SEATTLE GENETICS INC /WA
Form 10-Q
October 26, 2018
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018
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 October 22, 2018, there were 160,145,888 shares of the registrant's common stock outstanding.

Table of Contents

Seattle Genetics, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 2018
INDEX

		Page
PART I. FINANCIAL INFORMATION (Unaudited)		
Item 1.	Condensed Consolidated Financial Statements	3
	Condensed Consolidated Balance Sheets	3
	Condensed Consolidated Statements of Comprehensive Income (Loss)	4
	Condensed Consolidated Statements of Cash Flows	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	16
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	28
Item 4.	Controls and Procedures	28
PART II. OTHER INFORMATION		
Item 1.	Legal Proceedings	29
Item 1A.	Risk Factors	29
Item 5.	Other Information	59
Item 6.	Exhibits	62
SIGNATURE		64

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Seattle Genetics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except par value)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 115,457	$ 160,945
Short-term investments	347,619	252,226
Accounts receivable, net	152,520	84,774
Inventories	75,172	59,978
Prepaid expenses and other current assets	26,180	19,138
Total current assets	716,948	577,061
Property and equipment, net	100,966	103,756
Long-term investments	22,635	—
In-process research and development	300,000	—
Goodwill	251,017	—
Other non-current assets	176,279	197,132
Total assets	$ 1,567,845	$ 877,949
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 157,157	$ 132,672
Current portion of deferred revenue	36,495	34,457
Total current liabilities	193,652	167,129
Long-term liabilities:		
Deferred revenue, less current portion	6,004	30,618
Other long-term liabilities	3,668	2,633
Total long-term liabilities	9,672	33,251
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; 160,053 shares issued and outstanding at September 30, 2018 and 144,395 shares issued and outstanding at December 31, 2017	160	144
Additional paid-in capital	2,569,449	1,806,159
Accumulated other comprehensive income (loss)	(305)	63,836
Accumulated deficit	(1,204,783)	(1,192,570)
Total stockholders' equity	1,364,521	677,569
Total liabilities and stockholders' equity	$ 1,567,845	$ 877,949

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

Table of Contents

Seattle Genetics, Inc.
Condensed Consolidated Statements of Comprehensive Income (Loss)
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Net product sales	$126,976	$79,177	$344,776	$223,841
Collaboration and license agreement revenues	19,786	39,444	76,524	82,779
Royalty revenues	22,662	16,670	58,887	46,025
Total revenues	169,424	135,291	480,187	352,645
Costs and expenses:				
Cost of sales	12,348	9,019	35,863	24,555
Cost of royalty revenues	5,320	5,196	16,845	13,900
Research and development	140,175	113,606	415,537	346,196
Selling, general and administrative	57,155	39,667	181,629	118,783
Total costs and expenses	214,998	167,488	649,874	503,434
Loss from operations	(45,574)	(32,197)	(169,687)	(150,789)
Investment and other income (loss), net	(21,872)	82,218	66,799	84,460
Net income (loss)	$(67,446)	$50,021	$(102,888)	$(66,329)
Net income (loss) per share - basic	$(0.42)	$0.35	$(0.66)	$(0.46)
Net income (loss) per share - diluted	$(0.42)	$0.34	$(0.66)	$(0.46)
Shares used in computation of per share amounts - basic	159,304	143,357	156,799	142,876
Shares used in computation of per share amounts - diluted	159,304	148,068	156,799	142,876
Comprehensive income (loss):				
Net income (loss)	$(67,446)	$50,021	$(102,888)	$(66,329)
Other comprehensive income (loss):				
Unrealized gain (loss) on securities available-for-sale, net of tax of $0, $5,915, $0, and $11,087, respectively	(144)	9,627	(12)	18,044
Foreign currency translation gain (loss)	13	14	(10)	16
Total other comprehensive income (loss)	(131)	9,641	(22)	18,060
Comprehensive income (loss)	$(67,577)	$59,662	$(102,910)	$(48,269)

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

Table of Contents

Seattle Genetics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2018	2017
Operating activities:		
Net loss	$(102,888)	$(66,329)
Adjustments to reconcile net loss to net cash used by operating activities		
Share-based compensation	53,168	47,899
Depreciation and amortization	19,045	16,393
Amortization of premiums, accretion of discounts, and (gains) losses on debt securities	(1,384)	653
Gains on equity securities	(62,882)	—
Gain on Immunomedics warrant derivative	—	(76,699)
Income tax benefit on unrealized loss on available-for-sale securities	—	(5,415)
Deferred income taxes	—	(5,672)
Other long-term liabilities	1,035	(102)
Changes in operating assets and liabilities		
Accounts receivable, net	(51,472)	(28,504)
Inventories	(15,194)	7,287
Prepaid expenses and other assets	4,183	(2,084)
Accounts payable and accrued liabilities	2,152	6,208
Deferred revenue	(25,014)	(10,141)
Net cash used by operating activities	(179,251)	(116,506)
Investing activities:		
Purchases of securities	(374,356)	(445,659)
Proceeds from maturities of securities	270,721	538,200
Proceeds from sales of securities	140,352	60,056
Purchases of property and equipment	(14,941)	(42,615)
Acquisition of Cascadian Therapeutics, Inc., net of cash acquired	(598,151)	—
Net cash provided (used) by investing activities	(576,375)	109,982
Financing activities:		
Net proceeds from issuance of common stock	658,242	—
Proceeds from exercise of stock options and employee stock purchase plan	51,896	25,991
Net cash provided by financing activities	710,138	25,991
Net increase (decrease) in cash and cash equivalents	(45,488)	19,467
Cash and cash equivalents at beginning of period	160,945	108,673
Cash and cash equivalents at end of period	$115,457	$128,140

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

Table of Contents

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 3. 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, Switzerland, and the United Kingdom.

The condensed consolidated balance sheet data as of December 31, 2017 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, 2017, 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 and nine month periods ended September 30, 2018 are not necessarily indicative of the results to be expected for the full year or any other interim period.

Non-cash investing activities

We had $1.2 million and $1.0 million of accrued capital expenditures as of September 30, 2018 and December 31, 2017, respectively. Accrued capital expenditures have been treated as a non-cash investing activity and, accordingly, have not been included in the statement of cash flows until such amounts have been paid in cash.

Investments

We adopted Accounting Standards Update, or ASU, "ASU 2016-01, Financial Instruments: Overall" on January 1, 2018, which addressed certain aspects of recognition, measurement, presentation and disclosure of financial instruments, including that changes in the fair value of equity securities be recorded in income or loss rather than accumulated other comprehensive income or loss in stockholders' equity. We used the modified retrospective method and recognized a $64.1 million cumulative effect of initially applying this ASU as an adjustment to decrease the opening accumulated deficit at January 1, 2018. Accordingly, comparative information has not been adjusted and continues to be reported under previous accounting standards. The implementation of this standard increases the volatility of net income or loss to the extent that we continue to hold equity securities.

We invest 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 investments judged to be other-than-temporary are included in investment and other income (loss), net. The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Amortization of premiums and accretion of discounts on debt securities are included in investment and other income (loss), net.

Interest and dividends earned on all securities are included in investment and other income (loss), 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. We also hold certain equity securities, which are reported at estimated fair value.

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

Table of Contents

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 (loss), net.

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 the present value of future discounted cash flows, an income approach. The significant estimates in the discounted cash flow model primarily include the discount rate, rates of future revenue growth and/or profitability of the acquired business, and working capital effects. 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.

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. 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 restricted stock units. The payment of cash and the grant 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 cumulative catch-up, net of estimated forfeitures.

During the first quarter of 2018, an LTIP milestone was achieved related to the U.S. Food and Drug Administration, or FDA, approval of a label expansion in the U.S. for ADCETRIS, based on clinical trial data from the ECHELON-1 study. As of September 30, 2018, the estimated unrecognized compensation expense related to all LTIPs was $35.4 million. The total estimate of unrecognized compensation expense could change in the future for several reasons, including the addition or termination of employees or the addition, termination, or modification of an LTIP.

Revenue recognition

We adopted Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to our accounting policy for revenue recognition. We used the modified retrospective method and recognized the cumulative effect of initially applying Topic 606 as an adjustment to decrease the opening accumulated deficit at January 1, 2018. Accordingly, comparative information has not been adjusted and continues to be reported under previous accounting standards. Refer to Note 2 for additional information.

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.

Table of Contents

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 most-likely-amount 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 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 most-likely-amount 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 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 milestone payments or royalties may be payable to us by our ADC collaborators. As such, the milestone payments associated with our ADC collaborations involve a substantial degree of uncertainty and risk that they may never be received. 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

Table of Contents

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. 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. 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 February 2016, the Financial Accounting Standards Board, or FASB, issued “ASU 2016-02, Leases.” The standard requires entities to recognize in the consolidated balance sheet a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. We will adopt the standard on January 1, 2019 using the modified retrospective method of adoption. We expect that the adoption of the standard will result in the recognition of additional assets and liabilities related to our existing operating leases in the consolidated balance sheets. We are continuing to evaluate the impact of this standard on our existing leases.

In June 2016, 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. 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.

Table of Contents

2. Revenue from contracts with customers

On January 1, 2018, we adopted Topic 606 applying the modified retrospective method to all contracts that were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 were presented under Topic 606, while prior period amounts were not adjusted and reported under the accounting standards in effect for the prior periods. We recorded the following cumulative effect as of January 1, 2018, itemized here (in thousands) and further described below:

Collaboration and license agreement revenues	$10,281
Royalty revenues	22,230
Cost of royalty revenues	(5,955)
Accumulated deficit – (debit) credit	$26,556

Impact to net product sales

Topic 606 does not generally change the practice under which we recognize product revenue from sales of ADCETRIS.

Impact to collaboration and license agreement revenues

The achievement of development milestones under our collaborations will be recorded during the period their achievement becomes probable, which may result in earlier recognition as compared to previous accounting principles. Each of our current ADC collaborations contain a single performance obligation under Topic 606.

The Takeda ADCETRIS collaboration is the only ongoing collaboration that was significantly impacted by the adoption of Topic 606. The Takeda ADCETRIS collaboration provides for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. Under this collaboration, we have retained commercial rights for ADCETRIS in the U.S. and its territories and in Canada, and Takeda has commercial rights in the rest of the world and pays us a royalty. Our performance obligations under the collaboration include providing intellectual property licenses, performing technology transfer, providing research and development services for co-funded activities, allowing access to data, submitting regulatory filings and other information for co-funded activities, and providing manufacturing support including supply of ADCETRIS drug components, finished ADCETRIS product, and know-how. We determined that our performance obligations under the collaboration as evaluated at contract inception were not distinct and represented a single performance obligation, and that the obligations for goods and services provided would be completed over the performance period of the agreement. Any payments received by us from Takeda, including the upfront payment, progress-dependent development and regulatory milestone payments, reimbursement for drug product supplied, and net development cost reimbursement payments, are recognized as revenue upon transfer of control of the goods or services over the ten-year development period (December 2009 through November 2019) of the collaboration, within collaboration and license agreement revenues. Updates to the Takeda ADCETRIS collaboration transaction price for variable consideration, such as approval of the co-development annual budget and binding production forecast, are considered at each reporting period as to whether they are not subject to significant future reversal. Shipments of drug supply that occurred after the expiration of the drug supply agreement in September 2018 were recorded as a separate performance obligation.

Impact to royalty revenues

Commercial sales-based milestones and sales royalties, primarily earned under the Takeda ADCETRIS collaboration, are recorded in the period of the related sales by Takeda, based on estimates if actual information is not yet available, rather than recording them as reported by the customer one quarter in arrears under previous accounting guidance. Takeda also bears a portion of third-party royalty costs owed on its sales of ADCETRIS which is included in royalty revenues.

Disaggregation of total revenues

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 (in thousands):

	Three months	Nine months

	ended September 30, 2018	ended September 30, 2018
Takeda	$ 18,805	$ 41,122
AbbVie	300	13,000
Genmab	—	7,000
GSK	—	6,000
Other	681	9,402
Collaboration and license agreement revenues	$ 19,786	$ 76,524

Table of Contents

Contract balances and performance obligations

Contract assets consist of unbilled receivables related to the Takeda ADCETRIS collaboration and were $12.7 million and $1.0 million as of January 1, 2018 and September 30, 2018, respectively. These were recorded in prepaid expenses and other current assets on the consolidated balance sheet. The decrease from January 1, 2018 to September 30, 2018 was primarily due to reimbursement for drug product supplied against the 2018 production forecast during the nine months ended September 30, 2018.

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 consolidated balance sheet. Deferred revenue will be recognized as the remaining performance obligations are satisfied through November 2019.

We recognized collaboration and license agreement revenues of $26.0 million during the nine months ended September 30, 2018 that were included in the deferred revenue balance as of January 1, 2018. For the three and nine months ended September 30, 2018, collaboration and license agreement revenues from Takeda also included substantially all of a $10.0 million regulatory milestone.

Impacts to September 30, 2018 condensed consolidated financial statements (in thousands)

	As reported	Adjustments	Balances without the adoption of Topic 606
Condensed Consolidated Balance Sheet data:			
Accounts receivable, net	$152,520	$ (16,730)	$135,790
Prepaid expenses and other current assets	26,180	(990)	25,190
Current portion of deferred revenue	36,495	(99)	36,396
Deferred revenue, less current portion	6,004	(16)	5,988
Accumulated deficit	(1,204,783)	(17,605)	(1,222,388)
Condensed Consolidated Statements of Comprehensive Loss data:			
Three months ended September 30, 2018			
Collaboration and license agreement revenues	$19,786	$ 7,448	$27,234
Royalty revenues	22,662	(1,747)	20,915
Total revenues	169,424	5,701	175,125
Cost of royalty revenues	5,320	826	6,146
Net loss	(67,446)	4,875	(62,571)
Nine months ended September 30, 2018			
Collaboration and license agreement revenues	$76,524	$ 9,407	$85,931
Royalty revenues	58,887	179	59,066
Total revenues	480,187	9,586	489,773
Cost of royalty revenues	16,845	634	17,479
Net loss	(102,888)	8,952	(93,936)

3. 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 5. The acquisition of Cascadian expanded our late-stage pipeline, providing global rights to tucatinib, an investigational oral tyrosine kinase inhibitor, or TKI, that is currently 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 nine months ended September 30, 2018, we incurred $8.5 million in acquisition-related costs, which were recorded in selling, general and administrative expenses.

Table of Contents

The preliminary purchase price allocation of the assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date was as follows (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	251,017
Accounts payable and accrued liabilities	(22,138)
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 amount allocated to goodwill is preliminary, since the acquisition accounting is not yet finalized as it relates to income taxes.

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 period in which the acquisition occurred and the comparative period as though the companies had been combined as of January 1, 2017. Pro forma adjustments have been made primarily related to acquisition-related transaction costs and employee costs. The following unaudited pro forma financial information is presented for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved had the acquisition occurred as of January 1, 2017 or indicative of future results (in thousands, except for per share information):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues	$169,424	$135,291	$480,187	$352,645
Net income (loss)	(67,446)	35,960	(131,822)	(136,401)
Net income (loss) per share - basic	(0.42)	0.23	(0.83)	(0.88)
Net income (loss) per share - diluted	(0.42)	0.22	(0.83)	(0.88)

4. Net income (loss) per share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of 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 September 30, 2018 and the nine months ended September 30, 2018 and 2017, we excluded all restricted stock units and stock options from the per share calculations as such securities were anti-dilutive. For the three months ended September 30, 2017, we excluded stock options with an exercise price greater than the average price from the per share calculations. The weighted average number of restricted stock units and stock options that were excluded totaled approximately 13,258,000 and 3,460,000 for the three months ended September 30, 2018 and 2017, respectively, and approximately 13,338,000 and 13,367,000 for the nine months ended September 30, 2018 and 2017, respectively.

Table of Contents

The following table presents the computations of basic and diluted net income (loss) per share (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income (loss)	$(67,446)	$50,021	$(102,888)	$(66,329)
Weighted average common shares outstanding - basic	159,304	143,357	156,799	142,876
Dilutive potential common shares	—	4,711	—	—
Weighted average common shares outstanding - diluted	159,304	148,068	156,799	142,876
Net income (loss) per share - basic	$(0.42)	$0.35	$(0.66)	$(0.46)
Net income (loss) per share - diluted	$(0.42)	$0.34	$(0.66)	$(0.46)

5. 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.

6. Investments

As of September 30, 2018 and December 31, 2017, we held common stock of Immunomedics, Inc., or Immunomedics, and Unum Therapeutics, Inc., or Unum, each holding purchased in connection with strategic collaborations with the respective company. The collaboration agreement with Immunomedics was terminated in 2017. As of September 30, 2018 and December 31, 2017, the fair values of these equity securities were $169.4 million and $188.4 million, respectively.

Investment and other income (loss), net includes the realized and unrealized holding gains and losses on these equity securities. During the three and nine months ended September 30, 2018, we recognized a net loss of $23.8 million and a net gain of $62.9 million, respectively, from changes in the fair values of these equity securities. This included the impact of selling a portion of our Immunomedics common stock holdings for $91.9 million during the nine months ended September 30, 2018. Net unrealized gains recognized during the nine months ended September 30, 2018 on equity securities still held at that date were $34.6 million.

In 2017, investment and other income (loss), net also included activity related to an Immunomedics warrant derivative prior to the warrant's exercise by us in December 2017. During the three and nine months ended September 30, 2017, we recognized net gains from changes in the fair value of the warrant derivative of $78.7 million and $76.7 million, respectively, and related income tax benefits of $2.7 million and $5.4 million, respectively.

We also held debt securities, which consisted of the following (in thousands):

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
September 30, 2018				
U.S. Treasury securities	$370,551	$—	$(297)	$370,254
Contractual maturities (at date of purchase)				
Due in one year or less	$284,377			$284,230
Due in one to two years	86,174			86,024
Total	$370,551			$370,254
December 31, 2017				
U.S. Treasury securities	$252,511	$—	$(285)	$252,226
Contractual maturities (at date of purchase)				

Due in one year or less	$ 151,903	$ 151,842
Due in one to two years	100,608	100,384
Total	$ 252,511	$ 252,226

Table of Contents

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 (in thousands):

	Fair value measurement using:			
	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
September 30, 2018				
Short-term investments—U.S. Treasury securities	$347,619	$ —	$ —	$347,619
Long-term investments—U.S. Treasury securities	22,635	—	—	22,635
Other non-current assets—equity securities	169,358	—	—	169,358
Total	$539,612	$ —	$ —	$539,612
December 31, 2017				
Short-term investments—U.S. Treasury securities	$252,226	$ —	$ —	$252,226
Other non-current assets—equity securities	188,358	—	—	188,358
Total	$440,584	$ —	$ —	$440,584

8. Inventories

The following table presents our inventories of ADCETRIS (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 60,819	$ 52,398
Finished goods	14,353	7,580
Total	$ 75,172	$ 59,978

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.

9. Legal matters

On March 29, 2017, a stockholder derivative lawsuit, or the Stockholder Derivative Action, was filed in Washington Superior Court for the County of Snohomish, or the Snohomish County Superior Court. The complaint names as defendants certain of our current and former executives and members of our board of directors. We are named as a nominal defendant. The Stockholder Derivative Action was largely based on a January 2017 securities class action

suit, or the CD33A Class Action, that was filed in the United States District Court for the Western District of Washington and which alleged material misrepresentations and omissions in public statements regarding our business, operational and compliance policies, as well as violations of Sections 10(b) and 20(b) of the Securities Exchange Act. Following the dismissal with prejudice of the CD33A Class Action, on August 30, 2018, the plaintiffs in the Stockholder Derivative Action filed an amended complaint. This complaint alleges that the defendants breached their fiduciary duties by making or failing to correct certain allegedly improper public statements regarding our former SGN-CD33A program and by wasting our assets by allowing certain SGN-CD33A

Table of Contents

trials to continue. The complaint seeks unspecified damages, disgorgement of compensation, corporate governance changes, and attorneys' fees and costs. Because the complaint is derivative in nature, it does not seek monetary damages from us. On October 4, 2018, we filed a motion to dismiss the amended complaint for failure to plead demand futility. The plaintiffs' opposition brief is due on November 9, 2018. A hearing on our motion to dismiss is scheduled for December 14, 2018. As a result of this lawsuit, we may incur litigation and indemnification expenses.

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. 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.

10. Subsequent event

In October 2018, we established an additional LTIP to provide eligible employees with the opportunity to receive performance-based incentive compensation, which is comprised of restricted stock units. The grant and/or vesting of restricted stock units is contingent upon the achievement of pre-determined regulatory milestones. The estimated value under this LTIP at its inception was approximately $33.4 million. We will record compensation expense related to this LTIP as described in Note 1 under "Long-term incentive plans."

Table of Contents

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

The following discussion of our financial condition and results of operations contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "int 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 focused on the development and commercialization of targeted therapies for the treatment of cancer. Our antibody-drug conjugate, or ADC, technology utilizes the targeting ability of monoclonal antibodies to deliver cell-killing agents directly to cancer cells. We are commercializing ADCETRIS®, or brentuximab vedotin, for the treatment of several types of lymphomas. We are also advancing a pipeline of novel therapies for solid tumors and blood-related cancers designed to address unmet medical needs and improve treatment outcomes for patients.

ADCETRIS® (brentuximab vedotin)

Our marketed product ADCETRIS® is commercially available in 71 countries, including in the U.S., Canada, members of the European Union, and Japan. We are collaborating with Takeda Pharmaceutical Company Limited, or Takeda, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Seattle Genetics has retained commercial rights for ADCETRIS in the U.S. and its territories and in Canada, and 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, for five indications, including several settings for the treatment of Hodgkin lymphoma, for relapsed systemic anaplastic large cell lymphoma, or sALCL, and for certain types of cutaneous T-cell lymphoma, or CTCL. In March 2018, the FDA approved ADCETRIS in combination with chemotherapy for the treatment of newly diagnosed adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma. The approval was based on the successful outcome of the phase 3 ECHELON-1 clinical trial that compared ADCETRIS plus AVD (adriamycin, vinblastine and dacarbazine) to ABVD (adriamycin, bleomycin, vinblastine and dacarbazine). In September 2018, the Japanese Ministry of Health, Labour and Welfare approved ADCETRIS in combination with AVD as a frontline treatment option for CD30-positive Hodgkin lymphoma patients in Japan based on the ECHELON-1 trial results. In addition, Takeda has submitted applications for approval of ADCETRIS in combination with AVD in previously untreated Hodgkin lymphoma to several other regulatory authorities, including the European Medicines Agency. ADCETRIS is approved by the European Commission for four indications, encompassing several settings for the treatment of relapsed Hodgkin lymphoma, relapsed sALCL, and certain types of CTCL.

Beyond our current labeled indications, we are evaluating ADCETRIS in two ongoing phase 3 trials:

- In collaboration with Takeda, we are conducting the phase 3 ECHELON-2 trial in mature T-cell lymphoma, or MTCL, also known as peripheral T-cell lymphoma, or PTCL, including sALCL. ECHELON-2 is evaluating ADCETRIS in combination with CHP versus CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) for the treatment of newly-diagnosed MTCL patients. In October 2018, we and Takeda announced top-line results from

the trial. The trial met its primary endpoint, demonstrating a statistically significant improvement in progression-free survival, or PFS, of ADCETRIS in combination with CHP versus the control arm, CHOP (hazard ratio=0.71, p-value=0.0110). The ADCETRIS plus CHP arm also demonstrated superior overall survival, or OS, a key secondary endpoint, compared to CHOP (hazard ratio=0.66; p-value=0.0244). All other key secondary endpoints, including PFS in patients with sALCL, complete remission rate, and objective response rate, were statistically significant in favor of the ADCETRIS plus CHP arm. The safety profile of ADCETRIS plus CHP in the ECHELON-2 trial was comparable to CHOP and consistent with the established safety profile of ADCETRIS in combination with chemotherapy. Based upon the positive outcome of the ECHELON-2 trial, we plan to submit a Supplemental Biologics License Application, or sBLA, to the FDA in November 2018 to seek approval of

Table of Contents

ADCETRIS as part of a frontline combination chemotherapy regimen in patients with previously untreated CD30-expressing PTCL.

- In collaboration with Bristol-Myers Squibb Company, or BMS, we are conducting another phase 3 trial of ADCETRIS, the CHECKMATE 812 trial, that is evaluating the combination of BMS's immunotherapy nivolumab (Opdivo) with ADCETRIS for the treatment of relapsed or refractory, or transplant-ineligible, classical Hodgkin lymphoma.

Late-stage clinical product candidates

Enfortumab vedotin: 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 the EV-201 trial, for patients with locally advanced or metastatic urothelial cancer who were previously treated with checkpoint inhibitor therapy. In July 2018, we completed enrollment in the first cohort of patients who previously received both platinum chemotherapy and a checkpoint inhibitor (PD-L1 or PD-1). We expect to report top-line data from this cohort in the first quarter of 2019. We believe that positive data in this cohort could support potential registration under the FDA's accelerated approval pathway. In addition, we are continuing enrollment in a second cohort of patients who previously received checkpoint inhibitor therapy but who were not candidates for treatment with a platinum agent, which we believe could serve as the basis for a second labeled indication. In July 2018, we and Astellas initiated a phase 3 trial called EV-301 for patients with metastatic urothelial cancer who previously received both platinum chemotherapy and a checkpoint inhibitor (PD-L1 or PD-1). EV-301 is intended to support global regulatory submissions for approval and serve as a confirmatory trial in the U.S. The FDA granted Breakthrough Therapy Designation, or BTD, in March 2018 to enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who were previously treated with a checkpoint inhibitor. We and Astellas are also conducting a phase 1b trial of enfortumab vedotin in combination with either pembrolizumab or other cancer agents for patients with first- or second-line locally advanced or metastatic urothelial cancer.

Tucatinib: Tucatinib is an investigational oral tyrosine kinase inhibitor, or TKI, targeting HER2. Tucatinib is currently being evaluated in a randomized global pivotal 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. We expect to achieve enrollment of 480 patients in the HER2CLIMB trial in early 2019 to support analysis of the primary endpoint of PFS. In addition, based on interactions with the FDA, we intend to continue enrollment up to 600 patients to strengthen the analyses of key secondary endpoints, including PFS in patients with brain metastases and overall survival. We anticipate completing enrollment of the additional patients in mid-2019.

Tisotumab vedotin: In collaboration with Genmab A/S, or Genmab, we are developing tisotumab vedotin, which is an ADC targeting tissue factor. In June 2018, we initiated a potentially pivotal phase 2 trial, called the innovaTV 204 trial, 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 registration under the FDA's accelerated approval pathway. In July 2018, we initiated a phase 2 clinical trial, called innovaTV 207, for patients with colorectal, non-small cell lung, pancreatic or head and neck cancers. The trial is intended to inform a potential broad development program.

Early-stage clinical product candidates and other collaborations

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 also includes SGN-CD48A, which utilizes our ADC technology, SEA-CD40 and SEA-BCMA, which are both based on our sugar-engineered antibody, or SEA, technology, and SGN-2FF, which is a novel small molecule. In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies. 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. We and Unum are conducting a phase 1 clinical trial studying Unum's ACTR087 in combination with SEA-BCMA for the treatment of relapsed or refractory multiple myeloma.

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

Outlook

Our ongoing research, development, manufacturing and commercial activities will require substantial amounts of capital and may not ultimately be successful. In addition, we may encounter unexpected difficulties during our integration and

Table of Contents

development activities related to our March 2018 acquisition of Cascadian Therapeutics, Inc., or Cascadian, and tucatinib, any of which may cause us to expend greater funds and efforts, or may slow, delay or limit development progress with respect to tucatinib. 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. Our other product candidates are in relatively early stages of development. Enfortumab vedotin, tucatinib, tisotumab vedotin, and our other product candidates will require significant further development, financial resources and personnel to pursue and obtain regulatory approval and to develop them into commercially viable products, if at all. 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, 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 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 2018 as compared to 2017, for the above and other reasons, we expect that our ability to accelerate ADCETRIS sales growth, 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 newly diagnosed patients with previously untreated Stage III and IV classical Hodgkin lymphoma, and physician prescribing decisions with respect to ADCETRIS in this indication. Our ability to accelerate ADCETRIS sales growth also will be affected by our ability to continue to expand ADCETRIS' utilization across all labeled indications of use, particularly in the ECHELON-2 treatment setting if ADCETRIS is approved for use in that treatment setting. Although we reported positive top-line data in our ECHELON-2 trial in October 2018, there can be no assurance that we will ultimately obtain regulatory approval of ADCETRIS in the ECHELON-2 treatment setting, which would limit our sales, and the commercial potential, of ADCETRIS. In addition, Takeda may be unable to obtain regulatory approvals of ADCETRIS in the ECHELON-1 treatment setting in its territories (other than in Japan where ADCETRIS was recently approved in combination with 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, and the commercial potential, of ADCETRIS.

We also expect that amounts earned from our collaboration agreements, including royalties, will continue to be an important source of our revenues and cash flows. These revenues will be impacted by future development funding and the achievement of development, clinical and commercial success by our collaborators under our existing collaboration and license agreements, including our ADCETRIS collaboration with Takeda, as well as by entering into potential new collaboration and license agreements. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and should not be relied upon as being indicative of our future performance.

Table of Contents

Financial summary

For the nine months ended September 30, 2018, total revenues increased to $480.2 million, compared to $352.6 million for the same period in 2017. This increase was driven primarily by higher ADCETRIS net product sales. Net product sales of ADCETRIS were $344.8 million for the nine months ended September 30, 2018, compared to $223.8 million for the same period in 2017.

For the nine months ended September 30, 2018, total costs and expenses increased to $649.9 million, compared to $503.4 million for the same period in 2017. This primarily reflected higher research and development expenses, due to upfront payments for in-license agreements and continued investment in our late-stage pipeline, as well as higher selling, general, and administrative costs to support the ADCETRIS launch in patients diagnosed with previously untreated Stage III or IV classical Hodgkin lymphoma and costs related to the acquisition of Cascadian, or the Cascadian Acquisition. In addition, our costs and expenses included Cascadian operations subsequent to March 9, 2018. Net loss for the nine months ended September 30, 2018 was favorably impacted by a net gain of $62.9 million resulting from the change in the fair value of our equity securities.

As of September 30, 2018, we had $485.7 million in cash, cash equivalents and investments and $1.4 billion in total stockholders' equity.

Comparability

In March 2018, we acquired Cascadian for $10.00 per share in cash, or approximately $614.1 million. Cascadian was included in our results of operations as of the acquisition date. Accordingly, the results discussed below were impacted by the timing of this acquisition. Refer to "Part I. Item 1. Note 3—Acquisition of Cascadian" for additional information on the Cascadian Acquisition.

We adopted Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to our accounting policy for revenue recognition. We used the modified retrospective method and recognized the cumulative effect of initially applying Topic 606 as an adjustment to decrease the opening accumulated deficit at January 1, 2018. Accordingly, comparative information has not been adjusted and continues to be reported under previous accounting standards. Refer to "Part I. Item 1. Note 2—Revenue from contracts with customers" for additional information.

We adopted Accounting Standards Update, or ASU, "ASU 2016-01, Financial Instruments: Overall" on January 1, 2018, which addressed certain aspects of recognition, measurement, presentation and disclosure of financial instruments, including that changes in the fair value of equity securities be recorded in income or loss rather than accumulated other comprehensive income or loss in stockholders' equity. We used the modified retrospective method and recognized the cumulative effect of initially applying this ASU as an adjustment to decrease the opening accumulated deficit at January 1, 2018. Accordingly, comparative information has not been adjusted and continues to be reported under previous accounting standards. Refer to "Part I. Item 1. Note 1—Summary of significant accounting policies—Investments" for additional information.

Results of operations

Net product sales

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

	Three months ended September 30,			Nine months ended September 30,		
(dollars in thousands)	2018	2017	% Change	2018	2017	% Change
Net product sales	$126,976	$79,177	60 %	$344,776	$223,841	54 %

The increases in net product sales for the three and nine months ended September 30, 2018 from the comparable periods in 2017 primarily resulted from higher sales volume during the 2018 periods and, to a lesser extent, from the effect of price increases. Higher sales volume during the 2018 periods was driven by label expansions of ADCETRIS for new indications; in particular, for certain types of CTCL in November 2017 and for frontline Stage III or IV Hodgkin lymphoma in March 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

Table of Contents

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, 2017	$ 14,374	$ 3,521	$17,895
Provision related to current period sales	129,564	8,455	138,019
Adjustment for prior period sales	438	(457)	(19)
Payments/credits for current period sales	(107,670)	(5,733)	(113,403)
Payments/credits for prior period sales	(10,970)	(916)	(11,886)
Balance as of September 30, 2018	$ 25,736	$ 4,870	$30,606

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 nine months ended September 30, 2018 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 2018 as compared to 2017, 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 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 September 30,			Nine months ended September 30,		
(dollars in thousands)	2018	2017	% Change	2018	2017	% Change
Takeda	$18,805	$21,665	(13)%	$41,122	$59,158	(30)%
AbbVie	300	17,350	(98)%	13,000	21,393	(39)%
Genmab	—	—	N/A	7,000	—	N/A
GSK	—	—	N/A	6,000	—	N/A
Other	681	429	59 %	9,402	2,228	322 %
Collaboration and license agreement revenues	$19,786	$39,444	(50)%	$76,524	$82,779	(8)%

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

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 decreased for the three and nine months ended September 30, 2018 from the comparable periods in 2017, primarily driven by a decrease in drug product

supply activities. As of September 30, 2018, we recorded $42.0 million of deferred revenue related to our collaboration with Takeda, which we will recognize as the remaining performance obligations are satisfied through November 2019. Collaboration revenues from Takeda also can fluctuate based on the achievement of milestones by Takeda; accordingly, activity for the three and nine months ended September 30, 2018 included substantially all of a $10.0 million regulatory milestone upon its achievement in September 2018.

Table of Contents

Changes in collaboration revenues from AbbVie, Genmab, and GSK reflected the timing of development milestones from our ADC collaborations with each respective collaborator. The development milestone from Genmab recorded in the nine months ended September 30, 2018 was related to a product candidate other than tisotumab vedotin.

Other collaboration revenues were comparable for the three months ended September 30, 2018 and 2017. Other collaboration revenues increased for the nine months ended September 30, 2018 from the comparable period in 2017, primarily due to clinical manufacturing services performed for BMS under a transitional services agreement related to our acquisition of a manufacturing facility, or the North Creek manufacturing facility, in October 2017. 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 2018 to be lower than 2017, driven by the timing of milestones and lower expected volume of drug to be supplied to Takeda.

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 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 September 30, 2018, total future potential milestone payments to us under the ADCETRIS collaboration could total approximately $155.0 million. Of that amount, up to approximately $7.0 million relates to the achievement of development milestones, up to approximately $108.0 million relates to the achievement of regulatory milestones and up to approximately $40.0 million relates to the achievement of commercial milestones. As of September 30, 2018, $80.0 million in milestones had been achieved as a result of regulatory and commercial progress by Takeda.

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 October 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.

Table of Contents

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. Each party has the option to co-promote up to a specified percentage of the sales effort in the other party's 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 September 30, 2018, our ADC collaborations had generated approximately $400.0 million, primarily in the form of upfront and milestone payments. Total milestone payments to us under our current ADC collaborations could total up to approximately $2.6 billion if all potential product candidates achieved all of their milestone events. Of this amount, approximately $0.4 billion relates to the achievement of development milestones, approximately $1.0 billion relates to the achievement of regulatory milestones and approximately $1.2 billion relates to the achievement of commercial milestones. Since we do not control the research, development or commercialization of any of the products that would generate these milestones, we are not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable by our collaborators. Successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing it is a significantly lengthy and highly uncertain process which entails a significant risk of failure. In addition, business combinations, changes in a collaborator's business strategy and financial difficulties or other factors could result and have resulted in a collaborator abandoning or delaying development of its product candidates. As such, the potential 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 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 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.

Table of Contents

	Three months ended September 30,			Nine months ended September 30,		
(dollars in thousands)	2018	2017	% Change	2018	2017	% Change
Royalty revenues	$22,662	$16,670	36 %	$58,887	$46,025	28 %
Cost of royalty revenues	$5,320	$5,196	2 %	$16,845	$13,900	21 %

Royalty revenues increased for the three and nine months ended September 30, 2018 from the comparable periods in 2017 primarily driven by higher net sales volume of ADCETRIS by Takeda in its territories and the impact of the adoption of Topic 606. We expect that royalty revenues will increase in 2018 as compared to 2017, 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 increased for the three and nine months ended September 30, 2018 from the comparable periods in 2017 due to the same factors that impacted royalty revenues. The increase in cost of royalty revenues for the three months ended September 30, 2018 from the comparable period in 2017 was partially offset by 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 September 30,			Nine months ended September 30,		
(dollars in thousands)	2018	2017	% Change	2018	2017	% Change
Cost of sales	$12,348	$9,019	37 %	$35,863	$24,555	46 %

Cost of sales increased for the three and nine months ended September 30, 2018 from the comparable periods in 2017 primarily due to increased sales volumes. The increase in cost of sales for the three months ended September 30, 2018 from the comparable period in 2017 was partially offset by lower amounts owed to certain third-party licensors. We expect cost of sales to increase in 2018 as compared to 2017, primarily due to anticipated increases in sales volumes.

Research and development

	Three months ended September 30,			Nine months ended September 30,		
(dollars in thousands)	2018	2017	% Change	2018	2017	% Change
Research and clinical development	$90,670	$72,343	25 %	$290,412	$217,467	34 %
Process sciences and manufacturing	49,505	41,263	20 %	125,125	128,729	(3)%
Total research and development	$140,175	$113,606	23 %	$415,537	$346,196	20 %

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 increases for the three and nine months ended September 30, 2018 from the comparable periods in 2017 reflected increases in internal and co-development costs to support our late stage pipeline of product candidates, and, for the nine months ended September 30, 2018, the increase also included $35.0 million of upfront in-licensing payments made during the first quarter of 2018.

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 September 30, 2018 from the comparable period in 2017 primarily reflected increases in staffing and other costs to support our late stage pipeline of product candidates, including operating costs of the North

Creek manufacturing facility, partially offset by decreased drug product supplied to Takeda. The decrease for the nine months ended September 30, 2018 from the comparable period in 2017 primarily reflected decreased drug product supplied to Takeda, partially offset by 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

Table of Contents

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 September 30,		Nine months ended September 30,		Five years ended
(in thousands)	2018	2017	2018	2017	September 30, 2018
ADCETRIS (brentuximab vedotin)	$13,688	$23,698	$31,681	$65,626	$ 298,675
Enfortumab vedotin	7,479	3,703	16,982	15,399	48,565
Tucatinib	11,654	—	24,392	—	24,392
Tisotumab vedotin	5,064	1,682	15,303	1,682	21,325
SGN-LIV1A (ladiratuzumab vedotin)	7,403	4,523	20,683	8,179	49,403
SGN-CD33A (vadastuximab talirine)	685	1,440	2,795	31,003	109,965
Other clinical stage programs	6,618	14,517	18,227	34,401	149,055
Total third-party costs for clinical stage programs	52,591	49,563	130,063	156,290	701,380
Other costs and overhead	87,584	64,043	285,474	189,906	1,126,209
Total research and development	$140,175	$113,606	$415,537	$346,196	$ 1,827,589

Third-party costs for ADCETRIS decreased for the three and nine months ended September 30, 2018 from the comparable periods in 2017 primarily due to decreases in drug product supplied to Takeda, as well as decreases in related clinical trial activities. The cost of drug product supplied to Takeda is charged to research and development expense. We are reimbursed for the drug product, which is included in collaboration and license agreement revenues.

Third-party costs for enfortumab vedotin increased for the three and nine months ended September 30, 2018 from the comparable periods in 2017 primarily due to increases in clinical trial costs related to progression of this later-stage program.

Third-party costs for tucatinib increased for the three and nine months ended September 30, 2018 from the comparable periods in 2017 due to the Cascadian Acquisition, under which we acquired global rights to tucatinib in March 2018. Tucatinib is currently being evaluated in a phase 2 pivotal 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.

Third-party costs for tisotumab vedotin increased for the three and nine months ended September 30, 2018 from the comparable periods in 2017 with the exercise of the co-development option in September 2017.

Third-party costs for ladiratuzumab vedotin increased for the three and nine months ended September 30, 2018 from the comparable periods in 2017 primarily due to increases in drug supply and clinical trial costs related to the progression of this program.

Third-party costs for SGN-CD33A decreased for the three and nine months ended September 30, 2018 from the comparable periods in 2017 due to the discontinuation of our phase 3 CASCADE and other SGN-CD33A clinical trials in 2017. We subsequently discontinued our SGN-CD33A program.

Other costs and overhead include third-party costs of our preclinical programs and costs associated with personnel and facilities, which increased for the three and nine months ended September 30, 2018. Additionally, other costs and overhead increased for the nine months ended September 30, 2018 due to $35.0 million of upfront in-licensing payments in the first quarter of 2018.

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;
- the number and location of sites included in the trials;

Table of Contents

- 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 2018 will increase compared to 2017 due primarily to higher costs for the development of our product candidates, primarily enfortumab vedotin, tucatinib, tisotumab vedotin, and ladiratuzumab vedotin, the operation of the North Creek manufacturing facility that we acquired in October 2017, and upfront in-license payments. 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 September 30,			Nine months ended September 30,		
(dollars in thousands)	2018	2017	% Change	2018	2017	% Change
Selling, general and administrative	$57,155	$39,667	44 %	$181,629	$118,783	53 %

Selling, general and administrative expenses increased for the three and nine months ended September 30, 2018 from the comparable periods in 2017 primarily due to increases in staffing and investments to launch ADCETRIS in patients diagnosed with previously untreated Stage III or IV classical Hodgkin lymphoma, as well as higher infrastructure costs to support our continued growth. Additionally, selling, general and administrative expenses increased for the nine months ended September 30, 2018 due to costs associated with the Cascadian Acquisition.

We anticipate that selling, general and administrative expenses will increase in 2018 compared to 2017 as we continue our commercial activities in support of the commercialization of ADCETRIS, as well as our support of general operations, which now includes Cascadian.

Investment and other income (loss), net

	Three months ended September 30,			Nine months ended September 30,		
(dollars in thousands)	2018	2017	% Change	2018	2017	% Change
Gain (loss) on equity securities	$(23,765)	$78,714	(130)%	$62,882	$76,699	(18)%
Income tax benefit on unrealized gain on equity securities	—	2,739	N/A	—	5,415	N/A
Investment income, net	1,893	765	147 %	3,917	2,346	67 %
Total investment and other income (loss), net	$(21,872)	$82,218	(127)%	$66,799	$84,460	(21)%

N/A: Not a meaningful comparison.

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. In 2017, gains and losses on equity securities also included activity related to an Immunomedics warrant derivative prior to the warrant's exercise by us in December 2017.

We adopted “ASU 2016-01, Financial Instruments: Overall” on January 1, 2018, which required that changes in the fair value of equity securities be recorded in income or loss rather than accumulated other comprehensive income or loss in stockholders' equity. Comparative information has not been adjusted and continues to be reported under previous

accounting standards.

The decreases in investment and other income (loss), net for the three and nine months ended September 30, 2018 from the comparable periods in 2017 were driven by a $23.8 million net loss and a $62.9 million net gain, respectively, from changes

Table of Contents

in the fair value of our equity securities, which included the impact of selling a portion of our Immunomedics common stock holdings. This was offset by the prior year increase in the fair value of the Immunomedics warrant derivative and the related income tax benefit.

Liquidity and capital resources

(in thousands)	September 30, 2018	December 31, 2017
Cash, cash equivalents, and investments	$485,711	$413,171
Working capital	523,296	409,932
Stockholders' equity	1,364,521	677,569

	Nine months ended September 30,	
(in thousands)	2018	2017
Cash provided (used) by:		
Operating activities	$(179,251)	$(116,506)
Investing activities	(576,375)	109,982
Financing activities	710,138	25,991

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. For the nine months ended September 30, 2018, we paid $614.1 million (or $598.2 million net of the cash acquired) for the Cascadian Acquisition in March 2018 and received approximately $91.9 million from the sale of a portion of our Immunomedics common stock holdings.

The change in net cash from financing activities included proceeds from stock option exercises and our employee stock purchase plan for all periods presented. For the nine months ended September 30, 2018, financing activities also included $658.2 million in net proceeds from the public offering of our common stock in February 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 September 30, 2018, we had $463.1 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 commercialize additional product candidates. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to our plans to build a commercial infrastructure in Europe and to otherwise continue to expand our operations internationally. We also anticipate continuing to commit substantial capital

resources to the integration and development activities related to Cascadian and tucatinib. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS, the research, continued development and manufacturing of our product candidates and 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

Table of Contents

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, 2017. In September 2018, we entered into three 10-year leases totaling approximately 207,000 square feet of facilities, to be used for office space. The leases will commence in January 2019. The aggregate base rent due over the non-cancelable lease terms is approximately $50.6 million. Each of the leases contains a 10-year renewal option.

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 nine months ended September 30, 2018 were consistent with those in Part II Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2017, with the following updates:

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 the present value of future discounted cash flows, an income approach. The significant estimates in the discounted cash flow model primarily include the discount rate, rates of future revenue growth and/or profitability of the acquired business, and working capital effects. 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. Specific to in-process research and development, significant estimates primarily include the number of potential patients and the market prices of future commercial products, costs required to conduct clinical trials and commercialize future products, and estimates for the probability of success and discount rate. These estimates and the resulting valuations require significant judgment.

Revenue recognition: We adopted Topic 606 on January 1, 2018, resulting in a change to our accounting policy for revenue recognition. This standard did not generally change the practice under which we recognize product revenue from sales of ADCETRIS. As it relates to product revenue, we applied and will continue to apply significant judgment to our estimates for gross-to-net deductions as we applied under the previous accounting standards.

For collaboration and license agreement revenues, we applied and may continue to apply significant judgment to our Takeda ADCETRIS collaboration:

- We evaluated whether our contractual obligations represented distinct performance obligations. Such evaluation required significant judgment since it was made from the customer's perspective. We determined that our performance obligations under the collaboration at contract inception were not distinct and represented a single performance obligation.
- The Takeda ADCETRIS collaboration includes variable consideration. We assess variable consideration at each reporting period as to whether it is not subject to significant future reversal and, therefore, should be included in the

transaction price. Assessing the probability of future reversal requires significant judgment.

In future ADC and other collaboration and license agreements, we may be required to make significant judgments regarding our performance obligations and any variable consideration.

Commercial sales-based milestones and sales royalties, which relate predominantly to the license of intellectual property, are recorded in the period of the related sale and based on estimates if actual information is not yet available. Royalty revenues primarily reflect amounts earned under the Takeda ADCETRIS collaboration based on a percentage of Takeda's net sales of

Table of Contents

ADCETRIS. Since we do not take a substantive role or control the commercial sales of ADCETRIS by Takeda, estimating their net sales of ADCETRIS may require significant judgment to the extent actual information is not yet available.

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

Interest rate risk

There have been no material changes to our interest rate risk during the nine months ended September 30, 2018. For additional information, see Part II Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2017.

Foreign currency risk

There have been no material changes to our foreign currency risk during the nine months ended September 30, 2018. For additional information, see Part II Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2017.

Equity price risk

There have been no material changes to our equity price risk during the nine months ended September 30, 2018. For additional information, see Part II Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2017.

Following adoption of "ASU 2016-01, Financial Instruments: Overall" on January 1, 2018, we record changes in the fair value of equity securities in net income or loss. To the extent that we continue to hold equity securities, our operating results may fluctuate significantly.

Item 4. Controls and Procedures

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

(b) Changes in internal control over financial reporting. There have not been any changes in our internal control over financial reporting during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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 9. 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 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;
- 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 any indications for frontline peripheral T-cell lymphoma, or PTCL, or frontline Hodgkin lymphoma 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 Stage III or IV Hodgkin lymphoma indication and other approved indications;
- we may fail to obtain regulatory approval and commercialize ADCETRIS in the ECHELON-2 treatment setting notwithstanding the positive data we reported from the ECHELON-2 trial, which would limit sales of, and the commercial potential of, ADCETRIS;
- 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;

- the estimated incidence rate of new patients in ADCETRIS' approved indications may be lower than our projections;
- there may be adverse results or events reported in any of the clinical trials that we and/or Takeda are conducting or may in the future conduct for ADCETRIS;
- we may be unable to continue to effectively market, sell and distribute ADCETRIS;

Table of Contents

- 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 European Commission 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 European Commission 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 and changes in tariffs, including any further retaliatory tariffs imposed by foreign countries in response to U.S. tariffs imposed by the Trump administration.

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 treatment of adult patients with pcALCL and CD30-expressing MF who have received prior systemic therapy and newly diagnosed patients with previously untreated Stage III and IV classical Hodgkin lymphoma, 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 accelerate ADCETRIS sales growth, 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 newly diagnosed patients with previously untreated Stage III and IV classical Hodgkin lymphoma, and physician prescribing decisions with respect to ADCETRIS in this indication. Our ability to accelerate ADCETRIS sales growth also will be affected by our ability to continue to expand ADCETRIS' utilization across all labeled indications of use, particularly in the ECHELON-2 treatment setting if ADCETRIS is approved for use in that treatment setting. Although we reported positive top line data in our ECHELON-2 trial in October 2018, there can be no assurance that we will ultimately obtain regulatory approval of ADCETRIS in the ECHELON-2 treatment setting, which would limit our sales of, and the commercial potential of, ADCETRIS. In addition, Takeda may be unable to obtain regulatory approvals of ADCETRIS in the ECHELON-1 treatment setting in its territories (other than in Japan where ADCETRIS was recently approved in combination with 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

FDA and similar regulatory authorities outside the United States regulate companion diagnostics. Companion diagnostics require separate or coordinated regulatory approval prior to or in association with commercialization of the related therapeutic product. In this regard, we expect that concurrent approval of a CD30 companion diagnostic may be required for approval of ADCETRIS in the ECHELON-2 treatment setting. However, Ventana may not be able to successfully develop and obtain regulatory approval for a companion diagnostic to support regulatory approval of ADCETRIS in the ECHELON-2 treatment setting if required in a timely manner or at all. If Ventana is unable to successfully develop a required companion diagnostic, or experiences delays in doing so, the development of ADCETRIS in the ECHELON-2 treatment setting may be adversely affected, we may fail to receive regulatory approval for ADCETRIS in the ECHELON-2 treatment setting and we may not realize the full commercial potential of ADCETRIS. Further, if a companion diagnostic requirement were included in the ADCETRIS label, such a

Table of Contents

requirement may limit our ability to commercialize ADCETRIS in the applicable setting due to potential label requirements, prescriber practices, constraints on availability of the diagnostic, or other factors.

Even if we and Takeda receive the required regulatory approvals to market ADCETRIS for any additional indications or in additional jurisdictions, we and Takeda may not be able to effectively commercialize ADCETRIS, including for the reasons set forth above. Our ability to grow ADCETRIS product sales in future periods is also dependent on price increases and we periodically increase the price of ADCETRIS. Price increases on ADCETRIS and negative publicity regarding drug pricing and price increases generally, whether on ADCETRIS or products distributed by other pharmaceutical companies, could negatively affect market acceptance of, and sales of, ADCETRIS. In any event, we cannot assure you that price increases we have taken or may take in the future will not in the future negatively affect ADCETRIS sales.

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

Reports of adverse events or safety concerns involving ADCETRIS could interrupt, delay or halt clinical trials of ADCETRIS, including the post-approval confirmatory studies that Takeda is required to conduct as a condition of the marketing authorization of ADCETRIS by the European Commission. 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 (G-CSF) 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. 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, or PML, and death can occur in patients receiving ADCETRIS. Further, based on the identification of future adverse events, we may be required to further revise the prescribing information, including ADCETRIS' boxed warning, which could negatively impact sales of ADCETRIS or adversely affect ADCETRIS' acceptance in the market.

Likewise, reports of adverse events or safety concerns involving ADCETRIS or our product candidates could interrupt, delay or halt clinical trials of such product candidates, or could result in our inability to obtain regulatory approvals for any of our product candidates. For example, in June 2017, we discontinued the phase 3 CASCADE clinical trial of SGN-CD33A based on unexpected adverse events following a higher rate of deaths in the SGN-CD33A containing arm versus the control arm of this trial, and the Investigational New Drug application, or IND, for SGN-CD33A was subsequently placed on hold by the FDA. We subsequently discontinued our SGN-CD33A program altogether and do not expect to receive any return on our investment in SGN-CD33A.

In addition, we are conducting pivotal trials for enfortumab vedotin, tucatinib and tisotumab vedotin based on only limited phase 1 clinical data. There may 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 ongoing 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 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,

Table of Contents

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 Europe, in each case under regulations which allow for approval of products for cancer or other serious or life threatening illnesses based on a surrogate endpoint or on a clinical endpoint other than survival or irreversible morbidity. Under these types of approvals, 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 Europe, 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 European Commission withdrawing approval of ADCETRIS in the European Union for certain indications, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda in the European Union and could adversely affect our results of operations.

In addition, 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 product. For example, we and Astellas are conducting a pivotal phase 2 trial of enfortumab vedotin, called the EV-201 trial, for patients with locally advanced or metastatic urothelial cancer who were previously treated with checkpoint inhibitor therapy. In July 2018, we completed enrollment in the first cohort of patients who previously received both platinum chemotherapy and a checkpoint inhibitor (PD-L1 or PD-1). We believe that positive data in this cohort could support potential registration under the FDA's accelerated approval pathway. As a condition of any 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, packaging, adverse event reporting, storage, advertising and promotion of enfortumab vedotin would be subject to extensive regulatory requirements, all of which would entail significant expense and could negatively impact the potential future 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 these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject an approved product, its manufacturer and the manufacturer’s facilities to continual review and inspections, including periodic unannounced inspections. The subsequent discovery of previously unknown problems with ADCETRIS, including adverse events of unanticipated severity or frequency, or problems with the facilities where ADCETRIS is manufactured, may result in restrictions on the marketing of ADCETRIS, up to and including withdrawal of ADCETRIS from the market. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, such noncompliance could

result in regulatory action and additional costs to us.

Failure to comply with applicable FDA and other regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

- issuance of Form FDA 483 notices or Warning Letters by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;

Table of Contents

- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us;
- refusals to permit drugs to be imported into or exported from the United States;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

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

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

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaborators are permitted to market our product candidates in the United States or foreign countries until we obtain marketing approval from the FDA or other foreign regulatory authorities, and we or our collaborators may never receive regulatory approval for the commercial sale of any of our product candidates. In addition, part of our strategy is to continue to explore the use of ADCETRIS 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, including in the ECHELON-2 treatment setting. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured, and we have only limited experience in preparing and submitting the applications necessary to gain regulatory approvals. Further, the FDA and other foreign regulatory agencies have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate we develop, including any regulatory approvals for the potential commercial sale of ADCETRIS in additional indications or in any additional territories. In this regard, even if we believe the data collected from clinical trials of ADCETRIS and our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other foreign regulatory authority. In addition, the FDA or their advisors may disagree with our interpretations of data from preclinical studies and clinical trials. For example, based on the positive data we reported from the ECHELON-2 trial, we plan to submit a sBLA to FDA for approval of ADCETRIS as part of a frontline chemotherapy regimen in patients with previously untreated CD30-expressing PTCL. However, the FDA may disagree with our interpretations of the data from the ECHELON-2 trial or may otherwise determine not to approve our sBLA submission in a timely manner or at all. Moreover, even though our ECHELON-2 trial is being conducted under a SPA agreement with the FDA, this is not a guarantee or indication of approval, and we cannot be certain that the design of, or data collected from, any of our current or potential future clinical trials that were or are being conducted under SPA agreements with the FDA will be sufficient to support FDA approval. Further, a SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise, new drugs are approved in the same indication, or if we have failed to comply with the agreed upon trial protocols, including as a result of completing a clinical trial with fewer events than planned. In addition, a SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of a SPA agreement and the data and results from the applicable clinical trial. For example, even though we believe that the data from the ECHELON-2 trial is supportive of approval of ADCETRIS in the ECHELON-2 treatment setting, our SPA agreement with the FDA covering the ECHELON-2 trial is not a guarantee or indication of approval of ADCETRIS in ECHELON-2 treatment setting (or in any other treatment settings). 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 pcALCL and CD30-expressing MF, which are two subtypes of CTCL. Additionally, the FDA 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 additional indications, including in the ECHELON-2 treatment setting.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols and/or related SPA agreements to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards, or IRBs, for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In addition, as part of the U.S. Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to

Table of Contents

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 in part on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.

Successful sales of ADCETRIS and any future products will depend, in part, on the extent to which coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new products and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. In light of 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, even though the FDA approved ADCETRIS in combination with chemotherapy for the treatment of newly diagnosed adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma, we cannot be certain that third-party payors will provide coverage and adequate reimbursement for ADCETRIS in that indication based on the relative price or perceived benefit of ADCETRIS as compared to alternative treatment options, which may materially harm our ability to maintain or increase sales of ADCETRIS or may otherwise negatively affect future ADCETRIS sales. In addition, even if we are able to obtain approval of our planned sBLA submission to the FDA to expand the labeled indications of use for ADCETRIS to the frontline CD30-expressing PTCL setting based on the results from the ECHELON-2 trial, we also cannot be certain that third party payors will provide reimbursement for ADCETRIS in that indication based on the relative price or perceived benefit of ADCETRIS as compared to alternative treatment options or other factors, which may also materially harm our ability to maintain or increase sales of ADCETRIS or may otherwise negatively affect future ADCETRIS sales.

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

The unavailability or inadequacy of third-party coverage and reimbursement could have a material adverse effect on the market acceptance of ADCETRIS and any of our future products and the future revenues we may expect to receive from those products. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business. Continuing negative publicity regarding pharmaceutical pricing

practices and ongoing presidential and Congressional focus on this issue create significant uncertainty regarding regulation of the healthcare industry and third-party coverage and reimbursement. If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of ADCETRIS or the pricing of pharmaceutical products generally, the prices that we charge for ADCETRIS and any future approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of ADCETRIS and any future approved products may be negatively impacted.

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

In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA, became law in the United States. PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. The provisions of PPACA of greatest importance to the pharmaceutical industry include increased Medicaid rebates, expanded Medicaid eligibility, extension of Public Health Service eligibility, annual fees payable by manufacturers and importers of branded prescription drugs, annual reporting of financial relationships with physicians and teaching hospitals, and a new

Table of Contents

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." In addition, citing legal guidance from the U.S. Department of Justice, the U.S. Department of Health and Human Services, has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the PPACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until such appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. While Congress is considering legislation to appropriate funds for CSR payments, the future of that legislation is uncertain. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business.

Further, on March 23, 2018, the Centers for Medicare & Medicaid Services, or 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. In addition, the Department of Health and Human Services, or 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. In September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019. While most 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. At the state level, legislatures are increasingly passing

Table of Contents

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 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. On January 30, 2017, the White House Office of Management and Budget withdrew the draft August 2015 Omnibus Guidance document that was issued by the Department of Health and Human Services Health Resources and Services Administration, or HRSA, that addressed a broad range of topics including, among other items, the definition of a patient's eligibility for 340B drug pricing. However, as concerns continue to grow over the need for tighter oversight, there remains the possibility that HRSA or other agency under the HHS will propose a similar regulation or that Congress will explore changes to the 340B program through legislation. For example, legislation was introduced in 2018 that would require hospitals to report their low-income utilization of the program. Further, CMS has issued a final rule that revised the Medicare hospital outpatient prospective payment system for calendar year 2018, including a new reimbursement methodology for drugs purchased under the 340B program for Medicare patients. In addition, HHS has currently set July 1, 2019 for implementation of the final rule setting forth the calculation of the ceiling price and application of civil monetary penalties under the 340B program. A significant portion of ADCETRIS purchases are eligible for 340B drug pricing, 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 ongoing initiatives to increase pressure on drug pricing. We cannot assure you as to the ultimate content, timing, or effect of changes, nor is it possible at this time to estimate the impact of any such potential legislation; however, such changes or the ultimate impact of changes could negatively affect our revenue or sales of ADCETRIS or any potential future approved products.

Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations may require us to modify our programs and could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

To help patients afford our products, we have a patient assistance program and also occasionally make donations to independent charitable foundations that help financially needy patients. These types of programs designed to assist patients in affording pharmaceuticals have become the subject of scrutiny. In recent years, some pharmaceutical manufacturers were

Table of Contents

named in class action lawsuits challenging the legality of their patient assistance programs and support of independent charitable patient support foundations under a variety of federal and state laws. Our patient assistance program and support of independent charitable foundations could become the target of similar litigation. At least one insurer also has directed its network pharmacies to no longer accept manufacturer co-payment coupons for certain specialty drugs the insurer identified. In addition, certain state and federal enforcement authorities and members of Congress have initiated inquiries about co-pay assistance programs. Some state legislatures have also been considering proposals that would restrict or ban co-pay coupons.

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

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-L1 or PD-1). Additionally, we are conducting a pivotal phase 2 trial of tucatinib for patients with HER2 positive, or HER2+, 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 potentially 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. 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 demonstrate the safety and efficacy of enfortumab vedotin, tucatinib or tisotumab vedotin, or will otherwise be sufficient to support FDA or any foreign regulatory approvals. In addition, we do not have SPA 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 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 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

Table of Contents

unknown to the FDA, different standards of medical care, and foreign currency transactions insofar as changes in the relative value of the U.S. dollar to the foreign currency where the trial is being conducted may impact our actual costs. Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies, 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, other foreign governmental agencies or the applicable data safety monitoring boards, IRBs and Ethics Committees could delay, suspend, halt or modify our clinical trials of ADCETRIS or any of our product candidates, and we, our collaborators and/or the FDA could terminate or modify any related SPA agreements, for numerous reasons, including:

- ADCETRIS or the applicable product candidate may have unforeseen safety issues or adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements, GCP, 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;
- 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

Table of Contents

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. Although we reported positive top-line data 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, and the FDA and regulatory agencies outside of the U.S., may disagree with our interpretations of data from the ECHELON-2 trial. 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 and ECHELON-2 treatment settings, and the FDA may not approve the use of ADCETRIS in 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 current product candidates are in various stages of development, and it is possible that none of our product candidates will ever become commercial products.

Our late-stage product candidates are enfortumab vedotin, tucatinib, and tisotumab vedotin, which are in pivotal trials based on only limited phase 1 clinical data. Our earlier-stage clinical pipeline includes ladiratuzumab vedotin, which is in phase 2 clinical development, and SGN-CD48A, SEA-CD40, SEA-BCMA and SGN-2FF, which are in phase 1 clinical development. 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 and obtain regulatory approval 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, we still have only limited data from our early trials of our product candidates. Preclinical studies and any encouraging or positive preliminary and interim data from our clinical trials of our product candidates may not be predictive of the results of ongoing or later clinical trials. Even if we or our collaborators are able to complete our planned clinical trials of our product candidates according to our current development timeline, the encouraging or positive results from clinical trials of our product candidates in earlier stage trials may not be replicated in subsequent 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 phase 1 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, enfortumab vedotin, tucatinib and tisotumab vedotin may fail to demonstrate sufficient efficacy in our pivotal trials despite the results observed in earlier-stage trials. In addition, there may 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 ongoing 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

Table of Contents

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 phase 2 trials for enfortumab vedotin, tucatinib and tisotumab vedotin. We have not yet completed any late-stage clinical trials for our current product candidates, and if we or our collaborators fail to produce positive results in our ongoing or planned clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Due to the uncertain and time-consuming clinical development and regulatory approval process, we may not successfully develop any of our product candidates, 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 current 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.

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

We have established collaborations with third parties to develop and market ADCETRIS and some of our current and future product candidates. For example, we entered into a collaboration agreement with Takeda in December 2009 that granted Takeda rights to develop and commercialize ADCETRIS outside of the United States and Canada. In addition, we have entered into 50:50 co-development collaborations with Astellas for the development of enfortumab vedotin, and with Genmab for the development of tisotumab vedotin. We are also collaborating with Bristol-Myers Squibb Co., or BMS, with respect to the CHECKMATE 812 pivotal phase 3 clinical trial evaluating the combination of Opdivo (nivolumab) with ADCETRIS for the treatment of relapsed or refractory, or transplant-ineligible, advanced classical Hodgkin lymphoma. In addition, we have antibody-drug conjugate, or ADC, collaborations with AbbVie, Bayer, Celldex, Genentech, GSK, Pfizer and Progenics, and we have entered into a collaboration agreement with Unum Therapeutics, Inc., or Unum, to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies incorporating our antibodies for the treatment of cancer and with Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals AG, or together, Pieris, to develop targeted bispecific immuno-oncology therapies for the treatment of cancer. Our dependence on collaborative arrangements to assist in the development and commercialization of ADCETRIS and for the development and commercialization of product candidates utilizing or incorporating our technologies subjects us to a number of risks, including:

- we are not able to control the amount and timing of resources that our collaborators devote to the development or commercialization of products and product candidates utilizing or incorporating our technologies, including enfortumab vedotin and tisotumab vedotin, and because control of development and commercialization is shared with our collaborators, we do not have sole discretion and control over the development and commercialization of these product candidates;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of the applicable products and product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;
-

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

- our current and potential future collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- significant delays in the development of product candidates by current and potential collaborators could allow competitors to bring products to market before product candidates utilizing or incorporating our technologies are

Table of Contents

approved and impair the ability of current and potential future collaborators to effectively commercialize these product candidates;

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

If our collaborative arrangements are not successful as a result of any of the above factors, or any other factors, then our ability to advance the development and commercialization of the applicable products and product candidates and to otherwise generate revenue from these arrangements and to become profitable will be adversely affected, and our business and business prospects may be materially harmed. In particular, if Takeda were to terminate the ADCETRIS collaboration, which it may do for any reason upon prior written notice to us, we would not receive milestone payments, co-funded development payments or royalties for the sale of ADCETRIS outside the United States and Canada. As a result of such termination, we may have to engage another collaborator to complete the ADCETRIS development process and to commercialize ADCETRIS outside the United States and Canada, or to complete the development process and undertake commercializing ADCETRIS outside the United States and Canada ourselves, either of which could significantly delay the continued development and commercialization of ADCETRIS and increase our costs. Similarly, both Astellas and Genmab have the right to opt-out of their co-development obligations relating to enfortumab vedotin and tisotumab vedotin, respectively. If either Astellas or Genmab were to opt-out of their co-development collaborations with us, this would significantly delay the development of the impacted product candidate and increase our costs. Any of these events could significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing ADCETRIS, enfortumab vedotin or tisotumab vedotin, which are now being co-funded by our collaboration partners. Moreover, in the future, we may not be able to locate third-party collaborators to develop and market products and product candidates utilizing or incorporating our technologies, and we may lack the capital and resources necessary to develop and market these products and product candidates alone.

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

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

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

Table of Contents

parties compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to our programs.

With respect to ADCETRIS, there are several other FDA-approved drugs for its approved indications. BMS's nivolumab (Opdivo) and Merck's pembrolizumab (Keytruda) are approved for the treatment of certain patients with relapsed or refractory classical Hodgkin lymphoma, and Celgene's romidepsin (Istodax) and Spectrum Pharmaceuticals' pralatrexate (Folotyn) and belinostat (Beleodaq) are approved for relapsed or refractory sALCL among other T-cell lymphomas. Kyowa Kirin's mogamulizumab (Poteligeo) is approved for adult patients with relapsed or refractory mycosis fungoidies or Sézary syndrome. The competition ADCETRIS faces from these and other therapies is intensifying. Additionally, Merck is conducting a phase 3 clinical trial in relapsed or refractory classical Hodgkin lymphoma comparing pembrolizumab (Keytruda) with ADCETRIS. If this clinical trial demonstrates that pembrolizumab is more effective than ADCETRIS in that treatment setting, our sales of ADCETRIS would be negatively impacted. We are also aware of multiple investigational agents that are currently being studied, including Roche's atezolizumab and Pfizer's avelumab, which, if successful, may compete with ADCETRIS in the future. Data have also been presented on several developing technologies, including bispecific antibodies and CAR modified T-cell therapies that may compete with ADCETRIS in the future. Further, there are many competing approaches used in the treatment of patients in ADCETRIS' approved indications, including autologous hematopoietic stem cell transplant, allogeneic stem cell transplant, combination chemotherapy, clinical trials with experimental agents and single-agent regimens.

With respect to enfortumab vedotin, treatment in second line metastatic urothelial cancer is limited to checkpoint inhibitor monotherapy or generic chemotherapy. There are other investigational agents that, if approved, could be competitive with enfortumab vedotin, including Immunomedics' sacituzumab govitecan, Lilly's ramucirumab, and Janssen's erdafitinib. Treatment in front line metastatic urothelial cancer is evolving and includes two approved checkpoint inhibitor therapies with several trials of investigational agents in combination with chemotherapy potentially reporting data in 2019.

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

With respect to tisotumab vedotin, in June 2018, Merck's pembrolizumab (Keytruda) was approved for the treatment of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy in patients whose tumors express PD-L1. We are also aware of other companies that currently have products in development for the treatment of late-stage cervical cancer which could be competitive with tisotumab vedotin, including Agenus, BMS, Iovance Biotherapeutics, Merck, Regeneron Pharmaceuticals and Roche.

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

We are aware of other companies that have technologies that may be competitive with ours, including Abbvie, ADC Therapeutics, Astellas, AstraZeneca, BMS, Daiichi Sankyo, ImmunoGen, Immunomedics, MedImmune, Mersana, Pfizer, and Roche, all of which have ADC technology. ImmunoGen has several ADCs in development that may compete with our product candidates. ImmunoGen has also established partnerships with other pharmaceutical and

biotechnology companies to allow those other companies to utilize ImmunoGen's technology, including Sanofi-Aventis, Genentech, Novartis, Takeda and Lilly. We are also aware of a number of companies developing monoclonal antibodies directed at the same antigen targets or for the treatment of the same diseases as our product candidates.

In addition, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" or "biosimilar" to or "interchangeable" with an FDA-approved biological product. This pathway allows competitors to reference the FDA's prior approvals regarding innovative biological products and data submitted with a Biologics License Application, or BLA, to obtain approval of a biosimilar application 12 years after the time of approval of the innovative biological product. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the 12-year exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another

Table of Contents

company cannot rely on the FDA's prior approvals in approving a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. In the European Union, the European Commission has granted marketing authorizations for biosimilars pursuant to a set of general and product class-specific guidelines. We are aware of many pharmaceutical and biotechnology and other companies that are actively engaged in research and development of biosimilars or interchangeable products.

It is possible that our competitors will succeed in developing technologies that are more effective than ADCETRIS, enfortumab vedotin, tucatinib, tisotumab vedotin or our other product candidates or that would render our technology obsolete or noncompetitive, or will succeed in developing biosimilar, interchangeable or generic products for ADCETRIS, enfortumab vedotin, tucatinib, tisotumab vedotin or our other product candidates. We anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other cancer therapies continue to accelerate. We cannot predict to what extent the entry of biosimilars or other competing products will impact potential future sales of ADCETRIS, enfortumab vedotin, tucatinib, tisotumab vedotin or our other product candidates.

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

Our operating results are difficult to predict and may fluctuate significantly from quarter to quarter and year to year, including due to our receipt of marketing approvals for ADCETRIS in two additional indications since November 2017. As a result, although we provide sales guidance for ADCETRIS from time to time, you should not rely on ADCETRIS sales results in any period as being indicative of future performance. In addition, such guidance is based on assumptions that may be incorrect or that may change from quarter to quarter, and it may be particularly difficult to correctly forecast sales in indications for which we have recently received marketing approval. Moreover, sales of ADCETRIS have, on occasion, been below the expectations of securities analysts and investors and have been below prior period sales, and sales of ADCETRIS in the future may also be below prior period sales, our own guidance and/or the expectations of securities analysts and investors. To the extent that we again do not meet our guidance or the expectations of analysts or investors, our stock price may be adversely impacted, perhaps significantly. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- customer ordering patterns for ADCETRIS, which may vary significantly from period to period;
- the overall level of demand for ADCETRIS, including the impact of any competitive or biosimilar products and the duration of therapy for patients receiving ADCETRIS;
- the extent to which coverage and reimbursement for ADCETRIS is available from government and health administration authorities, private health insurers, managed care programs and other third-party payors;
- our ability to establish or demonstrate in the medical community the safety, efficacy or value of ADCETRIS and its potential advantages compared to existing and future therapies in the Stage III or IV Hodgkin lymphoma indication and other approved indications;
- changes in the amount of deductions from gross sales, including government-mandated rebates, chargebacks and discounts that can vary because of changes to the government discount percentage, including increases in the government discount percentage resulting from price increases we have taken or may take in the future, or due to different levels of utilization by entities entitled to government rebates and discounts and changes in patient demographics;
- increases in the scope of eligibility for customers to purchase ADCETRIS at the discounted government price or to obtain government-mandated rebates on purchases of ADCETRIS;
- changes in our cost of sales;
- the incidence rate of new patients in ADCETRIS' approved indications;
- the timing, cost and level of investment in our sales and marketing efforts to support ADCETRIS sales;
- the timing, cost and level of investment in our research and development and other activities involving ADCETRIS, enfortumab vedotin, tucatinib, tisotumab vedotin and our other product candidates by us or our collaborators;

- changes in the prices of the Immunomedics, Inc., or Immunomedics, and Unum common stock that affect the valuation of the common stock of those companies that we hold; and

Table of Contents

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

In addition, we have entered into licensing and collaboration agreements with other companies that include development funding and milestone payments to us, and we expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues. Accordingly, our revenues will also depend on development funding and the achievement of development and clinical milestones under our existing collaboration and license agreements, including, in particular, our ADCETRIS collaboration with Takeda, as well as entering into potential new collaboration and license agreements. These upfront and milestone payments may vary significantly from quarter to quarter and any such variance could cause a significant fluctuation in our operating results from one quarter to the next.

Further, changes in our operations, such as increased development, manufacturing and clinical trial expenses in connection with our expanding pipeline programs, or our undertaking of additional programs, business activities, and the integration and development activities related to Cascadian and tucatinib, or entry into strategic transactions, including potential future acquisitions of products, technologies or businesses may also cause significant fluctuations in our expenses. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price, the magnitude of the expense that we must recognize may vary significantly. Additionally, we have implemented long-term incentive plans for our employees, and the incentives provided under these plans are contingent upon the achievement of certain regulatory milestones. Costs of performance-based compensation under our long-term incentive plans are not recorded as an expense until the achievement of the applicable milestones is deemed probable of being met, which may result in large fluctuations to the expense we must recognize in any particular period.

Additionally, as of September 30, 2018, we held 7.7 million shares of Immunomedics common stock and 0.8 million shares of Unum common stock. Beginning on January 1, 2018, we adopted ASU 2016-01 "Financial Instruments: Overall," and as a result, we record changes in the fair value of our equity securities, including the Immunomedics and Unum common stock that we hold, in net income or loss, which is expected to increase the volatility of net income or loss to the extent that we continue to hold common stock or other equity securities.

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

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

We have incurred substantial net losses in each of our years of operation. We have incurred these losses principally from costs incurred in our research and development programs and from our selling, general and administrative expenses. We expect to continue to spend substantial amounts on research and development, including amounts for conducting clinical trials of ADCETRIS as well as commercializing ADCETRIS for the treatment of patients in its five approved indications. In addition, we expect to make substantial expenditures to further develop and potentially commercialize enfortumab vedotin, tucatinib, tisotumab vedotin and our other product candidates. Likewise, in connection with the Cascadian Acquisition and the integration of Cascadian's business, we have incurred and expect to incur substantial expenses, including to further develop and potentially commercialize tucatinib. We may also pursue new operations or continue the expansion of our existing operations, including with respect to our plans to build a commercial infrastructure in Europe and to otherwise continue to expand our operations internationally. Accordingly, we expect to continue to incur net losses in future periods and may not achieve profitability in the future for some time, if at all. Although we recognize revenue from ADCETRIS product sales and we continue to earn amounts under our collaboration agreements, our revenue and profit potential is unproven and our limited commercialization history makes our future operating results difficult to predict. Even if we do achieve profitability in the future, we may not be

able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

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

We actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses. For example, in March 2018, we made significant investment in tucatinib through the Cascadian Acquisition. The Cascadian Acquisition and any potential future acquisitions or in-licensing transactions entail numerous risks, including but not limited to:

Table of Contents

- risks associated with satisfying the closing conditions relating to such transactions and realizing their anticipated benefits;
- increased operating expenses and cash requirements;
- difficulty integrating acquired technologies, products, operations, and personnel with our existing business;
- the potential disruption of our historical core business;
- diversion of management's attention in connection with both negotiating the acquisition or license and integrating the business, technology or product;
- retention of key employees;
- difficulties in assimilating employees and corporate cultures of any acquired companies;
- uncertainties in our ability to maintain key business relationships of any acquired companies;
- strain on managerial and operational resources;
- difficulty implementing and maintaining effective internal control over financial reporting at businesses that we acquire, particularly if they are not located near our existing operations;
- exposure to unanticipated liabilities of acquired companies or companies in which we invest;
- the potential need to write down assets or recognize impairment charges; and
- potential costly and time-consuming litigation, including stockholder lawsuits.

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

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

Even if we are able to successfully identify and acquire complementary products, technologies or businesses, we cannot assure you that we will be able to successfully manage the risks associated with integrating acquired products, technologies or businesses or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing transaction. For example, as a result of the Cascadian Acquisition, we now operate our historical core business along with the Cascadian business as one combined organization utilizing common information and communication systems, operating procedures, financial controls and human resources practices. There may be substantial difficulties, costs and delays involved in the integration of our historical core business with the Cascadian business, including as a result of challenges relating to the diversion of management's attention, the possibility of faulty assumptions underlying expectations regarding the integration process, retaining and attracting business and operational relationships, eliminating duplicative operations and inconsistent standards and procedures and increased or unforeseen liabilities or costs relating to the Cascadian Acquisition or the Cascadian business. We have also incurred substantial expenses in connection with and as a result of completing the Cascadian Acquisition and, over a period of time following the completion of the Cascadian Acquisition, we expect to incur substantial additional expenses in connection with coordinating the businesses, operations, policies and procedures of the

combined company. Further, while we seek to mitigate risks and liabilities of potential acquisitions and in-licensing transactions through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks, liabilities and uncertainties effectively, including in connection with the Cascadian Acquisition, could have a material adverse effect on our business and

Table of Contents

adversely affect our results of operations and financial condition. Additionally, we may not realize the anticipated benefits of such transactions, including the possibility that expected synergies and accretion will not be realized or will not be realized within the expected time frame.

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

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

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

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

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

Although we own a biologics manufacturing facility located in Bothell, Washington, we rely and expect to continue to rely on corporate collaborators and contract manufacturing organizations to supply drug product or intermediates for commercial supply and our IND-enabling studies and clinical trials.

For the monoclonal antibody used in ADCETRIS, we have contracted with AbbVie for clinical and commercial supplies. For the drug linker used in ADCETRIS, we have contracted with Sigma Aldrich Fine Chemicals, or SAFC, for clinical and commercial supplies. We have multiple contract manufacturers for conjugating the drug linker to the antibody and producing the ADCETRIS product. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, vial and store sufficient quantities of ADCETRIS for use in our clinical trials and for commercial sale. If our contract manufacturers or other third parties fail to deliver ADCETRIS for clinical use or sale on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or otherwise discontinue development, production and sale of ADCETRIS. Moreover, contract manufacturers have a limited number of facilities in which ADCETRIS can be produced and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters or as the result of regulatory actions could result in the cancellation of shipments, loss of product in the manufacturing process, a shortfall in ADCETRIS supply, or the inability to sell our products in the U.S. or abroad. In addition, we have committed to provide Takeda with their needs of certain parts of the ADCETRIS supply chain for a limited period of time, which may require us to arrange for additional manufacturing supply. Moreover, we depend on outside vendors for the supply of raw materials used to produce ADCETRIS. If the third-party suppliers were to cease

production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have ADCETRIS manufactured to meet commercial and clinical requirements would be adversely affected.

For the clinical supply of our product candidates, which include ADCs as well as antibodies and small molecules, we rely on multiple contract manufacturers and other third parties to perform manufacturing services for us. With respect to enfortumab vedotin and tisotumab vedotin specifically, we rely on manufacturing services provided by our collaborators and have little control over their supply chains or the contract manufacturers they utilize. For the foreseeable future, we expect to continue to rely on contract manufacturers and, in the case of enfortumab vedotin and tisotumab vedotin, on our collaborators,

Table of Contents

for manufacturing of clinical supplies, and for potential future commercial manufacturing. For example, under our joint commercialization agreement with Astellas, Astellas has the sole right and responsibility to manufacture enfortumab vedotin worldwide. If our third-party manufacturers and collaborators cease or interrupt production, if our third-party manufacturers, collaborators and other service providers fail to supply satisfactory materials, products or services for any reason or experience performance delays or quality concerns, if materials or products are lost in transit or in the manufacturing process, or if we encounter challenges in assuming responsibility for new processes such as the manufacture of tucatinib, such challenges or interruptions could substantially delay progress on our programs or impact clinical trial drug supply, with the potential for additional costs and an adverse effect on our business.

We are using our own manufacturing facility to support our clinical-stage pipeline. As an organization, we have no prior experience operating a manufacturing facility.

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

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

Our operations may be directly or indirectly subject to various state and federal healthcare laws, including, without limitation, the federal Anti-Kickback Statute, federal civil and criminal false claims laws, the federal Health Insurance Portability and Accountability Act, or HIPAA, the federal Health Information Technology for Economic and Clinical Health Act, or HITECH, the federal civil monetary penalties statute, and the federal transparency requirements under the PPACA. These laws may impact, among other things, the sales, marketing and education programs for ADCETRIS.

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

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false claim to, or the knowing use of false statements to obtain payment from or approval by the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease, or conceal an obligation to pay money to the federal government. PPACA

provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Suits filed under the civil False Claims Act, known as “qui tam” actions, can be brought by any individual on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and other healthcare companies have recently been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing or other activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company’s products; and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs.

Table of Contents

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the Anti-Kickback Statute, PPACA amended the intent requirement of the criminal healthcare fraud statutes such that a person or entity no longer needs to have actual knowledge of the statute or intent to violate it to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, governs certain types of individuals and entities with respect to the conduct of certain electronic healthcare transactions and imposes certain obligations with respect to the security and privacy of protected health information.

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

The federal transparency requirements under PPACA, known as the Physician Payments Sunshine Act, require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to the CMS information related to payments and other transfers of value to physicians and teaching hospitals, and physician ownership and investment interests.

There are foreign and state law versions of these laws and regulations, such as anti-kickback, false claims, and data privacy and security laws, to which we are currently and/or may in the future, be subject. For example, European Union, or EU, member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, effective May 25, 2018, the collection and use of personal health data in the EU is governed by the provisions of the EU General Data Protection Regulation, or the GDPR. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the control over personal data by individuals to whom the personal data relates, the information provided to the individuals, the documentation we must maintain, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, provides an enforcement authority and authorizes the imposition of large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information.

The GDPR has increased our responsibility and potential liability in relation to personal data that we process compared to prior EU law, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. However, despite our ongoing efforts to bring our practices into compliance with the GDPR, we may not be successful either due to various factors within our control or other factors outside our control. It is also possible that local data protection authorities may have different interpretations of the GDPR, leading to potential inconsistencies amongst various EU member states. Any failure or alleged failure (including as a result of deficiencies in our policies, procedures or measures relating to privacy, data security, marketing or communications) by us to comply with laws, regulations, policies, legal or contractual obligations, industry standards or regulatory guidance relating to privacy or data security, may result in governmental investigations and enforcement actions, litigation, fines and penalties or adverse publicity. In addition, new regulation, legislative actions or changes in interpretation of existing laws or regulations regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018, which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States, and we cannot determine the impact such new laws, regulations and standards may have on our

business. We may also be subject to state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or other reporting and registration requirements related to our business activities. Many of these state laws differ from each other in significant ways, thus complicating compliance efforts.

The FDA and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. In recent years, private whistleblowers have also pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of off-label promotion. If we are found to have promoted an approved product, including ADCETRIS, for off-label uses we may be subject to significant liability, including civil and administrative financial penalties and other remedies as well as criminal financial penalties and other sanctions. Even when a company is not determined to have engaged in off-label promotion, the allegation from government authorities or market participants that a company has engaged in such activities could have a significant

Table of Contents

impact on the company's sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies.

We are also subject to numerous other laws and regulations that are not specific to the healthcare industry. For instance, the U.S. Foreign Corrupt Practices Act, or FCPA, prohibits companies and individuals from engaging in specified activities to obtain or retain business or to influence a person working in an official capacity. Under the FCPA, it is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, governmental staff members, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

The number and complexity of both U.S. federal and state laws continue to increase. In addition to enforcement by governmental agencies, we also expect a continuation of the trend of private plaintiff lawsuits against pharmaceutical manufacturers under the whistleblower provisions of the civil False Claims Act and state equivalents or other laws and regulations such as securities rules and the evolution of new theories of liability under those statutes. Government agencies will likely continue to intervene in such private whistleblower lawsuits and such intervention typically raises the company's cost significantly. For example, federal enforcement agencies have recently scrutinized product and patient assistance programs, including manufacturer reimbursement support services as well as relationships with specialty pharmacies. Several investigations have resulted in government enforcement authorities intervening in related whistleblower lawsuits and obtaining significant civil and criminal settlements.

In order to comply with these laws, we have implemented a compliance program to actively identify, prevent and mitigate risk through the implementation of compliance policies and systems and by promoting a culture of compliance. Although we take our obligation to maintain our compliance with these various laws and regulations seriously and our compliance program is designed to prevent the violation of these laws and regulations, we cannot guarantee that our compliance program will be sufficient or effective, that we will be able to integrate the operations of acquired businesses into our compliance program on a timely basis, that our employees will comply with our policies and that our employees will notify us of any violation of our policies, that we will have the ability to take appropriate and timely corrective action in response to any such violation, or that we will make decisions and take actions that will necessarily limit or avoid liability for whistleblower claims that individuals, such as employees or former employees, may bring against us or that governmental authorities may prosecute against us based on information provided by individuals. If we are found to be in violation of any of the laws and regulations described above or other applicable state and federal healthcare laws, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, imprisonment, diminished profits and future earnings, exclusion from government healthcare reimbursement programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and/or the curtailment or restructuring of our operations, any of which could have a material adverse effect on our business, results of operations and growth prospects. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal, state and foreign healthcare laws is costly and time-consuming for our management.

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

We are continuing to expand our operations internationally, and plan to build a commercial infrastructure in Europe. In this regard, we currently have subsidiaries in Australia, Canada, Ireland, Luxembourg, Switzerland and the United

Kingdom. Our business activities outside of the United States are and will continue to be subject to the FCPA, which is described above, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we currently and may in the future operate, including the U.K. Bribery Act. The U.K. Bribery Act prohibits giving, offering, or promising bribes to any person, including non-U.K. government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the U.K. Bribery Act, companies which carry on a business or part of a business in the U.K. may be held liable for bribes given, offered or promised to any person, including non-U.K. government officials and private persons, by employees and persons associated with such company in order to obtain or retain business or a business advantage for such company. In the course of expanding our operations internationally, we will need to establish and expand business relationships with various third parties, such as independent contractors, distributors, vendors, advocacy groups and physicians, and we will interact more frequently with foreign officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA, U.K. Bribery Act or

Table of Contents

similar laws of other countries that may govern our activities. Any interactions with any such parties or individuals where compensation is provided that are found to be in violation of such laws could result in substantial fines and penalties and could materially harm our business. Furthermore, any finding of a violation under one country's laws may increase the likelihood that we will be prosecuted and be found to have violated another country's laws. If our business practices outside the United States are found to be in violation of the FCPA, U.K. Bribery Act or other similar laws, we may be subject to significant civil and criminal penalties which could have a material adverse effect on our business, results of operations and growth prospects. We are also subject to foreign laws and regulations covering data privacy and the protection of health-related and other personal information. In this regard, EU member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations, such as the GDPR, which impose significant compliance obligations. Failure to comply with these laws could lead to government enforcement actions and significant penalties against us, which could have a material adverse effect on our business, results of operations and growth prospects.

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

ADCETRIS and our enfortumab vedotin, tisotumab vedotin, and ladiratuzumab vedotin product candidates are all based on our ADC technology, which utilizes proprietary stable linkers and potent cell-killing synthetic agents. Our ADC technology is also the basis of our collaborations with AbbVie, Astellas, Bayer, Celldex, Genentech, GSK, Pfizer, and Progenics, and our collaboration agreements with Takeda, Astellas, and Genmab. Although ADCETRIS has received marketing approval in the United States, Canada, the European Union, Japan and other countries, ADCETRIS is our first and only ADC product that has been approved for commercial sale in any jurisdiction. In addition, certain of our ADC product candidates include additional proprietary technologies that have not yet been proven in late stage clinical development. Any failures or further setbacks in our ADC development program or with respect to our additional proprietary technologies, including adverse effects resulting from the use of this technology in human clinical trials and/or the imposition of additional clinical holds on our trials of any of our other product candidates, could have a detrimental impact on the continued commercialization of ADCETRIS in its current or any potential future approved indications and on our internal product candidate pipeline, as well as our ability to maintain and/or enter into new corporate collaborations regarding our ADC technology, which would negatively affect our business and financial position.

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

In January 2017, a purported securities class action lawsuit was commenced in the United States District Court for the Western District of Washington, or the Court, naming as defendants us and certain of our officers. While on May 24, 2018, the Court granted our motion to dismiss the class action lawsuit with prejudice and entered a final judgment and order dismissing all claims against all defendants, including us, a related stockholder derivative lawsuit, or the Stockholder Derivative Action, was filed in Washington Superior Court for the County of Snohomish, or the Snohomish County Superior Court, on March 29, 2017. Following the dismissal with prejudice of the class action lawsuit, on August 30, 2018, the plaintiffs in the stockholder derivative lawsuit filed an amended complaint. On October 4, 2018, we filed a motion to dismiss the amended complaint for failure to plead demand futility. The plaintiffs' opposition brief is due November 9, 2018. A hearing on our motion to dismiss is scheduled for December 14, 2018. As a result of the Stockholder Derivative Action, we may incur litigation and indemnification expenses. In addition, we may be the target of securities-related litigation in the future, both related and unrelated to the Stockholder Derivative Action and the dismissed class action. Moreover, three purported stockholders of Cascadian filed a complaint seeking to inspect books and records in order to determine whether wrongdoing or mismanagement has taken place such that it would be appropriate to file claims for breach of fiduciary duty, and to investigate the independence and disinterestedness of the former Cascadian directors with respect to the Cascadian Acquisition. As a result of such complaint or otherwise, it is possible that additional lawsuits may be brought against us and/or

Cascadian related to the Cascadian Acquisition.

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

These and potential future litigations are subject to inherent uncertainties, and the actual costs to be incurred relating to litigations may be impacted by unknown factors. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of these and potential future litigations, and we may not prevail. Monitoring and defending against legal actions can be time-consuming for our management and detract from our ability to fully focus our internal resources on our business activities, which could result in delays of our clinical trials or our development and commercialization efforts. In addition, we may incur substantial legal fees and costs in connection with these and potential future litigations. Decisions adverse to our interests in these and potential future litigations could result in the payment of

Table of Contents

substantial damages, or possibly fines, or affect our intellectual property rights and could have a material adverse effect on our cash flow, results of operations and financial position. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price.

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

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees, support our development, manufacturing and clinical trial activities for ADCETRIS and our other pipeline programs, as well as commercialize ADCETRIS and prepare to potentially commercialize additional product candidates. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to our plans to build a commercial infrastructure in Europe and to otherwise continue to expand our operations internationally. We also anticipate continuing to commit substantial capital resources to the integration and development activities related to Cascadian and tucatinib. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS, the research, continued development and manufacturing of our product candidates and the anticipated expansion of our pipeline and operations will likely require us to raise substantial amounts of additional capital. Further, we actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses, and we may require significant additional capital in order to complete or otherwise provide funding for such transactions. For example, in connection with the Cascadian Acquisition, we sold 13,269,230 shares of our common stock in an underwritten public offering with a portion of the net proceeds used to fund the costs of the Cascadian Acquisition. We may seek additional funding through some or all of the following methods: corporate collaborations, licensing arrangements and public or private debt or equity financings. We do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs, which may adversely affect our business and operations. Our future capital requirements will depend upon a number of factors, including:

- the level of sales and market acceptance of ADCETRIS;
- the time and costs involved in obtaining regulatory approvals of ADCETRIS in additional indications, if any;
- the size, complexity, timing, progress and number of our clinical programs and our collaborations;
- the timing, receipt and amount of milestone-based payments or other revenue from our collaborations or license arrangements, including royalty revenue generated from commercial sales of ADCETRIS by Takeda;
- the cost of establishing and maintaining clinical and commercial supplies of ADCETRIS;
- the costs associated with acquisitions or licenses of additional technologies, products, or companies as well as licenses we may need to commercialize our products;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- expenses associated with the pending and potential additional related purported securities class action or derivative lawsuits, as well as any other potential litigation;
- the potential costs associated with international, state and federal taxes; and
- competing technological and market developments.

In addition, changes in our spending rate may occur that would consume available capital resources sooner, such as increased development, manufacturing and clinical trial expenses in connection with our expanding pipeline programs and the Cascadian Acquisition, or our undertaking of additional programs, business activities or entry into additional strategic transactions, including potential future acquisitions of products, technologies or businesses. Moreover, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

During the past several years, domestic and international financial markets have experienced extreme disruption from time to time, including, among other things, high volatility and significant declines in stock prices and severely

diminished liquidity and credit availability for both borrowers and investors. Such adverse capital and credit market conditions could make it more difficult to obtain additional capital on favorable terms, or at all, which could have a material adverse effect on our business and growth prospects.

Table of Contents

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

We have entered into agreements with third-party commercial and academic institutions to license technology for use in ADCETRIS, our product candidates and technologies such as our ADC technology. Currently, we have license agreements with BMS, the University of Miami and Array BioPharma, Inc., among others. In addition to royalty provisions, some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon royalty or diligence requirements or milestones may allow the licensor to terminate the agreement. Many of our license agreements grant us exclusive licenses to the underlying technologies. If our licensors terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize ADCETRIS or our product candidates, including tucatinib. Further, we have had in the past, and may in the future have, disputes with our licensors, which may impact our ability to develop and commercialize ADCETRIS or our product candidates or require us to enter into additional licenses. An adverse result in potential future disputes with our licensors may impact our ability to develop and commercialize ADCETRIS and our product candidates, or may require us to enter into additional licenses or to incur additional costs in litigation or settlement. In addition, continued development and commercialization of ADCETRIS and our product candidates will likely require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

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

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

The standards that the U.S. Patent and Trademark Office, or USPTO, and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our products. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the United States or other countries may be applied retroactively to affect the validity, enforceability, or term of our patent. For example, the U.S. Supreme Court has modified some legal standards applied by the USPTO in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license. In addition, changes to the U.S. patent system have come into force under the Leahy-Smith America Invents Act, or the America Invents Act, including changes from a “first-to-invent” system to a “first to file” system, changes to examination of U.S. patent applications and changes to the processes for challenging issued patents. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, and post-grant review and covered business methods. These proceedings are conducted before the Patent Trial and Appeal Board, or PTAB, of the USPTO. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of some patents on the grounds that it was anticipated or made obvious by prior art. As a result, non-practicing entities associated with hedge funds, pharmaceutical companies who may be our

competitors and others have challenged certain valuable pharmaceutical U.S. patents based on prior art through the IPR process. A decision in such a proceeding adverse to our interests could result in the loss of valuable patent rights which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any event, the America Invents Act and any other potential future changes to the U.S. patent system could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We rely on trade secrets and other proprietary information where we believe patent protection is not appropriate or obtainable. However, trade secrets and other proprietary information are difficult to protect. We have taken measures to protect our unpatented trade secrets and know-how, including the use of confidentiality and assignment of inventions agreements with our employees, consultants and certain contractors. It is possible, however, that these persons may breach the agreements or

Table of Contents

that our competitors may independently develop or otherwise discover our trade secrets or other proprietary information. Our research collaborators may publish confidential data or other restricted information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

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

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

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

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

We are highly dependent on the efforts and abilities of the principal members of our senior management. Additionally, we have scientific personnel with significant and unique expertise in monoclonal antibodies, ADCs and related technologies, and tucatinib. The loss of the services of any one of the principal members of our managerial or scientific staff may prevent us from achieving our business objectives. With respect to tucatinib, we expect to rely on the experience and expertise of personnel formerly employed by Cascadian in the development of tucatinib. If we were to lose the services of a significant portion or key individuals of this team, such development activities could be adversely impacted and our business could be adversely affected.

In addition, the competition for qualified personnel in the biotechnology field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. In order to

Table of Contents

continue to commercialize ADCETRIS, and advance the development and commercialization of our additional product candidates, we will be required to expand our workforce, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, sales and marketing, both in the United States and in Europe. We continue to face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, as well as academic and other research institutions. To the extent we are not able to retain these individuals on favorable terms or attract any additional personnel that may be required, our business may be harmed. For example, we may not be successful in attracting or retaining key personnel necessary to support our strategy to develop and commercialize ADCETRIS in earlier lines of therapy, including potentially in the ECHELON-2 treatment setting, to build a commercial infrastructure in Europe or to support the commercialization of our product candidates alone or jointly with our collaborators.

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

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

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

The current and future use of ADCETRIS by us and our corporate collaborators in clinical trials and the sale of ADCETRIS, expose us to product liability claims. These claims have and may in the future be made directly by patients or healthcare providers or indirectly by pharmaceutical companies, our corporate collaborators or others selling such products. Additionally, in connection with our acquisition of the manufacturing facility from BMS, we agreed to enter into certain transitional services agreements under which we manufactured certain clinical drug product components for BMS for a period of time. As a result, it is possible that we may be named as a defendant in product liability suits that may allege that drug products we manufacture for BMS have resulted in injury to patients. We may experience substantial financial losses in the future due to product liability claims. We have obtained product liability coverage, including coverage for human clinical trials and product sold commercially. However, such insurance is subject to coverage limits and exclusions, as well as significant deductibles. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against all losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured amounts, our assets may not be sufficient to cover such claims and our business operations could be impaired. Product recalls may be issued at our discretion, or at the discretion of government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of ADCETRIS could materially adversely affect our business by rendering us unable to sell ADCETRIS for some time and by adversely affecting our reputation.

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

We are expanding our operations internationally. We currently have subsidiaries in Australia, Canada, Ireland, Luxembourg, Switzerland and the United Kingdom, and we plan to build a commercial infrastructure in Europe. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- the increased complexity and costs inherent in managing international operations, including in geographically disparate locations;
- diverse regulatory, financial and legal requirements, and any future changes to such requirements, in one or more countries where we are located or do business;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- adverse tax consequences, including changes in applicable tax laws and regulations;
- applicable trade laws, tariffs, export quotas, custom duties or other trade restrictions, and any changes to them;

Table of Contents

- economic weakness, including inflation, or political or economic instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;
- liabilities for activities of, or related to, our international operations;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations;
- workforce uncertainty in countries where labor unrest is more common than in the United States; and
- laws and regulations relating to data security and the unauthorized use of, or access to, commercial and personal information.

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

In addition, since a significant proportion of the regulatory framework in the U.K. is derived from European Union directives and regulations, Brexit could materially change the regulatory regime applicable to our operations and those of our collaborators, including with respect to marketing authorizations for ADCETRIS and our product candidates. We may also face new regulatory costs and challenges as result of Brexit that could have a material adverse effect on our operations. Depending on the terms of Brexit, the U.K. could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers which could make our doing business in Europe more difficult. In addition, currency exchange rates for the British Pound and the Euro with respect to each other and the U.S. dollar have already been affected by Brexit. Should this foreign exchange volatility continue, it could cause volatility in our quarterly financial results. In any event, we cannot predict to what extent these changes will impact our business or results of operations, or our ability to continue to conduct operations or to build a commercial infrastructure in Europe. Moreover, the Trump administration has recently imposed tariffs on certain U.S. imports, and certain countries have responded with retaliatory tariffs on certain U.S. exports. We cannot predict what effects these and potential additional tariffs will have on our business, including in the context of escalating trade tensions. However, such tariffs and other trade restrictions could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our financial results.

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

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

We are subject to environmental, health and safety laws and regulations, including those governing the use of hazardous materials, and we spend considerable time complying with such laws and regulations. Our business activities involve the controlled use of hazardous materials and although we take precautions to prevent accidental contamination or injury from these materials, we cannot completely eliminate the risk of using these materials. In addition, with respect to our manufacturing facility, we may incur substantial costs to comply with environmental laws and regulations and may become subject to the risk of accidental contamination or injury from the use of hazardous materials in our manufacturing process. It is also possible that our manufacturing facility may expose us to environmental liabilities associated with historical site conditions that we are not currently aware of and did not cause. In this regard, some environmental laws impose liability for contamination on current owners and operators of affected sites, regardless of fault. In the event of an accident or environmental discharge, or new or previously unknown contamination is discovered or new cleanup obligations are otherwise imposed in connection with any of our currently or previously owned or operated facilities, we may be held liable for any resulting damages, which may

materially harm our business, financial condition and results of operations.

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

We conduct most of our business in a limited number of facilities in Bothell and Seattle, Washington. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates or interrupt the sales process for ADCETRIS. Although we maintain property damage and business

Table of Contents

interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

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

We rely on information technology systems to keep financial records, capture laboratory data, maintain clinical trial data and corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses or other disruptive events including but not limited to natural disaster. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors, it could delay or negatively impact the development and commercialization of ADCETRIS and our product candidates, which could adversely impact our business. Although we maintain offsite back-ups of our data, if operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable timeframe. In addition, our information technology systems are potentially vulnerable to data security breaches—whether by employees or others—which may expose sensitive or personal data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, patients in our clinical trials, customers and others, any of which could have a material adverse effect on our business, financial condition and results of operations. Moreover, a security breach or privacy violation that leads to destruction, loss, alteration, unauthorized use or access, disclosure or modification of, personally identifiable information or personal data, could harm our reputation, compel us to comply with federal, state and/or international breach notification laws, subject us to mandatory corrective or regulatory action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, including the GDPR, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. In addition, a data security breach could result in loss of clinical trial data or damage to the integrity of that data. If we are unable to implement and maintain adequate organizational and technical measures to prevent such security breaches or privacy violations, or to respond adequately in the event of a breach, our operations could be disrupted, and we may suffer loss of reputation, problems with regulatory authorities, financial loss and other negative consequences. Moreover, failure to maintain effective internal accounting controls related to data security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and could subject us to regulatory scrutiny. In addition, security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Increasing use of social media could give rise to liability.

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

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

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

For example, in May 2014, the Financial Accounting Standards Board, or FASB, issued "ASU 2014-09, Revenue from Contracts with Customers" which replaced previous revenue recognition guidance under U.S. GAAP when it became effective for us on January 1, 2018. The new standard did not generally change the way in which we recognize product revenue from sales of ADCETRIS. However, sales-based royalties and commercial sales-based milestones are now recorded in the period of the related sale based on estimates, rather than recording them as reported by the customer. In addition, the achievement of development milestones under our collaborations will be recorded in the period their achievement becomes probable, which may result in their recognition earlier than under prior accounting principles. Additionally, on January 1, 2018, we adopted ASU 2016-01 "Financial Instruments: Overall," and as a result, we now record changes in the fair value of equity securities in net income or loss, which is expected to increase the volatility of net income or loss to the extent that we continue to hold

Table of Contents

common stock or other equity securities. In any event, the application of existing or future financial accounting standards, particularly those relating to the way we account for revenues and costs, could have a significant impact on our reported results. In addition, compliance with new regulations regarding corporate governance and public disclosure may result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from science and business activities to compliance activities.

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

As of September 30, 2018, we had recorded $551.0 million of in-process research and development and goodwill related to the Cascadian Acquisition. In-process research and development and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Our results of operations and financial position in future periods could be negatively impacted should future impairments of in-process research and development or goodwill occur.

Risks Related to Our Common Stock

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

The market price of our stock has in the past been, and is likely to continue in the future to be, very volatile. During the third quarter of 2018, our closing stock price fluctuated between $67.20 and $80.06 per share. As a result of fluctuations in the price of our common stock, you may be unable to sell your shares at or above the price you paid for them. The market price of our common stock may be subject to substantial volatility in response to many risk factors listed in this section, and others beyond our control, including:

- the level of ADCETRIS sales in the United States, Canada, the European Union, Japan and other countries in which Takeda has received approval by relevant regulatory authorities;
- announcements regarding the results of discovery efforts and preclinical, clinical and commercial activities by us, or those of our competitors;
- announcements of FDA or foreign regulatory approval or non-approval of ADCETRIS, or specific label indications for or restrictions, warnings or limitations in its use, or delays in the regulatory review or approval process, including in connection with our planned sBLA submission to the FDA seeking approval of ADCETRIS in the ECHELON-2 treatment setting;
- announcements regarding the results of the clinical trials we, Takeda and/or BMS are conducting or may in the future conduct for ADCETRIS, including the CHECKMATE 812 trial;
- announcements regarding the results of the clinical trials we and our collaborators are conducting for enfortumab vedotin, tucatinib and tisotumab vedotin;
- announcements regarding, or negative publicity concerning, adverse events or safety concerns associated with the use of ADCETRIS or our product candidates;
- issuance of new or changed analysts' reports and recommendations regarding us or our competitors;
- termination of or changes in our existing collaborations or licensing arrangements, especially our ADCETRIS collaboration with Takeda, our enfortumab vedotin co-development and joint commercialization collaboration with Astellas and our tisotumab vedotin co-development collaboration with Genmab, or establishment of new collaborations or licensing arrangements;
- our failure to achieve the perceived benefits of our strategic transactions, including the Cascadian Acquisition, as rapidly or to the extent anticipated by financial analysts or investors;
- our entry into additional material strategic transactions including licensing or acquisition of products, businesses or technologies;
- actions taken by regulatory authorities with respect to our product candidates, our clinical trials or our regulatory filings;
- our raising of additional capital and the terms upon which we may raise any additional capital;

- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- developments or disputes concerning our proprietary rights;

Table of Contents

- developments regarding the pending and potential additional related purported securities class action lawsuits, as well as any other potential litigation;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- changes in government regulations; and
- economic or other external factors.

The stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, as a result of Brexit and/or significant changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade and health care spending and delivery, including the possible repeal and/or replacement of all or portions of PPACA or changes in tariffs and other trade restrictions stemming from Trump administration and foreign government policies, the financial markets could experience significant volatility that could also negatively impact the markets for biotechnology and pharmaceutical stocks. These broad market fluctuations have adversely affected and may in the future adversely affect the trading price of our common stock.

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

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

Sales of a substantial number of shares of our common stock into the public market, including sales by members of our management or board of directors or entities affiliated with such members, could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-related securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of September 30, 2018, we had 160,053,203 shares of common stock outstanding, all of which shares are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144. In addition, we may issue a substantial number of shares of our common stock or equity-related securities, including convertible debt, to meet our capital needs, including in connection with funding potential future acquisition or licensing opportunities, capital expenditures or product development costs, which issuances could be substantially dilutive and could adversely affect the market price of our common stock. Likewise, future issuances by us of our common stock upon the exercise, conversion or settlement of equity-based awards or other equity-related securities would dilute existing stockholders' ownership interest in our company and any sales in the public market of these shares, or the perception that these sales might occur, could also adversely affect the market price of our common stock.

Moreover, we have in the past and may in the future grant rights to some of our stockholders that require us to register the resale of our common stock or other securities on behalf of these stockholders and/or facilitate public offerings of our securities held by these stockholders, including in connection with potential future acquisition or capital-raising transactions. For example, in connection with our September 2015 public offering of common stock, we entered into a registration rights agreement with entities affiliated with Baker Bros. Advisors LP, or the Baker Entities, that together, based on information available to us as of September 30, 2018, collectively beneficially owned approximately 32% of our common stock. Under the registration rights agreement, if at any time and from time to time the Baker Entities demand that we register their shares of our common stock for resale under the Securities Act of 1933, as amended, or the Securities Act, we would be obligated to effect such registration. On July 26, 2018, pursuant to the registration

rights agreement, we registered for resale, from time to time, up to 50,977,960 shares of our common stock held by the Baker Entities. Our registration obligations under the registration rights agreement cover all shares now held or hereafter acquired by the Baker Entities, will continue in effect for up to ten years, and include our obligation to facilitate certain underwritten public offerings of our common stock by the Baker Entities in the future. Accordingly, we expect to register additional shares held by the Baker Entities for resale from time to time, including in certain cases, shares that we have previously registered for resale by the Baker Entities, whether in connection with the expiration of registration statements that we previously filed with the SEC or otherwise. If the Baker Entities, by exercise of these registration and/or underwriting rights and our registration of shares held by the Baker Entities for resale from time to time, or otherwise, sell a large number of our shares, or the market perceives that the Baker Entities intend to sell a large number of our shares, including in connection with our registrations of shares held by the Baker Entities for resale, this could

Table of Contents

adversely affect the market price of our common stock. We have also filed registration statements to register the sale of our common stock reserved for issuance under our equity incentive and employee stock purchase plans. Accordingly, these shares will be able to be freely sold in the public market upon issuance as permitted by any applicable vesting requirements.

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

Based solely on the most recent Schedules 13G and 13D filed with the SEC, reports filed with the SEC under Section 16 of the Exchange Act, and our outstanding shares of common stock as of September 30, 2018, our executive officers and directors and holders of greater than five percent of our outstanding common stock beneficially owned approximately 51% of our voting power as of September 30, 2018. As a result, these stockholders, acting together, are able to control our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, including a merger, consolidation, takeover or other business combination involving us or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control, which might affect the market price of our common stock.

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

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, or the Tax Act, which significantly revises the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

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

Item 5. Other Information

Executive Employment Agreements

On October 25, 2018, upon the approval of the Compensation Committee of our Board of Directors, or the Compensation Committee, we entered into amended and restated employment agreements, or the Amended Employment Agreements, with each of our executive officers, including Clay Siegall, our President and Chief Executive Officer, Todd Simpson, our Chief Financial Officer, Roger Dansey, our Chief Medical Officer, Vaughn Himes, our Chief Technical Officer, Darren Cline, our Executive Vice President, Commercial, and Jean Liu, our General Counsel and Executive Vice President, Legal Affairs. The Amended Employment Agreements amend and restate the employment agreements that we previously entered into with our executive officers. Provisions that were amended include, among other things:

- With respect to Dr. Siegall, in the event that his employment is constructively terminated or terminated by us without cause, he will be entitled to receive cash severance in the form of his monthly base salary for 18 months and a payment equal to his annual target bonus multiplied by one and one-half. If such termination occurs immediately prior to or within 12 months after a change of control of Seattle Genetics, he will be entitled to receive a payment equal to

Table of Contents

his annual target bonus multiplied by two plus an amount equal to a pro-rated portion of his annual target bonus based on the percentage of time during the applicable year he was employed by us (and the cash severance related to monthly base salary in the employment agreement that we previously entered into with Dr. Siegall remains unchanged). The Amended Employment Agreement also replaces the single-trigger change of control vesting acceleration provision with a double-trigger providing for vesting acceleration of all of Dr. Siegall's outstanding and unvested equity awards if his employment is constructively terminated or terminated by us without cause immediately prior to or within 12 months after a change of control of Seattle Genetics.

- With respect to Mr. Simpson, Dr. Dansey, Dr. Himes, Mr. Cline and Ms. Liu, in the event that the applicable executive officer's employment is constructively terminated or terminated by us without cause immediately prior to or within 12 months after a change of control of Seattle Genetics, then such executive officer will be entitled to receive payment of COBRA health insurance premiums and cash severance in an amount equal to his or her monthly base salary for 18 months plus an amount equal to his or her annual target bonus multiplied by one and one-half. The double-trigger change of control vesting acceleration provisions in the employment agreements that we had previously entered into with these executive officers remain unchanged. If such termination is not immediately prior to or within 12 months after a change of control of Seattle Genetics, the executive officer will be entitled to receive a payment equal to his or her annual target bonus (and the cash severance related to monthly base salary in the employment agreements that we previously entered into with these executive officers remains unchanged).

The foregoing is only a brief description of certain terms of the Amended Employment Agreements, does not purport to be complete and is qualified in its entirety by reference to the full text of the Amended Employment Agreements which are filed as Exhibits 10.1 through 10.6 to this quarterly report on Form 10-Q.

Long Term Incentive Plan for Tucatinib

The Compensation Committee approved a performance-based Long Term Incentive Plan for tucatinib, or the Tucatinib LTIP, effective October 24, 2018, for the purpose of incentivizing our employees to potentially achieve regulatory approval of tucatinib. All of our employees located in the United States, Europe or Canada who were in good standing as of October 24, 2018, or the Eligible Employees, are eligible to participate in the Tucatinib LTIP. Under the Tucatinib LTIP, Eligible Employees may receive grants of equity awards relating to our common stock, which may consist of a "First Tranche" and a "Second Tranche" as set forth in the Tucatinib LTIP, each of which shall be granted as a separate stock unit award on the applicable date of grant. Any stock unit awards provided under the Tucatinib LTIP will be granted under, and subject to the terms of, our Amended and Restated 2007 Equity Incentive Plan and our standard forms of Stock Unit Grant Notice and Stock Unit Agreement for United States employees and non-United States employees.

The total target award value (expressed in dollars) for each Eligible Employee, or the Target Award Value, is set pursuant to the terms of the Tucatinib LTIP based on the Eligible Employee's position level with us as of October 24, 2018. The Target Award Value for each of our executive officers is as follows: $920,000 for Clay Siegall, President and Chief Executive Officer; $280,000 for Todd Simpson, Chief Financial Officer; $280,000 for Roger Dansey, Chief Medical Officer; $280,000 for Vaughn Himes, Chief Technical Officer; $200,000 for Darren Cline, Executive Vice President, Commercial, and $200,000 for Jean Liu, General Counsel and Executive Vice President, Legal Affairs.

The target number of stock units granted in the First Tranche will be equal to 50% of the Target Award Value applicable to each Eligible Employee divided by the average closing sales price of our common stock for the 30 calendar day period ending on October 31, 2018. The First Tranche will be granted on November 1, 2018 and will only vest upon certification by the Compensation Committee of the first approval by the FDA for the commercial sale and marketing of tucatinib in the United States by us or any of our partners for any indication, which such approval is based on the clinical trial data from the pivotal HER2CLIMB trial (such achievement, the Tucatinib Milestone, and the date on which the Compensation Committee certifies achievement, the Certification Date), provided that the employee is still employed by us as of the date of vesting. If the First Tranche vests due to achievement of the Tucatinib Milestone, the number of shares that vest will be determined by multiplying the target number of stock units subject to each stock unit award by the applicable earn out percentage. An earn out percentage, on a sliding scale from 0% to 144%, will be determined based on the date of achievement of the Tucatinib Milestone and the breadth of the

indication or indications, as the case may be, for which tucatinib is approved by the FDA for commercial sale and marketing in the United States on the date that the Tucatinib Milestone occurs.

The Second Tranche will be granted upon certification by the Compensation Committee of achievement of the Tucatinib Milestone provided that the Eligible Employee is still employed by us as of the date of grant. The number of stock units granted, if any, with respect to the Second Tranche will be equal to 50% of the Target Award Value applicable to each Eligible Employee multiplied by the applicable earn out percentage determined by the Compensation Committee on the Certification Date, with the product of these numbers then divided by the average closing sales price of our common stock for the 30 calendar day period ending on the calendar day prior to the date of grant of the Second Tranche. If the Second Tranche is

Table of Contents

granted due to achievement of the Tucatinib Milestone, it will vest on the second anniversary of the Certification Date, provided that the Eligible Employee's continuous service with us has not terminated prior to the vesting date. The vesting of each outstanding stock unit award is subject to partial or full acceleration in the event of a termination of service (without cause or due to constructive termination) immediately prior to, or within twelve months after, a change of control of Seattle Genetics, or in the event an acquirer in a change of control of Seattle Genetics fails to assume the stock unit awards.

If the Tucatinib Milestone is not achieved by a specified date, then the First Tranche will not vest, the Second Tranche will not be granted and the Tucatinib LTIP will automatically terminate. In addition, in the event that we cease to have rights to tucatinib, the Tucatinib LTIP shall automatically terminate.

The foregoing is only a brief description of the terms of the Tucatinib LTIP, does not purport to be complete and is qualified in its entirety by reference to the Tucatinib LTIP which is filed as Exhibit 10.7 to this quarterly report on Form 10-Q.

Table of Contents

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation By Reference Form	SEC File No.	Exhibit	Filing Date
2.1**	Agreement and Plan of Merger, dated as of January 30, 2018, by and among Seattle Genetics, Inc., Valley Acquisition Sub, Inc. and Cascadian Therapeutics, Inc.	8-K	000-32405	2.1	1/31/2018
3.1	Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.	10-Q	000-32405	3.1	11/7/2008
3.2	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.	8-K	000-32405	3.3	5/26/2011
3.3	Amended and Restated Bylaws of Seattle Genetics, Inc.	8-K	000-32405	3.1	11/25/2015
4.1	Specimen Stock Certificate.	S-1/A	333-50266	4.1	2/8/2001
4.2	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.	10-Q	000-32405	4.3	11/7/2008
4.3	Registration Rights Agreement, dated September 10, 2015, between Seattle Genetics, Inc. and the persons listed on Schedule A attached thereto.	8-K	000-32405	10.1	9/11/2015
10.1+*	Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Clay Siegall.	—	—	—	—
10.2+*	Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Todd Simpson.	—	—	—	—
10.3+*	Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Roger Dansey.	—	—	—	—
10.4+*	Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Vaughn Himes.	—	—	—	—
10.5+*	Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Darren Cline.	—	—	—	—
10.6+*	Amended and Restated Employment Agreement dated October 25, 2018, between Seattle Genetics, Inc. and Jean Liu.	—	—	—	—
10.7+*	Seattle Genetics, Inc. Long Term Incentive Plan for Tucatinib.	—	—	—	—
10.8+*	Form of Stock Option Agreement for U.S. Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved August 30, 2018).	—	—	—	—
10.9+*	Form of Stock Option Agreement for non-US Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved August 30, 2018).	—	—	—	—
10.10+*	Form of Performance-Based Stock Unit Agreement for U.S. Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved August 30, 2018).	—	—	—	—
10.11+*	Form of Stock Unit Grant Notice and Stock Unit Agreement for US Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved October 24, 2018).	—	—	—	—
10.12+*	Form of Stock Unit Grant Notice and Stock Unit Agreement for non-US Participants under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved October 24, 2018).	—	—	—	—

10.13+*	Compensation Information for Executive Officers.	—	—	—	—
31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).	—	—	—	—
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).	—	—	—	—
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.	—	—	—	—
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.	—	—	—	—
101.INS+	XBRL Instance Document.	—	—	—	—
101.SCH+	XBRL Taxonomy Extension Schema Document.	—	—	—	—

Table of Contents

101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document.	———
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document.	———
101.LAB+	XBRL Taxonomy Extension Labels Linkbase Document.	———
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document.	———

\+ Filed herewith.

* Indicates a management contract or compensatory plan or arrangement.

** Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The registrant will furnish copies of any such schedules to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934.

Table of Contents

SIGNATURE

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

SEATTLE GENETICS, INC.

By: /s/ Todd E. Simpson
Todd E. Simpson
Duly Authorized and Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: October 26, 2018