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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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 change