quality concerns, or if materials or products are lost in transit or in the manufacturing process, such challenges or interruptions could substantially impact clinical trial drug supply, with the potential for additional costs and an adverse effect on our business. In addition, with respect to tucatinib specifically, we have limited prior experience as an organization manufacturing tucatinib and small molecule drug products generally, and have relatively new working relationships with many of the third party manufacturers involved in tucatinib manufacture. These factors increase the chance that we could encounter manufacturing challenges that could increase our costs, cause delays or otherwise negatively impact our business.

For enfortumab vedotin and tisotumab vedotin, we or our collaborators will likely need to obtain additional manufacturing arrangements or increase manufacturing capability to meet potential future commercial needs with respect to these product candidates, which could require additional capital investment by us or cause potential delays if our collaborators encounter challenges in negotiating commercially reasonable arrangements with these manufacturers. Likewise, with respect to tucatinib, we will need to put in place additional manufacturing arrangements with third party manufacturers to meet future potential commercial needs and while we are currently negotiating those arrangements, we cannot assure you that we can enter into such arrangements on commercially reasonable terms or at all. We or our collaborators may also encounter difficulties in meeting the regulatory requirements applicable to the manufacturing process for these agents, and in managing the additional complexity of manufacturing for a number of markets outside the U.S. Any failures or delays to meet these requirements could substantially delay or impede our ability to obtain regulatory approvals for and market these agents, which could negatively impact our operating results and adversely affect our business.

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We are using our own manufacturing facility to support our clinical-stage pipeline. As an organization, we have limited experience operating a manufacturing facility.

We own a biologics manufacturing facility located in Bothell, Washington, which we acquired in October 2017. We have commenced using this facility to support our clinical supply needs. As an organization, we have limited experience operating a manufacturing facility, as we had no prior experience manufacturing for ourselves before acquiring this facility. 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. Any of these risks, if actualized, could materially and adversely affect our business and financial position. In addition, despite the acquisition and operation 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 and foreign laws and regulations, including healthcare, privacy and data security 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, the federal Health Insurance Portability and Accountability Act, or HIPAA, the federal Health Information Technology for Economic and Clinical Health Act, or 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 to have committed a violation. 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 civil 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 to have committed a violation.

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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, known as 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 CMS 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 versions 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. For example, European Union, or EU, member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, effective May 25, 2018, the collection and use of personal health data in the EU is governed by the provisions of the EU General Data Protection Regulation, or the GDPR. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the control over personal data by individuals to whom the personal data relates, the information provided to the individuals, the documentation we must maintain, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, provides an enforcement authority and authorizes the imposition of large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information. The GDPR has increased our responsibility and potential liability in relation to personal data that we process compared to prior EU law, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. However, despite our ongoing efforts to bring our practices into compliance with the GDPR, we may not be successful either due to various factors within our control or other factors outside our control. It is also possible that local data protection authorities may have different interpretations of the GDPR, leading to potential inconsistencies amongst various EU member states. Any failure or alleged failure (including as a result of deficiencies in our policies, procedures or measures relating to privacy, data security, marketing or communications) by us to comply with laws, regulations, policies, legal or contractual obligations, industry standards or regulatory guidance relating to privacy or data security, may result in governmental investigations and enforcement actions, litigation, fines and penalties or adverse publicity. In addition, new regulation, legislative actions or changes in interpretation of existing laws or regulations regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018, which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States, and we cannot determine the impact such new laws, regulations and standards may have on our business. Further, Brexit has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR, how data transfers to and from the United Kingdom will be regulated and what impact this will have on our business.

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, marketing expenditures, or other reporting and registration requirements related to our business activities. 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

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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 civil 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 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 we will be able to integrate the operations of acquired businesses into our compliance program on a timely basis, 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, criminal and administrative 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.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a

prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could potentially impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

As we continue to 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.

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We are continuing to expand our operations internationally, and plan to build a commercial infrastructure in Europe. In this regard, we currently have subsidiaries in Australia, Canada, Ireland, Luxembourg, the Netherlands, Switzerland and the United Kingdom, and plan in the future to have subsidiaries in additional jurisdictions. Our business activities outside of the United States are and will continue to be 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 recently established French Anti-corruption Law on Transparency, Fight against Corruption and the Modernization of the Economy, referred to as Sapin II. In Europe, national anti-corruption laws prohibit giving, offering, or promising bribes to any person, including foreign government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. Various European anti-corruption laws have broad extraterritorial reach and therefore we may be subject to those laws even if we do not have an established entity in those countries and we may be held liable for bribes given, offered or promised to any person, including private persons, by employees and persons associated with us in order to obtain or retain business or a business advantage. 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, and advocacy groups, and we will interact with physicians, which are generally considered foreign officials in Europe, as well as with regulatory authorities who may be deemed to be foreign officials under the FCPA or similar laws of other countries that may govern our activities. Any interactions with any such parties or individuals 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, the Sapin II 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, EU member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations, such as the GDPR, 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, and ladiratuzumab vedotin 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, Genentech, GSK, 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.

We have been and may in the future be subject to litigation, including securities-related litigation, litigation pertaining to the conduct of our business, and litigation in connection with the Cascadian Acquisition and potential future strategic transactions. Such litigation could result in substantial damages and may divert management's time and attention from our business.

In January 2017, a purported securities class action lawsuit was commenced in the United States District Court for the Western District of Washington, or the Court, naming as defendants us and certain of our officers. A related stockholder derivative lawsuit, or the Stockholder Derivative Action, was also filed in Washington Superior Court for the County of Snohomish, or the Snohomish County Superior Court, on March 29, 2017. While the class action lawsuit and the related Stockholder Derivative Action were subsequently dismissed, we may be the target of securities-related litigation in the future, both related and unrelated to the dismissed class action and Stockholder Derivative Action. Moreover, three purported stockholders of Cascadian filed a complaint seeking to inspect books and records in order to determine whether wrongdoing or mismanagement has taken place such that it would be appropriate to file claims for breach of fiduciary duty, and to investigate the independence and disinterestedness of the former Cascadian directors with respect to the Cascadian Acquisition. As a result of such complaint or otherwise, it is possible that additional lawsuits may be brought against us and/or Cascadian related to the Cascadian Acquisition.

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In addition, from time to time in the ordinary course of business we become involved in various lawsuits, claims and proceedings relating to the conduct of our business, including but not limited to those pertaining to the defense and enforcement of our patent or other intellectual property rights.

These and potential future litigations are subject to inherent uncertainties, and the actual costs to be incurred relating to litigations may be impacted by unknown factors. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of these and potential future litigations, and we may not prevail. Monitoring and defending against legal actions can be time-consuming for our management and detract 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 and potential future litigations. Decisions adverse to our interests in these and potential future litigations could result in the payment of substantial damages, or possibly fines, or affect our intellectual property rights and could have a material adverse effect on our cash flow, results of operations and financial position. In addition, the uncertainty associated with 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 development, manufacturing and clinical trial activities for ADCETRIS and our other pipeline programs, as well as commercialize ADCETRIS and prepare to potentially launch and commercialize additional products. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to our plans to build a commercial infrastructure in Europe and to otherwise continue to expand our operations internationally. We also anticipate continuing to commit substantial capital resources to development and commercialization activities related to enfortumab vedotin, tucatinib and tisotumab vedotin. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS, the research, continued development and manufacturing of our product candidates, our pursuit of regulatory approvals for and preparing to potentially launch and commercialize our product candidates, and the anticipated expansion of our pipeline and operations 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 such transactions. For example, in connection with the Cascadian Acquisition, we sold 13,269,230 shares of our common stock in an underwritten public offering with the primary use of the net proceeds used to fund the Cascadian Acquisition. 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 time and costs involved in obtaining regulatory approvals of ADCETRIS in additional indications, if any, and potentially of enfortumab vedotin and/or any of our other product candidates;
- 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 and the Cascadian Acquisition, or our undertaking of additional programs, business activities or entry into additional strategic transactions, including potential future acquisitions of products, technologies or businesses. Moreover, we may choose to raise

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additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. 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, as well as a rising interest rate environment, 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, our product candidates and technologies such as 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, our product candidates and technologies such as our ADC technology. Currently, we have license agreements with BMS, the University of Miami and Array BioPharma, Inc., 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, including tucatinib. 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 validity, enforceability, or term of our patent. For example, the U.S. Supreme Court has 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

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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,

and that we do not have the right to stop a third party from using the patented subject matter. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary technologies without a license from us or our collaborators, which may also result in loss of future royalty payments. Furthermore, if such challenges to our rights are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing potential products, which could adversely affect our business and results of operations. In addition, we may challenge the patent or other intellectual property rights of third parties and if we are unsuccessful in actions we bring against the rights of such parties, through litigation or otherwise, and it is determined that we infringe the intellectual property rights of such parties, we may be prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those rights or develop or obtain alternative technologies, any of which could harm our business.

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

We are highly dependent on the efforts and abilities of the principal members of our senior management. Additionally, we have scientific personnel with significant and unique expertise in monoclonal antibodies, ADCs and related technologies, and tucatinib. 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 the development and commercialization of our additional product candidates, we will be required to expand our workforce, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, sales and marketing, both in the United States and in Europe. 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 commercialize ADCETRIS in earlier lines of therapy, including in the frontline PTCL indication, to build a commercial infrastructure in Europe or to support the commercialization of our product candidates alone or jointly with our collaborators.

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 efforts to transition into a multi-product oncology company, our operation of a manufacturing facility and our continuing international expansion. 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 agreed to enter into certain transitional services agreements under which we manufactured 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 manufactured 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, such insurance is subject to coverage limits and exclusions, as well as significant deductibles. 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 our expanding operations in foreign countries could materially adversely affect our business.

We are expanding our operations internationally. We currently have subsidiaries in Australia, Canada, Ireland, Luxembourg, the Netherlands, Switzerland, and the United Kingdom, and we plan to build a commercial infrastructure in Europe. 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:

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- the increased complexity and costs inherent in managing international operations, including in geographically disparate locations;
- 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;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- 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;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations;
- 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.

As a result of our expanding international operations, including potentially with respect to a commercial presence in Europe, our business and corporate structure has and will become substantially more complex. There can be no assurance that we will effectively manage the increased complexity without experiencing operating inefficiencies or control deficiencies. Significant management time and effort is required to effectively manage the increasing complexity of our company, and our failure to successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, 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 potential future marketing authorizations for ADCETRIS and potential future marketing authorizations for our product candidates. We may also face new regulatory costs and challenges as result of Brexit that could have an adverse effect on our operations, including the need to change the location of our release of clinical product supplies into the European Union from the U.K. to a location that will be within the European Union following Brexit, potential stresses and constraints on the capacity of service providers providing product release services in new locations outside of the U.K., and potential challenges with releasing clinical product supplies into the U.K. any of which could potentially impede our ability to timely supply clinical product to our clinical trials, and increase our costs. It is also possible that Brexit will cause additional unanticipated negative impacts on our ability to supply clinical or commercial product, or on that of our collaborators, including Takeda. Moreover, we do not currently have certainty as to the terms of the U.K.’s future relationship with the European Union and if the U.K. withdraws from the European Union without a ratified withdrawal agreement in place, there will be a period of considerable uncertainty particularly in relation to U.K. financial and banking markets as well as on the regulatory process in Europe. In addition, 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 and Takeda's 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 or Takeda's ability to continue to conduct operations in Europe or our ability to build and maintain a commercial infrastructure in Europe.

Moreover, the Trump administration has imposed tariffs on certain U.S. imports, and certain countries have responded with retaliatory tariffs on certain U.S. exports. We cannot predict what effects these and potential additional tariffs

will have on our business, including in the context of escalating global trade and political tensions. However, such tariffs and other trade restrictions, whether resulting from Brexit or otherwise, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our financial results.

These and other risks described elsewhere in these risk factors associated with expanding our international operations could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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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 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 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.

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 Bothell and Seattle, 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 or personal 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, patients in our clinical trials, 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 destruction, loss, alteration, unauthorized use or access, disclosure or modification of, personally identifiable information or personal data, could harm our reputation, compel us to comply with federal, state and/or international breach notification laws, subject us to mandatory corrective or regulatory action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, including the GDPR, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. 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 implement and maintain adequate organizational and technical measures to prevent such security breaches or privacy violations, or to respond adequately in the event of a breach, our operations could be disrupted, and we may suffer loss of reputation, problems with regulatory authorities, financial loss and other negative

consequences. Moreover, failure to maintain effective internal accounting controls related to data security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and could subject us to regulatory scrutiny. In addition, security 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

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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.

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.

The potential future impairment of in-process research and development and goodwill related to the Cascadian Acquisition may negatively affect our results of operations and financial position.

As of March 31, 2019, we had recorded $574.7 million of in-process research and development and goodwill related to the Cascadian Acquisition. In-process research and development and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Our results of operations and financial position in future periods could be negatively impacted should future impairments of in-process research and development or goodwill occur.

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 quarter ended March 31, 2019, our closing stock price fluctuated between $56.37 and $77.03 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 any of our product candidates, or specific label indications for or restrictions, warnings or limitations in its use, or delays in the regulatory review or approval process;
- 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 CHECKMATE 812 trial;
- announcements regarding the results of the clinical trials we and our collaborators are conducting for enfortumab vedotin, tucatinib 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 co-development and joint

commercialization collaboration with Astellas and our tisotumab vedotin co-development collaboration with Genmab, or establishment of new collaborations or licensing arrangements;

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- our failure to achieve the perceived benefits of our strategic transactions, including the Cascadian Acquisition, as rapidly or to the extent anticipated by financial analysts or investors;
- 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 invalidation, repeal and/or replacement of all or portions of PPACA or changes in tariffs and other trade restrictions stemming from Trump administration and foreign government 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. 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 March 31, 2019, we had 161,140,940 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 potential future 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 as of March 31, 2019, collectively beneficially owned approximately 32% of our common stock. Under the

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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, as amended, or the Securities Act, we would be obligated to effect such registration. On July 26, 2018, pursuant to the registration rights agreement, we registered for resale, from time to time, up to 50,977,960 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. Accordingly, we expect to register additional shares held by the Baker Entities for resale from time to time, including in certain cases, shares that we have previously registered for resale by the Baker Entities, whether in connection with the expiration of registration statements that we previously filed with the SEC or otherwise. If the Baker Entities, by exercise of these registration and/or underwriting rights and our registration of shares held by the Baker Entities for resale from time to time, 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 registrations 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.

Based solely on the most recent Schedules 13G and 13D filed with the SEC, reports filed with the SEC under Section 16 of the Exchange Act, and our outstanding shares of common stock as of March 31, 2019, our executive officers and directors and holders of greater than five percent of our outstanding common stock beneficially owned approximately 77% of our voting power as of March 31, 2019. 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.

The U.S. comprehensive tax reform bill passed in 2017 could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, or the Tax Act, which significantly revises the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, our business and financial condition could be adversely affected in future periods by the overall impact of the Tax Act. In addition, the Tax Act could be amended or subject to technical correction, possibly with retroactive effect, which could change the financial impacts that were recorded in prior periods, or are expected to be recorded in future periods. Additionally, further guidance may be forthcoming from the Financial Accounting Standards Board and SEC, as well as regulations, interpretations and rulings from federal and state tax agencies, which could result in additional impacts, possibly with retroactive effect. Any such changes or potential additional impacts could adversely affect our business and financial condition.

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**	Agreement and Plan of Merger, dated as of January 30, 2018, by and among Seattle Genetics, Inc., Valley Acquisition Sub, Inc. and Cascadian Therapeutics, Inc.	8-K	000-32405	2.1	1/31/2018
3.1	Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.	10-Q	000-32405	3.1	11/7/2008
3.2	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.	8-K	000-32405	3.3	5/26/2011
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	2/8/2001
4.2	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.	10-Q	000-32405	4.3	11/7/2008
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*	Seattle Genetics, Inc. Senior Executive Annual Bonus Plan	10-K	000-32405	10.69	2/7/2019
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.

* Indicates a management contract or compensatory plan or arrangement.

** Schedules have been omitted pursuant to Item 601(b)(2) of Regulations 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: April 25, 2019