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 June 30, 2019

OR

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

For the transition period from _____to _____

Commission file number 0-32405

SEATTLE GENETICS, INC.
(Exact name of registrant as specified in its charter)

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

21823 30th Drive SE
Bothell , Washington 98021
(Address of principal executive offices, including zip code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001	SGEN	The Nasdaq Stock Market LLC

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 July 11, 2019 , there were 161,720,181 shares of the registrant's common stock outstanding.

Seattle Genetics, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended June 30, 2019

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 64,112	$ 78,186
Short-term investments	312,017	332,486
Accounts receivable, net	182,264	146,281
Inventories	73,150	53,239
Prepaid expenses and other current assets	40,398	43,403
Total current assets	671,941	653,595
Property and equipment, net	130,900	103,820
Operating lease right-of-use assets	69,056	—
Long-term investments	—	49,194
In-process research and development	300,000	300,000
Goodwill	274,671	274,671
Other non-current assets	120,997	122,049
Total assets	$ 1,567,565	$ 1,503,329
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 36,877	$ 44,179
Accrued liabilities and other	168,073	147,293
Current portion of deferred revenue	17,002	33,600
Total current liabilities	221,952	225,072
Long-term liabilities:		
Operating lease liabilities, long-term	71,430	—
Other long-term liabilities	2,357	4,314
Total long-term liabilities	73,787	4,314
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000 shares authorized; none issued	—	—
Common stock, $0.001 par value, 250,000 shares authorized; 161,638 shares issued and outstanding at June 30, 2019 and 160,262 shares issued and outstanding at December 31, 2018	162	160
Additional paid-in capital	2,688,333	2,598,411
Accumulated other comprehensive income (loss)	486	(40)
Accumulated deficit	(1,417,155)	(1,324,588)
Total stockholders' equity	1,271,826	1,273,943
Total liabilities and stockholders' equity	$ 1,567,565	$ 1,503,329

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Net product sales	$ 158,980	$ 122,443	$ 293,981	$ 217,800
Collaboration and license agreement revenues	36,130	27,179	80,708	56,738
Royalty revenues	23,337	20,551	38,957	36,225
Total revenues	218,447	170,173	413,646	310,763
Costs and expenses:				
Cost of sales	8,609	13,157	16,520	23,515
Cost of royalty revenues	2,288	6,148	4,677	11,525
Research and development	163,929	122,860	322,194	275,362
Selling, general and administrative	82,331	58,292	162,602	124,474
Total costs and expenses	257,157	200,457	505,993	434,876
Loss from operations	(38,710)	(30,284)	(92,347)	(124,113)
Investment and other income (loss), net	(40,528)	106,557	(220)	88,671
Net income (loss)	$ (79,238)	$ 76,273	$ (92,567)	$ (35,442)
Net income (loss) per share - basic	$ (0.49)	$ 0.48	$ (0.57)	$ (0.23)
Net income (loss) per share - diluted	$ (0.49)	$ 0.47	$ (0.57)	$ (0.23)
Shares used in computation of per share amounts - basic	161,436	158,381	161,049	155,525
Shares used in computation of per share amounts - diluted	161,436	163,382	161,049	155,525
Comprehensive income (loss):				
Net income (loss)	$ (79,238)	$ 76,273	$ (92,567)	$ (35,442)
Other comprehensive income:				
Unrealized gain on securities available-for-sale, net of tax	252	105	474	132
Foreign currency translation gain (loss)	18	(15)	52	(23)
Total other comprehensive income	270	90	526	109
Comprehensive income (loss)	$ (78,968)	$ 76,363	$ (92,041)	$ (35,333)

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

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

	Common stock					
	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
Balances as of December 31, 2017	144,395	$ 144	$ 1,806,159	$ 63,836	$ (1,192,570)	$ 677,569
Net loss	—	—	—	—	(111,715)	(111,715)
Other comprehensive income	—	—	—	19	—	19
Cumulative effects of accounting changes	—	—	—	(64,119)	90,675	26,556
Issuance of common stock for employee stock purchase plan	106	—	4,424	—	—	4,424
Stock option exercises	375	1	7,403	—	—	7,404
Restricted stock vested during the period, net	24	—	—	—	—	—
Issuance of common stock	13,269	13	658,229	—	—	658,242
Share-based compensation	—	—	16,838	—	—	16,838
Balances as of March 31, 2018	158,169	158	2,493,053	(264)	(1,213,610)	1,279,337
Net income	—	—	—	—	76,273	76,273
Other comprehensive income	—	—	—	90	—	90
Stock option exercises	418	1	11,221	—	—	11,222
Restricted stock vested during the period, net	59	—	—	—	—	—
Share-based compensation	—	—	15,517	—	—	15,517
Balances as of June 30, 2018	158,646	$ 159	$ 2,519,791	$ (174)	$ (1,137,337)	$ 1,382,439
Balances as of December 31, 2018	160,262	$ 160	$ 2,598,411	$ (40)	$ (1,324,588)	$ 1,273,943
Net loss	—	—	—	—	(13,329)	(13,329)
Other comprehensive income	—	—	—	256	—	256
Issuance of common stock for employee stock purchase plan	104	—	6,147	—	—	6,147
Stock option exercises	719	1	20,678	—	—	20,679
Restricted stock vested during the period, net	56	—	—	—	—	—
Share-based compensation	—	—	25,715	—	—	25,715
Balances as of March 31, 2019	161,141	161	2,650,951	216	(1,337,917)	1,313,411
Net loss	—	—	—	—	(79,238)	(79,238)
Other comprehensive income	—	—	—	270	—	270
Stock option exercises	393	1	11,225	—	—	11,226
Restricted stock vested during the period, net	104	—	—	—	—	—
Share-based compensation	—	—	26,157	—	—	26,157
Balances as of June 30, 2019	161,638	$ 162	$ 2,688,333	$ 486	$ (1,417,155)	$ 1,271,826

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

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

	Six Months Ended June 30,	
	2019	**2018**
Operating activities:		
Net loss	$ (92,567)	$ (35,442)
Adjustments to reconcile net loss to net cash used by operating activities		
Share-based compensation	51,872	32,355
Depreciation and amortization	9,905	13,322
Amortization of right-of-use assets	4,833	—
(Gains) losses on equity securities	4,568	(86,647)
Changes in operating assets and liabilities		
Accounts receivable, net	(35,983)	(48,928)
Inventories	(19,911)	(10,955)
Prepaid expenses and other assets	6,275	(4,992)
Lease liability	(2,955)	—
Deferred revenue	(16,598)	(17,279)
Other liabilities	(679)	(9,569)
Net cash used by operating activities	(91,240)	(168,135)
Investing activities:		
Purchases of securities	(147,555)	(242,679)
Proceeds from maturities of securities	220,000	210,022
Proceeds from sales of securities	—	125,483
Purchases of property and equipment	(33,331)	(9,490)
Acquisition of Cascadian Therapeutics, Inc., net of cash acquired	—	(598,151)
Net cash provided (used) by investing activities	39,114	(514,815)
Financing activities:		
Net proceeds from issuance of common stock	—	658,242
Proceeds from exercise of stock options and employee stock purchase plan	38,052	23,050
Net cash provided by financing activities	38,052	681,292
Net decrease in cash and cash equivalents	(14,074)	(1,658)
Cash and cash equivalents at beginning of period	78,186	160,945
Cash and cash equivalents at end of period	$ 64,112	$ 159,287

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

Seattle Genetics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements reflect the accounts of Seattle Genetics, Inc. and its wholly-owned subsidiaries (collectively "Seattle Genetics," "we," "our," or "us"). All intercompany transactions and balances have been eliminated. We acquired Cascadian Therapeutics, Inc., or Cascadian, in March 2018, as further described in Note 4. Management has determined that we operate in one segment: the development and sale of pharmaceutical products on our own behalf or in collaboration with others. Substantially all of our assets and revenues are related to operations in the U.S.; however, we have multiple subsidiaries in foreign jurisdictions, including several subsidiaries in Europe.

The condensed consolidated balance sheet data as of December 31, 2018 were derived from audited financial statements not included in this quarterly report on Form 10-Q. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and generally accepted accounting principles in the United States of America, or GAAP, for unaudited condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements reflect all adjustments consisting of normal recurring adjustments that, in the opinion of management, are necessary for a fair statement of our financial position and results of our operations as of and for the periods presented.

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

The preparation of financial statements in accordance with GAAP requires us to make estimates, assumptions, and judgments that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The results of our operations for the three and six month periods ended June 30, 2019 are not necessarily indicative of the results to be expected for the full year or any other interim period.

Non-cash financing and investing activities

We had $10.6 million and $4.6 million of accrued capital expenditures as of June 30, 2019 and December 31, 2018 , respectively. Accrued capital expenditures have been treated as a non-cash investing activity and, accordingly, have not been included in the statement of cash flows until such amounts have been paid in cash. During the six months ended June 30, 2019 , we recorded $39.2 million right-of-use assets in exchange for lease liabilities. Refer to Note 3.

Investments

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

We invest our available cash primarily in debt securities. These debt securities are classified as available-for-sale, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive income and loss in stockholders' equity. Realized gains, realized losses and declines in the value of debt securities judged to be other-than-temporary are included in investment and other income (loss), net . The cost of debt securities for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Amortization of premiums and accretion of discounts on debt securities are included in investment and other income (loss), net . Interest and dividends earned 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.

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

Leases

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

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

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

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

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

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

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

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

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

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

Long-term incentive plans

We have established Long-Term Incentive Plans, or LTIPs. The LTIPs provide eligible employees with the opportunity to receive performance-based incentive compensation, which may be comprised of cash, stock options, and/or RSUs. The payment of cash and the grant and/or vesting of equity are contingent upon the achievement of pre-determined regulatory milestones. We record compensation expense over the estimated service period for each milestone subject to the achievement of the milestone being considered probable in accordance with the provisions of Accounting Standards Codification Topic 450, Contingencies. At each reporting date, we assess whether achievement of a milestone is considered probable and, if so, record compensation expense based on the portion of the service period elapsed to date with respect to that milestone, with a cumulative catch-up, net of estimated forfeitures. We recognize compensation expense with respect to a milestone over the remaining estimated service period. As of June 30, 2019 , the estimated unrecognized compensation expense related to all LTIPs was $51.2 million .

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

Revenue recognition

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

Net product sales

We sell ADCETRIS through a limited number of pharmaceutical distributors in the U.S. and Canada. Customers order ADCETRIS through these distributors, and we typically ship product directly to the customer. The delivery of ADCETRIS to the end-user site represents a single performance obligation for these transactions. We record product sales at the point in time when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. The transaction price for product sales represents the amount we expect to receive, which is net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. Accruals are established for these deductions, and actual amounts incurred are offset against applicable accruals. We reflect these accruals as either a reduction in the related account receivable from the distributor or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider payor mix in target markets and experience to-date. These estimates involve a substantial degree of judgment. We have applied a portfolio approach as a practical expedient for estimating net product sales from ADCETRIS.

Government-mandated rebates and chargebacks: We have entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate based on covered purchases of ADCETRIS. Medicaid rebates are invoiced to us by the various state Medicaid programs. We estimate Medicaid rebates using the expected value approach, based on a variety of factors, including our experience to-date.

We have also completed a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. In addition, we have entered into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services, which enables certain entities that qualify for government pricing under the Public Health Services Act, or PHS, to receive discounts on their qualified purchases of ADCETRIS. Under these agreements, distributors process a chargeback to us for the difference between wholesale acquisition cost and the applicable discounted price. As a result of our direct-ship distribution model, we can identify the entities purchasing ADCETRIS and this information enables us to estimate expected chargebacks for FSS and PHS purchases based on the expected value of each entity's eligibility for the FSS and PHS programs. We also review historical rebate and chargeback information to further refine these estimates.

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

Collaboration and license agreement revenues

We have collaboration and license agreements with a number of biotechnology and pharmaceutical companies. Our proprietary technology for linking cytotoxic agents to monoclonal antibodies called antibody-drug conjugates, or ADCs, is the basis for many of these collaboration and license agreements, including the ADC collaborations that we have entered into in the ordinary course of business, under which we granted our collaborators research and commercial licenses to our technology and typically provide technology transfer services, technical advice, supplies and services for a period of time.

Our collaboration and license agreements include contractual milestones. Generally, the milestone events coincide with the progression of the collaborators' product candidates. These consist of development milestones (such as designation of a product candidate or initiation of preclinical studies and the initiation of phase 1, phase 2, or phase 3 clinical trials), regulatory milestones (such as the filing of regulatory applications for marketing approval), and commercialization milestones (such as first commercial sale in a particular market and product sales in excess of a pre-specified threshold). Our ADC collaborators are solely responsible for the development of their product candidates, and the achievement of milestones in any of the categories identified above is based solely on the collaborators' efforts. Since we do not take a substantive role or control the research, development or commercialization of any products generated by our ADC collaborators, we are not able to reasonably estimate when, if at all, any potential future milestone payments or royalties may be payable to us by our ADC collaborators. As such, the potential future milestone payments associated with our ADC collaborations involve a substantial degree of uncertainty and risk that they may never be received. In the case of our ADCETRIS collaboration with Takeda Pharmaceutical Company Limited, or Takeda, we may be involved in certain development activities; however, the achievement of milestone events under the agreement is primarily based on activities undertaken by Takeda.

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

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

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

We generally invoice our collaborators and licensees on a monthly or quarterly basis, or upon the completion of the effort or achievement of a milestone, based on the terms of each agreement. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

Royalty revenues and cost of royalty revenues

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

Recent accounting pronouncements not yet adopted

In June 2016, Financial Accounting Standards Board, or FASB, issued "ASU 2016-13, Financial Instruments: Credit Losses", as clarified in ASU 2019-04 and ASU 2019-05. 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.

In November 2018, FASB issued "ASU 2018-18, Clarifying the Interaction between Topic 808 and Topic 606." The objective of the standard is to clarify the interaction between Topic 808, Collaborative Arrangements, and Topic 606, Revenue from Contracts with Customers. Currently, Topic 808 does not provide comprehensive recognition or measurement guidance for collaborative arrangements, and the accounting for those arrangements is often based on an analogy to other accounting literature or an accounting policy election. Similarly, aspects of Topic 606 have resulted in uncertainty in practice about the effect of the revenue standard on the accounting for collaborative arrangements. The standard will become effective for us beginning on January 1, 2020, with early adoption permitted. We are currently evaluating the guidance to determine the potential impact on our financial condition, results of operations, cash flows, and financial statement disclosures.

2. Revenue from contracts with customers

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

	Three months ended June 30,		Six months ended June 30,	
(dollars in thousands)	**2019**	**2018**	**2019**	**2018**
Takeda	$ 28,760	$ 8,745	$ 72,139	$ 22,317
AbbVie	600	4,700	925	12,700
Genentech	6,670	583	6,873	1,299
Genmab	—	7,000	—	7,000
GSK	—	6,000	—	6,000
Other	100	151	771	7,422
Collaboration and license agreement revenues	$ 36,130	$ 27,179	$ 80,708	$ 56,738

Contract liabilities consist of deferred revenue primarily related to our remaining performance obligations under the Takeda ADCETRIS collaboration and are presented on the condensed consolidated balance sheets. Deferred revenue will be recognized as the remaining performance obligations are satisfied through November 2019.

We recognized collaboration and license agreement revenues of $18.5 million during the six months ended June 30, 2019 that were included in the deferred revenue balance as of December 31, 2018 . For the six months ended June 30, 2019 , collaboration and license agreement revenues from Takeda also included substantially all of $37.5 million for two regulatory milestones achieved, which were related to additional approvals of ADCETRIS in frontline Hodgkin lymphoma received by Takeda.

3. Operating leases

We have operating leases for our office and laboratory facilities with terms that expire from 2021 through 2029. Upon adoption of Topic 842 on January 1, 2019, we recognized $35.2 million of operating lease liabilities and $34.7 million of operating lease right-of-use assets for our existing leases on our condensed consolidated balance sheet. As of June 30, 2019 , our operating lease liabilities and operating lease right-of-use assets were $79.4 million and $69.1 million , respectively. The increases in operating lease liabilities and operating lease right-of-use assets during the six months ended June 30, 2019 reflected new facilities leases that commenced during the period. All of our significant leases include options for us to extend the lease term. None of our options to extend the rental term of any existing leases were considered reasonably certain as of June 30, 2019 .

Supplemental operating lease information were as follows:

(dollars in thousands)	Three months ended June 30, 2019	Six months ended June 30, 2019
Operating lease cost	$ 3,401	$ 6,587
Variable lease cost	751	1,429

As of June 30, 2019 , the weighted average remaining lease term for our operating leases was 7.4 years, and the weighted average discount rate for our operating leases was 5.4% .

Future minimum lease payments under the lease agreements as of June 30, 2019 were as follows:

Years ending December 31,	(dollars in thousands)
2019 (remaining six months)	$ 5,463
2020	13,086
2021	14,028
2022	13,585
2023	13,478
Thereafter	38,701
Total future minimum lease payments	$ 98,341
Less: imputed interest	(18,962)
Total	$ 79,379

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

(dollars in thousands)	June 30, 2019
Accrued liabilities and other	$ 7,949
Operating lease liabilities, long-term	71,430
Total	$ 79,379

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

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

4. Acquisition of Cascadian

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

The acquisition of Cascadian was accounted for as a business combination. During the six months ended June 30, 2018 , we incurred $8.5 million in acquisition-related costs, which were recorded in selling, general and administrative expenses.

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

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

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

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

(dollars in thousands)	Three months ended June 30, 2018	Six months ended June 30, 2018
Revenues	$ 170,173	$ 310,763
Net income (loss)	76,273	(64,376)

5. 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 and six months ended June 30, 2019 , and the six months ended June 30, 2018 , 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 June 30, 2018, 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 12,464,000 and 1,674,000 for the three months ended June 30, 2019 and 2018 , respectively, and approximately 12,831,000 and 13,379,000 for the six months ended June 30, 2019 and 2018 , respectively.

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

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Net income (loss)	$ (79,238)	$ 76,273	$ (92,567)	$ (35,442)
Weighted average common shares outstanding - basic	161,436	158,381	161,049	155,525
Dilutive potential common shares	—	5,001	—	—
Weighted average common shares outstanding - diluted	161,436	163,382	161,049	155,525
Net income (loss) per share - basic	$ (0.49)	$ 0.48	$ (0.57)	$ (0.23)
Net income (loss) per share - diluted	$ (0.49)	$ 0.47	$ (0.57)	$ (0.23)

6. Common stock

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

7. Fair value

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

Level 1:	Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
Level 2:	Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.
Level 3:	Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

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

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

	Fair value measurement using:			
(dollars in thousands)	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
June 30, 2019				
Short-term investments—U.S. Treasury securities	$ 312,017	$ —	$ —	$ 312,017
Other non-current assets—equity securities	109,244	—	—	109,244
Total	$ 421,261	$ —	$ —	$ 421,261
December 31, 2018				
Short-term investments—U.S. Treasury securities	$ 332,486	$ —	$ —	$ 332,486
Long-term investments—U.S. Treasury securities	49,194	—	—	49,194
Other non-current assets—equity securities	113,812	—	—	113,812
Total	$ 495,492	$ —	$ —	$ 495,492

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

Our debt securities consisted of the following:

(dollars in thousands)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
June 30, 2019				
U.S. Treasury securities	$ 311,536	$ 481	$ —	$ 312,017
Contractual maturities (at date of purchase):				
Due in one year or less	$ 195,367			$ 195,505
Due in one to two years	116,169			116,512
Total	$ 311,536			$ 312,017
December 31, 2018				
U.S. Treasury securities	$ 381,673	$ 133	$ (126)	$ 381,680
Contractual maturities (at date of purchase):				
Due in one year or less	$ 246,440			$ 246,402
Due in one to two years	135,233			135,278
Total	$ 381,673			$ 381,680

8. Investment and other income (loss), net

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

	Three months ended June 30,		Six months ended June 30,	
(dollars in thousands)	2019	2018	2019	2018
Gain (loss) on equity securities	$ (42,693)	$ 105,472	$ (4,568)	$ 86,647
Investment income, net	2,165	1,085	4,348	2,024
Total investment and other income (loss), net	$ (40,528)	$ 106,557	$ (220)	$ 88,671

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

9. Inventories

The following table presents our inventories of ADCETRIS:

(dollars in thousands)	June 30, 2019	December 31, 2018
Raw materials	$ 64,828	$ 43,986
Finished goods	8,322	9,253
Total	$ 73,150	$ 53,239

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

10. Legal matters

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

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

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

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

Overview

Seattle Genetics is a biotechnology company that develops and commercializes therapies targeting cancer. We are commercializing ADCETRIS ®, or brentuximab vedotin, for the treatment of several types of lymphoma. We are also advancing a pipeline of novel therapies for solid tumors and blood-related cancers designed to address unmet medical needs and improve treatment outcomes for patients. Many of our programs, including ADCETRIS, are based on our antibody-drug conjugate, or ADC, technology that utilizes the targeting ability of monoclonal antibodies to deliver cell-killing agents directly to cancer cells.

Our marketed product ADCETRIS is commercially available in more than 70 countries worldwide. We commercialize ADCETRIS in the U.S. and its territories and in Canada, and we are collaborating with Takeda Pharmaceutical Company Limited, or Takeda, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Takeda has commercial rights in the rest of the world and pays us a royalty. ADCETRIS is approved by the U.S. Food and Drug Administration, or FDA, in six indications. In Hodgkin lymphoma, ADCETRIS is approved as monotherapy for patients whose disease has relapsed and as consolidation therapy following prior treatment, and in combination with chemotherapy for the treatment of patients with previously untreated disease. In T-cell lymphomas, ADCETRIS is approved as monotherapy for patients with relapsed or refractory systemic anaplastic large cell lymphoma, or sALCL, or certain types of cutaneous T-cell lymphoma, or CTCL, or in combination with chemotherapy for patients with previously untreated CD30-expressing peripheral T-cell lymphoma, or PTCL.

Beyond our current labeled indications, we are evaluating ADCETRIS in several clinical trials. These include ADCETRIS in combination with nivolumab (Opdivo ®) for Hodgkin and non-Hodgkin lymphoma under a clinical collaboration with Bristol-Myers Squibb Company, or BMS. Nivolumab is a programmed death-1, or PD-1, immune checkpoint inhibitor. In addition, we plan to initiate registrational trials evaluating retreatment with ADCETRIS in Hodgkin and T-cell lymphoma patients who progress after a prior response and in Hodgkin lymphoma and PTCL patients who are unfit for combination chemotherapy due to older age or comorbidities.

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

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

In March 2019, we and Astellas announced positive top-line results from the first cohort of EV-201 that enrolled 128 patients who previously received both platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor. In June 2019, additional data were reported at the American Society of Clinical Oncology annual meeting. Results from the first cohort showed the primary endpoint of confirmed objective response rate, or ORR, was 44 percent per blinded independent central review. Complete responses were observed in 12 percent of patients. Responses were observed across all pre-specified patient subgroups irrespective of lines of therapy, response to prior PD-1 or PD-L1 inhibitor, or presence of liver metastases which is a factor that is associated with poor prognosis. The median duration of tumor response was 7.6 months. Median overall survival, or OS, was 11.7 months and the median progression-free survival, or PFS, was 5.8 months. Target lesions were reduced in 84 percent of evaluable patients. The most common treatment-related adverse events were fatigue (50 percent), alopecia (49 percent), rash (48 percent), decreased appetite (44 percent), taste distortion (40 percent) and peripheral neuropathy (50 percent). The most common Grade 3 or higher adverse events were neutropenia (8 percent), anemia (7 percent), and fatigue (6 percent). One death due to interstitial lung disease occurred outside the safety-reporting period of the trial and was confounded by prolonged high-dose steroid use and suspected pneumonia. Based on these results, we and Astellas submitted a Biologics License Application, or BLA, to the FDA in July 2019 under the FDA's accelerated approval pathway for the treatment of patients with locally advanced or metastatic urothelial cancer who have received a PD-1 or PD-L1 inhibitor and who have received a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting. The second cohort of the EV-201 trial continues to enroll patients.

We and Astellas are also conducting a global, randomized phase 3 trial, called EV-301, for patients with metastatic urothelial cancer who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor. EV-301 is intended to support global regulatory applications for potential approvals in regions where EV-201 does not support approval and to potentially serve as a confirmatory trial in the U.S. if we are able to obtain accelerated approval based on the July 2019 enfortumab vedotin BLA submission. Additionally, we and Astellas are conducting a phase 1b trial of enfortumab vedotin, called EV-103, in earlier lines of treatment for patients with locally advanced or metastatic urothelial cancer, including in combination with pembrolizumab and/or platinum chemotherapy in newly diagnosed patients as well as patients whose cancer progressed from earlier-stage disease. We expect to report initial data from the EV-103 trial in 2019.

We are also developing tucatinib, an oral TKI targeting HER2, a growth factor receptor overexpressed in many cancers. Tucatinib is currently being evaluated as part of a combination regimen in a global randomized (2:1) pivotal trial, called HER2CLIMB, comparing tucatinib vs. placebo, each in combination with capecitabine and trastuzumab (Herceptin ®). The trial is evaluating patients with HER2-positive metastatic breast cancer who have been previously treated with trastuzumab, pertuzumab (Perjeta ®) and ado-trastuzumab emtansine, or T-DM1 (Kadcyla ®), including patients with or without brain metastases. In January 2019, we announced that we achieved enrollment of 480 patients in the trial to enable analysis of the primary endpoint of PFS with top-line data expected to be reported in 2019. In April 2019, we reached the target enrollment of 600 patients in the HER2CLIMB trial to support the analyses of key secondary endpoints, including OS as well as PFS in patients with brain metastases. Additionally, we plan to initiate a phase 3 randomized trial comparing tucatinib vs. placebo, each in combination with T-DM1 in patients with HER2-positive metastatic breast cancer who have been previously treated with a taxane and trastuzumab. The primary endpoint of the planned trial will be PFS.

In collaboration with Genmab A/S, or Genmab, we are developing tisotumab vedotin, which is an ADC targeting tissue factor. We and Genmab are conducting a pivotal phase 2 trial, called the innovaTV 204 trial, evaluating single-agent tisotumab vedotin for patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment. The trial is intended to support potential regulatory submission under the FDA's accelerated approval pathway. In March 2019, we completed enrollment in the innovaTV 204 trial and we anticipate reporting top-line data from the trial in the first half of 2020. We are also conducting a phase 2 clinical trial called innovaTV 207 for patients with other solid tumors that is intended to inform a potential future broad development program. In addition, we are conducting a phase 2 clinical trial, called innovaTV 208, for patients with platinum-resistant ovarian cancer.

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

We are advancing a pipeline of early-stage clinical candidates as well as multiple preclinical and research-stage programs that employ our proprietary technologies. We plan to submit several investigational new drug applications to the FDA in 2019 and 2020.

We have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd., or AbbVie; Astellas; Genentech, Inc., a member of the Roche Group, or Genentech; Genmab; GlaxoSmithKline LLC, or GSK; and Progenics Pharmaceuticals Inc. Of these collaborators, Genentech and GSK have ADCs using our technology in late-stage clinical trials. In June 2019, Genentech received accelerated approval from the FDA for polatuzumab vedotin-piiq (Polivy™), an ADC that uses our technology, to treat patients with relapsed or refractory diffuse large B-cell lymphoma. Under our ADC collaboration with Genentech, the accelerated approval of Polivy triggered a milestone payment to us and we are entitled to receive royalties on net sales of Polivy worldwide. In addition, we have a collaboration with Unum Therapeutics, Inc., or Unum, to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies incorporating our antibodies for the treatment of cancer. Unum is conducting a phase 1 trial evaluating Unum's ACTR087 drug candidate in combination with SEA-BCMA in patients with relapsed/refractory multiple myeloma.

Outlook

Our ongoing research, development, manufacturing and commercial activities will require substantial amounts of capital and may not ultimately be successful. We expect that we will incur substantial expenses, primarily as a result of activities related to the commercialization and continued development of ADCETRIS, as well as the continued development and potential commercialization of enfortumab vedotin, tucatinib and tisotumab vedotin. We will require significant financial resources and additional personnel in order to continue to advance the development of, to pursue, obtain and maintain regulatory approvals for, and to potentially commercialize, enfortumab vedotin, tucatinib and tisotumab vedotin, if we are able to do so at all. Our other product candidates are in early or relatively early stages of development. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to our plans to build a commercial infrastructure in Europe and to otherwise continue to expand our operations internationally. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS, the research, continued development and manufacturing of our product candidates, launch and commercialization activities for potential new products, and the anticipated expansion of our pipeline and operations will likely require us to raise substantial amounts of additional capital, and our operating expenses may fluctuate as a result of such activities. We may also incur significant milestone payment obligations to certain of our licensors as our product candidates progress through clinical trials towards potential commercialization.

We recognize revenue from ADCETRIS product sales in the U.S. and Canada. Our future ADCETRIS product sales are difficult to accurately predict from period to period and are dependent on, among other things, the incidence flow of patients eligible for treatment with ADCETRIS. In this regard, our product sales have varied, and may continue to vary, significantly from period to period and may be affected by a variety of factors. Such factors include the approval of ADCETRIS in additional indications, the extent to which coverage and reimbursement for ADCETRIS is available from government and other third-party payors, competition, the incidence rate of new patients in ADCETRIS' approved indications, customer ordering patterns, physicians' perception and adoption of ADCETRIS, the overall level of demand for ADCETRIS, and the duration of therapy for patients receiving ADCETRIS. In particular:

- Obtaining and maintaining appropriate coverage and reimbursement for ADCETRIS is increasingly challenging due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide, as well as increasing legislative and enforcement interest in the U.S. with respect to pharmaceutical drug pricing practices. We anticipate that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for ADCETRIS. We also anticipate that Congress, state legislatures, and third-party payors may continue to review and assess alternative healthcare delivery and payment systems and may in the future propose and adopt legislation or policy changes or implementations effecting additional fundamental changes in the healthcare delivery system, any of which could negatively affect our revenue or sales of ADCETRIS or any future approved products.
- The competition ADCETRIS faces from competing therapies is intensifying, and we anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other cancer therapies continue to accelerate.

The FDA approved ADCETRIS in combination with chemotherapy for patients with newly-diagnosed, previously untreated Stage III and IV classical Hodgkin lymphoma, or the frontline Hodgkin lymphoma indication, in March 2018 based on the results of the phase 3 ECHELON-1 clinical trial. The FDA approved ADCETRIS in combination with chemotherapy for patients with newly diagnosed, previously untreated sALCL or other CD30-expressing PTCL, including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, or the frontline PTCL indication, in November 2018 based on the results of the phase 3 ECHELON-2 clinical trial. While we expect continued growth in ADCETRIS sales in 2019 as compared to 2018 , we expect that our ability to continue to grow ADCETRIS sales, if at all, will depend primarily on our ability to establish or demonstrate to the medical community the value of ADCETRIS and its potential advantages compared to existing and future therapeutics in the frontline Hodgkin lymphoma indication and frontline PTCL indication, and the extent to which physicians make prescribing decisions with respect to ADCETRIS in these indications. Further, our ability to continue to grow ADCETRIS sales, if at all, will be affected by our ability to continue to expand ADCETRIS' utilization across key labeled indications of use. In addition, Takeda may be unable to obtain regulatory approvals of ADCETRIS in the ECHELON-2 treatment setting in its territories, which also would limit their sales of, and the commercial potential of, ADCETRIS.

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

Financial summary

For the six months ended June 30, 2019 , total revenues increase d to $413.6 million , compared to $310.8 million for the same period in 2018 . This increase was driven primarily by 35% higher ADCETRIS net product sales. Net product sales of ADCETRIS were $294.0 million for the six months ended June 30, 2019 , compared to $217.8 million for the same period in 2018 , which increased primarily driven by ADCETRIS label expansions.

For the six months ended June 30, 2019 , total costs and expenses increase d to $506.0 million , compared to $434.9 million for the same period in 2018 . This primarily reflected higher research and development expenses from continued investment in our late-stage pipeline, as well as higher sales, general and administrative costs related to our late-stage product candidates and ADCETRIS commercialization efforts related to the frontline Hodgkin lymphoma and frontline PTCL indications. For the six months ended June 30, 2018, net loss was favorably impacted by a net gain of $86.6 million from the change in the fair value of our equity securities.

As of June 30, 2019 , we had $376.1 million in cash, cash equivalents and investments and $1.3 billion in total stockholders' equity.

Results of operations

Net product sales

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

	Three months ended June 30,			Six months ended June 30,		
(dollars in thousands)	**2019**	**2018**	**% Change**	**2019**	**2018**	**% Change**
Net product sales	$ 158,980	$ 122,443	30%	$ 293,981	$ 217,800	35%

The increase in net product sales for the three and six months ended June 30, 2019 from the comparable periods in 2018 primarily resulted from higher sales volume during 2019 and, to a lesser extent, from the effect of price increases. Higher sales volume during the 2019 period was driven by label expansions of ADCETRIS; in particular, for the frontline Hodgkin lymphoma indication in March 2018, and for the frontline PTCL indication in November 2018.

We sell ADCETRIS through a limited number of pharmaceutical distributors in the U.S. and Canada. Customers order ADCETRIS through these distributors, and we typically ship product directly to the customer. The delivery of ADCETRIS to the end-user site represents a single performance obligation for these transactions. We record product sales at the point in time when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. The transaction price for product sales represents the amount we expect to receive, which is net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. Accruals are established for these deductions, and actual amounts incurred are offset against applicable accruals. We reflect these accruals as either a reduction in the related account receivable from the distributor or as an accrued liability depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider payor mix in target markets and experience to date. These

estimates involve a substantial degree of judgment. We have applied a portfolio approach as a practical expedient for estimating net product sales from ADCETRIS.

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

(in thousands)	Rebates and chargebacks	Distribution fees, product returns and other	Total
Balance as of December 31, 2018	$ 26,968	$ 5,604	$ 32,572
Provision related to current period sales	119,505	7,111	126,616
Adjustment for prior period sales	215	(188)	27
Payments/credits for current period sales	(90,845)	(3,955)	(94,800)
Payments/credits for prior period sales	(18,519)	(1,520)	(20,039)
Balance as of June 30, 2019	$ 37,324	$ 7,052	$ 44,376

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 six months ended June 30, 2019 as a result of price increases we instituted that exceeded the rate of inflation. Generally, the change in government prices is limited to the rate of inflation. We expect future gross-to-net deductions to fluctuate based on the volume of purchases eligible for government mandated discounts and rebates, as well as changes in the discount percentage which is impacted by potential future price increases, the rate of inflation, and other factors. We expect gross-to-net deductions to increase in 2019 as compared to 2018 , driven by growth in ADCETRIS gross sales.

Collaboration and license agreement revenues

We have collaboration and license agreements with a number of biotechnology and pharmaceutical companies. Our proprietary ADC technology is the basis of many of these collaboration and license agreements, including the ADC collaborations that we have entered into in the ordinary course of our business, under which we grant our collaborators research and commercial licenses to our technology and typically provide technology transfer services, technical advice, supplies and services for a period of time. Our collaboration and license agreements include contractual milestones. Generally, the milestone events coincide with the progression of the collaborators' product candidates. These consist of development milestones (such as designation of a product candidate or initiation of preclinical studies and the initiation of phase 1, phase 2, or phase 3 clinical trials), regulatory milestones (such as the filing of regulatory applications for marketing approval or 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 June 30,			Six months ended June 30,		
(dollars in thousands)	2019	2018	% Change	2019	2018	% Change
Takeda	$ 28,760	$ 8,745	229 %	$ 72,139	$ 22,317	223 %
AbbVie	600	4,700	(87)%	925	12,700	(93)%
Genentech	6,670	583	1,044 %	6,873	1,299	429 %
Genmab	—	7,000	(100)%	—	7,000	(100)%
GSK	—	6,000	(100)%	—	6,000	(100)%
Other	100	151	(34)%	771	7,422	(90)%
Total collaboration and license agreement revenues	$ 36,130	$ 27,179	33 %	$ 80,708	$ 56,738	42 %

Collaboration revenues from Takeda fluctuate based on changes in the recognized portion of reimbursement funding under the ADCETRIS collaboration, which are impacted by the activities each party is performing under the collaboration agreement at a given time. For example, when Takeda's level of spending on clinical collaboration activities increases above our own, our earned portion of reimbursement funding generally decreases. Additionally, we receive reimbursement for the cost of drug product supplied to Takeda for its use, the timing of which fluctuates based on Takeda's product supply needs. Collaboration revenues from Takeda can also fluctuate based on the achievement of milestones by Takeda. The increase in collaboration revenues from Takeda for the three months ended June 30, 2019 compared to the comparable period in 2018 was driven by substantially all of a $7.5 million regulatory milestone achieved in the second quarter 2019, as well as reimbursement for drug product supplied. The increase in collaboration revenues from Takeda for the six months ended June 30, 2019 reflected substantially all of two regulatory milestones achieved totaling $37.5 million , which were related to additional approvals of

ADCETRIS in frontline Hodgkin lymphoma. As of June 30, 2019 , $16.9 million of deferred revenue was related to our collaboration with Takeda, which we will recognize as the remaining performance obligations are satisfied through November 2019.

Collaboration revenues from AbbVie decreased for the three and six months ended June 30, 2019 from the comparable periods in 2018 due to the recognition of development milestones from our ADC collaboration in 2018 .

Collaboration revenues from Genentech increased for the three and six months ended June 30, 2019 from the comparable periods in 2018 due to the recognition of a development milestone in the second quarter of 2019.

Collaboration revenues from Genmab decreased for the three and six months ended June 30, 2019 from the comparable periods in 2018 due to the recognition of a development milestone from our ADC collaboration in 2018.

Collaboration revenues from GSK decreased for the three and six months ended June 30, 2019 from the comparable periods in 2018 due to the recognition of a development milestone from our ADC collaboration in 2018.

Other collaboration revenues during the three months ended June 30, 2019 were consistent with the comparable period in 2018 . Other collaboration revenues decrease d for the six months ended June 30, 2019 from the comparable period in 2018 , primarily due to clinical manufacturing services performed for BMS during the three months ended March 31, 2018, under a transitional services agreement related to our acquisition of a manufacturing facility. These activities concluded as of March 31, 2018.

Our collaboration and license agreement revenues are impacted by the term and duration of those agreements and by progress-dependent milestones, annual maintenance fees, and reimbursement of materials and support services. Collaboration and license agreement revenues may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their product candidates, the level of support we provide to our collaborators, specifically to Takeda under our ADCETRIS collaboration, the timing of milestones achieved and our ability to enter into potential additional collaboration and license agreements. We expect our collaboration and license agreement revenues in 2019 to be higher than 2018 , driven by the timing of milestones.

Collaboration agreements

Takeda

Our ADCETRIS collaboration with Takeda provides for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. We received an upfront payment and have received and are entitled to receive progress- and sales-dependent milestone payments based on Takeda's achievement of significant events under the collaboration, in addition to tiered royalties with percentages ranging from the mid-teens to the mid-twenties based on net sales of ADCETRIS within Takeda's licensed territories. Additionally, we and Takeda equally co-fund the cost of selected development activities conducted under the collaboration. We recognize as collaboration revenue the upfront payment, progress-dependent development and regulatory milestone payments, and net development cost reimbursement payments from Takeda over the ten-year development period of the collaboration, which ends in November 2019. When the performance of development activities under the collaboration results in us making a reimbursement payment to Takeda, the effect is to reduce the amount of collaboration revenue that we record. We also receive reimbursement for the cost of drug product supplied to Takeda for its use and, in some cases, pay Takeda for drug product they supply to us. The earned portion of net collaboration payments is reflected in collaboration and license agreement revenues.

As of June 30, 2019 , total future potential milestone payments to us under the ADCETRIS collaboration could total $117.0 million . Of that amount, up to $7.0 million relates to the achievement of development milestones, up to $70.0 million relates to the achievement of regulatory milestones and up to $40.0 million relates to the achievement of commercial milestones. As of June 30, 2019 , $117.5 million in milestones had been achieved as a result of regulatory and commercial progress by Takeda.

Astellas

We have a collaboration agreement with Agensys, Inc., which subsequently became an affiliate of Astellas, to jointly research, develop and commercialize ADCs for the treatment of several types of cancer. The collaboration encompasses combinations of our ADC technology with fully-human antibodies developed by Astellas to proprietary cancer targets. Under this collaboration, we and Astellas are co-funding all development costs for enfortumab vedotin. Costs associated with co-development activities are included in research and development expense.

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

- In the U.S., we and Astellas will jointly promote enfortumab vedotin. We will record sales of enfortumab vedotin in the U.S. and be responsible for all U.S. distribution activities. The companies will share the costs associated with commercializing enfortumab vedotin in the U.S. and will share equally in any profits realized in the U.S.
- Outside the U.S., we have commercialization rights in all countries in North and South America, and Astellas has commercialization rights 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 profit share for both parties.

Either party may terminate the collaboration agreement if the other party becomes insolvent or the other party materially breaches the agreement and such breach remains uncured. Subject to certain restrictions, either party may terminate the collaboration agreement for any reason upon prior written notice to the other party. The collaboration agreement can also be terminated by mutual written consent of the parties. If neither party exercises its option to terminate the collaboration agreement, then the agreement will automatically terminate on the later of the expiration of all payment obligations pursuant to the collaboration agreement, or the day upon which we and Astellas cease to develop and commercialize products under the agreement. However, the collaboration agreement may not be terminated with respect to enfortumab vedotin for so long as the joint commercialization agreement continues to survive.

Either party may terminate the joint commercialization agreement if the other party becomes insolvent. The joint commercialization agreement expires on a country-by-country basis upon complete cessation of the commercialization, launch and selling of enfortumab vedotin in that country.

Either party may also opt out of co-development and profit-sharing under the collaboration agreement in return for receiving milestones and royalties from the continuing party. In addition, either party may opt out of co-development and profit-sharing for enfortumab vedotin on a country-by-country basis, in return for receiving royalties pursuant to the collaboration agreement from the continuing party with respect to that country.

Genmab

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

Unum

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

We and Unum would co-commercialize any successfully developed product candidates and share any profits equally on any co-developed programs in the U.S. We retain exclusive commercial rights outside of the U.S., paying Unum a royalty that is a high single digit to mid-teens percentage of ex-U.S. sales. The potential future licensing and progress-dependent milestone payments to Unum under the collaboration may total up to $400.0 million between the two ACTR programs, payment of which is triggered by the achievement of development, regulatory and commercial milestones.

ADC Collaboration Agreements

We have other active collaborations with a number of companies to allow them to use our proprietary ADC technology. Under these ADC collaborations, which we have entered into in the ordinary course of business, we typically receive or are entitled to receive upfront cash payments, progress- and sales-dependent milestones and royalties on net sales of products incorporating our ADC technology, as well as annual maintenance fees and support fees for research and development services and materials provided under the agreements. These amounts are recognized as revenue over the performance obligation period or, if there is no performance obligation, upon transfer of control of the goods or services to the customer. Our ADC

collaborators are solely responsible for research, product development, manufacturing and commercialization of any product candidates under these collaborations, which includes achievement of the potential milestones.

As of June 30, 2019 , our ADC collaborations had generated approximately $425 million , primarily in the form of upfront and milestone payments. Remaining milestone payments to us under our current ADC collaborations could total approximately $2.2 billion if all potential product candidates achieved all of their milestone events. Of this amount, approximately $0.3 billion relates to the achievement of development milestones, approximately $0.9 billion relates to the achievement of regulatory milestones and approximately $1.0 billion relates to the achievement of commercial milestones. Since we do not control the research, development or commercialization of any of the products that would generate these milestones, we are not able to reasonably estimate when, if at all, any potential future milestone payments or royalties may be payable by our collaborators. Successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing it is a significantly lengthy and highly uncertain process which entails a significant risk of failure. In addition, business combinations, changes in a collaborator's business strategy and financial difficulties or other factors could result and have resulted in a collaborator abandoning or delaying development of its product candidates. As such, the potential future milestone payments associated with our ADC collaboration agreements involve a substantial degree of risk and may never be received. Accordingly, we do not expect, and investors should not assume, that we will receive all of the potential milestone payments described above, and it is possible that we may never receive any additional significant milestone payments under these agreements in the future.

Royalty revenues and cost of royalty revenues

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

	Three months ended June 30,			Six months ended June 30,		
(dollars in thousands)	**2019**	**2018**	**% Change**	**2019**	**2018**	**% Change**
Royalty revenues	$ 23,337	$ 20,551	14 %	$ 38,957	$ 36,225	8 %
Cost of royalty revenues	$ 2,288	$ 6,148	(63)%	$ 4,677	$ 11,525	(59)%

Royalty revenues increase d for the three and six months ended June 30, 2019 from the comparable periods in 2018 . Takeda net sales of ADCETRIS in its territories increased during the 2019 periods. Royalty revenue for the comparable periods in 2018 included additional royalty revenue attributable to Takeda's portion of certain third-party royalty obligations which expired during 2018. We expect that royalty revenues will increase in 2019 as compared to 2018 , primarily due to anticipated increases in sales volume by Takeda.

Cost of royalty revenues fluctuates based on the amount of net sales of ADCETRIS by Takeda in its territories. Cost of royalty revenues decrease d for the three and six months ended June 30, 2019 from the comparable periods in 2018 due to lower amounts owed to certain third-party licensors.

Cost of sales

ADCETRIS cost of sales includes manufacturing costs of product sold, third-party royalty costs, amortization of technology license costs, and distribution and other costs.

	Three months ended June 30,			Six months ended June 30,		
(dollars in thousands)	**2019**	**2018**	**% Change**	**2019**	**2018**	**% Change**
Cost of sales	$ 8,609	$ 13,157	(35)%	$ 16,520	$ 23,515	(30)%

Cost of sales decrease d for the three and six months ended June 30, 2019 from the comparable periods in 2018 primarily due to a reduction in amounts owed to certain third-party licensors, offset in part by increased ADCETRIS sales volumes. We expect cost of sales to decrease in 2019 as compared to 2018 , primarily due to a reduction in royalties owed under technology license agreements.

Research and development

(dollars in thousands)	Three months ended June 30, 2019	Three months ended June 30, 2018	% Change	Six months ended June 30, 2019	Six months ended June 30, 2018	% Change
Research and clinical development	$ 108,120	$ 83,202	30%	$ 214,322	$ 199,742	7%
Process sciences and manufacturing	55,809	39,658	41%	107,872	75,620	43%
Total research and development	$ 163,929	$ 122,860	33%	$ 322,194	$ 275,362	17%

Research and clinical development expenses includes 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 increase for the three and six months ended June 30, 2019 from the comparable periods in 2018 reflected increases in employee-related costs and development costs primarily to support our late stage pipeline of product candidates. The increase for the six months ended June 30, 2019 from the comparable period in 2018 was offset in part by $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 and six months ended June 30, 2019 from the comparable periods in 2018 primarily reflected increases in staffing and other costs to support our late-stage pipeline of product candidates.

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

(dollars in thousands)	Three months ended June 30, 2019	Three months ended June 30, 2018	Six months ended June 30, 2019	Six months ended June 30, 2018	Five years ended June 30, 2019
ADCETRIS (brentuximab vedotin)	$ 14,798	$ 10,462	$ 21,779	$ 17,993	$ 296,429
Enfortumab vedotin	6,743	5,340	13,194	9,503	68,051
Tucatinib	23,415	9,864	43,828	12,738	84,567
Tisotumab vedotin	7,095	2,871	14,675	10,239	42,950
Ladiratuzumab vedotin	5,121	6,025	10,680	13,280	62,393
Other clinical stage programs	1,307	6,472	6,486	13,719	252,124
Total third-party costs for clinical stage programs	58,479	41,034	110,642	77,472	806,514
Other costs and overhead	105,450	81,826	211,552	197,890	1,334,079
Total research and development	$ 163,929	$ 122,860	$ 322,194	$ 275,362	$ 2,140,593

Third-party costs for ADCETRIS increase d for the three and six months ended June 30, 2019 from the comparable periods in 2018 primarily due to higher costs for drug product supplied to Takeda, offset in part by a reduction in clinical trial activities. The cost of drug product supplied to Takeda is charged to research and development expense. We are reimbursed for the drug product, which is included in collaboration and license agreement revenues.

Third-party costs for enfortumab vedotin increase d for the three and six months ended June 30, 2019 from the comparable periods in 2018 primarily due to increases in clinical trial and manufacturing expenses.

Third-party costs for tucatinib increase d for the three and six months ended June 30, 2019 from the comparable periods in 2018 due to higher clinical trial expenses for the HER2CLIMB trial, and higher manufacturing expenses.

Third-party costs for tisotumab vedotin increased for the three and six months ended June 30, 2019 from the comparable periods in 2018 due to higher clinical trial and manufacturing expenses.

Third-party costs for ladiratuzumab vedotin decrease d for the three and six months ended June 30, 2019 from the comparable periods in 2018 primarily due to lower drug supply expenses.

Other costs and overhead include third-party costs of our preclinical programs and costs associated with personnel and facilities. These costs increase d for the three and six months ended June 30, 2019 from the comparable periods in 2018, due primarily to higher expenses associated with our preclinical programs, offset in part by $35.0 million of upfront in-licensing payments made 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 for ADCETRIS, we are required to conduct additional extensive clinical trials. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

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

We anticipate that our total research and development expenses in 2019 will increase compared to 2018 due primarily to higher costs for the development of our product candidates, primarily enfortumab vedotin, tucatinib, tisotumab vedotin, and ladiratuzumab vedotin. Certain ADCETRIS development activities, including some clinical studies, will be conducted by Takeda, the costs of which are not reflected in our research and development expenses. Because of these and other factors, expenses will fluctuate based upon many factors, including the degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial event.

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

Selling, general and administrative

	Three months ended June 30,			Six months ended June 30,		
(dollars in thousands)	**2019**	**2018**	**% Change**	**2019**	**2018**	**% Change**
Selling, general and administrative	$ 82,331	$ 58,292	41%	$ 162,602	$ 124,474	31%

Selling, general and administrative expenses increase d for the three and six months ended June 30, 2019 from the comparable periods in 2018 primarily due to increases in staffing, external spend related to our late-stage product candidates and ADCETRIS commercialization efforts related to the frontline Hodgkin lymphoma and frontline PTCL indications, as well as higher infrastructure costs to support our continued growth.

We anticipate that selling, general and administrative expenses will increase in 2019 compared to 2018 as we continue our commercial activities in support of the commercialization of ADCETRIS, pre-commercialization activities for our late-stage pipeline, and support of general operations.

Investment and other income (loss), net

	Three months ended June 30,			Six months ended June 30,		
(dollars in thousands)	**2019**	**2018**	**% Change**	**2019**	**2018**	**% Change**
Gain (loss) on equity securities	$ (42,693)	$ 105,472	(140)%	$ (4,568)	$ 86,647	(105)%
Investment income, net	2,165	1,085	100 %	4,348	2,024	115 %
Total investment and other income (loss), net	$ (40,528)	$ 106,557	(138)%	$ (220)	$ 88,671	(100)%

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.

Investment and other income (loss), net for the three and six months ended June 30, 2019 primarily reflected net losses from changes in the fair value of our equity securities. Investment and other income (loss), net for the comparable periods in 2018 was driven by net gains from changes in the fair value of our equity securities. As of June 30, 2019 , our shares held of Immunomedics common stock had a fair value of $107.1 million , which are included in other non-current assets.

Liquidity and capital resources

(dollars in thousands)	June 30, 2019	December 31, 2018
Cash, cash equivalents, and investments	$ 376,129	$ 459,866
Working capital	449,989	428,523
Stockholders' equity	1,271,826	1,273,943

	Six months ended June 30,	
(dollars in thousands)	2019	2018
Cash provided (used) by:		
Operating activities	$ (91,240)	$ (168,135)
Investing activities	39,114	(514,815)
Financing activities	38,052	681,292

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

The change in net cash from investing activities reflected differences between the proceeds received from sale and maturity of our investments and amounts reinvested, as well as payments for business combinations. Cash used for investing activities during the six months ended June 30, 2018 included $614.1 million cash paid (or $598.2 million net of the cash acquired) for the acquisition of Cascadian in 2018.

The change in net cash from financing activities included proceeds from stock option exercises and our employee stock purchase plan for all periods presented. Cash provided by financing activities during the six months ended June 30, 2018 included $658.2 million in net proceeds from our public offering in 2018.

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

Our cash, cash equivalents, and investments are held in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate securities, taxable municipal bonds, commercial paper and money market accounts. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs. However, if our liquidity needs should be accelerated for any reason in the near term, or investments do not pay at maturity, we may be required to sell investment securities in our portfolio prior to their scheduled maturities, which may result in a loss. As of June 30, 2019 , we had $376.1 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 launch and commercialize additional products. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to our plans to build a commercial infrastructure in Europe and to otherwise continue to expand our operations internationally. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS, the research, continued development and manufacturing of our product candidates, our pursuit of regulatory approvals for and preparing to potentially launch and commercialize our product candidates, and the anticipated expansion of our pipeline and operations will likely require us to raise substantial amounts of additional capital. Further, we actively evaluate

various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses, and we may require significant additional capital in order to complete or otherwise provide funding for such transactions. Moreover, in the event of a termination of the ADCETRIS collaboration agreement with Takeda, we would not receive development cost sharing payments or milestone payments or royalties for the development or sale of ADCETRIS in Takeda's territory, and we would be required to fund all ADCETRIS development and commercial activities, which could lead to a need for us to raise additional capital. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. We may seek additional capital through some or all of the following methods: corporate collaborations, licensing arrangements, and public or private debt or equity financings. We do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional capital when we need it, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs, which may adversely affect our business and operations.

Commitments

Our future minimum contractual commitments were reported in our Annual Report on Form 10-K for the year ended December 31, 2018 , and updated in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019.

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 six months ended June 30, 2019 were consistent with those in Part II Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2018 .

Recent accounting pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

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

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

(b) *Changes in internal control over financial reporting.* There have not been any changes in our internal control over financial reporting during the quarter ended June 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

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

Risks Related to Our Business

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

ADCETRIS ®, or brentuximab vedotin, is our only product approved for marketing and our ability to generate revenue from product sales and our prospects for profitability are substantially dependent on our ability to effectively commercialize ADCETRIS for the treatment of patients in its approved indications and our ability to continue to expand its labeled indications of use. We may not be able to fully realize the commercial potential of ADCETRIS for a number of reasons, including:

- we may be unable to effectively commercialize ADCETRIS in any new indications for which we receive marketing approval, including in the newly diagnosed, previously untreated Stage III and IV classical Hodgkin lymphoma indication, for which the Food and Drug Administration, or FDA, approved ADCETRIS in combination with chemotherapy in March 2018 based on the results of the phase 3 ECHELON-1 clinical trial, or the frontline Hodgkin lymphoma indication, and the newly diagnosed, previously untreated systemic anaplastic large-cell lymphoma, or sALCL or other CD30-expressing peripheral T-cell lymphomas, or PTCL, including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified indication, for which the FDA approved ADCETRIS in combination with chemotherapy in November 2018 based on the results of the phase 3 ECHELON-2 clinical trial, or the frontline PTCL indication;
- we and/or Takeda Pharmaceutical Company Limited, or Takeda, our collaborator in the development and commercialization of ADCETRIS, may not be able to obtain and maintain regulatory approvals to market ADCETRIS in its currently approved indications or for any additional indications in our respective territories, including in the ECHELON-2 treatment setting outside the U.S., which would limit sales of, and the commercial potential of, ADCETRIS;
- we may not be able to establish or demonstrate in the medical community the safety, efficacy, or value of ADCETRIS and its potential advantages compared to existing and future therapeutics in the frontline Hodgkin lymphoma and frontline PTCL indications as well as other approved indications;
- new competitive therapies, including immuno-oncology agents such as programmed death-1, or PD-1, inhibitors (e.g., nivolumab and pembrolizumab) and other novel agents (e.g., mogamulizumab), 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, Takeda and/or Bristol-Myers Squibb Company, or BMS, are conducting or may in the future conduct for ADCETRIS, including investigator-sponsored studies and in the post-approval confirmatory studies that Takeda is required to conduct as a condition to the conditional marketing authorization of ADCETRIS granted by the European Commission, or the EC;
- the estimated incidence rate of new patients in ADCETRIS' approved indications may be lower than our projections;

- there may be adverse results or events reported in any of the clinical trials that we, Takeda and/or BMS are conducting or may in the future conduct for ADCETRIS;
- we may be unable to continue to effectively market, sell and distribute ADCETRIS;
- ADCETRIS may be impacted by adverse reimbursement and coverage policies from government and private 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 longer term efficacy and safety data exist;
- there may be changed or increased regulatory restrictions;
- we may not have adequate financial or other resources to effectively commercialize ADCETRIS; and
- we may not be able to obtain adequate commercial supplies of ADCETRIS to meet demand or at an acceptable cost.

In 2009, we entered into an agreement with Takeda to develop and commercialize ADCETRIS, under which we have commercial rights in the United States and its territories and Canada, and Takeda has commercial rights in the rest of the world. The success of this collaboration and the activities of Takeda will significantly impact the commercialization of ADCETRIS in countries other than the United States and in Canada. In October 2012, Takeda announced that it had received conditional marketing authorization for ADCETRIS from the EC for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL, and has since obtained marketing approvals for ADCETRIS in many other countries. Conditional marketing authorization by the EC includes obligations to provide additional clinical data at a later stage to confirm the positive benefit-risk balance. We cannot control the amount and timing of resources that Takeda dedicates to the commercialization of ADCETRIS, or to its marketing and distribution, and our ability to generate revenues from ADCETRIS product sales by Takeda depends on Takeda's ability to achieve market acceptance of, and to otherwise effectively market, ADCETRIS for its approved indications in Takeda's territory. Further, foreign sales of ADCETRIS could be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions or barriers and changes in tariffs, including as a result of the United Kingdom's planned separation from the European Union, commonly referred to as Brexit, escalating global trade and political tensions, or otherwise.

While ADCETRIS product sales have grown over time, and our future plans assume that sales of ADCETRIS will increase, we cannot assure you that, even with the recent expansions to the prescribing label for ADCETRIS in the United States, which now includes the frontline Hodgkin lymphoma and frontline PTCL indications, ADCETRIS sales will continue to grow or that we can maintain sales of ADCETRIS at or near current levels. We also expect that our ability to continue to grow ADCETRIS sales, if at all, will depend primarily on our ability to establish or demonstrate to the medical community the value of ADCETRIS and its potential advantages compared to existing and future therapeutics in the frontline Hodgkin lymphoma and frontline PTCL indications, and the extent to which physicians make prescribing decisions with respect to ADCETRIS in these indications. Further, our ability to continue to grow ADCETRIS sales, if at all, will be affected by our ability to continue to expand ADCETRIS' utilization across key labeled indications of use. In addition, Takeda may be unable to obtain regulatory approvals 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 may require separate or coordinated regulatory approval prior to or in association with commercialization of the related therapeutic product. While the FDA did not require the concurrent approval of a CD30 companion diagnostic for approval of ADCETRIS in the frontline PTCL indication or in any other of its approved indications, the FDA's approval of ADCETRIS in the frontline PTCL indication included a post-marketing commitment to develop a clinically validated in-vitro diagnostic device for the selection of patients with CD30-expressing PTCL, not including sALCL, for treatment with ADCETRIS in this indication. If Ventana develops an in-vitro diagnostic device that we are able to clinically validate, the FDA may revise our label for the frontline PTCL indication to require the use of the in-vitro test as a companion diagnostic or to include additional clinical data regarding the use of the in-vitro test as a complementary diagnostic. If the FDA or another regulatory authority requires a companion diagnostic in the ADCETRIS label for the frontline PTCL indication or in connection with or as a condition of future regulatory approvals, such a requirement may limit our ability to commercialize ADCETRIS in the applicable treatment setting due to potential label requirements, prescriber practices, constraints on availability of the diagnostic, or other factors.

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

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

In furtherance of our growth strategy, we have made significant investments in a number of product candidates, including our later-stage product candidates enfortumab vedotin, tucatinib and tisotumab vedotin. Based on the positive results from the first cohort in a pivotal phase 2 trial of enfortumab vedotin that we and Astellas Pharma Inc., or Astellas, are conducting, or the EV-201 trial, in patients who previously received both platinum chemotherapy and a PD-1 or programmed death-ligand 1, or PD-L1, inhibitor, we and Astellas submitted a Biologics License Application, or BLA, to the FDA in July 2019 under the FDA's accelerated approval pathway. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured, and we have only limited experience in preparing and submitting the applications necessary to gain regulatory approvals. Further, the FDA and foreign regulatory agencies have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for enfortumab vedotin or any of our other product candidates. In addition, although enfortumab vedotin was granted Breakthrough Therapy designation by the FDA for patients with locally advanced or metastatic urothelial cancer who were previously treated with a checkpoint inhibitor, Breakthrough Therapy designation does not guarantee that we will be able to take advantage of the expedited review procedures and does not increase the likelihood that the BLA we and Astellas submitted to the FDA in July 2019 for enfortumab vedotin will be approved or that enfortumab vedotin will otherwise receive any marketing approvals. In any event, we cannot predict whether the BLA we and Astellas submitted to the FDA in July 2019 for enfortumab vedotin will be accepted or approved in a timely manner, if at all, and we cannot otherwise assure you that enfortumab vedotin or any of our other product candidates will receive any marketing approvals. In fact, it is possible that none of our product candidates will ever become commercial products. Even if approved for commercial sale, our ability to realize the anticipated benefits from our product candidates is subject to a number of risks and uncertainties, including our and our collaborators' ability to successfully launch, market and commercialize any approved products, our reliance, in the case of enfortumab vedotin and tisotumab vedotin, on Astellas and Genmab A/S, or Genmab, respectively, to effectively jointly commercialize any future approved products with us, the acceptance of any future approved products by the medical community and patients, and the extent to which coverage and reimbursement for any future approved products will be available from government and health administration authorities, private health insurers and other third-party payors.

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

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

Reports of adverse events or safety concerns involving ADCETRIS could interrupt, delay or halt clinical trials of ADCETRIS, including the post-approval confirmatory studies that Takeda is required to conduct as a condition of the marketing authorization of ADCETRIS by the EC. In addition, reports of adverse events or safety concerns involving ADCETRIS could result in regulatory authorities limiting, denying or withdrawing approval of ADCETRIS for any or all indications, including the use of ADCETRIS for the treatment of patients in its approved indications. For example, there was an increased incidence of febrile neutropenia and peripheral neuropathy in the ADCETRIS plus doxorubicin (Adriamycin ®), vinblastine and dacarbazine, or AVD, arm of the ECHELON-1 trial. The ADCETRIS label provides for use of prophylactic growth factors for Stage III or IV classical Hodgkin lymphoma patients receiving ADCETRIS plus AVD to mitigate events of neutropenia and febrile neutropenia, but despite this, these product safety concerns could limit prescribing of ADCETRIS for newly diagnosed patients with previously untreated Stage III and IV classical Hodgkin lymphoma and negatively impact sales of ADCETRIS or adversely affect ADCETRIS' acceptance in the market. There are no assurances that patients receiving ADCETRIS will not experience serious adverse events in the future. Further, there are no assurances that patients receiving ADCETRIS with co-morbid diseases not previously studied, such as autoimmune diseases, will not experience new or different serious adverse events in the future.

Adverse events may negatively impact the sales of ADCETRIS. We may be required to further update the ADCETRIS prescribing information, including boxed warnings, based on reports of adverse events or safety concerns or implement a Risk Evaluation and Mitigation Strategy, or REMS, which could adversely affect ADCETRIS' acceptance in the market, make competition easier or make it more difficult or expensive for us to distribute ADCETRIS. For example, the prescribing information for ADCETRIS also includes pancreatitis, impaired hepatic function, impaired renal function, pulmonary toxicity, and gastrointestinal complications as known adverse events as well as a boxed warning related to the risk that JC virus infection resulting in progressive multifocal leukoencephalopathy and death can occur in patients receiving ADCETRIS. Further, based on the identification of future adverse events, we may be required to further revise the prescribing information, including ADCETRIS' boxed warning, which could negatively impact sales of ADCETRIS or adversely affect ADCETRIS' acceptance in the market.

Likewise, reports of adverse events or safety concerns involving ADCETRIS or our product candidates could interrupt, delay or halt clinical trials of ADCETRIS or such product candidates, or could result in our or our collaborators' inability to obtain regulatory approvals for ADCETRIS in any additional indications or for any of our product candidates.

We initiated the pivotal trials of enfortumab vedotin, tucatinib and tisotumab vedotin, in each case based on only limited phase 1 clinical data. Although data continues to be generated in these pivotal and other trials, and we and Astellas recently announced positive results from the first cohort in the EV-201 trial, there may still be important facts about the safety, efficacy, and risk versus benefit of these product candidates that are not known to us at this time which may negatively impact our ability to develop and commercialize these product candidates. In addition, in response to safety events observed in our clinical trials of enfortumab vedotin and tisotumab vedotin, including patient deaths, we have in the past, and may in the future, institute additional precautionary safety measures such as dosing caps and delays, enhanced monitoring for side effects, and modified patient inclusion and exclusion criteria. Additional and/or unexpected safety events could be observed in these pivotal or other later-stage trials that could delay or prevent us from advancing the clinical development of, or obtaining regulatory approvals for, enfortumab vedotin, tucatinib or tisotumab vedotin and may adversely affect our business, results of operations and prospects.

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

Even if we and our collaborators obtain regulatory approvals to market our current and potential future products, we and our collaborators will remain subject to extensive ongoing regulatory obligations and oversight, including post-approval requirements, that could result in significant additional expense and could negatively impact our and our collaborators' ability to commercialize our current and potential future products.

ADCETRIS is approved for treating patients in the relapsed sALCL and relapsed Hodgkin lymphoma indications with conditions in Canada, and approved under conditional marketing authorization in relapsed Hodgkin lymphoma and sALCL in the European Union, in each case under regulations which allow for approval of products for cancer or other serious or life threatening illnesses based on a surrogate endpoint or on a clinical endpoint other than survival or irreversible morbidity. For the European Union indications, Takeda is subject to certain post-approval requirements, including the requirement to conduct clinical trials to confirm clinical benefit. In Canada, the ECHELON-1 results may be sufficient to confirm the clinical benefit of ADCETRIS in relapsed Hodgkin lymphoma, and the ECHELON-2 results may be sufficient to confirm the clinical benefit of ADCETRIS in relapsed sALCL. In the European Union, there are other post approval requirements to convert the conditional marketing authorization for ADCETRIS in relapsed Hodgkin lymphoma and relapsed sALCL into a standard marketing authorization. Takeda's failure to provide these additional clinical data from confirmatory studies could result in the EC withdrawing approval of ADCETRIS in the European Union for certain indications, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda in the European Union and could adversely affect our results of operations.

In addition, we are subject to extensive ongoing obligations and continued regulatory review from applicable regulatory agencies with respect to any product for which we have obtained regulatory approval, including ADCETRIS in each of its approved indications, such as continued adverse event reporting requirements and the requirement to have some of our promotional materials pre-cleared by the FDA. There may also be additional post-marketing obligations, all of which may result in significant expense and limit our and our collaborators' ability to commercialize ADCETRIS and any future-approved product. For example, we and Astellas are conducting the EV-201 trial. Based on the positive results from the first cohort of

patients enrolled in the EV-201 trial who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor, we and Astellas submitted a BLA to the FDA in July 2019 for enfortumab vedotin under the FDA's accelerated approval pathway. As a condition of any potential approval under the FDA's accelerated approval pathway, the FDA may require that we and/or Astellas perform confirmatory post-marketing studies to verify and describe the clinical benefit of enfortumab vedotin. Moreover, in connection with any such accelerated approval, the labeling and advertising and promotion of enfortumab vedotin would be subject to additional regulatory requirements, which could entail significant expense and could negatively impact the potential future launch and commercialization of enfortumab vedotin. In addition, even if the BLA we and Astellas submitted to the FDA in July 2019 for enfortumab vedotin is approved, enfortumab vedotin may later produce adverse events that limit or prevent its widespread use or that force us or Astellas to withdraw enfortumab vedotin from the market, and any problems with enfortumab vedotin or any violation of ongoing regulatory obligations could result in restrictions on the approved product, including its withdrawal from the market.

We and the manufacturers of ADCETRIS and any future approved product are also required, or will be required, to comply with current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture ADCETRIS and our product candidates, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject an approved product, its manufacturer and the manufacturer’s facilities to continual review and inspections, including periodic unannounced inspections. The subsequent discovery of previously unknown problems with ADCETRIS or any future approved product, including adverse events of unanticipated severity or frequency, or problems with the facilities where ADCETRIS or any future approved product is manufactured, may result in restrictions on the marketing of ADCETRIS or any such future approved product, up to and including withdrawal of the affected product from the market. If our manufacturing facilities, our collaborators' manufacturing facilities, or those of our respective suppliers, fail to comply with applicable regulatory requirements, such noncompliance could result in regulatory action and additional costs to us.

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

- issuance of Form FDA 483 notices or Warning Letters by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us;
- refusals to permit drugs to be imported into or exported from the United States;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

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

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

We are currently conducting multiple clinical trials for ADCETRIS and our product candidates and we plan to commence additional trials of ADCETRIS and our product candidates in the future. In this regard, we and Astellas are conducting the EV-201 trial and a phase 3 clinical trial of enfortumab vedotin, called the EV-301 trial, in metastatic urothelial cancer patients who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor. Additionally, we are conducting a pivotal phase 2 trial of tucatinib for patients with HER2-positive metastatic breast cancer who have been previously treated with HER2-targeted agents, including patients with or without brain metastases, which we refer to as the HER2CLIMB trial, and a pivotal phase 2 trial of tisotumab vedotin with Genmab in patients with recurrent and/or metastatic

cervical cancer, which we refer to as the innovaTV 204 trial. Each of these trials was initiated based on only limited phase 1 clinical data. In particular, enfortumab vedotin, tucatinib and tisotumab vedotin have not previously been evaluated in later-stage clinical trials and we cannot be certain that the design of, or data collected from, these trials will be sufficient to support FDA or any foreign regulatory approvals. In this regard, while we and Astellas reported positive results from the first cohort in the EV-201 trial and we and Astellas submitted a BLA to the FDA in July 2019 for enfortumab vedotin under the FDA's accelerated approval pathway based on the results from the first cohort, the FDA may disagree with our interpretation of the data from the first cohort in the EV-201 trial and/or may otherwise determine not to accept or approve the BLA we and Astellas submitted in July 2019 in a timely manner or at all. Furthermore, we do not have Special Protocol Assessment agreements with the FDA for any of these trials.

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

Additionally, patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials, perceived side effects and the availability of alternative or new treatments. Many of our future and ongoing clinical trials are being or will be coordinated or conducted with Takeda, BMS, Astellas, Genmab and other collaborators, which may delay the commencement or adversely affect the continuation or completion of these trials. From time to time, we have experienced enrollment-related delays in clinical trials and we will likely continue to experience similar delays in our current and future trials. We depend on medical institutions and clinical research organizations, or CROs, to conduct some of our clinical trials in compliance with Good Clinical Practice, or GCP, and to the extent they fail to enroll patients for our clinical trials, fail to conduct our trials in accordance with GCP, or are delayed for a significant time in achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, different standards of medical care, and foreign currency transactions insofar as changes in the relative value of the U.S. dollar to the foreign currency where the trial is being conducted may impact our actual costs.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, foreign governmental agencies, including data protection authorities, the data safety monitoring boards for such trials and the IRBs or Ethics Committees for the institutions in which such trials are being conducted. In addition, clinical trials must be conducted with supplies of ADCETRIS or our product candidates produced under cGMP and other requirements in foreign countries, and may require large numbers of test patients. We or our collaborators, the FDA, foreign governmental agencies or the applicable data safety monitoring boards, IRBs and Ethics Committees could delay, suspend, halt or modify our clinical trials of ADCETRIS or any of our product candidates, for numerous reasons, including:

- ADCETRIS or the applicable product candidate may have unforeseen safety issues or adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements, GCP, clinical protocols or regulations relating to data protection;
- problems, errors or other deficiencies with respect to data collection, data processing and analysis;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- the time required to determine whether ADCETRIS or the applicable product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- ADCETRIS or the applicable product candidate may not appear to be more effective than current therapies;
- the quality or stability of ADCETRIS or the applicable product candidate may fall below acceptable standards;
- our inability and the inability of our collaborators to produce or obtain sufficient quantities of ADCETRIS or the applicable product candidate to complete the trials;

- our inability and the inability of our collaborators to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability and the inability of our collaborators to obtain IRB or Ethics Committee approval to conduct a clinical trial at a prospective site;
- changes in governmental regulations or administrative actions that adversely affect our ability and the ability of our collaborators to continue to conduct or to complete clinical trials;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- our inability and the inability of our collaborators to recruit and enroll patients to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications;
- our inability and the inability of our collaborators to retain patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up; or
- our inability and the inability of our collaborators to ensure adequate statistical power to detect statistically significant treatment effects, whether through our inability to enroll or retain patients in trials or because the specified number of events designated for a completed trial have not occurred.

In addition, we or our collaborators may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, including unexpected adverse events that may occur when our product candidates are combined with other therapies.

Negative or inconclusive clinical trial results could adversely affect our ability and the ability of our collaborators to obtain regulatory approvals of our product candidates or to market ADCETRIS and/or expand ADCETRIS into additional indications. In particular, negative or inconclusive results in our HER2CLIMB trial would negatively impact or preclude altogether our ability to obtain any regulatory approvals of tucatinib, which could result in our failure to realize the anticipated benefits of our acquisition of Cascadian Therapeutics, Inc., or Cascadian, referred to as the Cascadian Acquisition, and negatively impact our plans to build a commercial infrastructure in Europe. In addition, clinical trial results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. For example, although we and Astellas reported positive results from the first cohort in the EV-201 trial, regulatory agencies, including the FDA, or its advisors, may disagree with our interpretations of the data from the first cohort in the EV-201 trial and may not accept or approve the BLA that we and Astellas submitted to the FDA in July 2019 for enfortumab vedotin. Moreover, although we reported positive results in our ECHELON-2 trial, regulatory agencies outside of the U.S., or their advisors, may disagree with Takeda's interpretations of data from the ECHELON-2 trial and may not approve the expansion of the ADCETRIS labeled indications of use to the ECHELON-2 treatment setting. Adverse medical events during a clinical trial, including patient fatalities, could cause a trial to be redone or terminated, require us to cease development of a product candidate or the further development or commercialization of ADCETRIS, result in our failure to expand ADCETRIS into additional indications, adversely affect our ability to market ADCETRIS, and may result in other negative consequences to us, including the inclusion of unfavorable information in our product labeling. Further, some of our clinical trials are overseen by an independent data monitoring committee, or IDMC, and an IDMC may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial. In addition, we may be required to implement additional risk mitigation measures that could require us to suspend our clinical trials if certain safety events occur.

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

Our late-stage product candidates are enfortumab vedotin, tucatinib, and tisotumab vedotin, each of which was advanced to 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 SEA-BCMA, which is in phase 1 clinical development. As a result of recent portfolio prioritization decisions, we are no longer developing SGN-2FF and SGN-CD48A. In addition, we have multiple preclinical and research-stage programs that employ our proprietary technologies. We will require significant financial resources and additional personnel in order to continue to advance the development of, to pursue, obtain and maintain regulatory approvals for, and to potentially commercialize, enfortumab vedotin, tucatinib and tisotumab vedotin, if we are able to do so at all. Our other product candidates are in early or relatively early stages of development.

If a product candidate fails at any stage of development or fails to receive regulatory approval, 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. For example, with respect to enfortumab vedotin, we have incurred significant expenditures related to its development and potential launch, but there can be no assurances that the FDA will approve the BLA we and Astellas submitted to the FDA in July 2019 for enfortumab vedotin or that enfortumab vedotin will otherwise receive any regulatory approvals, and we may therefore fail to receive any return on our investment in enfortumab vedotin. Likewise, if we are unable to successfully complete the development of, obtain regulatory approvals for and commercialize tucatinib, we will not realize the anticipated benefits of the Cascadian Acquisition. Moreover, with the exception of data from the first cohort of EV-201, we have reported only limited data from early trials of our product candidates. Preclinical studies and any encouraging or positive 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 initiated 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, tucatinib and tisotumab vedotin may fail to demonstrate sufficient efficacy in our pivotal trials despite the results observed in earlier-stage trials, and despite the positive results we and Astellas reported for the first cohort in the EV-201 trial, we cannot be certain that enfortumab vedotin will demonstrate sufficient efficacy in other trials, including in the EV-301 and EV-103 trials, or will ever be approved for commercial sale. In addition, there may still be important facts about the safety, efficacy, and risk versus benefit of these product candidates that are not known to us at this time which may negatively impact our ability to develop and commercialize these product candidates. In particular, in response to safety events observed in our clinical trials of enfortumab vedotin and tisotumab vedotin, including patient deaths, we have in the past, and may in the future, institute additional precautionary safety measures such as dosing caps and delays, enhanced monitoring for side effects, and modified patient inclusion and exclusion criteria. Additional and/or unexpected safety events or our failure to generate additional efficacy data in our clinical trials that support registration could significantly impact the value of enfortumab vedotin, tucatinib and tisotumab vedotin to our business. Many companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in late-stage clinical trials after achieving encouraging or positive results in early-stage development. We cannot be certain that we will not face similar setbacks in our ongoing or planned clinical trials, including in the ongoing pivotal trials for enfortumab vedotin, tucatinib and tisotumab vedotin. We have not yet completed any late-stage clinical trials for our product candidates, and if we or our collaborators fail to produce positive results in our ongoing or planned clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business, financial condition, results of operations and growth prospects, would be materially adversely affected.

Due to the uncertain and time-consuming clinical development and regulatory approval process, we may not successfully develop any of our product candidates, or we may choose to discontinue the development of product candidates for a variety of reasons such as due to safety, risk versus benefit profile, exclusivity, competitive landscape, or prioritization of our resources. It is possible that none of our product candidates will ever become commercial products. In addition, we have to make decisions about which clinical stage and pre-clinical product candidates to develop and advance, and we may not have the resources to invest in certain product candidates, or clinical data and other development considerations may not support the advancement of one or more product candidates. Decision-making about which product candidates to prioritize involves inherent uncertainty, and our development program decision-making and resource prioritization decisions may not improve our results of operations or prospects or enhance the value of our common stock. Our failure to effectively advance our development programs could have a material adverse effect on our business and prospects, and cause the price of our common stock to decline.

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

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaborators are permitted to market our product candidates in the United States or foreign countries until we obtain marketing approval from the FDA or foreign regulatory authorities, and we or our collaborators may never receive regulatory approval for the commercial sale of any of our product candidates. In addition, part of our strategy is to continue to explore the use of ADCETRIS in CD30-expressing lymphomas, and we are currently conducting multiple clinical trials for ADCETRIS. However, we and/or Takeda may be unable to obtain or maintain any regulatory approvals for the commercial sale of ADCETRIS for any additional indications. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured, and we have only limited experience in preparing and submitting the applications necessary to gain regulatory approvals. Further, the FDA and foreign regulatory agencies have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate we develop, including any regulatory approvals for the potential commercial sale of ADCETRIS in additional indications or in any additional territories. In this regard, even if we believe the data collected from clinical trials of ADCETRIS and our product candidates are promising, such data may not be sufficient to support approval by the FDA or any foreign regulatory authority. In addition, the FDA or any foreign regulatory authority or their respective advisors may disagree with our interpretations of data from preclinical studies and clinical trials. For example, based on the positive results we and Astellas reported from the first cohort in the EV-201 trial, we and Astellas submitted a BLA to the FDA in July 2019 for enfortumab vedotin under the FDA's accelerated approval pathway. However, the FDA may disagree with our interpretation of the data from the first cohort in the EV-201 trial and/or may otherwise determine not to accept or approve the BLA we and Astellas submitted in July 2019 in a timely manner or at all. Regulatory agencies also may approve a product candidate for fewer or narrower indications than requested, or with a label that includes only subtypes of a particular indication rather than a more general disease classification. For example, the label approved by the FDA based on our phase 3 ALCANZA trial covered only primary cutaneous anaplastic large cell lymphoma, or pcALCL, and CD30-expressing mycosis fungoides, or MF, which are two subtypes of cutaneous T-cell lymphoma, or CTCL. Additionally, the FDA or foreign regulatory authorities may grant approval subject to the performance of post-approval studies or REMS for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of ADCETRIS in any additional indications or of any future approved product.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs, for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In addition, as part of the U.S. Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all regulatory submissions in a given time frame. However, the FDA does not always meet its PDUFA targeted action dates and if the FDA were to fail to meet a PDUFA targeted action date in the future for ADCETRIS, enfortumab vedotin or any of our other product candidates, the commercialization of the affected product candidate or of ADCETRIS in any additional indications could be delayed or impaired. Due to these and other factors, ADCETRIS and our product candidates could take a significantly longer time to gain regulatory approvals than we expect or may never gain new regulatory approvals, which could delay or eliminate any potential product revenue from sales of our product candidates or of ADCETRIS in any additional indications, which could significantly delay or prevent us from achieving profitability.

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

Successful sales of ADCETRIS and any future approved products will depend, in part, on the extent to which coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new products and require increasing levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. In light of this pricing scrutiny, we cannot be sure that we will achieve and continue to have coverage available for ADCETRIS and any other product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. If we are unable to obtain coverage and adequate levels of reimbursement for ADCETRIS and any future approved products that we commercialize, their marketability will be negatively and materially impacted. For example, we cannot be certain that third-party payors will provide coverage and adequate reimbursement for ADCETRIS in the frontline Hodgkin lymphoma indication based on the relative price and perceived benefit of ADCETRIS as compared to alternative treatment options, which may materially harm our ability to maintain or increase sales of ADCETRIS or may otherwise negatively affect future ADCETRIS sales. Similarly, even if we and Astellas are able to obtain approval of the BLA that we submitted to the FDA in July 2019 for enfortumab vedotin, we cannot be certain that third party payors will

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

Eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. In addition, obtaining and maintaining adequate coverage and reimbursement status is time-consuming and costly. Third-party payors may deny coverage and reimbursement status altogether of a given drug product, or cover the product but may also establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development. Further, in the United States, there is no uniform policy of coverage and reimbursement among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided is made on a payor-by-payor basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Because the rules and regulations regarding coverage and reimbursement change frequently, in some cases at short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact the favorable status.

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

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

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

In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA, became law in the United States. PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. The provisions of PPACA of greatest importance to the pharmaceutical industry include increased Medicaid rebates, expanded Medicaid eligibility, extension of Public Health Service eligibility, annual fees payable by manufacturers and importers of branded prescription drugs, annual reporting of financial relationships with physicians and teaching hospitals, and a new Patient-Centered Outcomes Research Institute. Many of these provisions have had the effect of reducing the revenue generated by our sales of ADCETRIS and will have the effect of reducing any revenue generated by sales of any future commercial products we may have.

Certain provisions of the PPACA have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. For example, since January 20, 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provision of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or

part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed. While the Texas U.S. District Court Judge, as well as the Trump administration and the Centers for Medicare & Medicaid Services, or CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and our business. In addition, citing legal guidance from the U.S. Department of Justice, the U.S. Department of Health and Human Services, has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the PPACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until such appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. While Congress is considering legislation to appropriate funds for CSR payments, the future of that legislation is uncertain. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business.

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

We anticipate that the PPACA, as well as other healthcare reform measures that have been adopted, or 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 ADCETRIS or any future approved products. 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. The recommendations in the Blueprint, if enacted by Congress and the Department of Health and Human Services, or HHS, could lead to changes to Medicare Parts B and D, including the transition of certain drugs covered under Part B to Part D or the offering of alternative purchasing options under the Competitive Acquisition Program that currently applies to selected drugs and biologics covered under Part B. While many of the proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative, administrative and/or additional measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing, cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect further federal and state legislation and healthcare reforms to continue to be proposed to control increasing healthcare costs and to control the rising cost of prescription drugs. These proposals, if implemented, could limit the price for ADCETRIS or any future approved products. Commercial opportunity could be negatively impacted by legislative action that controls pricing, mandates price negotiations, or increases government discounts and rebates.

Also, price increases on ADCETRIS and negative publicity regarding drug pricing and price increases generally, whether on ADCETRIS or products distributed by other pharmaceutical companies, could negatively affect market acceptance of, and sales of, ADCETRIS. In addition, although ADCETRIS is approved in the European Union, Japan and other countries

outside of the United States, government austerity measures or further healthcare reform measures and pricing pressures in other countries could adversely affect demand and pricing for ADCETRIS, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda.

Other legislative changes have also been proposed and adopted since PPACA was enacted. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes a 2% reduction in Medicare provider payments paid under Medicare Part B to physicians for physician-administered drugs, such as certain oncology drugs, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, legislation has been proposed to shorten the period of biologic data and market exclusivity granted by the FDA. If such legislation is enacted, we may face competition from biosimilars of ADCETRIS or any future approved products earlier than otherwise would have occurred. Increased competition may negatively impact coverage and pricing of ADCETRIS, which could negatively affect our financial condition or results of operations.

We also expect to experience pricing pressures in connection with the sale of ADCETRIS due to certain managed healthcare initiatives. For example, the PPACA increased the mandated Medicaid rebate from 15.1% to 23.1% of Average Manufacturer Price, expanded the rebate to Medicaid managed care utilization and increased the types of entities eligible for the federal 340B drug discount program. As concerns continue to grow over the need for tighter oversight, there remains the possibility that the Heath Resources and Services Administration or another agency under the HHS will propose a similar regulation or that Congress will explore changes to the 340B program through legislation. For example, a bill was recently introduced in 2018 that would require hospitals to report their low-income utilization of the program. Further, the Centers for Medicare & Medicaid Services issued a final rule that would revise the Medicare hospital outpatient prospective payment system for calendar year 2019, including a new reimbursement methodology for drugs purchased under the 340B program for Medicare patients at the hospital setting and recently announced the same change for physician-based practices under 340B in 2019. In addition, HHS has set January 1, 2019, as the effective date of the final rule setting forth the calculation of the ceiling price and application of civil monetary penalties. Pursuant to the final rule, after January 1, 2019, manufacturers must calculate 340B program ceiling prices on a quarterly basis. Moreover, manufacturers could be subject to a $5,000 penalty for each instance where they knowingly and intentionally overcharge a covered entity under the 340B program. A significant portion of ADCETRIS purchases are eligible for 340B drug pricing, and therefore an expansion of the 340B program or reduction in 340B pricing, whether in the form of the final rule or otherwise, would likely have a negative impact on our net sales of ADCETRIS.

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

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

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

In addition, there has been regulatory review and enhanced government scrutiny of donations by pharmaceutical companies to patient assistance programs operated by charitable foundations. For example, the Office of Inspector General 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 and other enforcement authorities seeking information related to their patient assistance programs and support, and certain of these organizations have entered into significant civil settlements with applicable enforcement authorities. In connection with these civil settlements, the U.S. government has and may in the future require the affected companies to enter into complex corporate integrity agreements that impose significant reporting and other requirements on those companies. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

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

We have established collaborations with third parties to develop and market ADCETRIS and some of our current and future product candidates. For example, we entered into a collaboration agreement with Takeda in December 2009 that granted Takeda rights to develop and commercialize ADCETRIS outside of the United States and Canada. In addition, we have entered into co-development collaborations with Astellas for the development of enfortumab vedotin, and with Genmab for the development of tisotumab vedotin. We also have a clinical collaboration with BMS to evaluate the combination of Opdivo ® (nivolumab) with ADCETRIS for the treatment of Hodgkin and non-Hodgkin lymphoma. In addition, we have antibody-drug conjugate, or ADC, collaborations with AbbVie Biotechnology Ltd., or AbbVie; Astellas; Genentech, Inc., a member of the Roche Group, or Genentech; Genmab; GlaxoSmithKline LLC, or GSK; and Progenics Pharmaceuticals Inc., or Progenics, and we have entered into a collaboration agreement with Unum Therapeutics, Inc., or Unum, to develop and commercialize novel antibody-coupled T-cell receptor, or ACTR, therapies incorporating our antibodies for the treatment of cancer. Our dependence on collaborative arrangements to assist in the development and commercialization of ADCETRIS and for the development and commercialization of product candidates utilizing or incorporating our technologies subjects us to a number of risks, including:

- we are not able to control the amount and timing of resources that our collaborators devote to the development or commercialization of products and product candidates utilizing or incorporating our technologies, including ADCETRIS, 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 the applicable products and 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 co-development and related agreements with Astellas and Genmab, we may have differing opinions, processes or priorities than our collaborators, or we may encounter challenges in joint decision making and joint execution, including with respect to any joint commercialization plans, which may result in the delay or termination of the research, development, launch or commercialization of the applicable products and product candidates, including ADCETRIS, enfortumab vedotin and tisotumab vedotin;
- our current and potential future collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- significant delays in the development of product candidates by current and potential collaborators could allow competitors to bring products to market before product candidates utilizing or incorporating our technologies are approved and impair the ability of current and potential future collaborators to effectively commercialize these product candidates;
- our relationships with our collaborators may divert significant time and effort of our scientific staff and management team and require the effective allocation of our resources to multiple internal collaborative projects;

- 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 future 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 case of enfortumab vedotin and tisotumab vedotin, the success of any approved enfortumab vedotin or tisotumab vedotin product will depend, in part, on our ability to effectively jointly commercialize enfortumab vedotin and tisotumab vedotin with Astellas and Genmab, respectively, in accordance with our joint commercialization obligations and any joint commercialization plans. The success, if any, of our joint commercialization efforts with Astellas and Genmab, as well as the activities of Astellas and Genmab, will significantly impact the potential future commercialization of enfortumab vedotin and tisotumab vedotin, respectively. In addition, we have active ADC collaborations with a number of companies to allow them to use our proprietary ADC technology and we rely solely on our ADC collaborators for research, product development, manufacturing and commercialization of any product candidates under these ADC collaborations. The product candidates being developed by our collaborators under these ADC collaborations are in various stages of development and we cannot guarantee that any of the product candidates utilizing or incorporating our ADC technology will be successful. In this regard, certain of our ADC collaborators have advanced product candidates utilizing or incorporating our ADC technology to later stage clinical trials that were not successful. In the future, we may not be able to locate third-party collaborators to develop and market products and product candidates utilizing or incorporating our technologies, and we may lack the capital and resources necessary to develop and market these products and product candidates alone.

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

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

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

With respect to ADCETRIS, there are several other FDA-approved drugs for its approved indications. BMS's nivolumab (Opdivo ®) and Merck's pembrolizumab (Keytruda ®) are approved for the treatment of certain patients with relapsed or refractory classical Hodgkin lymphoma, and Celgene's romidepsin (Istodax ®) and Spectrum Pharmaceuticals' pralatrexate (Folotyn ®) and belinostat (Beleodaq ®) are approved for relapsed or refractory sALCL among other T-cell lymphomas. Kyowa Kirin's mogamulizumab (Poteligeo ®) is approved for adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome. The competition ADCETRIS faces from these and other therapies is intensifying. Additionally, Merck is conducting a phase 3 clinical trial in relapsed or refractory classical Hodgkin lymphoma comparing pembrolizumab (Keytruda ®) with ADCETRIS. If this clinical trial demonstrates that pembrolizumab is more effective than ADCETRIS in that treatment setting, our sales of ADCETRIS would be negatively impacted. We are also aware of multiple investigational agents that are currently being studied, including 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 hematopoietic stem cell transplant, combination chemotherapy, clinical trials with experimental agents and single-agent regimens.

With respect to enfortumab vedotin, treatment in pre-treated metastatic urothelial cancer is limited to checkpoint inhibitor monotherapy, generic chemotherapy or, for patients with select fibroblast growth factor receptor genetic alterations, Janssen's erdafitinib (Balversa ®). There are other investigational agents that, if approved, could be competitive with enfortumab vedotin, such as Immunomedics' sacituzumab govitecan. Treatment in front line metastatic urothelial cancer has traditionally been treated with chemotherapy alone, but is evolving to include two recently approved PD-1 and PD-L1 inhibitor therapies with several trials of investigational agents in combination with chemotherapy or other novel agents potentially reporting data in 2019.

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

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

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

We are aware of other companies that have technologies that may be competitive with ours, including AbbVie, ADC Therapeutics, Astellas, AstraZeneca, BMS, Daiichi Sankyo, ImmunoGen, Immunomedics, MedImmune, Mersana, Pfizer, and Roche, all of which have ADC technology. ImmunoGen has several ADCs in development that may compete with our product candidates. ImmunoGen has also established partnerships with other pharmaceutical and biotechnology companies to allow those other companies to utilize ImmunoGen's technology, including Sanofi-Aventis, Genentech, Novartis, Takeda and Lilly. We are also aware of a number of companies developing monoclonal antibodies directed at the same antigen targets or for the treatment of the same diseases as our product candidates.

In addition, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" or "biosimilar" to or "interchangeable" with an FDA-approved biological product. This pathway allows competitors to reference the FDA's prior approvals regarding innovative biological products and data submitted with a BLA to obtain approval of a biosimilar application 12 years after the time of approval of the innovative biological product. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the 12-year exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another company cannot rely on the FDA's prior approvals in approving a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. In the European Union, the EC has granted marketing authorizations for biosimilars pursuant to a set of general and product class-specific guidelines. We are aware of many pharmaceutical and biotechnology and other companies that are actively engaged in research and development of biosimilars or interchangeable products.

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

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

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

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

- the timing, cost and level of investment in our research and development and other activities involving ADCETRIS, enfortumab vedotin, tucatinib, tisotumab vedotin and our other product candidates by us or our collaborators;
- changes in the prices of the Immunomedics, Inc., or Immunomedics, and Unum common stock that affect the valuation of the common stock of those companies that we hold; and
- expenditures we will or may incur to develop and/or commercialize any additional products, product candidates, or technologies that we may develop, in-license, or acquire.

In addition, we have entered into licensing and collaboration agreements with other companies that include development funding and milestone and royalty 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, or business activities, or entry into strategic transactions, including potential future acquisitions of products, technologies or businesses may also cause significant fluctuations in our expenses. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price, the magnitude of the expense that we must recognize may vary significantly. Additionally, we have implemented long-term incentive plans for our employees, and the incentives provided under these plans are contingent upon the achievement of certain regulatory milestones. Costs of performance-based compensation under our long-term incentive plans are not recorded as an expense until the achievement of the applicable milestones is deemed probable of being met, which may result in large fluctuations to the expense we must recognize in any particular period.

Additionally, as of June 30, 2019 , we held shares of Immunomedics common stock with a fair value of $107.1 million . We record changes in the fair value of our equity securities, including the Immunomedics and Unum common stock that we hold, in net income or loss, which can lead to volatility of net income or loss to the extent that we continue to hold common stock or other equity securities. For example, in three months ended June 30, 2019 , our net loss included a loss of $41.2 million associated with our holdings of Immunomedics common stock.

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

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

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

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

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

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

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

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

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

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

We have collaborations with a limited number of companies. To date, a substantial portion of our revenue has resulted from payments made under agreements with our corporate collaborators, and although ADCETRIS sales currently comprise a greater proportion of our revenue, we expect that a portion of our revenue will continue to come from corporate collaborations.

Even though we market ADCETRIS in the United States and Canada, our revenues still depend in part on Takeda's ability and willingness to market ADCETRIS outside of the United States and Canada. The loss of our collaborators, especially Takeda, changes in product development or business strategies of our collaborators, or the failure of our collaborators to perform their obligations under their agreements with us for any reason, including paying license or technology fees, milestone payments, royalties or reimbursements, could have a material adverse effect on our financial performance. Payments under our existing and potential future collaboration agreements are also subject to significant fluctuations in both timing and amount, which could cause our revenue to fall below the expectations of securities analysts and investors and cause a decrease in our stock price.

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

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

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

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

For the monoclonal antibody used in ADCETRIS, we have contracted with AbbVie for clinical and commercial supplies. For the drug linker used in ADCETRIS, we have contracted with Millipore Sigma, an affiliate of Merck KGaA, for clinical and commercial supplies. We have multiple contract manufacturers for conjugating the drug linker to the antibody and producing the ADCETRIS product. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce and store sufficient quantities of ADCETRIS for use in our clinical trials and for commercial sale. If our contract manufacturers or other third parties fail to deliver ADCETRIS for clinical use or sale on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may bear costly losses or be required to delay or suspend clinical trials or otherwise discontinue development, production and sale of ADCETRIS. Moreover, contract manufacturers have a limited number of facilities in which ADCETRIS can be produced and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters or as the result of regulatory actions or contractual disputes could result in the cancellation of shipments, loss of product in the manufacturing process, a shortfall in ADCETRIS supply, or limit our ability to sell our products in the U.S. and Canada or for Takeda to sell ADCETRIS in its territories. Moreover, we and Takeda depend on outside vendors for the supply of raw materials used to produce ADCETRIS. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have ADCETRIS manufactured to meet clinical and commercial requirements would be adversely affected.

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

For enfortumab vedotin and tisotumab vedotin, we or our collaborators will likely need to obtain additional manufacturing arrangements or increase manufacturing capability to meet potential future commercial needs with respect to

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

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

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

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

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

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

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false claim to, or the knowing use of false statements to obtain payment from or approval by the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease, or conceal an obligation to pay money to the federal government. PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Suits filed under the civil False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and other healthcare companies have recently been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing or other activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them

to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs.

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

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

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

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

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

The FDA and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. In recent years, private whistleblowers have also pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of off-label

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

We are also subject to numerous other laws and regulations that are not specific to the healthcare industry. For instance, the U.S. Foreign Corrupt Practices Act, or FCPA, prohibits companies and individuals from engaging in specified activities to obtain or retain business or to influence a person working in an official capacity. Under the FCPA, it is illegal to pay, offer to 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 laws and the evolution of new theories of liability under those laws and regulations. Government agencies will likely continue to intervene in such private whistleblower lawsuits and such intervention typically raises the company's cost significantly. For example, federal enforcement agencies have recently scrutinized product and patient assistance programs, including manufacturer reimbursement support services as well as relationships with specialty pharmacies. Several investigations have resulted in government enforcement authorities intervening in related whistleblower lawsuits and obtaining significant civil and criminal settlements.

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

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

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

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

which could have a material adverse effect on our business. Further, future government shutdowns could potentially impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

We are continuing to expand our operations internationally, and plan to build a commercial infrastructure in Europe. In this regard, we currently have multiple subsidiaries in foreign jurisdictions, including several subsidiaries in Europe, and plan in the future to have subsidiaries in additional jurisdictions. Our business activities outside of the United States are and will continue to be subject to the FCPA, which is described above, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we currently and may in the future operate, including the recently established French Anti-corruption Law on Transparency, Fight against Corruption and the Modernization of the Economy, referred to as Sapin II. In Europe, national anti-corruption laws prohibit giving, offering, or promising bribes to any person, including foreign government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. Various European anti-corruption laws have broad extraterritorial reach and therefore we may be subject to those laws even if we do not have an established entity in those countries and we may be held liable for bribes given, offered or promised to any person, including private persons, by employees and persons associated with us in order to obtain or retain business or a business advantage. In the course of expanding our operations internationally, we will need to establish and expand business relationships with various third parties, such as independent contractors, distributors, vendors, and advocacy groups, and we will interact with physicians, which are generally considered foreign officials in Europe, as well as with regulatory authorities who may be deemed to be foreign officials under the FCPA or similar laws of other countries that may govern our activities. Any interactions with any such parties or individuals that are found to be in violation of such laws could result in substantial fines and penalties and could materially harm our business. Furthermore, any finding of a violation under one country's laws may increase the likelihood that we will be prosecuted and be found to have violated another country's laws. If our business practices outside the United States are found to be in violation of the FCPA, the Sapin II or other similar laws, we may be subject to significant civil and criminal penalties which could have a material adverse effect on our business, results of operations and growth prospects. We are also subject to foreign laws and regulations covering data privacy and the protection of health-related and other personal information. In this regard, EU member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations, such as the GDPR, which impose significant compliance obligations. Failure to comply with these laws could lead to government enforcement actions and significant penalties against us, which could have a material adverse effect on our business, results of operations and growth prospects.

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

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

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

In January 2017, a purported securities class action lawsuit was commenced in the United States District Court for the Western District of Washington, or the Court, naming as defendants us and certain of our officers. A related stockholder derivative lawsuit, or the Stockholder Derivative Action, was also filed in Washington Superior Court for the County of Snohomish, or the Snohomish County Superior Court, on March 29, 2017. While the class action lawsuit and the related

Stockholder Derivative Action were subsequently dismissed, we may be the target of securities-related litigation in the future, both related and unrelated to the dismissed class action and Stockholder Derivative Action. Moreover, three purported stockholders of Cascadian filed a complaint seeking to inspect books and records in order to determine whether wrongdoing or mismanagement has taken place such that it would be appropriate to file claims for breach of fiduciary duty, and to investigate the independence and disinterestedness of the former Cascadian directors with respect to the Cascadian Acquisition. As a result of such complaint or otherwise, it is possible that additional lawsuits may be brought against us and/or Cascadian related to the Cascadian Acquisition.

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 and our contractual rights.

These and potential future litigations are subject to inherent uncertainties, and the actual costs to be incurred relating to litigations may be impacted by unknown factors. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of these and potential future litigations, and we may not prevail. Monitoring and defending against legal actions can be time-consuming for our management and detract from our ability to fully focus our internal resources on our business activities, which could result in delays of our clinical trials or our development and commercialization efforts. In addition, we may incur substantial legal fees and costs in connection with these and potential future litigations. Decisions adverse to our interests in these and potential future litigations could result in the payment of substantial damages, or possibly fines, or affect our intellectual property rights and could have a material adverse effect on our cash flow, results of operations and financial position. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price.

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

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

- the level of sales and market acceptance of ADCETRIS or of any future approved products;
- the time and costs involved in obtaining regulatory approvals of ADCETRIS in additional indications, if any, and potentially of enfortumab vedotin and/or any of our other product candidates;
- the size, complexity, timing, progress and number of our clinical programs and our collaborations;
- the timing, receipt and amount of milestone-based payments or other revenue from our collaborations or license arrangements, including royalty revenue generated from commercial sales of ADCETRIS by Takeda;
- the cost of establishing and maintaining clinical and commercial supplies of ADCETRIS;
- the costs associated with acquisitions or licenses of additional technologies, products, or companies as well as licenses we may need to commercialize our products;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- expenses associated with future 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, as well as a rising interest rate environment, could make it more difficult to obtain additional capital on favorable terms, or at all, which could have a material adverse effect on our business and growth prospects.

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

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

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

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

The standards that the U.S. Patent and Trademark Office, or USPTO, and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our products. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the United States or other countries may be applied retroactively to affect the validity, enforceability, or term of our patent. For example, the U.S. Supreme Court has modified some legal standards applied by the USPTO in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license. In addition, changes to the U.S. patent system have come into force under the Leahy-Smith America Invents Act, or the America Invents Act, including changes from a “first-to-invent” system to a “first to file” system, changes to examination of U.S. patent applications and changes to the processes for challenging issued patents. These changes include provisions that

affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, and post-grant review and covered business methods. These proceedings are conducted before the Patent Trial and Appeal Board, or PTAB, of the USPTO. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of some patents on the grounds that it was anticipated or made obvious by prior art. As a result, non-practicing entities associated with hedge funds, pharmaceutical companies who may be our competitors and others have challenged certain valuable pharmaceutical U.S. patents based on prior art through the IPR process. A decision in such a proceeding adverse to our interests could result in the loss of valuable patent rights which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any event, the America Invents Act and any other potential future changes to the U.S. patent system could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

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

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

and results of operations. In addition, we may challenge the patent or other intellectual property rights of third parties and if we are unsuccessful in actions we bring against the rights of such parties, through litigation or otherwise, and it is determined that we infringe the intellectual property rights of such parties, we may be prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those rights or develop or obtain alternative technologies, any of which could harm our business.

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

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

In addition, the competition for qualified personnel in the biotechnology field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. In order to continue to commercialize ADCETRIS, and advance the development and commercialization of our additional product candidates, we will be required to expand our workforce, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, sales and marketing, both in the United States and in Europe. We continue to face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, as well as academic and other research institutions. To the extent we are not able to retain these individuals on favorable terms or attract any additional personnel that may be required, our business may be harmed. For example, we may not be successful in attracting or retaining key personnel necessary to support our strategy to commercialize ADCETRIS in earlier lines of therapy, including in the frontline PTCL indication, to build a commercial infrastructure in Europe or to support the commercialization of our product candidates alone or jointly with our collaborators.

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

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

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

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

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

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

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

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

In addition, since a significant proportion of the regulatory framework in the U.K. is derived from European Union directives and regulations, Brexit could materially change the regulatory regime applicable to our operations and those of our collaborators, including with respect to potential future marketing authorizations for ADCETRIS and potential future marketing authorizations for our product candidates. We may also face new regulatory costs and challenges as result of Brexit that could have an adverse effect on our operations, including the need to change the location of our release of clinical product supplies into the European Union from the U.K. to a location that will be within the European Union following Brexit, potential stresses and constraints on the capacity of service providers providing product release services in new locations outside of the U.K., and potential challenges with releasing clinical product supplies into the U.K. any of which could potentially impede our ability to timely supply clinical product to our clinical trials, and increase our costs. It is also possible that Brexit will cause additional unanticipated negative impacts on our ability to supply clinical or commercial product, or on that of our collaborators, including Takeda. Moreover, we do not currently have certainty as to the terms of the U.K.'s future relationship with the European Union and if the U.K. withdraws from the European Union without a ratified withdrawal agreement in place, there will be a period of considerable uncertainty particularly in relation to U.K. financial and banking markets as well as on the regulatory process in Europe. In addition, the U.K. could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers which could make our and Takeda's doing business in Europe more difficult. In addition, currency exchange rates for the British Pound and the Euro with respect to each other and the U.S. dollar have already been affected by Brexit. Should this foreign exchange volatility continue, it could cause volatility in our quarterly financial results. In any event, we cannot predict to what extent these changes will impact our business or results of operations, or our or Takeda's ability to continue to conduct operations in Europe or our ability to build and maintain a commercial infrastructure in Europe.

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

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

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

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

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

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

Increasing use of social media could give rise to liability.

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

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

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

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

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

As of June 30, 2019 , we had recorded $574.7 million of in-process research and development and goodwill related to the Cascadian Acquisition. In-process research and development and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Our results of operations and financial position in future periods could be negatively impacted should future impairments of in-process research and development or goodwill occur.

Risks Related to Our Common Stock

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

The market price of our stock has in the past been, and is likely to continue in the future to be, very volatile. During the quarter ended June 30, 2019 , our closing stock price fluctuated between $63.90 and $80.91 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 of FDA or foreign regulatory approval or non-approval of ADCETRIS or any of our product candidates, including enfortumab vedotin, or specific label indications for or restrictions, warnings or limitations in its use, or delays in the regulatory review or approval process;
- announcements regarding the results of discovery efforts and preclinical, clinical and commercial activities by us, or those of our competitors;
- 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;
- developments regarding the pending and potential additional related purported securities class action lawsuits, as well as any other potential litigation;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- changes in government regulations; and
- economic or other external factors.

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

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

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

Sales of a substantial number of shares of our common stock into the public market, including sales by members of our management or board of directors or entities affiliated with such members, could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-related securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of June 30, 2019 , we had 161,637,889 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 June 30, 2019 , 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 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 June 30, 2019 , our executive officers and directors and holders of greater than five percent of our outstanding common stock beneficially owned approximately 73% of our voting power as of June 30, 2019 . As a result, these stockholders, acting together, are able to control our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, including a merger, consolidation, takeover or other business combination involving us or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control, which might affect the market price of our common stock.

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

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

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

Our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders, which authority could be used to adopt a “poison pill” that could act to prevent a change of control of Seattle Genetics that has not been approved by our Board of Directors. The rights of the holders of common stock may be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control of Seattle Genetics without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. Further, certain provisions of our charter documents, including provisions eliminating the ability of stockholders to take action by

written consent and limiting the ability of stockholders to raise matters at a meeting of stockholders without giving advance notice, may have the effect of delaying or preventing changes in control or management of Seattle Genetics, which could have an adverse effect on the market price of our stock. In addition, our charter documents provide for a classified board, which may make it more difficult for a third party to gain control of our Board of Directors. Similarly, state anti-takeover laws in Delaware and Washington related to corporate takeovers may prevent or delay a change of control of Seattle Genetics.

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+†	Joint Commercialization Agreement dated October 20, 2018 between Seattle Genetics, Inc. and Agensys, Inc.	—	—	—	—
10.2+†	Twelfth Amendment to Development and Supply Agreement, effective as of April 25, 2019 between Seattle Genetics, Inc. and AbbVie, Inc. (formerly part of Abbott Laboratories, Inc.).	—	—	—	—
10.3+*	Employment Agreement, dated May 20, 2019, between Seattle Genetics, Inc. and Robin Taylor.	—	—	—	—
10.4*	Seattle Genetics, Inc. Amended and Restated 2000 Employee Stock Purchase Plan, effective as of May 20, 2019.	S-8	333-232397	99.1	6/27/2019
31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).	—	—	—	—
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).	—	—	—	—
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.	—	—	—	—
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.	—	—	—	—
101.INS+	Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	—	—	—	—
101.SCH+	XBRL Taxonomy Extension Schema Document.	—	—	—	—
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	—
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	—
101.LAB+	XBRL Taxonomy Extension Labels Linkbase Document.	—	—	—	—
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	—

+	Filed herewith.
†	Certain confidential information contained in this Exhibit, marked by brackets in the Exhibit, has been omitted, because it is both not material and would likely cause competitive harm if publicly disclosed.
*	Indicates a management contract or compensatory plan or arrangement.
**	Schedules have been omitted pursuant to Item 601(b)(2) of Regulations S-K. The registrant will furnish copies of any such schedules to the Securities and Exchange Commission upon request.

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: July 16, 2019

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.

Exhibit 10.1

EXECUTION VERSION

JOINT COMMERCIALIZATION AGREEMENT

by and between

AGENSYS, INC.

and

SEATTLE GENETICS, INC.,

Dated October 20, 2018

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JOINT COMMERCIALIZATION AGREEMENT

THIS JOINT COMMERCIALIZATION AGREEMENT (this " Agreement ") is made as of October 20, 2018 (the " Effective Date "), by and between AGENSYS, INC., a California corporation (" Agensys "), and SEATTLE GENETICS, INC., a Delaware corporation (" SGI "). Agensys and SGI are sometimes referred to herein individually as a " Party " and collectively as the " Parties ."

RECITALS

WHEREAS , Agensys and SGI entered into a Collaboration and License Agreement, dated as of January 7, 2007, as amended (the " Collaboration Agreement "), to, among other things, collaborate on the development and commercialization of Collaboration Products (as defined in the Collaboration Agreement);

WHEREAS , Agensys was acquired indirectly by Astellas Pharma, Inc. (" Astellas ") and remains an indirect wholly owned subsidiary of Astellas;

WHEREAS , since such acquisition, certain obligations of Agensys under the Collaboration Agreement have been performed on behalf of Agensys by Astellas and its Affiliates, and it is the intention of the Parties that certain obligations of Agensys under this Agreement will be performed on behalf of Agensys by Astellas and its Affiliates;

WHEREAS , Astellas, Agensys, and SGI are party to the Clinical Supply Agreement relating to the Collaboration (as such terms are defined below);

WHEREAS , the Parties and their Affiliates are jointly developing the Product (as hereinafter defined) as a Collaboration Product pursuant to the Collaboration Agreement;

WHEREAS , upon obtaining Regulatory Approval in the relevant jurisdiction, the Parties, together with their Affiliates, have agreed to jointly Promote the Product in the United States and to permit each Party and its Affiliates to, subject to Section 3.6, exclusively Commercialize the Product in their respective Royalty Territory and their respective Exclusive Profit Share Territory;

WHEREAS , the Parties wish to enter into this Agreement to set forth the terms and conditions for such Commercialization of the Product, which terms and conditions amend and further define the terms of the Collaboration Agreement; and

WHEREAS , the terms and conditions of this Agreement are intended to apply only to the Product and not to any other Collaboration Product, Unilateral Product or any other product developed under the Collaboration Agreement.

NOW , **THEREFORE** , in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

ARTICLE 1
DEFINITIONS

The following terms shall have the following meanings as used in this Agreement:

1.1 " Adverse Event " means any untoward medical occurrence in a human patient or subject who is administered the Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of the Product, whether or not considered related to the Product.

1.2 " Affiliate " of a Person means any corporation or other business entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Person. As used in this definition of Affiliate, the term "control" means the direct or indirect ownership of fifty percent (50%) or more of the stock having the right to vote for directors thereof or the ability to otherwise control the management thereof.

1.3 " Agensys Profit Share Territory " means the EU5.

1.4 " Agensys Royalty Territory " means each country in the Territory other than (a) the United States, (b) the SGI Profit Share Territory, (c) the SGI Royalty Territory, and (d) the Agensys Profit Share Territory.

1.5 " Allowable Expenses " means the US Allowable Expenses, the Exclusive Profit Share Territory Allowable Expenses and the Global Allowable Expenses, or the aggregate of the foregoing as the context requires.

1.6 " Americas Region " means North America, Central America and the Caribbean, and South America, including the countries and territories set forth on Schedule 1.6.

1.7 " Applicable Law " means the laws, rules, statutes, orders, ordinances, regulations, guidance and guidelines, or other requirements of any Governmental Authority that may be in effect from time to time and that are applicable to a Party or a Party's activities under this Agreement (including the marketing, sale, and promotion of pharmaceutical products for human use), including GMP, GLP, GCP, and any other rules, regulations, guidelines, or other requirements of Regulatory Authorities. For example, in the United States Applicable Law includes the FFDCA, the Public Health Service Act, the Prescription Drug Marketing Act, the Federal False Claims Act (31 U.S.C. §3729 et seq.), the Federal Health Care Program Anti-Kickback Law (42 U.S.C. §§1320a-7b), the Health Insurance Portability and Accountability Act of 1996, and all rules and regulations

promulgated thereunder as any of the foregoing may be amended. In the EU, Applicable Law includes the Directive 2001/83/EC on the Community code relating to medicinal products for human use, the Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the EU Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, the Commission Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products, the related national implementing laws and regulations of individual EU Member States, provisions of the national laws and industry and professionals codes in individual EU Member States governing anti-bribery and anti-kickback practices. Regarding Personal Data (as defined in the Data Protection Laws), Applicable Law means any law, rule, regulation, ordinance, directive, interpretation, judgment, or decision of any Governmental Authority in relation to data protection; privacy; restrictions on, or requirements in respect of, the processing of Personal Data (as defined in the Data Protection Laws) of any kind, including the Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (GDPR), as any of the foregoing may be amended from time to time (collectively, " Data Protection Laws ").

1.8 " Approved Plans " means the Global Development Plan, the Commercialization Plans, the Medical Affairs Plans, and the Global Manufacturing Plan, in each case, as amended from time to time, and as approved in accordance with the terms hereof, including any corresponding budgets incorporated therein, as the context requires.

1.9 " Approved Subcontractors " means those Third Party subcontractors engaged by SGI, Agensys, or their respective Affiliates for their sales and distribution (including shipping and Third Party logistics (3PL) services) and other commercialization activities prior to or as of the Effective Date.

1.10 " Biosimilar Product " means, with respect to the Product in a given country in the Royalty Territory, any biological product on the market in such country that is approved (a) by the applicable Regulatory Authority in such country under the biosimilarity standard set forth in the United States under 42 U.S.C. §§262(i)(2) and (k), or any similar standard under its foreign equivalent Applicable Law, on a country-by-country basis where the Product is marketed, *provided* that such Applicable Law exists and (b) in reliance in whole or in part, on a prior Regulatory Approval (or on any safety or efficacy data submitted in support of such prior Regulatory Approval) of the Product. For countries or jurisdictions where no explicit biosimilar laws or regulations exist, "Biosimilar Product" includes products which have been deemed to be a Biosimilar Product or otherwise deemed interchangeable with the Product by a Regulatory Authority in the United Sates or EU. Any product or component thereof (including any Product or component thereof) licensed,

marketed, sold, manufactured, or produced by or on behalf of a Party, its Affiliates or (sub)licensees (to the extent such (sub)licensee commercializes a Biosimilar Product in reliance on or with access to the intellectual property rights licensed under the Collaboration Agreement) will not constitute a Biosimilar Product for the purpose of the royalty reduction pursuant to Section 4.2.3(b).

1.11 " BLA " means a Biologics License Application submitted to FDA, and all supplements and amendments that may be submitted with respect to the foregoing.

1.12 " Business Day " means a day that is not a Saturday, Sunday or a day on which banking institutions in New York, New York or Tokyo, Japan are required by Applicable Law to remain closed.

1.13 " Centralized Procedure " means, to the extent compulsory or permitted for the Regulatory Approval of a pharmaceutical product in **[*]** any country in the EU, the procedure administrated by the EMA which results in a single Regulatory Approval granted by the European Commission (excluding any pricing or reimbursement approval) that is valid in all countries in the EU and following recognition, **[*]** .

1.14 " Change in Control " means, with respect to a Party the acquisition after the Effective Date, directly or indirectly, by any Third Party or "group" of Third Parties (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the " Exchange Act ")) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than fifty percent (50%) of the combined voting power of such Party's (or, in the case of Agensys, Astellas') then-outstanding voting securities entitled to vote generally in the election of directors.

1.15 " Clinical Supply Agreement " means the Clinical Supply Agreement among Astellas, Agensys, and SGI, dated as of June 2, 2017, as amended.

1.16 " Clinical Trial " means a Phase I Clinical Trial, a Phase II Clinical Trial, a Phase III Clinical Trial, a Phase III-B Study, a Required Phase IV Study or a Voluntary Phase IV Study, as the case may be.

1.17 " CMC Development " means the Development activities related to the composition, manufacture, and specification of the drug substance and the drug product (including Combination Products) intended to assure the proper identification, quality, purity and strength of the drug, including: site transfer, test method development and stability testing, process development, process improvements (improving product robustness or manufacturing efficiencies), drug substance development, process validation, process scale-up, formulation development, delivery system development, QA and QC development.

1.18 " CMC Development Costs " means, with respect to the Product, the internal costs and direct out-of-pocket costs that are incurred by a Party or any of its Affiliates on or after the Effective Date that are directly attributable or reasonably allocable to CMC Development activities undertaken directly or indirectly by such Party or its Affiliates with respect to the Product, in each case, determined in accordance with the Collaboration Accounting Standards, including the costs incurred by a Party or its Affiliates directly attributable or reasonably allocable to the establishment (but not the on-going supply costs) of site(s) for the Manufacture of Product.

1.19 " Collaboration " means the collaboration between Agensys and SGI and their respective Affiliates for the Development of the Product pursuant to the Collaboration Agreement and the Commercialization of the Product pursuant to this Agreement.

1.20 " Collaboration Accounting Standards " means (a) U.S. generally accepted accounting principles (GAAP), in the case of SGI, and (b) International Financial Reporting Standards (IFRS), in the case of Agensys, in each case, as consistently applied by such Party and its Affiliates.

1.21 " Combination Product " means, any product or therapy containing (a) as a single formulation, (i) a Product and (ii) one or more other active pharmaceutical ingredients (that are not Products), or (b) in a single package or container or intended and approved for marketing as a coordinated use, two or more products or therapies as components including (i) a Product, and (ii) one or more other products or therapies containing one or more other active pharmaceutical ingredients (that are not Products).

1.22 " Commercial Packaging and Labeling Costs " means, the **[*]** to Packaging and Labeling of commercial Product (including safety stock) calculated in accordance with the Collaboration Accounting Standards. For clarity, Commercial Packaging and Labeling Costs do not include any travel costs unless expressly provided for in the applicable budget.

1.23 " Commercialization " means, with respect to the Product, any and all activities to establish and maintain commercial sales for the Product which are undertaken pursuant to an Approved Plan. These activities shall include: (a) the pre-Launch marketing and other preparation activities and Launch activities for the Product, (b) the marketing, Promotion, distribution, offering for sale and selling of the Product, (c) importing and exporting the Product for commercial sale, and (d) Manufacturing the Product for commercial sale (except for CMC Development activities, which shall be considered Development activities), including inventory build to support the Launch and making Manufacturing improvements after Launch; in each case, in accordance with the applicable Approved Plan. For the avoidance of doubt, as used herein, "Commercialization" shall not include Manufacture of the Product other than for commercial sale. When used as a verb, " Commercialize " means to engage in Commercialization.

1.24 " Commercialization Costs " means the US Commercialization Costs, the Exclusive Profit Share Territory Commercialization Costs and the Global Commercialization Costs, or the aggregate of the foregoing as the context requires.

1.25 " Commercialization Plan " means the Global Commercialization Plan, US Commercialization Plan, the SGI Profit Share Territory Commercialization Plan, and the Agensys Profit Share Territory Commercialization Plan, or any combination, as the context requires.

1.26 " Commercially Reasonable Efforts " means (a) with respect to the efforts to be expended by a Party to accomplish a particular objective, the good faith and diligent efforts that such Party and its Affiliates would normally use to accomplish a similar objective under similar circumstances, and (b) with respect to the **[*]** , such efforts as are **[*]** for a comparable product, taking into account commercially relevant factors such as (as applicable) stage of development, product life, market potential and regulatory issues. Commercially Reasonable Efforts shall be determined on a market-by-market and indication-by-indication basis for the Product and it is anticipated that the level of effort may be different for different markets, and may change over time, reflecting changes in the status of the Product and the market(s) involved. Without limiting the forgoing, Commercially Reasonable Efforts with respect to the Product requires that the relevant Party and its Affiliates: (i) set and consistently seek to achieve specific objectives for carrying out its obligations, and (ii) consistently make and implement decisions and allocate resources for the purpose of advancing progress with respect to such objectives.

1.27 " Committee " means any of the Joint Steering Committee, Joint Development Committee, Joint Commercialization Committee, Joint Medical Affairs Committee, Joint Finance Committee, the Joint Chemistry, Manufacturing & Controls Committee, or the E&C Committee.

1.28 " Competing Product " means any product containing **[*]** . For clarity, **[*]** will be a Competing Product **[*]** .

1.29 " Control " and " Controlled by " means, with respect to any information or intellectual property right, possession by a Party of the ability to grant the right to access or use, or to grant a license or a sublicense to, such information or intellectual property right as provided for herein or in the Collaboration Agreement without violating (a) the terms of any agreement with any Third Party or (b) any Applicable Law.

1.30 " Core Data Sheet " means a document setting forth information relating to safety, efficacy, indications, dosing, pharmacology, and other information concerning the Product.

1.31 " Corporate Names " means (a) in the case of SGI, the trademark "Seattle Genetics" and the SGI corporate logo or such other names and logos as SGI may designate in writing from time to time and (b) in the case of Agensys, the trademarks "Agensys" and "Astellas" and the Agensys and Astellas corporate logos or such other names and logos as Agensys may designate in

writing from time to time, in each case ((a) and (b)), together with any variations and derivatives thereof.

1.32 " CSO " means a contract sales force organization.

1.33 " Detail " means a face-to-face meeting (including a group presentation if in accordance with an Approved Plan), including any such meeting conducted in a hospital or physician's office (a) with one or more physicians and other persons included in other medical professional categories identified in the applicable Commercialization Plan (such individuals, " Target Prescribers ") (where, in the case of group presentations, each such physician or other person participating in a group presentation shall be counted as a separate Detail) who are permitted under the Applicable Law of the country in which they work to prescribe the applicable Product in which key Product attributes are orally presented consistent with the terms of this Agreement and (b) that constitutes either a Primary Position Detail or, subject to Section 3.2.4(b) in the case of the United States, a Secondary Position Detail. For the avoidance of doubt, (i) a mere Sample drop without discussion with the professional about the Product shall not be considered a Detail and (ii) any contact or presentation between a Sales Representative and a Managed Care Organization (as distinguished from calls on individual physicians or other medical professionals permitted to prescribe drugs who may be affiliated with a Managed Care Organization, in connection with their professional prescribing decisions (but not with respect to the Managed Care Organization's formulary)) shall not be considered a Detail for purposes of this Agreement. " Detail ," when used as a verb, and " Detailing " shall have correlative meanings.

1.34 " Detailing Costs " means, subject to Section 3.2.4(b), those **[*]** and **[*]** that are **[*]** to the Detailing, but not **[*]** , of a Product for the Exclusive Profit Share Territory determined in accordance with the Collaboration Accounting Standards.

1.35 " Development " means all research and non-clinical and clinical drug development activities and processes, including toxicology, pharmacology, project management and other non-clinical efforts, statistical analysis, delivery system development, the performance of Clinical Trials (including the Manufacturing of Product for use in Clinical Trials) and other activities, reasonably necessary to prepare submissions for, and obtain or maintain, Regulatory Approval of a pharmaceutical product, including lifecycle management studies and other activities. For the avoidance of doubt, as used herein and in the Collaboration Agreement with respect to the Product, "Development" shall include CMC Development, but shall not include Manufacturing of the Product for Commercialization or Voluntary Phase IV Studies.

1.36 " Development Costs " has the meaning set forth in the Collaboration Agreement and also includes those items specifically identified as Development Costs in this Agreement including (a) the direct out-of-pocket costs incurred in connection with the planning and conduct of any Required Phase IV Studies, including Manufacturing costs for (i) Product for use in Required Phase

IV Studies and (ii) the costs for the Manufacture, purchase or packaging of comparators or placebo for use in Required Phase IV Studies (with the Manufacturing costs for comparators or placebo to be determined in the same manner as determined for the Product), as well as the direct costs and expenses of disposal of drugs and other supplies used in Required Phase IV Studies, (b) any internal costs (as determined under Section 4.1) and direct out-of-pocket costs to Manufacture a Product for uses other than for commercial sale or Voluntary Phase IV Studies (including for CMC Development activities) calculated in accordance with the Collaboration Accounting Standards, other than Standard Costs and Commercial Packaging and Labeling Costs, and (c) CMC Development Costs; in each case, determined in accordance with the Collaboration Accounting Standards.

1.37 " Divest " means, as it relates to a product or product development program: (a) the sale of all right, title and interest in such product or product development program, including all technology, intellectual property and other assets relating solely thereto, to a Third Party, without the retention or reservation of any rights, license or interest (other than solely an economic interest) by the selling entity or its Affiliates; or (b) the complete termination or withdrawal of such product, or shut-down of such product development program such that no technology, intellectual property or other asset solely relating thereto is used by the terminating entity or its Affiliates. " Divestiture " shall have a correlative meaning.

1.38 " Dollars " or " $ " means the legal tender of the United States.

1.39 " Drug Regulatory Approval Application " or " DAA " means an application for Regulatory Approval required before commercial sale or use of a Product in a regulatory jurisdiction, including a BLA filed with the FDA, an MAA filed with EMA in the EU or the Regulatory Authority of a country in the European Economic Area, or any foreign equivalents thereof.

1.40 " EMA " means the European Medicines Agency and any successor agency(ies) thereto.

1.41 " EU " means the European Union, as its membership may be constituted from time to time, and any successor thereto. For clarity, the term EU shall include the EU5 (whether or not such countries are EU member states).

1.42 " EU5 " means, individually or collectively, France, Germany, Italy, Spain, and the United Kingdom (whether or not such countries are EU member states).

1.43 " European Commission " means the executive body of the EU that is responsible for, among other things, granting marketing authorization for medicinal products through the Centralized Procedure.

1.44 " Exclusive Profit Share Territory " means the Agensys Profit Share Territory or the SGI Profit Share Territory, as the context requires.

1.45 " Exclusive Profit Share Territory Allowable Expenses " means, with respect to the Product for any period, subject to the provisions of this Agreement, the following expenses **[*]** :

1.45.1 Exclusive Profit Share Territory Commercialization Costs;

1.45.2 **[*]** ;

1.45.3 **[*]** ;

1.45.4 **[*]** ;

1.45.5 **[*]** ;

1.45.6 **[*]** ;

1.45.7 **[*]** ;

1.45.8 **[*]** ; and

1.45.9 **[*]** .

provided , that, in each of clauses **[*]** above, such expenses shall be included within Exclusive Profit Share Territory Allowable Expenses for the Product only to the extent **[*]** and shall not be included to the extent **[*]** . The components of **[*]** shall be **[*]** , and shall be **[*]** . If any cost or expense is **[*]** , such cost or expense shall **[*]** . Where appropriate, the Parties, **[*]** shall be determined **[*]** . Notwithstanding the foregoing, Exclusive Profit Share Territory Allowable Expense does not include **[*]** . For clarity, Exclusive Profit Share Territory Allowable Expense shall exclude **[*]** .

1.46 " Exclusive Profit Share Territory Commercialization Costs " means, with respect to the Product during a period, the internal FTE Costs and direct out-of-pocket costs that are incurred by a Party or any of its Affiliates on or after the Effective Date that are directly attributable or reasonably allocable to the sales and marketing of the Product for the Exclusive Profit Share Territory, in each case, determined in accordance with the Collaboration Accounting Standards, **[*]** . Subject to the foregoing, Exclusive Profit Share Territory Commercialization Costs for the Product shall include costs with respect to the Product incurred for:

1.46.1 **[*]** ;

1.46.2 **[*]** ;

1.46.3 **[*]** ;

1.46.4 **[*]** ;

1.46.5 **[*]** ;

1.46.6 **[*]** ;

1.46.7 **[*]** ;

1.46.8 **[*]** ;

1.46.9 **[*]** ;

1.46.10 **[*]** ;

1.46.11 **[*]** ;

1.46.12 **[*]** ;

1.46.13 **[*]** ;

1.46.14 **[*]** ;

1.46.15 **[*]** ;

1.46.16 **[*]** ;

1.46.17 **[*]** ; and

1.46.18 **[*]**

provided, that if any cost or expense is **[*]** , such cost or expense shall **[*]** . Where appropriate, the Parties, **[*]** be determined **[*]** .

Notwithstanding the foregoing, Exclusive Profit Share Territory Commercialization Costs do not include **[*]** . For clarity, Exclusive Profit Share Territory Commercialization Costs shall exclude **[*]**

1.47 " Exclusive Profit Share Territory Medical Affairs Costs " means, with respect to the Product, the internal FTE Costs and direct out-of-pocket costs that are incurred by a Party or any of its Affiliates on or after the Effective Date that are directly attributable or reasonably allocable to Medical Affairs Activities for the Product in the Exclusive Profit Share Territory (including the portion of such expenses incurred for the Europe region that are reasonably allocable to the Exclusive

Profit Share Territory), including costs **[*]** . For clarity, Exclusive Profit Share Territory Commercialization Costs shall exclude **[*]** .

1.48 " FDA " means the United States Food and Drug Administration, and any successor agency(ies) thereto.

1.49 " FFDCA " means the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.), as amended from time to time.

1.50 " FTE " means the equivalent of the work of one (1) employee full time for one (1) Year consisting of a total of **[*]** per Year (or such other number as may be agreed to by the Parties by Party Written Consent or Joint Committee Consent of the JCC) directly related to the Commercialization of the Product, or any other activities contemplated under this Agreement. Any individual who devotes less than **[*]** per Year (or such other number as may be agreed by the Parties by Party Written Consent or Joint Committee Consent of the JCC) shall be treated as an FTE on a pro-rata basis upon the actual number of hours worked divided by **[*]** (or such other number as may be agreed by the Parties by Party Written Consent or Joint Committee Consent of the JCC).

1.51 " FTE Cost " means the cost of an FTE based on the FTE rate applicable to such FTE determined from time to time in accordance with the Collaboration Agreement.

1.52 " GCP " means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Parts 50, 54, 56 and 312 (or any successor statute or regulation) and the guidelines adopted by the ICH, titled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance" (or any successor document), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the European Commission or other Regulatory Authority, as they may be updated from time to time.

1.53 " Global Allowable Expenses " means, with respect to the Product for any period, subject to the provisions of this Agreement, the following expenses **[*]** :

1.53.1 **[*]** ;

1.53.2 **[*]** ;

1.53.3 **[*]** ;

1.53.4 **[*]** ;

1.53.5 **[*]** ;

1.53.6 **[*]** .

1.53.7 **[*]** ; and

1.53.8 **[*]** ;

provided , that, in each of clauses **[*]** above, such expenses shall be included within Global Allowable Expenses for the Product only to the extent **[*]** and shall not be included to the extent **[*]** . The components of **[*]** shall be **[*]** , and shall be **[*]** . If any cost or expense is **[*]** , such cost or expense shall **[*]** . Where appropriate, the Parties, **[*]** shall be determined **[*]** . For further clarity, Global Allowable Expense shall exclude **[*]** .

1.54 " Global Commercialization Costs " means those internal FTE Costs (as determined under Section 4.1) and direct out-of-pocket costs for Commercialization activities generally applicable across the Territory consistent with the applicable Global Commercialization Plan. For further clarity, Global Commercialization Costs shall exclude **[*]** .

1.55 " Global Medical Affairs Costs " means those internal FTE Costs (as determined under Section 4.1) and direct out-of-pocket costs for Medical Affairs Activities generally applicable across the Territory consistent with the applicable Global Medical Affairs Plan, including global medical affairs board and publications for Product. For further clarity, **[*]** .

1.56 " GLP " means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Part 58 (or any successor statute or regulation), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the European Commission or other Regulatory Authority, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.

1.57 " GMP " means the then-current good manufacturing practices required by the FFDCA, as amended, and the regulations promulgated thereunder by the FDA, including 21 C.F.R. Parts 210 and 211, for the manufacture, testing, QA, and QC of pharmaceutical and biological materials and products, and comparable Applicable Law related to the manufacture, testing, QA and QC of pharmaceutical and biological materials and products in jurisdictions outside the U.S.

1.58 " Governmental Authority " means any supranational, national, federal, state, provincial, country, city or local government or any agency, department, authority, court, or other instrumentality thereof, including any Regulatory Authority.

1.59 " Hospital and MHC Activities " means, for a given country, (a) face-to-face meetings (including a live video presentation or a group presentation if in accordance with an Approved Plan) with one or more physicians, administrators, and other medical or other professional categories identified in the applicable Commercialization Plan, other than Details, that are conducted in a hospital setting or with Managed Care Organizations, (b) activities connected with pricing, rebate

and other contract-related negotiations, contracting, and processing and implementation of agreements with Managed Care Organizations, and (c) meetings and other activities connected with negotiations with Governmental Authorities and health insurance organizations related to pricing, reimbursement or any other market access related agreement and the implementation of such agreements.

1.60 " Hospital and MHC Costs " means, with respect to the Product, the **[*]** and, solely with respect to the Exclusive Profit Share Territory, **[*]** that are incurred by a Party or any of its Affiliates that are **[*]** to Hospital and MHC Activities for the Product in the Profit Share Territory, in each case, determined in accordance with the Collaboration Accounting Standards.

1.61 " ICH " means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use of the World Health Organization, or any successor conference, council or organization.

1.62 " IND " means (a) an Investigational New Drug Application filed with the FDA or its equivalent in any country outside the United States where a regulatory filing is required or obtained to conduct a clinical trial or (b) with respect to any country where a regulatory filing is not required or obtained to conduct a clinical trial, the first enrollment of a patient in the first trial involving the first use of the Product in humans.

1.63 " Indirect Taxes " means value added taxes, sales taxes, consumption taxes and other similar taxes.

1.64 " Information " means all technical, scientific, regulatory and other information, results, knowledge, techniques and data, in whatever form and whether or not confidential, proprietary, patented or patentable, invention disclosures, plans, processes, practices, methods, knowledge, know-how, skill, experience, ideas, concepts, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, formulae, specifications, marketing, pricing, distribution, cost, sales, and manufacturing data or descriptions. For clarity, Information does not include issued Patents or the inventions claimed thereby.

1.65 " Joint Committee Consent " means the mutual consent or agreement of both Parties' respective representatives on the specified Committee (or if no Committee is specified, the JSC), which shall be documented in the minutes of such Committee explicitly (*i.e.* , identified as a Joint Committee Consent); *provided* , that if a matter may be approved or agreed by Joint Committee Consent of a specified Committee, such consent or agreement may be given by Joint Committee Consent of any other Committee to which such Committee directly or indirectly reports, including in each case the JSC.

1.66 " Joint Compliance Standards " means the compliance standards to be prepared by the Parties for the Collaboration, subject to the approval of, and amendment by, the E&C Committee from time to time.

1.67 " Joint Steering Committee " or " JSC " means the joint steering committee established pursuant to the terms of the Collaboration Agreement to provide oversight for the research, development and commercialization of Collaboration Products.

1.68 " Launch " means, with respect to the Product, the first commercial sale of the Product to a Third Party after receipt of all necessary Regulatory Approvals with respect thereto. For the avoidance of doubt, sales prior to receipt of such Regulatory Approvals, such as so-called "treatment IND sales," "named patient sales" and "compassionate use sales," shall not be construed as a Launch.

1.69 " MAA " means a Marketing Authorization Application filed with the EMA pursuant to the Centralized Procedure or, under Applicable Law for Product, with the applicable Regulatory Authority of a country in the European Economic Area with respect to the decentralized procedure, mutual recognition or any national approval procedure.

1.70 " Managed Care Organizations " means pharmacies, pharmacy benefit managers, managed health care organizations, group purchasing organizations, large employers, long-term care organizations, formularies, government agencies, and programs (*e.g.* , Medicare and the VA), or similar organizations.

1.71 " Managed Market Activities " means health systems or managed markets activities, including activities related to pricing and reimbursement programs, patient assistance programs, contracting with managed care entities, hospitals, pharmacies, distribution partners (including wholesalers and specialty distributors), group purchasing organizations, pharmacy benefit managers, hospital systems such as integrated health networks and accountable care organizations, insurance agencies, and Governmental Authorities, as well as issues and decisions about the offer of discounts or rebates for formulary placement for the Product.

1.72 " Managed Market Costs " means, with respect to the Product, the **[*]** and, solely with respect to the Exclusive Profit Share Territory, **[*]** that are incurred by a Party or any of its Affiliates during the Term that are **[*]** to Managed Market Activities for the Product in the Profit Share Territory, in each case, determined in accordance with the Collaboration Accounting Standards.

1.73 " Manufacture " means all activities related to the manufacture and supply of the Product, including manufacturing supplies for Development or Commercialization, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of product (except for CMC Development), ongoing stability tests, storage, distribution and shipment, import

and export, and regulatory activities directly related to any of the foregoing. For clarity, " Manufacturing " has a correlative meaning.

1.74 " Medical Affairs Activities " means the following activities related to the Product: (a) activities of Medical Liaisons who, among other functions, may conduct service based medical activities such as providing input and assistance with consultancy meetings, recommend investigators for Clinical Trials and provide input in the design of trials, and deliver non-promotional scientific exchanges and conduct non-promotional activities such as presenting new Clinical Trial and other scientific Information, (b) grants to support continuing medical education or symposia relating to educational needs related to the Product's therapeutic use, (c) development, publication and dissemination of publications relating to the Product, (d) medical information services provided in response to inquiries communicated via Sales Representatives or received by letter, phone call or email, (e) conducting medical affairs or health economics outcomes research (HEOR) advisory board meetings or other consultant programs, (f) appropriate support of investigator-initiated trials and investigator sponsored research, (g) conducting health economics and outcomes research studies, (h) Post-Market Surveillance, and (i) Clinical Trials of the Product conducted following commencement of a Pivotal Clinical Trial for the Product that is not required for receipt of approval of the BLA or MAA (whether such Clinical Trial is conducted prior to or after receipt of such approval), but that may be useful in support of the post-approval exploitation of the Product (this clause (i), a " Voluntary Phase IV Study ").

1.75 " Medical Affairs Costs " means, the US Medical Affairs Costs, the Exclusive Profit Share Territory Medical Affairs Costs and the Global Medical Affairs Costs, or the aggregate of the foregoing as the context requires.

1.76 " Medical Affairs Plan " means the US Medical Affairs Plan, the SGI Medical Affairs Plan, the Agensys Medical Affairs Plan, and the Global Medical Affairs Plan, as the context requires.

1.77 " Medical Liaisons " means in the Profit Share Territory, those health care professionals employed or engaged by a Party with sufficient health care experience (including at least a four-year degree and either (a) clinical, residency or fellowship experience or (b) other highly specialized training relevant to a specific therapeutic area) to engage in in-depth dialogues with physicians regarding medical issues associated with a Product, and are not Sales Representatives or otherwise engaged in direct selling or Promotion of a Product.

1.78 " Net Profit/Net Loss " means, with respect to the Product **[*]** . For sake of clarity, **[*]** .

1.79 " Net Sales " means (a) the gross amount **[*]** in arm's-length transactions by Related Parties **[*]** from or on account of the sale of Product to a non-Related Party, other than a distributor (but excluding **[*]** or similar fees based on or reasonably allocable to the sale of Product, **[*]** to

a **[*]**), plus (b) the amount of any consideration paid by **[*]** to a **[*]** for the rights to distribute the Product, less the sum of the following:

1.79.1 credits or allowances, if any are actually allowed, **[*]** ;

1.79.2 import taxes, export taxes, excise taxes, sales taxes, value-added taxes, consumption taxes, duties or other taxes levied on, absorbed, determined or imposed with respect to such sales (excluding income or net profit taxes or franchise taxes of any kind), to the extent (a) added to the sale price and set forth separately as such in the total amount **[*]** and (b) not reimbursed by a non-Related Party;

1.79.3 **[*]** transportation costs incurred in shipping Product to such non-Related Parties, **[*]** ;

1.79.4 discounts **[*]** actually allowed, cash and non-cash coupons, retroactive price reductions, and charge-back payments and rebates granted to any non-Related Party **[*]** (and other similar entities and institutions)); and

1.79.5 rebates (or their equivalent), administrative fees, chargebacks and retroactive price adjustments and any other similar allowances granted to non-Related Parties (including to **[*]** (and other similar entities and institutions)) which effectively reduce the selling price or gross sales of the Product;

provided that each deduction from Net Sales may be made only once (*i.e.* , if any deduction is made from Net Sales of Product in a country, such deduction may not be made from Net Sales of the Product in any other country).

[*] .

Product shall be considered "sold" in accordance with such Related Party's sales terms and Collaboration Accounting Standards (*i.e.* , with respect to SGI, when delivered to the applicable delivery destination). Such amounts shall be determined from the books and records of the Related Party.

It is understood that any accruals for individual items reflected in Net Sales are periodically **[*]** trued up and adjusted by each Related Party consistent with its customary practices and in accordance with Collaboration Accounting Standards.

Sale or transfer of Product between any of the Related Parties shall not result in any Net Sales, with Net Sales to be based only on any subsequent sales or dispositions to a non-Related Party. To the extent that any Related Party receives **[*]** , Net Sales shall include **[*]** . For clarity, sales to a Third Party wholesaler or similar distributor, group purchasing organization, pharmacy

benefit manager, or retail chain customer shall be considered sales to a non-Related Party and not to a (sub)licensee; provided, that Net Sales by a Related Party to a non-Related Party consignee (such as the Third Parties described above above) are not recognized as Net Sales by such Related Party until the non-Related Party consignee sells the Product and Net Sales to such non-Related Party consignee shall include any mark-up added to the Product upon the sale by the consignee.

Net Sales of any Combination Product for the purpose of calculating milestones or royalties due under this Agreement shall be determined **[*]** . All net selling prices of the elements of such end-user product or service shall be calculated as the average net selling price of the said elements during the applicable accounting period for which the Net Sales are being calculated. In the event that, in any country, no separate sale of either the Product or any one or more of the active ingredients included in such Combination Product are made during the accounting period in which the sale was made or if net selling price for an active ingredient cannot be determined for an accounting period, Net Sales allocable to the Product in each such country shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, **[*]** , all relevant factors (including **[*]**).

In the case where a drug delivery device is sold with or for use with the Product and included in the gross sales amount, any appropriate adjustment to Net Sales shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account all relevant factors.

1.80 " Packaging and Labeling " means secondary packaging, labeling, and serializing (as required by Applicable Law) Product.

1.81 " Party Tactical Matter " means, with respect to a Party, operational or tactical level decisions with respect to matters and functions allocated to such Party pursuant to an Approved Plan or otherwise pursuant to this Agreement in the Party's applicable Royalty Territory and Profit Share Territory if such decisions are consistent with the terms of this Agreement, the scope of such allocation or delegation, Applicable Law, and the Approved Plans. For clarity, Party Tactical Matters exclude any responsibilities (a) expressly delegated to a Committee or Working Group hereunder, or (b) that expressly require the consent of the other Party or any Committee.

1.82 " Party Written Consent " means (a) with respect to a matter to be agreed by the Parties, the mutual written agreement of the Parties or the mutual consent of the Parties in writing, in each case executed on behalf of each Party by an appropriate officer or employee of such Party; and (b) with respect to a matter to be consented to or approved by a Party, the written consent or agreement of such Party executed by an appropriate officer or employee of such Party. For the avoidance of doubt, a writing evidencing Party Written Consent may be executed by delivery of electronically

scanned copies of original signatures delivered by facsimile or electronic mail, but electronic mail without execution will not evidence Party Written Consent.

1.83 " Patents " means: (a) patent applications filed in the Territory; (b) all patents including supplemental protection certificates that have issued or in the future issue from any of the foregoing, including utility models, design patents and certificates of invention; and (c) all divisionals, continuations, continuations-in-part, reissues, re-examination certificates, renewals, extensions or additions to any such patents and patent applications (as applicable).

1.84 " Payments to Third Parties " means any amounts paid to a Third Party (whether in the form of a royalty, up-front payment, milestone or otherwise) under a Third Party License Agreement.

1.85 " Person " means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, Governmental Authority, association, or other entity.

1.86 " Pivotal Clinical Trial " means, with respect to a Product, an adequate and well-controlled clinical investigation of such Product to provide substantial evidence that the Product is safe and efficacious for its intended use and to determine warnings, precautions, and adverse reactions that are associated with the product in the dosage range to be prescribed, and which is sufficient to support Regulatory Approval of the Product, including the trials referred to in 21 C.F.R. §312.21(c) (*i.e.* , Phase III Clinical Trials), as amended.

1.87 " Post-Market Surveillance " means a program in place after the receipt of Regulatory Approval to be further defined in a pharmacovigilance agreement pursuant to Section 7.2 that provides for monitoring the safety of a product in the market, including reporting of certain Adverse Events to Regulatory Authorities; monitoring, investigating, reporting, and responding to complaints from the market, whether medical, technical, or otherwise; and evaluating whether additional actions, such as a label amendment, dear doctor letter, or recall, may be necessary.

1.88 " Primary Position Detail " means, with respect to a Product, a Detail in which key attributes of a Product are orally presented consistent with the terms of this Agreement, where the Product is given primary emphasis (*i.e.* , an emphasis that is more important than the emphasis given to any other product presented).

1.89 " Product " means enfortumab vedotin, as developed under the Collaboration Agreement, in any and all forms, presentations, doses, and formulations.

1.90 " Product Liability " means any liability in respect of any personal injury or death (or risk of personal injury or death) arising from, relating to or otherwise in respect of, the use or ingestion of, or exposure to, a Product, whether based on negligence, strict product liability or any

other product liability theory, including liability predicated on any alleged or actual manufacturing, design or formulation defect or failure to warn or any breach of any express or implied warranties.

1.91 " Product Liability Losses " means any and all liabilities, losses, damages, and expenses that relate to Claims in respect of Product Liability or alleged Product Liability in the Profit Share Territory.

1.92 " Profit Share Territory " means any of the United States, the SGI Profit Share Territory or the Agensys Profit Share Territory or any combination thereof, as the context requires.

1.93 " Promote " means, with respect to the Product, promotional activities to be conducted by Sales Representatives of a Party in the Territory that are set forth in an applicable Commercialization Plan or otherwise approved by the JCC, including the following (as approved by the JCC or set forth in an applicable Commercialization Plan): (a) Detailing; (b) utilizing Promotional Materials during Details; (c) conducting display booths, displaying Promotional Materials and conducting meetings with Target Prescribers in exhibits at conferences and trade shows; (d) sponsoring advertising in journals and publications directed to Target Prescribers; (e) conducting company-directed peer-to-peer programs regarding a Product (including speakers bureau and speaker training) directed at Target Prescribers; (f) distributing Promotional Materials to Target Prescribers using direct mail, electronic media, digital channels or other appropriate dissemination methods; and (g) Hospital and MHC Activities. For clarity, "Promotion" shall not include: (i) discussing or responding to questions regarding the Product outside of the approved Product labeling; (ii) independently maintaining a website, call center or medical information hotline for the Product; (iii) taking Product orders or otherwise selling or offering the Product for sale; (iv) other activities reserved to the other Party pursuant to this Agreement, or (v) other marketing activities not allocated to the applicable Party under this Agreement or in an approved Commercialization Plan. " Promotion " and " Promotional " shall have the correlative meanings.

1.94 " QA " means quality assurance activities conducted to ensure that all products are of the quality required for their intended use and that quality systems are maintained in accordance with Applicable Law.

1.95 " QC " means quality control activities conducted to check or test that specifications are met in accordance with Applicable Law.

1.96 " Quarter " means each of the three (3) month periods ending on March 31, June 30, September 30 and December 31; *provided* , that the first Quarter under this Agreement shall commence on the Effective Date and the final Quarter under this Agreement shall end on the last day of the Term. " Quarterly " shall have the correlative meaning.

1.97 " Regulatory Approval " means final regulatory approval (including, where applicable, pricing approval in the event that actual commercial sales cannot take place before such

approval) required to market the Product for a disease or condition in accordance with the Applicable Laws and regulations of a given country. In the United States, Regulatory Approval means approval of a New Drug Application, BLA or an equivalent by the FDA. In the EU, Regulatory Approval means a marketing authorization for medicinal products granted by the European Commission or the Regulatory Authority of a country in the European Economic Area.

1.98 " Regulatory Authority " means the FDA, the EMA, the European Commission, or any comparable national or territorial regulatory entity within the Territory having substantially the same functions.

1.99 " Related Party " means a Party and its Affiliates and their respective (sub)licensees (and such (sub)licensees' Affiliates) of Product. For clarity, Related Party shall not include any distributors, wholesalers or the like unless such entity is an Affiliate of the applicable Party.

1.100 " Required Notice Date " means, with respect to a Competing Product, the first to occur of (a) the **[*]** day following the receipt of regulatory approval for the Competing Product and (b) the first commercial sale of such Competing Product; *provided* , *however* , that the Required Notice Date for a Competing Product resulting under Section 10.8.2 shall in no event be prior to the **[*]** following the consummation of the applicable acquisition.

1.101 " Required Phase IV Study " means a Clinical Trial of the Product to be conducted or conducted after Regulatory Approval of the Product has been obtained from an appropriate Regulatory Authority due to a request or requirement of such Regulatory Authority.

1.102 " Royalty Territory " means the Agensys Royalty Territory or the SGI Royalty Territory as the context requires.

1.103 " Sales and Distribution " means customer services, handling of returns, order processing, warehousing, shipping, serialization compliance, invoicing, booking of sales, distribution and collection of receivables, in each case, with respect to the sale and distribution of Product.

1.104 " Sales Representative " of a Party means (a) an employee of such Party or an Affiliate of such Party engaged by such Party or Affiliate to Detail any Product on behalf of such Party or such Affiliate, or (b) an independent contractor, including a CSO, engaged by such Party or Affiliate (to the extent permitted in this Agreement) to Detail any Product on behalf of such Party or such Affiliate (including individuals engaged to provide Hospital and MHC Activities) excluding in each case (i) those employees or independent contractors of either Party or such an Affiliate that are solely engaged in telemarketing, professional education or other indirect activities in support of direct selling, and (ii) Medical Liaisons of a Party or such Affiliate.

1.105 " Samples " means Product units which are not intended to be sold or traded, which are intended to be distributed to authorized healthcare professionals, and which are intended to promote the sale of such prescription drug in accordance with 21 U.S.C. §§353(c) and (d), and the applicable regulations of Title 21 of the U.S. Food and Drug Administration governing prescription drug samples, including 21 C.F.R. Part 203, or any successor provisions to such laws and regulations and in accordance with Applicable Law in any non-U.S. jurisdiction where the Product units are to be distributed, including with respect to the EU, Article 96 of Directive 2001/83. " Sampling " shall have a correlative meaning.

1.106 " Secondary Position Detail " means, with respect to the Product, a Detail in which key attributes of the Product are orally presented consistent with the terms of this Agreement, where the Product is given significant but not primary emphasis (*i.e.* , an emphasis that is at least or more important than the emphasis given to any other product presented other than the product that is presented as the primary position detail).

1.107 " Segregate " means, with respect to a Competing Product, to use diligent efforts to segregate, consistent with best industry practices, the research, development, manufacture and commercialization activities relating to such Competing Product from research, Development, Manufacture and Commercialization with respect to any Product under this Agreement, including using diligent efforts to ensure that: (a) no personnel involved in performing the research, development, manufacture or commercialization of such Competing Product have access to non-public plans or information relating to the research, Development, Manufacture or Commercialization of any Product (*provided* that **[*]** may **[*]** and **[*]** and **[*]** regarding the research, Development, Manufacture and Commercialization of any Product in connection with **[*]**); and (b) no personnel involved in performing the research, Development, Manufacture or Commercialization of any Product have access to **[*]** relating to the research, development, manufacture or commercialization of such Competing Product (*provided* that **[*]** may **[*]** and **[*]** and **[*]** regarding the research, development, manufacture and commercialization of such Competing Product in connection with **[*]**).

1.108 " Selling Party " means SGI in the United States, the SGI Profit Share Territory and the SGI Royalty Territory, and Agensys in the Agensys Profit Share Territory and the Agensys Royalty Territory.

1.109 " SGI Profit Share Territory " means Canada.

1.110 " SGI Royalty Territory " means each country in the Americas Region other than (a) the United States and (b) Canada.

1.111 " Supply Chain Management " means the planning, management and execution of internal activities and activities of Third Party suppliers that (a) provide raw materials used in the

manufacture of a Product; (b) manufacture, fill and finish, package and label any Product or any component thereof; or (c) test, assist in the release of, hold or distribute any Product or any component thereof. Supply Chain Management also includes management of forecasting activities.

1.112 " Territory " means the entire world.

1.113 " Third Party " means any Person other than Agensys, SGI or an Affiliate of either of them.

1.114 " Third Party License Agreement " means a license (or other appropriate acquisition agreement) with a Third Party regarding intellectual property that is reasonably necessary for the Commercialization of Product and that is approved by Joint Committee Consent of the JSC. For clarity, the **[*]** and **[*]** are not Third Party License Agreements.

1.115 " Trademark Costs " means, subject to Section 10.4, (a) the direct out-of-pocket costs (including the fees and expenses owed to outside counsel and other Third Parties for trademark searching, filing, prosecution, and maintenance fees) incurred after the Effective Date (or before the Effective Date if such costs have not already shared under the Collaboration Agreement) in connection with (i) the clearance of the Product Trademarks and the establishment of the Product Trademarks worldwide and (ii) the maintenance of rights of the Product Trademarks in the Profit Share Territory and (b) the reasonable fees and expenses of outside counsel and other reasonable direct costs incurred in bringing, maintaining and prosecuting any action described in Section 10.4.1, in each case, determined in accordance with the Collaboration Accounting Standards.

1.116 " United States " or " U.S. " means the United States of America, including its territories and possessions.

1.117 " US Allowable Expenses " means, with respect to the Product for any period, subject to the provisions of this Agreement, the following expenses **[*]** :

1.117.1 **[*]** ;

1.117.2 **[*]** ;

1.117.3 **[*]** ;

1.117.4 **[*]** ;

1.117.5 **[*]** ;

1.117.6 **[*]** ;

1.117.7 **[*]** ; and

1.117.8 **[*]** ;

provided , that, in each of clauses **[*]** above, such expenses shall be included within US Allowable Expenses for the Product only to the extent **[*]** and shall not be included to the extent **[*]** . The components of **[*]** shall be **[*]** , and shall be **[*]** . If any cost or expense is **[*]** , such cost or expense shall **[*]** . Where appropriate, the Parties, **[*]** shall be determined **[*]** . Notwithstanding the foregoing, US Allowable Expenses does not include **[*]** . For clarity, US Allowable Expense shall exclude **[*]** .

1.118 " US Commercialization Costs " means, with respect to the Product during a period, the direct out-of-pocket costs that are incurred by a Party or any of its Affiliates on or after the Effective Date that are directly attributable or reasonably allocable to the sales and marketing of the Product for the United States, in each case, determined in accordance with the Collaboration Accounting Standards, **[*]** . Subject to the foregoing, Commercialization Costs for the Product shall include costs with respect to the Product incurred for:

1.118.1 **[*]** ;

1.118.2 **[*]** ;

1.118.3 **[*]** ;

1.118.4 **[*]** ;

1.118.5 **[*]** ;

1.118.6 **[*]** ;

1.118.7 **[*]** ;

1.118.8 **[*]** ;

1.118.9 **[*]** ;

1.118.10 **[*]** ;

1.118.11 **[*]** ;

1.118.12 **[*]** ;

1.118.13 **[*]** ;

1.118.14 **[*]** ;

1.118.15 **[*]** ; and

1.118.16 **[*]** ;

provided, that if any cost or expense is **[*]** , such cost or expense shall **[*]** . Where appropriate, the Parties, **[*]** be determined **[*]** .

Notwithstanding the foregoing, Commercialization Costs do not include **[*]** . For clarity, US Commercialization Costs shall exclude **[*]** .

1.119 " US Medical Affairs Costs " means, with respect to the Product, direct out-of-pocket costs that are incurred by a Party or any of its Affiliates on or after the Effective Date that are directly attributable or reasonably allocable to Medical Affairs Activities for the Product in the Profit Share Territory (or in the case of Global Medical Affairs Costs, globally), including costs attributable to (a) **[*]** , (b) **[*]** , and (c) **[*]** , in each case, determined in accordance with the Collaboration Accounting Standards; but, in each case, only to the extent consistent with the budget included in the applicable Medical Affairs Plan. For clarity, **[*]** .

1.120 " Year " means a fiscal year beginning on **[*]** and ending on **[*]** ; *provided* , that the first Year under this Agreement shall commence on the Effective Date and the final Year under this Agreement shall end on the last day of the Term. When used without capitalization, the term " year " means a period of twelve (12) consecutive months (365 or 366 days, as applicable).

1.121 Other Definitions . Capitalized terms defined elsewhere in this Agreement shall have the meanings ascribed to such terms for all other provisions in this Agreement. See the Index of Defined Terms for the location of such other definitions in this Agreement. Except where the context otherwise requires, capitalized terms used in this Agreement without definitions have the meanings ascribed to such terms in the Collaboration Agreement. For the avoidance of doubt, in the event a term is defined in this Agreement and in the Collaboration Agreement, the definition in this Agreement shall govern and control with respect to all matters under this Agreement.

ARTICLE 2
GOVERNANCE

2.1 Governance Generally .

2.1.1 General . Each Party shall assign responsibilities for the various operational aspects of the Collaboration allocated to such Party pursuant to this Agreement to those portions of its organization that have the appropriate resources, expertise and responsibility for such functions. The Parties shall implement the necessary processes to ensure a close, cooperative working relationship.

2.1.2 Collaboration Committees. The Parties have established a JSC, a JDC, a JCC, a JCMC, and a JMAC pursuant to the Collaboration Agreement, which committees will have responsibilities and authority with respect to the Product as provided under this Agreement and/or the Collaboration Agreement, as applicable. The Parties desire to establish additional Committees (including the JFC and E&C Committee), as provided below, to further oversee the Collaboration, to provide additional decision-making structures and to provide a forum for discussion of matters relating to the Collaboration, in each case, with respect to the Product. Each Committee established hereunder shall have the responsibilities and authority allocated to it in this ARTICLE 2 and elsewhere in this Agreement. Subject to Section 15.11, the JSC shall have the responsibilities and authority allocated to it in this Agreement and the Collaboration Agreement (except, in the case of the Collaboration Agreement, where a responsibility is specifically precluded under this Agreement). The Parties intend that their respective organizations will work together to assure success of the Collaboration.

2.1.3 Limitations on the Authority of Committees. Notwithstanding the Committee structure established pursuant to this ARTICLE 2 to oversee the Collaboration, each Party shall retain the rights, powers and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be delegated to or vested in a Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree by Party Written Consent. The Parties hereby agree that (a) no Committee shall have any authority with respect to the amendment, modification or waiver of compliance with any provision of this Agreement, which matters may be approved only by Party Written Consent of the Parties or, in the case of a waiver of compliance, by the Party Written Consent of the Party entitled to waive such compliance, (b) other than with respect to approval of the Global Development Plan, Global Commercialization Plan, Global Manufacturing Plan, and Global Medical Affairs Plan, no Committee shall have decision-making authority with respect to the Royalty Territory, (c) other than with respect to approval of each SGI Profit Share Territory Commercialization Plan and each Agensys Profit Share Territory Commercialization Plan, the Committees shall have no decision-making authority with respect to either Party's Exclusive Profit Share Territory, (d) any matter that otherwise would be within the jurisdiction of any Committee may be agreed or resolved by Party Written Consent, (e) any matter that is expressly reserved to the consent or other decision-making authority of a Party in this Agreement may be decided only by such Party, (f) any matter that is expressly reserved to the consent or agreement of both of the Parties may be decided only by the Party Written Consent, where indicated, by Party Written Consent or Joint Committee Consent, (g) all determinations made by any Committee shall be subject to and shall comply with the terms of this Agreement, and (h) a Committee may not make any decision that is inconsistent with the Approved Plans unless an amendment to the applicable Approved Plan addressing such inconsistency is approved by the JSC.

2.2 Joint Development Committee .

2.2.1 Formation and Purpose . Agensys and SGI have established a joint development committee (the " Joint Development Committee " or " JDC ") pursuant to the Collaboration Agreement and wish to formalize its structure as set forth herein. The JDC shall consist of up to **[*]** representatives from each Party (or such other number as may be agreed by Party Written Consent). Subject to the oversight of the JSC and subject to Sections 2.1 and 2.9, the JDC shall be principally responsible for overseeing the Development of Product globally under the Collaboration Agreement and this Agreement, including coordination of activities between the Parties. The JDC shall operate by the procedures set forth in Section 2.9.

2.2.2 Global Development Plan . Prior to the Effective Date, the JDC adopted a plan that governs global Development and regulatory activities of the Parties with respect to the Product under the Collaboration Agreement. As promptly as practicable following the Effective Date, the JDC shall update such development plan if necessary to align the contents of such plan with the Approved Plans under this Agreement and to include the regulatory plan pursuant to Section 7.1.1, and shall submit such updated plan to the JSC for approval (as approved by the JSC, the " Global Development Plan "). Following its adoption by the JSC, the Initial Collaboration Product Plan attached as Schedule G to the Collaboration Agreement (or any other then-current development plan for Product) shall be replaced with the Global Development Plan. **[*]** , or more often as the Parties deem appropriate, the JDC shall prepare amendments to the then-current Global Development Plan for approval by the JSC. In the event of any inconsistency between the Global Development Plan and this Agreement or the Collaboration Agreement, the terms of this Agreement shall prevail.

2.2.3 Specific Responsibilities . Subject to the oversight of the JSC, the JDC shall be responsible for overseeing Development strategy for the Product globally under the Collaboration Agreement and this Agreement, including the following:

(a) overseeing the development of goals and strategy for the Development of the Product (including regulatory strategies and prioritization of Clinical Trials and indications for the Product) for review and approval by the JSC;

(b) overseeing the preparation of annual updates to, and other amendments of, the Global Development Plan for approval by the JSC;

(c) overseeing the development of goals and strategy for Drug Regulatory Approval Applications for review and approval by the JSC;

(d) preparing the Core Data Sheet pursuant to Section 7.1.6(b) and submitting draft to the JSC for approval;

(e) monitoring compliance with the then-current budget included in the Global Development Plan on a continuing basis;

(f) reviewing, coordinating and monitoring the activities and progress of the Parties in implementing the Development activities in the Global Development Plan;

(g) facilitating the flow of information with respect to the Development of the Product and coordinate with other Committees, as appropriate;

(h) overseeing the preparation of recommendations to the JSC for further Development of the Product, including Development for new indications that are not in the then current Global Development Plan;

(i) overseeing the conduct of Clinical Trials (including Required Phase IV Studies), including approval of the final version of all Clinical Trial protocols and any material amendments thereto;

(j) subject to the terms of this Agreement and the Approved Plans, recommending allocation of responsibilities for Development activities between Agensys and SGI to the JSC for approval;

(k) overseeing the forecasting of quantities of Product required for Clinical Trials for incorporation into the Global Manufacturing Plan;

(l) providing Quarterly updates on the JDC's activities and achievements to the JSC; and

(m) performing such other functions as the JSC may request from time to time or are expressly assigned to the JDC in this Agreement.

2.3 Joint Commercialization Committee .

2.3.1 Formation and Purpose . Agensys and SGI have established a joint commercialization committee (the " Joint Commercialization Committee " or " JCC ") pursuant to the Collaboration Agreement and wish to formalize its structure as set forth herein. The JCC shall consist of up to **[*]** representatives from each Party (or such other number as may be agreed by Party Written Consent). Subject to the oversight of the JSC and subject to Sections 2.1 and 2.9, the JCC shall be principally responsible for (a) strategic oversight for the Commercialization of the Product in the Territory in accordance with the Global Commercialization Plan, (b) monitoring the execution by each Party of its Commercialization of the Product in its Exclusive Profit Share Territory to ensure such execution is in accordance with each Agensys Profit Share Territory Commercialization Plan and SGI Profit Share Territory Commercialization Plan, as applicable, and (c) oversight of the implementation of the then-current US Commercialization Plan, including

coordination of activities between the Parties. The Parties anticipate that the responsibilities of the JCC with respect to the United States will be administered through one or more Working Groups. The JCC shall operate by the procedures set forth in Section 2.9. The specific allocation of responsibilities between Agensys and SGI in the United States shall be made in accordance with Section 3.2.4.

2.3.2 Specific Responsibilities . Subject to the oversight of the JSC, the JCC shall be responsible for general oversight of Commercialization of the Product globally and detailed oversight of the Product in the United States, including the following:

(a) overseeing the development of global goals and strategy for Product positioning, messaging, and branding in the Territory, in each case, for review and approval by the JSC;

(b) developing, reviewing and approving marketing resources deployed by account teams engaging with managing health systems accounts in the United States;

(c) overseeing the development of goals and strategy for Product pricing and reimbursement in the Exclusive Profit Share Territory and Royalty Territory, in each case for review and approval by the JSC; including:

(i) the JCC shall recommend **[*]** , **[*]** and **[*]** for the Product in the Exclusive Profit Share Territory and Royalty Territory to the JSC and the JSC shall approve final recommended **[*]** , **[*]** and **[*]** for the Product in the Exclusive Profit Share Territory and Royalty Territory; provided that neither the JSC nor the JCC shall have any authority with respect to establishing the specific prices in the Exclusive Profit Share Territory or Royalty Territory provided that the **[*]** is within the **[*]** approved by the JSC;

(ii) each applicable Party shall have the exclusive right to set pricing in its Exclusive Profit Share Territory and Royalty Territory within the **[*]** by the JSC, in compliance with Applicable Laws (including antitrust and competition laws);

(iii) any recommendations as to **[*]** and **[*]** for the Exclusive Profit Share Territory and Royalty Territory shall be justified in writing in relation to the **[*]** and **[*]** by the Parties in connection with the Collaboration and the Product;

(d) reviewing and recommending to the JSC for approval pricing (including, rebates, discounts, and alternative pricing arrangements (*e.g.* , **[*]** , **[*]** , **[*]** , and **[*]**)), gross to net target and contracting strategy in the United States;

(e) reviewing and approving proposed United States Product sales contract terms (including rate and price protection provisions);

(f) overseeing the preparation of the Global Commercialization Plan, and annual updates thereto, in each case for review and approval by the JSC;

(g) overseeing the preparation of an annual US Commercialization Plan, and annual updates thereto, in each case for review and approval by the JSC;

(h) monitoring compliance with the then-current budget included in each Commercialization Plan on a continuing basis;

(i) monitoring progress under and overseeing the implementation of each US Commercialization Plan;

(j) reviewing and commenting on each SGI Profit Share Territory Commercialization Plan and each Agensys Profit Share Territory Commercialization Plan, and annual updates thereto, which comments shall be considered in good faith by the applicable Party, and submitting each such proposed plan to the JSC for review and approval;

(k) reviewing quarterly reports submitted by each Party for the United States and its Exclusive Profit Share Territory with respect to its Commercialization activities;

(l) reviewing and coordinating packaging designs and Product Trademarks for use in the Territory and overseeing the use thereof;

(m) overseeing the forecasting of unit volume demand for each SKU of the Product in the Territory for purposes of the Global Manufacturing Plan as set forth in Section 5.4;

(n) subject to the terms of this Agreement and the Approved Plans, allocating responsibilities for Commercialization activities between Agensys and SGI in the United States;

(o) monitoring, in conjunction with the JFC, Allowable Expenses;

(p) selecting marketing vendors (*e.g.* , advertising agencies) in the United States;

(q) subject to the terms of this Agreement and each applicable Approved Plan, reviewing and coordinating sales force activities, including Sampling strategies, and targeting and segmentation strategies, in each case for the United States;

(r) reviewing, in conjunction with the JFC, each Party's sales and financial reports pertaining to Allowable Expenses for the Product in the Profit Share Territory;

(s) approving a strategy for free goods programs (including Sampling), vendor/Product returns policy, and patient assistance and indigent patient access programs in the United States;

(t) facilitating the flow of information with respect to the Commercialization of the Product and coordinate with other Committees as appropriate;

(u) providing Quarterly updates on the JCC's activities and achievements to the JSC; and

(v) performing such other functions as the JSC may request from time to time or are expressly assigned to the JCC in this Agreement.

2.3.3 US Commercialization Working Group .

(a) A Working Group of the JCC with responsibility for overseeing Commercialization of Product in the United States and such other matters as may be designated by the JCC from time to time is hereby established by the JCC (the " US Commercialization Working Group "). The US Commercialization Working Group shall consist of up to **[*]** representatives from each Party (or such other number as may be agreed by the JCC). The names of each Party's initial members of the US Commercialization Working Group shall be provided to the other Party within **[*]** after the Effective Date.

(b) The JCC hereby delegates to the US Commercialization Working Group responsibility for:

(i) developing a sales force deployment plan for the United States;

(ii) developing, reviewing and approving marketing resources deployed by account teams engaging with managing health systems accounts in the United States;

(iii) preparing the US Commercialization Plan and annual updates thereto, in each case for review and approval by the JSC;

(iv) monitoring progress under each US Commercialization Plan;

(v) subject to the terms of this Agreement and the Approved Plans, allocating responsibility for Commercialization activities between the Parties in the United States;

(vi) selecting marketing vendors (*e.g.* , advertising agencies) in the United States;

(vii) subject to the terms of this Agreement and each applicable Approved Plan, coordinating sales force activities, including Sampling strategies and targeting and segmentation strategies, in each case for the United States;

(viii) recommending a strategy for free goods programs (including Sampling), vendor/Product returns policy, and patient assistance and indigent patient access programs in the United States; and

(ix) evaluating the need for key account managers for the Product in the United States prior to preparation of each US Commercialization Plan and, to the extent needed, including as part of such US Commercialization Plan.

2.3.4 US Pricing Working Group .

(a) A Working Group of the JCC with responsibility for (i) oversight of all decisions related to pricing, discounts, payor strategy and contracting for sale of Product in the United States and recommending such matters to the JSC for approval, (ii) the periodic review and evaluation of the outcome of such decisions, and (iii) such other matters for the United States as may be designated by the JCC from time to time is hereby established by the JCC (the " US Pricing Working Group "). The US Pricing Working Group shall consist of up to **[*]** representatives from each Party (or such other number as may be agreed by the JCC). The names of each Party's initial members of the US Pricing Working Group shall be provided to the other Party within **[*]** after the Effective Date. The Parties shall provide the US Pricing Working Group with access to all information necessary to review and evaluate the outcome of such decisions, including contracts for the sale of Product in the United States, and data related to such contracts.

(b) The JCC hereby delegates to the US Pricing Working Group responsibility for reviewing and establishing pricing **[*]** .

2.4 Joint Finance Committee .

2.4.1 Formation and Purpose . Agensys and SGI hereby establish a joint finance committee (the " Joint Finance Committee " or " JFC "), which shall consist of up to **[*]** representatives from each Party (or such other number as may be agreed by Party Written Consent). Subject to the oversight of the JSC and subject to Sections 2.1 and 2.9, the JFC shall provide support to all other Committees with respect to accounting and financial matters relating to the Collaboration and the Product. The JFC shall report directly to the JSC. The JFC shall operate by the procedures set forth in Section 2.9.

2.4.2 Specific Responsibilities of the JFC . Subject to the oversight of the JSC, the JFC shall:

(a) work with the other Committees to assist in financial, budgeting and planning matters as required, including (i) assisting in the preparation of such reports on financial matters as are requested by the JSC for the implementation of the financial aspects of the Collaboration, (ii) assisting with the preparation by the Parties of the budget in the Global Development Plan, budget in each Commercialization Plan and Medical Affairs Plan, and (iii) as requested by a Party, coordinate the preparation of Quarterly updates to annual budgets and, in connection therewith, the provision of the projections contemplated by Section 2.11.2;

(b) agree on procedures, formats and timelines consistent with this Agreement for reporting financial data or recommend amendments to this Agreement for approval by the Parties (which recommendations shall be adopted only by Party Written Consent);

(c) assist in resolving differences that relate to the financial terms of this Agreement; *provided* that no Party shall be required to make any material change to its internal accounting and reporting systems and standards (as opposed to generating ad hoc or additional reports upon reasonable request);

(d) review a Party's reporting of Net Sales, and each Party's reporting of Allowable Expenses under this Agreement;

(e) facilitate the flow of financial information with respect to the Development, Commercialization or Manufacture of the Product and coordinate with other Committees as appropriate;

(f) review and approve the Standard Costs prepared by the JCMC; and

(g) perform such other functions as the JSC may request from time to time or are expressly assigned to the JFC in this Agreement.

2.5 Joint Chemistry, Manufacturing & Controls Committee .

2.5.1 Formation and Purpose . Agensys and SGI have established a joint chemistry, manufacturing & controls committee (the " Joint Chemistry, Manufacturing & Controls Committee " or " JCMC ") pursuant to the Collaboration Agreement and wish to formalize its structure as set forth herein. The JCMC shall consist of up to **[*]** representatives from each Party (or such other number as may be agreed by Party Written Consent). Subject to the oversight of the JSC and subject to Section 2.1 and 2.9, the JCMC shall oversee the Manufacture and supply of the Product globally as well as all CMC Development activities. The JCMC shall operate by the procedures set forth in Section 2.9.

2.5.2 Specific Responsibilities of the Joint Chemistry, Manufacturing & Controls Committee . Subject to the oversight of the JSC, and subject to Sections 2.1 and 2.9, the Joint Chemistry, Manufacturing & Controls Committee shall, in particular and in addition to its other responsibilities set forth in this Agreement:

(a) oversee clinical and commercial Manufacture of Product;

(b) oversee the preparation of an annual Global Manufacturing Plan for the Product and Quarterly updates thereto for review and approval by the JSC pursuant to Section 5.4;

(c) monitor compliance with the then-current budget included in the Global Manufacturing Plan on a continuing basis;

(d) determine the Standard Costs in accordance with Section 5.6.1 and submit proposed Standard Costs to the JFC for approval;

(e) in collaboration with the JDC, oversee the preparation of responses to regulatory requests for information (RFIs) related to CMC, CMC dossiers and similar submissions to Regulatory Authorities (including required local modifications but excluding routine GMP inspections), including the development of mutually agreed policies and procedures therefor, *provided* that (i) where the time limit for a response to the competent Regulatory Authorities would prevent the Parties from consulting the JDC and JCMC in advance, the Parties shall promptly notify the JDC and JCMC and send a copy of any response and any other document, request or demand issued by the competent Regulatory Authorities concerned, not later than **[*]** after the response to the competent Regulatory Authorities is submitted and (ii) final decision-making authority with respect to such submissions shall be as set forth in the quality agreement; *provided further* that any such responses that relate to critical issues or significant non-compliance shall be escalated to the JSC for review and approval of such responses;

(f) oversee the preparation for and reviewing responses to regulatory inspections related to the Product, including the development of policies and procedures therefor;

(g) oversee CMC Development activities and development of, and recommend to JSC for approval, strategies for second sourcing;

(h) oversee development of, and approve, logistical strategies, including capacity planning and inventory levels, to maintain consistency with the forecasts;

(i) review and approve any Manufacturing sites or testing sites proposed to be established following the Effective Date and changes to any existing or new Manufacturing sites or testing sites, and material changes in Manufacturing processes or

responsibilities in the supply chain for the Product (provided that (i) the JCMC shall **[*]** and (ii) in performing such review and approval, the JCMC shall take into consideration **[*]**);

(j) oversee and monitor all QA- and QC-related matters concerning the Product;

(k) cooperate with the JDC, JMAC and JCC to coordinate clinical and commercial supply of Product;

(l) if the travel costs of the Parties for activities related to the Manufacture of Product are not substantially equivalent, proposing budgets for such travel costs for the applicable Approved Plans;

(m) facilitate the flow of financial information with respect to the Manufacture of the Product and coordinate with other Committees as appropriate;

(n) provide updates on the JCMC's activities and achievements to the JSC no less frequently than once each Quarter after the Effective Date;

(o) reviewing and approving for inclusion in Global Allowable Expenses the portion of capital expenditures, **[*]** not otherwise reallocated to another product of the applicable Party or its Affiliates; and

(p) perform such other functions as the JSC may request from time to time or are expressly assigned to the JCMC in this Agreement.

2.6 Joint Medical Affairs Committee .

2.6.1 Formation and Purpose . Agensys and SGI have established a joint medical affairs committee (the " Joint Medical Affairs Committee " or " JMAC ") pursuant to the Collaboration Agreement and wish to formalize its structure as set forth herein. The JMAC shall consist of up to **[*]** representatives from each Party (or such other number as may be agreed by Party Written Consent). Subject to the oversight of the JSC and subject to Sections 2.1 and 2.9, the JMAC shall be principally responsible for (a) oversight of the Medical Affairs Activities of Product globally under the Collaboration Agreement and this Agreement, including coordination of such activities between the Parties, (b) oversight of Medical Affairs Activities in the Exclusive Profit Share Territories to ensure alignment with the Global Medical Affairs Plan, and (c) oversight of the US Medical Affairs Plan, including coordination of activities between the Parties. The JMAC shall operate by the procedures set forth in Section 2.9. The specific allocation of responsibilities for Medical Affairs Activities between Agensys and SGI shall be made in accordance with ARTICLE 6.

2.6.2 Specific Responsibilities of the Joint Medical Affairs Committee . Subject to the oversight of the JSC, the JMAC shall, in particular and in addition to its other responsibilities set forth in this Agreement:

(a) oversee the preparation of an annual Global Medical Affairs Plan, and annual updates thereto, for review and approval by the JSC pursuant to Section 6.2;

(b) oversee the preparation of an annual US Medical Affairs Plan, and annual updates thereto, for review and approval by the JSC pursuant to Section 6.3;

(c) review and comment on the SGI Profit Share Territory Medical Affairs Plan and Agensys Profit Share Territory Medical Affairs Plan prepared pursuant to Section 6.4.1, and annual updates thereto, which comments shall be considered in good faith by the applicable Party, for review and approval by the JSC for approval;

(d) monitor compliance with the then-current budget included in each Medical Affairs Plan on a continuing basis;

(e) monitor progress under the Global Medical Affairs Plan endorsed by the JSC;

(f) monitor progress under, and oversee the implementation of, each US Medical Affairs Plan endorsed by the JSC;

(g) provide a forum for discussion, debate, and decision-making to maximize patient benefits;

(h) discuss whether and when to initiate or discontinue any studies or trials in the United States that are Medical Affairs Activities;

(i) oversee the conduct of any studies or trials in the United States that are Medical Affairs Activities, and provide a forum for the sharing of information regarding the conduct of such studies or trials;

(j) review quarterly reports submitted by each Party with respect to its Medical Affairs Activities in the Profit Share Territory;

(k) review annual reports submitted by each Party for its Royalty Territory with respect to its Medical Affairs Activities in its Royalty Territory;

(l) review, discuss and coordinate the Parties' scientific presentation and publication strategy relating to the Product in accordance with the Publication Charter;

(m) facilitate the flow of information with respect to the Medical Affairs Activities for the Product and coordinate with other Committees as appropriate;

(n) monitor, in conjunction with the JFC, Allowable Expenses for Medical Affairs Activities;

(o) provide Quarterly updates on the JMAC's activities to the JSC; and

(p) perform such other functions as the JSC may request from time to time or are expressly assigned to the JMAC in this Agreement.

2.7 Ethics & Compliance Committee . Agensys and SGI hereby agree to establish an Ethics & Compliance Committee (the " E&C Committee ") within **[*]** after the Effective Date. The E&C Committee shall consist of up to **[*]** from each Party (or such other number as may be agreed by Party Written Consent). The E&C Committee shall report to the JSC. The E&C Committee shall meet at such times as it elects to do so, but in no event less frequently than **[*]** , to make recommendations to the JSC or to the Parties directly, and may establish sub-groups to address matters on a country-by-country basis, based on the following objectives:

2.7.1 to review, comment on, and approve Joint Compliance Standards and periodically update the Joint Compliance Standards, with approval of the initial Joint Compliance Standards and any amendments thereto by Joint Committee Consent;

2.7.2 subject to Section 8.3, to **[*]** , with respect to: **[*]** , in each case with the goal of **[*]** ;

2.7.3 to facilitate and ensure communication across the Collaboration on compliance-related issues with respect to the Product, subject to Section 7.1.10; and

2.7.4 to provide a forum for discussion on compliance policies, processes, standards and controls with respect to the Product and approve such policies.

2.8 Working Groups . From time to time, any Committee may establish and delegate duties to working groups for the United States (each, a " Working Group ") on an "as-needed" basis to oversee particular projects or activities with respect to the United States, which delegations shall be reflected in the minutes of the meetings of the applicable Committee. Such Working Groups may be established on an ad hoc basis for purposes of a specific project, for the life of a Product or on such other basis as the establishing Committee may determine, and shall be constituted and shall operate as the establishing Committee may determine; *provided* , that (a) decision making shall be by consensus, with each Party's representatives on the applicable Working Group collectively having one vote on all matters brought before the Committee and (b) a Working Group may not make any

decision that is inconsistent with the Approved Plans unless an amendment to the applicable Approved Plan addressing such inconsistency is approved by the JSC. Each Working Group and its activities shall be subject to the oversight, review and approval of, and, shall report to, the Committee that established such Working Group. In no event shall the authority of the Working Group exceed that specified for the relevant Committee in this ARTICLE 2.

2.9 General Committee and Working Group Membership and Procedures .

2.9.1 Membership . Each of Agensys and SGI shall designate representatives with appropriate expertise to serve as members of each Committee (or Working Group as they are established), and each representative may serve on more than one Committee (or Working Group) as appropriate in view of the individual's expertise. Each Party may replace its Committee or Working Group representatives at any time upon written notice to the other Party. Each member of each Committee and Working Group shall be made aware of the obligation of compliance with all Applicable Laws, including antitrust and competition laws, as set forth in Section 8.1.5. Each Committee and Working Group shall have co-chairpersons; *provided* , that primary responsibility for facilitating meetings will alternate annually. Agensys and SGI shall each select from their representatives a co-chairperson for each of the Committees and each of the Working Groups, and each Party may change its designated co-chairperson from time to time upon written notice to the other Party. The co-chairpersons of each Committee and Working Group, with assistance and guidance from the Alliance Managers (or their respective designees), shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting of such Committee or Working Group, and preparing and issuing minutes of each meeting within **[*]** thereafter; *provided* , that the Committee/Working Group co-chairpersons shall call a meeting of the applicable Committee or Working Group promptly upon the written request of either co-chairperson to convene such a meeting. Such minutes will not be finalized until the co-chairperson from each Party reviews and confirms in writing the accuracy of such minutes. The minutes of each meeting shall, among other things, record all matters acted upon and approved or disapproved by the Committee or Working Group, and any matters the Committee or Working Group failed to resolve.

2.9.2 Meetings . Each Committee and Working Group shall hold meetings at such times as it elects to do so, but in no event shall such meetings of each Committee be held less frequently than **[*]** . Each Committee or Working Group shall meet alternately at a location designated by Agensys and a location designated by SGI, or at such other locations, including by audio or video teleconference as permitted below, as the Parties may agree. The Alliance Managers (or their respective designees) may attend meetings of each Committee and Working Group (as non-voting participants, unless they are members of such Committee or Working Group). Additional employees, consultants, and representatives of a Party may, with the other Party's consent, attend meetings of each Committee or each Working Group as non-voting observers; *provided* , that (a) any such employees, consultants or representatives are (i) under obligations to comply with all

Applicable Laws (including antitrust and competition laws as set forth in Section 8.1.5), (ii) under obligations of confidentiality and non-use applicable to the Confidential Information of each Party that are at least as stringent as those set forth in Collaboration Agreement and (iii) obligated to assign to the Parties any inventions made by any of them arising out of their participation in such meetings, and, (b) with respect to non-employees of a Party, such attendance is subject to consent of the other Party, which shall not be unreasonably withheld, conditioned, or delayed. Each Party shall be responsible for all of its own expenses of participating in the JSC and all of its own costs of participating in any other Committee or Working Group. Meetings of any Committee or Working Group may be held by audio or video teleconference with the consent of each Party; *provided,* that at least **[*]** meetings per year of each such Committee shall be held in person at a location alternately designated by Agensys and SGI. No Committee or Working Group shall take any action or make any decision except at a meeting properly called, and no action taken at any meeting of a Committee or Working Group shall be effective unless a representative of each Party is present or participating.

2.9.3 Charter. Each Committee may adopt a charter setting forth such additional rules and procedures as may be necessary for the performance of its responsibilities; *provided* that such rules and procedures must be consistent with the terms of this Agreement. In the event of any conflict or inconsistency between any such Committee charter and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall govern and control.

2.9.4 Decision-Making.

(a) Decisions. Decisions on each Committee shall be made by consensus, with each Party's designees on a Committee collectively having one vote on all matters brought before the Committee; *provided* that, for clarity (i) Party Tactical Matters are not subject to Committee decision-making and, (ii) the Committees' authority is limited as set forth in Section 2.1.3. Notwithstanding anything to the contrary, each Approved Plan and updates thereto approved by the Committees is subject to final approval by Astellas' Executive Committee and SGI's Executive Committee. If either the Astellas Executive Committee or the SGI Executive Committee propose changes to any Approved Plan, then the applicable Committee will consider such changes in good faith, and if such changes are made, then the Approved Plan, as revised, will not be required to be resubmitted to each Party's Executive Committee for approval.

(b) Dispute Resolution in General. Except for Party Tactical Matters, any disagreement between the designees of Agensys and SGI on any Committee as to matters within such Committee's jurisdiction shall, at the election of either Party, be referred for resolution as follows: (i) disputes between the designees of Agensys and SGI on any Working Group shall be referred for resolution to the applicable Committee to which it reports, and (ii) disputes between the designees of Agensys and SGI on the JDC, JCC, JFC, JMAC and JCMC (including a dispute referred from a Working Group to the applicable Committee that is not resolved within

[*] after such referral) shall be referred, first, to the applicable functional leaders of each Party, and if the dispute is not resolved within **[*]** after such referral, to the JSC for resolution.

(c) Disputes at the JSC . Other than for disputes in the E&C Committee, which will be governed as set forth in subparagraph (d) below, any disputes or disagreement arising in the JSC as to matters within the JSC's jurisdiction or that are submitted to the JSC for attempted resolution that are unable to be resolved within **[*]** after the matter is first presented or referred to the JSC shall be referred to executive officers of each Party with subject matter expertise for the relevant dispute for resolution. If such executive officers are unable to resolve the matter within **[*]** after the matter is first referred to them, the matter shall be referred to the Chief Executive Officers of each Party for resolution. **[*]** .

(d) Disputes at the E&C Committee . In the event of any disagreement between the designees of Agensys and SGI on the E&C Committee as to matters within such Committee's jurisdiction shall be addressed, (i) first, by the applicable functional leaders and regional compliance officers of each Party, (ii) if the dispute is not resolved within **[*]** after such referral to the applicable functional leader (*e.g.* , chief compliance officer), then such dispute shall, at the election of either Party, be referred the president/region head of each Party of the country or jurisdiction to which such dispute relates, and (iii) **[*]** .

2.9.5 Meeting Agendas . Each Party will disclose to the other proposed agenda items along with appropriate information at least **[*]** in advance of each meeting of the JSC and at least **[*]** in advance of each meeting of any other applicable Committee or Working Group; *provided* , that under exigent circumstances requiring Committee or Working Group input, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as the representatives of such other Party on such Committee or Working Group consent to such later addition of such agenda items or the absence of a specific agenda for such Committee meeting or Working Group, which consent shall not be unreasonably withheld, conditioned, or delayed.

2.9.6 Party Tactical Matters . Party Tactical Matters shall be within the decision-making authority of (a) SGI in the SGI Royalty Territory and SGI Profit Share Territory, (b) Agensys in the Agensys Royalty Territory and Agensys Profit Share Territory, and (c) the Party to whom the applicable matters and functions are allocated by the applicable Approved Plans in the United States; *provided* that all such decisions shall be consistent with the terms of this Agreement, the scope of such allocation or delegation, Applicable Law, and the applicable Approved Plans. Subject to Section 2.1.3, Party Tactical Matters may be discussed by the applicable Committee(s); *provided* that Party Tactical Matters shall not be subject to Committee decision-making with respect to the Royalty Territory and Exclusive Profit Share Territory.

2.9.7 Exception for Urgent or Serious Safety Matter . Notwithstanding anything to the contrary in this Section 2.9, in the event of dispute at a Committee or otherwise between the Parties regarding an urgent or serious safety matter, including patient risk management and risk minimization events and safety issues that impact Product labeling, that a Party believes requires a determination on an expedited basis, then, either Party may require that the dispute be referred to their respective safety officers for the purpose of seeking to resolve the dispute on an expedited basis and within, where applicable, any timeframes required by Applicable Law. Such safety officers may designate an appropriate advisory group of each Party, as well as obtain any Third Party advice, to advise them on their decision. If such safety officers are not able to resolve the dispute on any action referred to them promptly and within, where applicable, any timeframes required by Applicable Law, the applicable Lead Regulatory Party shall have final decision-making authority with respect to such matter; *provided* that the escalation and process for dispute resolution shall be more fully set forth in the pharmacovigilance agreement described in Section 7.2.

2.10 Alliance Managers .

2.10.1 Each of the Parties shall appoint one representative who possesses a general understanding of Development, regulatory, medical affairs and Commercialization issues to act as its Alliance Manager (each, an " Alliance Manager "). The role of the Alliance Manager is to act as a single point of contact between the Parties to assure a successful Collaboration. The Alliance Managers (or their respective designees) may attend all meetings of any Committee and Working Group and support the co-chairpersons of each Committee in the discharge of their responsibilities. An Alliance Manager (or designee) may bring any matter to the attention of any Committee if such Alliance Manager (or designee) reasonably believes that such matter warrants such attention. In addition, Alliance Managers (or their respective designees) may attend any joint meetings of the Parties that are held outside of the Committees.

2.10.2 Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. An Alliance Manager may designate a substitute to temporarily perform the functions of such office upon written notice to the other Party's Alliance Manager.

2.11 Budgetary Matters in the Profit Share Territory .

2.11.1 Prior to each regular meeting of the JSC and not less than Quarterly, the JFC shall prepare an analysis of actual Allowable Expenses incurred, and Net Sales and Net Profit/Net Loss recorded by the Parties through the most recent practicable date, with respect to Allowable Expenses and Net Profit/Net Loss in relation to the amounts budgeted therefor in the Approved Plans applicable to the Profit Share Territory. The JFC shall determine the frequency and timing of projections for each category described in the previous sentence, with the goal of accommodating each Party's corporate financial process. Each Party shall provide to the JFC in a timely manner such information as the JFC may reasonably request for use in the preparation of such analysis and

which is in the possession of such Party. Each Party shall promptly notify the JFC in the event it anticipates any cost overrun with respect to Allowable Expenses in a given functional area (*i.e.* , Medical Affairs Activities or Commercialization activities) incurred or to be incurred by it with respect to any Year or any material variation in Net Sales amounts from the amounts projected in the Approved Plans. The JFC shall promptly review any actual or projected cost overrun that is reported to it and thereafter shall, in conjunction with the JSC, consider and recommend to the JSC for approval either (a) an appropriate variance to the applicable Approved Plans, which variance, if approved by the JSC, shall be considered a part of the Approved Plans or (b) such other amendments to the Approved Plans as may be necessary or appropriate to bring the operation of the Collaboration within the budgetary guidelines set forth in the Approved Plans; *provided* , that if such cost overrun **[*]** for a given **[*]** (*i.e.* , exceeds **[*]** for **[*]** or **[*]** for **[*]**) in a given Year the JFC and JSC may elect not to approve the variance or amend the applicable Approved Plan. The recommendations made to, and the actions taken by, the JSC pursuant to this Section 2.11 shall be consistent with Section 3.5, to the extent applicable.

2.11.2 In order to facilitate planning and budgetary control by the relevant Committees and by the Parties, each Party shall provide to the JFC and to the other Party not later than **[*]** prior to the end of **[*]** a projection (which shall represent its best good faith estimate) of the Allowable Expenses it expects to incur, and, with respect to SGI, the Net Sales it expects to record in such **[*]** and the remaining **[*]** of the budget period.

ARTICLE 3
COMMERCIALIZATION

3.1 Commercialization Generally . Subject to the terms and conditions of this Agreement, (a) the Parties shall jointly Promote and jointly Commercialize Product in the United States consistent with an annual Commercialization plan and budget for the United States (the " US Commercialization Plan "), (b) subject to Section 3.6, SGI shall have the sole right to Commercialize the Product in SGI Profit Share Territory or any portion thereof consistent with an annual Commercialization plan and budget for the SGI Profit Share Territory (the " SGI Profit Share Territory Commercialization Plan "), (c) subject to Section 3.6, Agensys shall have the sole right to Commercialize the Product in the Agensys Profit Share Territory or any portion thereof consistent with an annual Commercialization plan and budget for the Agensys Profit Share Territory (the " Agensys Profit Share Territory Commercialization Plan ") and (d) subject to Section 3.6, each Party shall have the sole right to Commercialize the Product in its Royalty Territory or any portion thereof consistent with an annual high-level Commercialization plan including a budget for Global Commercialization Costs (the " Global Commercialization Plan ").

3.2 Commercialization in the United States

3.2.1 US Commercialization Plan . Each US Commercialization Plan will describe the plan for Commercialization of the Product in the United States, specify in reasonable detail the Commercialization activities to be performed by each Party for the Product for a particular Year, and include a detailed budget for all such efforts. For clarity, the US Commercialization Plan shall not include any activities, responsibilities or budgetary items that are included in the other Commercialization Plans. The Parties shall jointly prepare each US Commercialization Plan through the US Commercialization Working Group. The Parties shall provide each US Commercialization Plan for review and comment to the JCC, which shall recommend such plans to the JSC for approval. The initial US Commercialization Plan shall be submitted to the JCC for review and approval at least **[*]** prior to the anticipated commencement of Commercialization activities in the United States, and thereafter each US Commercialization Plan shall be submitted to the JCC for review and approval by no later than **[*]** . Each US Commercialization Plan shall include the following with respect to the Product in the United States, as applicable:

(a) an executive summary;

(b) general strategies, consistent with JCC guidance, for the Promoting, Detailing and marketing of each indication for the Product and allocation of responsibilities for marketing activities in the United States, including **[*]** ;

(c) identification of individual accounts for Detailing in the United States, in accordance with Section 3.2.4;

(d) market research plans and market assessment,

(e) general plans for the marketing, promotion and sale of the Product to Managed Care Organizations, with appropriate input as to financial matters from the JFC;

(f) the nature of any other key promotional activities, if any, and any other information contemplated by Section 3.2.4;

(g) a market, unit sales, US Allowable Expenses, and Net Profit/Net Loss forecast; *provided* , *however* , that the Parties shall not be required to mutually agree to a Net Sales forecast or a Profit/Net Loss forecast (but shall cooperate as set forth in to Section 4.1.2(d));

(h) distribution and reimbursement strategy and associated tactics, and pricing and discounting policy for the United States consistent with JCC and US Pricing Working Group guidance;

(i) advertising, public relations and other promotional product support programs and activities, including speaker, peer-to-peer activity and promotional programs;

(j) the allocation of Commercialization activities between the Parties consistent with Article 3 and the Collaboration Agreement;

(k) free goods program plans, a vendor/Product returns policy, and patient assistance and indigent access programs;

(l) key performance indicators to monitor and assess Product performance, **[*]** ;

(m) general plans for field-facing activities, including a comprehensive joint call plan;

(n) advocacy/stakeholder engagement budgets; and

(o) other matters within the scope of the JCC involving a significant expenditure of funds or incurrence of expense, or a significant use of resources.

3.2.2 Joint Promotion of Product in the United States .

(a) All decisions with respect to all Commercialization matters for the Product in the United States (other than matters set forth in an Approved Plan, Party Tactical Matters, product distribution holds, recalls, withdrawals and other product quality decisions where the decision is to be made in accordance with the quality agreement agreed to by the Parties pursuant to Section 5.3 or 5.5) shall require the joint approval of the Parties, through Joint Committee Consent of the JCC.

(b) Following the recommendation by the JCC, the JSC may, from time to time, agree by Joint Committee Consent to revise the allocation of Commercialization responsibilities of a Product in the United States, including Promotion. Unless otherwise agreed by Joint Committee Consent or set forth in an approved US Commercialization Plan, responsibility for managing health systems accounts, including customer interactions, with respect to Product in the United States is allocated to the respective Party as follows:

1. Agensys: federal government accounts including **[*]** and other federal accounts; and
2. SGI: commercial accounts, including **[*]** .

For clarity, SGI, as the Selling Party in the United States shall remain responsible for executing contracts and booking sales of Product with respect to all health systems accounts in the United

States. In addition, the Parties will coordinate, as necessary, with respect to accounts (e.g., Humana) who provide coverage for both federal and private insurance.

3.2.3 Commercialization Diligence in the United States. Agensys and SGI each shall use Commercially Reasonable Efforts (a) to jointly Promote and otherwise perform the Commercialization activities assigned to it in respect of the Product in the United States in accordance with the then-Approved Plans (as the same may be amended in accordance with the terms hereof), and (b) to develop and agree on such plans and budgets. Once an Approved Plan has been adopted, each Party shall make and implement decisions, including with respect to Party Tactical Matters, and allocate resources designed to advance progress with respect to the objectives set forth in, and designed to ensure that it meets its obligations with respect to, such Approved Plans.

3.2.4 Sales Efforts and Sales Representative Deployment for the United States.

(a) No later than **[*]** prior to the anticipated Launch of the Product in the United States, the JCC (through the US Commercialization Working Group) will adopt by Joint Committee Consent a good faith rolling **[*]** forecast of the number of Sales Representatives required for Detailing for the accounts in the United States. Subject to reasonable and customary levels of vacant or unfilled positions, each Party will at all applicable times provide fifty percent (50%) of the required Sales Representatives. The JCC will identify the individual accounts in the United States and each Party will allocate a Sales Representative to each such individual account. The Sales Representatives and their respective managers will determine the account-specific tactics for Detailing such accounts and the Sales Representatives of each Party shall coordinate their activities with respect to the jointly serviced accounts. The JCC will review and adjust the Parties' allocation of activities periodically as determined by the Parties, to ensure that the required FTE resources are equivalent.

(b) From the date of the Launch of the Product, each Party's Sales Representatives conducting Detailing for Product in the United States shall not detail other products except in accordance with this Section 3.2.4(b). Following the **[*]** of Launch, if a Party desires to allow its Sales Representatives to detail another product in addition to the Product after the end of such **[*]** period, (i) such Party shall notify the other Party of such desire, (ii) upon receipt of such notice, the Parties, through the JCC, shall discuss in good faith the positioning of the Product and the other product based on the business circumstances and the competitive nature of the products, and (iii) subject to Joint Committee Consent of the JCC, the other Party's Sales Representatives may detail such other product in addition to the Product as authorized by such Joint Committee Consent (provided that in no case may such additional product be approved for the same indication(s) as the Product) and, if, as a result, the Detailing efforts for the Product by the Parties in the United States are no longer substantially equivalent, the Parties shall amend the definition of US Allowable Expenses (or its subcomponents) to account for such inequality.

(c) All Samples to be distributed in any Year, to the extent Samples are contemplated in the US Commercialization Plan, shall be allocated between the Parties equally. Each Party may determine the method by which it will distribute Samples (*e.g.* , Sample send or Sample carry), if and to the extent provided in the US Commercialization Plan.

(d) Within **[*]** , each Party shall report to the US Commercialization Working Group such information regarding the selling efforts provided by such Party for the Product in the United States as the US Commercialization Working Group or JCC may specify, in accordance with such guidelines as may be specified by the US Commercialization Working Group or JCC from time to time. Unless otherwise specified by the JCC, such internal reporting shall be determined in accordance with applicable self-reporting procedures customarily employed by such Party for other similarly sold and similarly reported pharmaceutical products to the target physician audience, consistently applied.

(e) For clarity, the costs of a Party's Sales Representatives in the United States shall not be taken into account for Commercialization Costs or US Allowable Expenses.

3.2.5 Sales Training for the United States .

(a) Each of Agensys and SGI shall comply with any training plan for a Product contained in the applicable US Commercialization Plan. The Parties (through the JCC) will jointly agree on common core objectives for Product-specific training materials. Prior to the submission of the BLA for a Product for an indication, the Parties (through the JCC) shall cooperate to develop a sales training plan and sales training materials for the Product for such indication that meet the same core objectives. Each Party may use such jointly developed materials and implement such sales training for its Sales Representatives in respect of the Product for such indication in a manner consistent with its customary procedures. Such training shall be updated from time to time, based on feedback from the FDA and approval of the ultimate label for the Product. Unless the JCC determines otherwise, each Party shall be responsible for providing its own Product-specific training to its Sales Representatives.

(b) The costs incurred by each Party with respect to training of its Sales Representatives shall be the sole responsibility of such Party and shall not be included in Commercialization Costs or Allowable Expenses.

3.2.6 Advertising and Promotional Materials and Promotional Policies for the United States .

(a) With respect to the United States, the Parties shall utilize only those Promotional, advertising, communication and educational tools and other materials relating to a Product to be used externally (" Promotional Materials "), and shall conduct only those

Promotional activities for the Product, that, in each case, have been included in the approved US Commercialization Plan or are otherwise approved by the JCC. The US Commercialization Working Group shall oversee development of all Promotional Materials and the core internal training and educational tools and material relating to the Product in the United States, which (in all cases) shall be consistent with the Approved Plans, and with the Product labeling approved by the FDA. All other internal training and educational tools and materials directly related to the Product and all Promotional Materials shall be subject to the prior review and approval of the US Commercialization Working Group; provided that the US Commercialization Working Group will endeavor to delegate such review to a joint team comprising members from each Party's internal promotional materials review team. The US Commercialization Working Group shall jointly review such materials prior to the use by either Party and the US Commercialization Working Group shall develop a process for such joint review and approval; *provided,* that the content of such Promotional Materials and such internal educational tools and materials, once approved by the process determined by the US Commercialization Working Group, need not be re-submitted for approval within **[*]** (or such shorter period designated by the US Commercialization Working Group) of its initial approval unless the nature of the Promotional Materials or internal educational tools or materials require more frequent review or approval or Product labeling in the Regulatory Approval applicable to such Promotional Materials and such internal educational tools and materials has been changed. For clarity, a Party's internal disease state education tools and materials (including, for example, preceptor programs and key opinion leader (KOL) presentations) outside the core training modules and general human resources and sales training materials are not subject to joint review under this Section 3.2.6(a).

(b) Both Parties will be identified and described as jointly Promoting the Product in the United States, and all materials and other Commercialization activities, including Samples (if applicable), oral presentations, direct-to-consumer advertising, patient information materials and patient benefit programs, that identify a Party shall identify both Parties as jointly promoting the Product and shall display the Astellas and SGI Corporate Names with equal prominence, in each case to the extent permitted by Applicable Law.

3.2.7 Title to Product; Invoicing; Booking of Sales in the United States . In the United States, SGI as the Selling Party, (a) will hold title to the Product inventories until sale to customers, and (b) shall effect all sales of Product and shall be responsible for invoicing all sales of Product and shall book all sales of Product for its own account. Agensys may not accept orders for Product in the United States or make sales for its own account or for SGI's account, and if Agensys receives any orders for Product for the United States, it shall refer such orders to SGI for acceptance or rejection. Prior to entering into any Product sales contracts for the United States, SGI shall submit such contract (and a summary of pricing-related terms) to the US Pricing Working Group for review and approval.

3.2.8 Packaging and Labeling, and Sales and Distribution in the United States . SGI, as the Selling Party, shall be responsible for all Packaging and Labeling, and all Sales and Distribution activities, for the Product in the United States. For clarity, as set forth in Section 3.12.2, if SGI wishes to subcontract such activities to a Third Party, any subcontractor that is not an Approved Subcontractor must be approved in the applicable US Commercialization Plan or otherwise approved by the JSC. The Parties will cooperate in good faith as necessary for SGI to perform such Sales and Distribution activities. SGI shall provide or make available to Agensys all data collected by SGI or its Affiliates in connection with their Sales and Distribution activities (including customer demographic information) in the United States. For clarity, customers include specialty distributors, specialty pharmacies, health care professionals, accounts, group purchasing organizations, integrated healthcare network, payer utilization data, and other customers of Product. SGI shall provide or make available such data to Agensys no later than **[*]** . SGI will provide such data to **[*]** for which it is available, *e.g.* , **[*]** at the **[*]** , data **[*]** , and data **[*]** .

3.2.9 Incentive Plans for Sales Representatives . Each Party shall establish and implement a target bonus or sales incentive program whereunder such Party's Sales Representatives in the United States are compensated for their actual performance results with respect to Product in a manner consistent with such Party's other programs. All such programs shall be in compliance with all Applicable Laws. For clarity, the costs of such incentive programs shall not be included in Allowable Expenses hereunder.

3.3 Commercialization in Royalty Territories .

3.3.1 Global Commercialization Plan .

(a) The Global Commercialization Plan for the Product shall set forth (i) the anticipated performance obligations and funding requirements for the Commercialization of the Product throughout the Territory, (ii) a high-level Commercialization strategy, resourcing plans and major regional strategies, (iii) recommended **[*]** , **[*]** and **[*]** for the Product, and (iv) budget for Global Commercialization Costs. For clarity, the Global Commercialization Plan shall not include any activities, responsibilities or budgetary items that are included in the other Commercialization Plans.

(b) The Global Commercialization Plan shall be used to guide the applicable Committees in formulating each US Commercialization Plan and shall represent a good faith estimate of each Party's anticipated long-term Commercialization commitments for the Territory.

(c) The Parties shall jointly prepare each Global Commercialization Plan. The Parties shall provide each such Global Commercialization Plan for review and comment to the JCC, which shall recommend such Global Commercialization Plan to the JSC

for approval. The Global Commercialization Plan shall be updated at least annually, and submitted to the JSC for review and approval by no later than **[*]** . The initial Global Commercialization Plan shall be submitted to the JCC for review and approval within **[*]** after the Effective Date, and subsequently shall be submitted to the JSC for review and approval by no later than **[*]** .

3.3.2 Royalty Territory . Subject to Section 3.6, each Party (itself or through its Affiliates or (sub)licensees as otherwise permitted herein) shall have the sole right to Commercialize the Product in its Royalty Territory or any portion thereof, and shall have the sole decision making authority with respect to such Commercialization activities; *provided* that such activities shall be consistent with the Global Commercialization Plan. Each Party shall be solely responsible for all costs and expenses incurred by or on behalf of such Party for Commercializing the Product in its Royalty Territory or any portion thereof (other than Global Commercialization Costs).

3.3.3 Commercialization Diligence in Royalty Territory . Each Party shall use Commercially Reasonable Efforts to Commercialize the Product in its Royalty Territory in accordance with and to the extent provided in the Global Commercialization Plan.

3.3.4 Sales Efforts Reporting for the Royalty Territory . **[*]** each Party shall provide a high-level report to the JCC summarizing its selling efforts for the Product in its Royalty Territory.

3.3.5 Packaging and Labeling; Booking of Sales; Distribution in Royalty Territory . In its Royalty Territory, the Selling Party (a) will hold title to the Product inventories until sale to customers, (b) shall effect all sales of Product and shall be responsible for invoicing all sales of Product and shall book all sales of Product for its own account, and (c) shall be responsible for all Packaging and Labeling and Sales and Distribution of the Product, in each case in its Royalty Territory.

3.4 Commercialization in the Exclusive Profit Share Territory

3.4.1 Exclusive Profit Share Territory Commercialization Plan . The Agensys Profit Share Territory Commercialization Plan and SGI Profit Share Territory Commercialization Plan will describe the plan for Commercialization of the Product in the applicable Exclusive Profit Share Territory, specify in reasonable detail the Commercialization activities to be performed by or on behalf of the applicable Party for the Product for a particular Year, and a budget for all such efforts in the Exclusive Profit Share Territory. For clarity, each Exclusive Profit Share Territory Commercialization Plan shall not include any activities, responsibilities or budgetary items that are included in the other Commercialization Plans. Agensys shall prepare the Agensys Profit Share Territory Commercialization Plan and SGI shall prepare the SGI Profit Share Territory Commercialization Plan. The Parties shall provide each such plan for review and comment to the JCC, which shall recommend such plans and budgets to the JSC for approval. The initial draft of

each such plan shall be submitted to the JCC for review and approval at least **[*]** prior to the anticipated Launch in the applicable Exclusive Profit Share Territory, and thereafter each such plan shall be submitted to the JCC for review and approval by no later than **[*]** . Each such plan shall include with respect to the Product and the applicable Exclusive Profit Share Territory, as applicable:

(a) executive summary;

(b) an overview of strategies, consistent with JCC guidance, for the promoting, Detailing and marketing of each indication for the Product in the Agensys Profit Share Territory and SGI Profit Share Territory (as applicable), **[*]** ;

(c) an overview of plans for the deployment of Sales Representatives by geography and target audience;

(d) an overview of (i) market research plans and market assessment and (ii) general plans for the marketing, promotion and sale of the Product, with appropriate input as to financial matters from the JFC;

(e) an overview the nature of any other key promotional activities, if any;

(f) a market, unit sales, and Net Sales forecast; *provided* , *however* , that the Parties shall not be required to mutually agree to a Net Sales forecast or a Profit/Net Loss forecast (but shall cooperate as set forth in to Section 4.1.2(d));

(g) pricing and discounting strategy for the applicable Exclusive Profit Share Territory consistent with JCC guidance, subject to Section 2.3.2(c);

(h) advertising, public relations and other promotional product support programs and activities, including speaker, peer-to-peer activity and promotional programs;

(i) an overview of free goods program plans, a vendor/Product returns policy, and patient assistance and indigent access programs;

(j) key performance indicators to monitor and assess Product performance, **[*]** ; and

(k) an overview of plans for field-facing activities, including prioritizing targets, promotional efforts and spend.

3.4.2 Promotion of Product in the Exclusive Profit Share Territory . Subject to the terms and conditions of this Agreement (including the Global Commercialization Plan, the Agensys Profit Share Territory Commercialization Plan, and Section 3.6), Agensys shall have the sole right

to Commercialize the Product in the Agensys Profit Share Territory or any portion thereof. Subject to the terms and conditions of this Agreement (including the Global Commercialization Plan the SGI Profit Share Territory Commercialization Plan and Section 3.6), SGI shall have the sole right to Commercialize the Product in the SGI Profit Share Territory or any portion thereof.

3.4.3 Commercialization Diligence in the Exclusive Profit Share Territory . Each Party shall use Commercially Reasonable Efforts to Commercialize the Product in its Exclusive Profit Share Territory in accordance with the then-Approved Plans (as the same may be amended in accordance with the terms hereof). Once the Agensys Profit Share Territory Commercialization Plan and SGI Profit Share Territory Commercialization Plan has been adopted, each of Agensys and SGI shall make and implement decisions and allocate resources designed to advance progress with respect to the objectives set forth in, and designed to ensure that it meets its obligations with respect to, the applicable Commercialization Plan.

3.4.4 Sales Efforts Reporting for Exclusive Profit Share Territory . Within **[*]** after the end of each **[*]** , each Party shall provide a high-level report to the JCC summarizing its selling efforts for the Product in its Exclusive Profit Share Territory, including total headcount, product share, and observed sales trends, and otherwise in accordance with such guidelines as may be specified by the JCC from time to time. Unless otherwise specified by the JCC, such internal reporting shall be determined in accordance with applicable self-reporting procedures customarily employed by such Party for other similarly Detailed and similarly reported pharmaceutical products to the target physician audience, consistently applied.

3.4.5 Packaging and Labeling; Booking of Sales; Distribution in Exclusive Profit Share Territory . In its Exclusive Profit Share Territory, the Selling Party (a) will hold title to the Product inventories until sale to customers, (b) shall effect all sales of Product and shall be responsible for invoicing all sales of Product and shall book all sales of Product for its own account, and (c) shall be responsible for all Packaging and Labeling and Sales and Distribution activities for the Product in its Exclusive Profit Share Territory.

3.5 Cost Overruns with Respect to Allowable Expenses . If the total Allowable Expenses incurred by a Party during a given Year in performing the responsibilities assigned to it for a given **[*]** (*i.e.* , **[*]** or **[*]**) under the applicable Approved Plan (as amended in accordance with Section 2.11.1) in the Profit Share Territory (or, in the case of Global Commercialization Costs or Global Medical Affairs Costs, globally) exceed those set forth in the budget allocable to such Party's responsibilities for such **[*]** during such Year, then (a) the Parties (through the JFC and JCC) shall address such overrun as provided in Section 2.11, and (b) unless otherwise agreed by Party Written Consent or Joint Committee Consent of the JSC, each Party shall continue to bear its share of the Allowable Expenses in excess of such budget (" Excess Allowable Expenses ") in the proportions set forth in Section 4.1.1, **[*]** to the extent such Excess Allowable Expenses are Negligently Incurred

Commercialization Costs (as defined below), **[*]** . As used herein, " Negligently Incurred Commercialization Costs " means with respect to all Commercialization activities or all Medical Affairs Activities **[*]** , as applicable, any portion of Excess Allowable Expenses in respect of such **[*]** or **[*]** , as applicable, that (i) exceeds **[*]** in a given Year for such **[*]** (*i.e.* , exceeds **[*]** for **[*]** or **[*]** for **[*]** and (ii) is not approved by the JSC or included in an amendment to the applicable Approved Plan. For the sake of clarity, **[*]** . The Parties shall use Commercially Reasonable Efforts, as appropriate, to mitigate any cost overrun. **[*]** .

3.6 Promotion Step-In Right . If the Selling Party in a given country in the Royalty Territory or Exclusive Profit Share Territory does not plan to **[*]** , or plans to **[*]** and **[*]** in such country, the Selling Party shall provide prompt written notice of such intention to the other Party and the other Party may provide written notice to the Selling Party that it wishes to take over Promotion responsibility for Product for such country unless Promotion in such country would adversely impact the Product in other countries in the Selling Party's Royalty Territory or Exclusive Profit Share Territory. Upon the Selling Party's receipt of such notice, the Parties shall negotiate and seek to agree in good faith on a definitive agreement establishing the terms and conditions for the other Party to Promote the Product and conduct Medical Affairs Activities in such country (a " Promotion Agreement ") with the goal of executing and delivering such Promotion Agreement within **[*]** days from the date of the other Party's notice. The Promotion Agreement shall establish commercially reasonable terms and conditions for the other Party's Promotion of Product and Medical Affairs Activities in the applicable country, including, solely if such country is in the Royalty Territory, and a mechanism for compensating such Party for its activities. If such country is in an Exclusive Profit Share Territory, all Promotion activities for such country by the other Party shall be subject to the applicable Commercialization Plan. If such country is in the Royalty Territory, all Promotion activities for such country by the other Party shall be subject to the Global Commercialization Plan but shall otherwise be subject to the Selling Party's final decision-making authority as set forth in this Agreement. The other Party acknowledges that, unless otherwise agreed by Party Written Consent or in a Promotion Agreement, the Selling Party will continue to have the sole right to conduct Commercialization activities other than Promotion activities and Medical Affairs Activities (*e.g.* , Sales and Distribution activities) for such country.

3.7 Responsibility for Acts and Omission of Personnel . Each Party shall be solely responsible for: (a) the acts and omissions of its Sales Representatives and other personnel while performing any of the activities to be performed under this Agreement and (b) all disciplinary, probationary and termination actions taken by it, as well as for the formulation, content, and for the dissemination (including content) of all human resources policies and rules (including written disciplinary, probationary and termination policies) applicable to any members of its personnel. Each Party shall comply with all Applicable Laws in the hiring, employment, and discharge of all members of its personnel.

3.8 Non-Compliance by Field Force . In the event that a Party **[*]** , then such Party shall **[*]** . The Party **[*]** shall **[*]** ; *provided* that a Party shall not **[*]** . For clarity, the foregoing shall not limit any rights or remedies of a Party hereunder.

3.9 No Participation in Benefit Plans; Other Matters . Each Party acknowledges and agrees that the members of its field force (including its Sales Representatives) are not, and are not intended to be or be treated as, employees of the other Party or any of its Affiliates, and that such individuals are not, and are not intended to be, eligible to participate in any benefits programs or in any "employee benefit plans", as such term is defined in Section 3(3) of ERISA, that are sponsored by the other Party or any of its Affiliates or that are offered from time to time by the other Party or its Affiliates to their own employees (each, a " Benefit Plan "). Subject to Section 3.2.9, all matters of compensation, benefits and other terms of employment for any such personnel shall be solely a matter between such Party and such individual. Each Party shall be solely responsible and liable for the payment of all compensation and benefits under any such employee benefit plan to any members of its field force, and each Party acknowledges and agrees that Party does not and will not maintain or procure any worker's compensation, healthcare, or other insurance for or on behalf of the other Party or its personnel, all of which shall be the sole responsibility of the Party to which such person is employed. Without limiting the foregoing, a Party shall not be responsible to the other Party, or to any members of the such other Party's field force (or any other personnel), for any compensation, expense reimbursements other than for expenses incurred in accordance with an Approved Plan (*e.g.* , related to a Promotional program) or benefits (including vacation and holiday remuneration, healthcare coverage or insurance, life insurance, severance or termination of employment benefits, pension or profit-sharing benefits and disability benefits), payroll-related taxes or withholdings, or any governmental charges or benefits (including unemployment and disability insurance contributions or benefits and workmen's compensation contributions or benefits) that may be imposed upon or be related to the performance by such other Party or such individuals of this Agreement, all of which shall be the sole responsibility of the Party to which such person is employed, even if it is subsequently determined by any court or Governmental Authority that any such individual may be an employee or a common law employee of the other Party or any of its Affiliates or is otherwise entitled to such payments and benefits.

3.10 Recalls and Withdrawals . The initiation and implementation of a product distribution hold, recall or clinical hold or market withdrawal of a Product from the market in the Territory will be determined in accordance with the quality agreement (including the process for consultation and, if possible, reaching consensus set forth therein); *provided* that the applicable Lead Regulatory Party shall have the final decision with respect to initiating a recall in a particular country if there is a dispute between the Parties. The costs of implementing any distribution hold, recall or withdrawal in accordance with this Section 3.10 relating to Commercialization activities or Medical Affairs Activities (a) in the Profit Share Territory shall be an Exclusive Profit Share Territory Commercialization Cost and (b) in the Royalty Territory shall be a Global Commercialization Cost,

except (in each case) to the extent that the distribution hold, recall or withdrawal is attributable to (i) the breach of this Agreement by a Party, or (ii) the gross negligence or willful misconduct of a Party or its Affiliates, in which event (A) such Party shall bear such costs to the extent it is responsible, and (B) such costs shall not be included in Commercialization Costs (if applicable), as the case may be.

3.11 Development Activities. For clarity, (a) any additional development activities conducted for Product (including CMC Development activities and any Required Phase IV Studies) shall be governed by the terms of this Section 3.11, the Collaboration Agreement and the Global Development Plan, and (b) for purposes of this Agreement and the Collaboration Agreement, Development Costs include costs of developing and conducting Required Phase IV Studies (calculated in accordance with the Collaboration Agreement) and CMC Development Costs, and all Development Costs (as defined herein) shall be deemed Development Costs (as defined in the Collaboration Agreement) under the Collaboration Agreement and shared in accordance with the Collaboration Agreement. Promptly after the Effective Date, the Parties shall amend the Collaboration Agreement to provide that treatment of Development Costs in excess of the budget for a given Year will be handled in a manner comparable to Section 3.5.

3.12 Sublicensing and Subcontracting of Commercialization Activities.

3.12.1 Sublicensing. Each Party may sublicense its Commercialization rights and obligations under this Agreement to any Third Party pursuant to the terms of Section 10.3 of the Collaboration Agreement; *provided* that any such sublicensing in connection with subcontracts for a Party's Royalty Territory or Exclusive Profit Share Territory under Section 3.12.2 entered into in the ordinary course shall be considered Approved Subcontractors for purposes of Section 10.3 or Section 10.7 of the Collaboration Agreement (and, accordingly, are not subject to any consent obligations thereunder); *provided further* that the Parties agree to share equally in the value of any consideration received under a sublicense granted to a Third Party (including any upfront or milestone payments, equity investments or reimbursement of expenses, but excluding any amounts that are included in Net Sales for the purposes of calculating royalties hereunder).

3.12.2 Subcontracting. Each Party may subcontract its Commercialization activities for Product in the United States to Approved Subcontractors or other Third Parties in accordance with the applicable US Commercialization Plan or as otherwise approved by the JSC. In addition, each Party may, in its discretion, subcontract Commercialization activities in its Royalty Territory or its Exclusive Profit Share Territory (or any portion thereof) to Third Parties; *provided* that such Party shall promptly inform the other Party of such subcontracting (including the identity of the subcontractor and a summary of the subcontracted activities). If either Party performs one or more of its Commercialization activities hereunder through any subcontractor, (i) none of the rights of the other Party hereunder are diminished or are otherwise adversely affected as a result of such

subcontracting, (ii) each subcontractor shall undertake in writing all obligations of confidentiality and non-use regarding each Party's Confidential Information which are substantially the same as those undertaken by the Parties hereunder, and (iii) the subcontracting Party shall be responsible for the performance of any subcontractors hereunder, and shall cause them to comply with the applicable terms of this Agreement. For clarity, any arrangements with shipping and transportation companies such as the United Parcel Service or FedEx shall be excluded from any notice requirements under this Section 3.12.2.

ARTICLE 4
FINANCIAL TERMS

The Parties shall make the payments provided for in this ARTICLE 4. For clarity, this ARTICLE 4 supersedes the following Sections of the Collaboration Agreement with respect to Product for activities after the Effective Date: Sections 12.3, 12.4, 12.5, and 12.6 (with respect to commercialization expenses). For clarity, **[*]** .

4.1 Sharing of Commercialization Expenses; Profit Sharing in the Profit Share Territory . Prior to the Effective Date, any Allowable Expenses incurred by a Party shall be shared equally and reimbursement thereof shall be made in accordance with the Collaboration Agreement. Following the Effective Date, the terms and conditions of this Section 4.1 shall govern the rights and obligations of Agensys and SGI with respect to Net Profit and Net Loss relating to the Product. For clarity, a Party shall not have the right to share Net Profits, and no obligation to bear any Allowable Expenses (other than Global Allowable Expenses and Allowable Expenses incurred prior to the Effective Date as set forth above), with respect to the Product in the other Party's Royalty Territory. Instead, a Party shall be entitled to the royalties set forth in Section 4.2 with respect to Net Sales of Product in the other Party's Royalty Territory.

4.1.1 Share of Net Profits and Net Losses . Subject to the terms of this Agreement and Section 5.9.1 of the Collaboration Agreement, for so long as Product is being sold in the Profit Share Territory, Agensys and SGI shall share all Net Profits and Net Losses (as applicable) for the Product on the basis of fifty percent (50%) to SGI and fifty percent (50%) to Agensys.

4.1.2 Calculation and Payment .

(a) Within **[*]** after the end of each **[*]** beginning with the first **[*]** in which Allowable Expenses are incurred, each Party shall report to the JFC its Net Sales in the Profit Share Territory and its Allowable Expenses. Each such report shall, as applicable, specify in reasonable detail all deductions allowed in the calculation of such Net Sales and all expenses included in Allowable Expenses, and, if requested by Agensys or SGI, any invoices or other supporting documentation for any payments to a Third Party that individually exceed **[*]** Dollars ($ **[*]**) or with respect to which documentation is otherwise reasonably requested shall be

promptly provided. In addition, each such report shall specify the following: **[*]** . Within **[*]** after receipt of such reports, the JFC shall confer and agree upon in writing a consolidated financial statement setting forth the Net Profit or Net Loss for such Quarter for the Product in the Profit Share Territory and calculating each Party's share of such Net Profits or Net Loss.

(b) Within **[*]** after the Parties (through the JFC) have reconciled the reports delivered under Section 4.1.2(a) for each **[*]** , the Party who will receive payment shall issue to the other Party an invoice for the agreed amount and the other Party shall, within **[*]** of such invoice, make a payment to SGI or Agensys, as applicable, so that each of Agensys and SGI has been compensated for its respective share of such Net Profits, or has borne its respective share of such Net Loss, as applicable, after giving effect to the (i) Net Sales invoiced and Allowable Expenses incurred by SGI, and (ii) Net Sales invoiced and Allowable Expenses incurred by Agensys; *provided* , *however* , that in the event of any disagreement with respect to the calculation of such payment, any undisputed portion of such payment shall be paid in accordance with the foregoing timetable and the remaining, disputed portion shall be paid within **[*]** after the date on which Agensys and SGI, using good faith efforts, resolve the dispute.

(c) In addition, for planning purposes, (i) with respect to the SGI Exclusive Profit Share Territory, SGI shall report to Agensys within **[*]** after **[*]** its actual Net Sales (including the amount of gross sales of Product by SKU of Product); (ii) with respect to the United States, (A) Agensys and SGI shall report to the JFC, (1) within **[*]** after **[*]** its estimated Allowable Expenses **[*]** and (2) **[*]** prior to the end of each Quarter, its estimated Allowable Expenses for such Quarter and (B) SGI shall report to the JFC (x) **[*]** , the gross sales of Product and (y) within **[*]** after **[*]** Launch, an estimate of its Net Sales **[*]** ; and (iii) with respect to the Agensys Exclusive Profit Share Territory, Agensys shall provide to SGI within **[*]** after **[*]** Launch its actual Net Sales **[*]** (including the amount of gross sales of Product by SKU of Product) and estimated Allowable Expenses. Further, each Party shall consider in good faith other reasonable procedures proposed by the other Party for sharing financial information in order to permit each Party to close its books periodically in a timely manner.

(d) If either Party **[*]** , the Parties agree to **[*]** ; *provided* that if the Parties **[*]** .

(e) For the avoidance of doubt, no cost or expense shall be counted more than once in calculating Allowable Expenses, even if such costs or expense falls into more than one of the cost categories that comprise Allowable Expenses. For purposes of determining Allowable Expenses and Net Profit or Net Loss, neither Party shall be required to record the actual FTE hours worked and all such allowed FTE expenses shall be charged based on percentage of time allocated to the Product and activities under this Agreement. Out-of-pocket costs will be charged based on actual expenses incurred or accrued. Each Party shall calculate, and maintain

records of, out-of-pocket Allowable Expenses incurred by it in the same manner as used by it for other products which it has developed.

4.1.3 Consistency with Accounting Treatment . All calculations of Net Profit and Net Loss hereunder shall be made in accordance with Collaboration Accounting Standards, including the provisions thereof regarding expense recognition, as applied by Agensys and SGI consistently with their application in their respective external financial reporting,

4.2 Royalty Territory Royalties .

4.2.1 Royalties .

(a) Subject to the terms of this Section 4.2, Agensys shall pay to SGI royalties calculated by multiplying the applicable royalty rate set forth in Schedule 4.2.1 by the aggregate Net Sales of the Product by Agensys' Related Parties in the Agensys Royalty Territory. Subject to the terms of this Section 4.2, SGI shall pay to Agensys royalties calculated by multiplying the applicable royalty rate set forth in Schedule 4.2.1 by the aggregate Net Sales of the Product by SGI's Related Parties in the SGI Royalty Territory.

(b) The Parties acknowledge and agree that the royalty payments set forth in this Section 4.2 are intended to approximate an equal split of net profit/net loss in the Royalty Territory over the duration of the Royalty Term **[*]** . The Parties acknowledge and agree that **[*]** . Consequently, if **[*]** , then the Parties, through the **[*]** ; *provided* that **[*]** and **[*]** . In **[*]** , the **[*]** shall: **[*]** . If, based on the foregoing, the **[*]** determines that **[*]** . If the **[*]** then, upon **[*]** shall be **[*]** . For clarity, any amendment **[*]** . Any dispute regarding a royalty rate determination or amendment to Schedule 4.2.1 under this Section 4.2.1(b) will be resolved by the Parties in accordance with Section 2.9.4 or by the arbitrator in accordance with Section 23.4 of the Collaboration Agreement, in each case taking into account the determination criteria set forth in this Section 4.2.1(b).

4.2.2 Royalty Term . Each Party's obligation to pay royalties under this Section 4.2 with respect to the Product in each country in such Party's Royalty Territory will commence upon **[*]** and will continue **[*]** (such period, the " Royalty Term ").

4.2.3 Reductions .

(a) If there is a Biosimilar Product(s) in a given country in the Royalty Territory and, as a result, the royalties payable with respect to Net Sales of the corresponding Product pursuant to Section 4.2.1 in such country no longer approximate an equal sharing of profits for such Product in such country, the JFC shall evaluate the impact of such Biosimilar Product(s) and propose to the JCC for its review and approval reduced royalty rates for such Product in such country that approximate an equal sharing of profits for such Product. Upon

Joint Committee Consent of the JCC, such reduced royalty rates shall apply with respect to such Product in such country as determined by the JCC.

(b) Each Party shall be entitled to deduct from any royalties payable hereunder with respect to a country in its Royalty Territory **[*]** of (i) the Payments to Third Parties and (ii) the payments under the **[*]** Agreement that are required to be shared pursuant to Section 4.5.4 of the Collaboration Agreement, in each case (clauses (i) and (ii)) made for or reasonably allocable to the grant of a license for Commercialization of the Product in such country.

4.2.4 Royalty Payments and Reports . Within (a) **[*]** after the end of **[*]** during which royalties are due (other than **[*]**) and (b) **[*]** after the end of **[*]** during which royalties are due, each Party shall deliver to the other Party a report including estimates of gross sales of Product, Net Sales and royalties payable, in each case in such Party's Royalty Territory during **[*]** . All royalty amounts payable to a Party pursuant to this Section 4.2 shall be paid in U.S. dollars within **[*]** days after **[*]** with respect to Net Sales **[*]** . Each payment of royalties due to a Party shall be accompanied by a final statement, **[*]** , of the amount of gross sales of Product in such Party's Royalty Territory **[*]** , a calculation of Net Sales in such Royalty Territory showing with reasonable specificity the aggregate deductions from gross sales provided for in the definition of Net Sales **[*]** , and a calculation of the amount of royalty payment due on such sales **[*]** .

4.3 Taxes .

4.3.1 Taxes on Income . Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the Collaboration under this Agreement.

4.3.2 Tax Cooperation . The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of royalties and other payments made by one Party to the other under this Agreement. Without limiting the generality of the foregoing, each Party shall provide the other any tax forms and other information that may be reasonably necessary in order not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide any such tax forms to the other at least thirty (30) days prior to the due date for any payment for which one Party desires that the other Party apply a reduced withholding rate. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, Indirect Taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax. For clarity, if such withholding taxes, Indirect Taxes, or similar obligations have been shared equally by the Parties as an Allowable Expense, the Parties shall share equally in the amount of such recovery.

4.3.3 Payment of Tax . To the extent a Party is required by Applicable Law to deduct and withhold taxes on any payment to the other Party, such Party shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the other an official tax certificate or other evidence of such withholding sufficient to enable the payee to claim such payment of taxes.

4.4 Currency . All payments hereunder will be in Dollars in immediately available funds and will be made by wire transfer from a United States bank located in the United States to such bank account as payee may designate in writing from time to time.

4.5 Foreign Exchange . The amounts accruing in a currency other than United States dollars will be converted to United States dollars using an exchange rate equal to the arithmetic average of the U.S. daily closing rates published by Reuters during the applicable Quarter for which payments are being made. The conversion calculations will be provided in any statement reporting converted amounts.

4.6 Late Payments . Any payments or portions thereof due hereunder which are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of (a) the prime rate as published in The Wall Street Journal, Eastern Edition, under the heading "Money Rates," on the first date of each Quarter in which such payments are overdue, plus **[*]** percentage points or (b) the maximum rate permitted by Applicable Law, calculated on the number of days such payment is delinquent, compounded **[*]** using a three hundred sixty-five (365)-day year.

4.7 Financial Records; Audits . Each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of any calculations by the other Party or any payments due by the other Party under this Agreement, including (a) amounts to be reimbursed, pursuant to this Article 4.7, with respect to Allowable Expenses or other amounts to be reimbursed or shared hereunder incurred or generated (as applicable) by such Party, (b) Net Sales, (c) royalty payments for purposes of determining any under or over payment of the royalties, (d) **[*]** , (e) amounts payable under any supply agreement, and (f) other compensation or reimbursement payable under this Agreement. Upon reasonable prior notice, such records for any Year(s) ending not more than **[*]** prior to the date of such request shall be open during regular business hours for examination at the auditing Party's expense, and not more often than once each **[*]** period, by an independent certified public accountant selected by the auditing Party and reasonably acceptable to the audited Party for the sole purpose of verifying for the auditing Party the accuracy of the financial statements or reports furnished by the audited Party pursuant to this Agreement or of any payments made, or required to be made, by or to the audited Party to the other pursuant to this Agreement. **[*]** . Any such auditor shall not disclose the audited Party's information to the auditing Party, except to the extent such disclosure is necessary to verify the accuracy of the

financial reports furnished by the audited Party or the amount of payments due by the audited Party under this Agreement. Any amounts shown to be owed but unpaid, or overpaid and in need of reimbursement, shall be paid or refunded (as the case may be) within **[*]** after the accountant's report, unless such report is challenged in good faith by the audited Party, in which case any undisputed portion shall be paid within **[*]** days after the accountant's report and any remaining disputed portion shall be paid within **[*]** days after resolution of the dispute, and interest shall not accrue with respect to the disputed portion during the period of time the dispute is being resolved. The auditing Party shall bear the full cost of such audit unless such audit reveals an overpayment to, or an underpayment by, the audited Party that resulted from a discrepancy in a report that the audited Party provided to the other Party during the applicable audit period, which underpayment or overpayment was more than **[*]** percent (**[*]** %) of the amount set forth in such report, in which case the audited Party shall bear the full cost of such audit.

4.8 Manner and Place of Payment . All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Agensys or SGI (as applicable), unless otherwise specified in writing by such Party. Neither Party shall have the right to offset any payment that is owed by the other Party but not paid against any payments owed by such Party, if any, under this Agreement.

ARTICLE 5
MANUFACTURE AND SUPPLY

5.1 Overview . The provisions of this ARTICLE 5 shall apply to the Manufacture of the Product unless otherwise agreed by Party Written Consent.

5.2 Manufacturing for Development . For clarity, the Manufacture of the Product (a) prior to the first Regulatory Approval (except for any Product Manufactured prior to the first Regulatory Approval that is subsequently sold commercially) or (b) otherwise for use in Clinical Trials other than Voluntary Phase IV Studies shall be (i) deemed Development hereunder, albeit subject to the oversight of the JCMC and (ii) Manufactured and supplied pursuant to the Clinical Supply Agreement or an appropriate amendment thereto. The costs incurred for Manufacturing such Product will be shared as Development Costs in accordance with the Collaboration Agreement.

5.3 Supply and Quality Agreements . Subject to the oversight of the JCMC as described in Section 2.5, Agensys or its Affiliates shall Manufacture and supply the initial requirements for the Product (in unpackaged, unlabeled form) in accordance with the terms hereof (and the supply and quality agreements contemplated by this Section 5.3) for Commercialization worldwide by each Party, and the Selling Party shall perform Packaging and Labeling and Sales and Distribution for such Product. Within **[*]** days after the Effective Date, the Parties shall negotiate and enter into a supply agreement and a quality agreement consistent with this Agreement setting forth the terms and conditions of such supply for the United States, the SGI Profit Share Territory and the

SGI Royalty Territory and, in the case of the quality agreement, quality-related matters globally. Such agreements shall reflect customary terms and conditions for the supply and quality of pharmaceutical products in the context of a profit sharing arrangement, including with respect to forecasting and ordering, payment terms, the calculation and reconciliation of Standard Cost, financial and compliance audits, the engagement of subcontractors, a fair and equitable allocation of Product between the Parties and their Affiliates in the event of any defects or Product shortfalls, and representations and warranties; provided that the Parties agree that the indemnification and limitation of liability provisions of ARTICLE 13 will apply to any and all Manufacturing Losses including those relating to such agreements. Such quality agreement shall govern product distribution holds, recalls, clinical holds, or market withdrawals (as set forth in Section 3.10) and any other quality control and quality assurance-related activities agreed between the Parties. The supply agreement will set forth the details of financial transaction to support the supply of Product with cost sharing consistent with this Agreement..

5.4 Global Manufacturing Plan . The JCMC shall prepare and submit to the JSC, for its approval, a proposed global manufacturing plan for the Product designed to provide reasonable assurance that the Parties are able to satisfy the forecasted demand for clinical and commercial quantities (including Samples, to the extent provided in the Global Commercialization Plan, Agensys Profit Share Territory Commercialization Plan, SGI Profit Share Territory Commercialization Plan, and US Commercialization Plan) of the Product (a " Global Manufacturing Plan "). Such Global Manufacturing Plan shall include (a) a plan for producing Launch quantities for the finished Product, (b) a plan for CMC Development, risk management and other related activities, (c) a Supply Chain Management plan, and (d) any activities related to process improvements that could materially impact cost, stability of supply, or changes to the facilities used to Manufacture. The JCMC shall prepare and submit to the JSC, the Global Manufacturing Plan for the Product promptly after the receipt of the initial forecasts provided for below from the JDC or JCC, as applicable. **[*]** , or more often as the Parties deem appropriate, the JCMC shall prepare amendments to the then-current Global Manufacturing Plan for approval by the JSC. In addition, no later than **[*]** , the JCMC shall prepare and submit to the JSC, for its review and approval, an update of such Global Manufacturing Plan to take into account changes in forecasted demand for clinical and commercial quantities of the Product.

5.5 Second Source .

5.5.1 The JCMC will, from time to time, evaluate the need for a second or additional source for the Manufacture (in whole or in part, but other than Packaging and Labeling) of the Product or any component thereof (i.e., source(s) other than the then-current source(s) for such Manufacture of the Product or components) for specific countries or regions or the entire Territory, and make applicable recommendations to the JSC.

5.5.2 If at any time the JSC, by Joint Committee Consent, agrees that it is necessary or desirable to establish a second or additional source for the Manufacture (in whole or in part, but other than Packaging and Labeling) of the Product or any component thereof (for clarity, not including the supply of raw materials or excipients for use in such Manufacture) for specific countries or regions or the entire Territory, subject to the oversight of the JCMC as described in Section 2.5 then SGI will have the first right and option, exercisable upon written notice to Agensys within **[*]** of the JSC's agreement, to (a) establish contracts and maintain arrangements with Third Parties approved by the JCMC (after conferring and discussing various potential Third Party manufacturers), for such second or additional source Manufacturing, or (b) conduct such second or additional source Manufacturing itself or through an Affiliate; *provided* , that any such party Manufacturing the Product (including SGI or its Affiliates) and any such Manufacturing site must be qualified in accordance with the applicable terms and conditions of any quality agreement then in place between the Parties. If SGI exercises such option, (i) the Parties will amend the then-existing supply agreement (or enter into a new supply agreement) to provide for such Manufacturing and the supply of Product or applicable components from SGI to Agensys or its designee under terms and conditions equivalent to those applicable for supply from Agensys to SGI, and (ii) the relevant activities and budget therefor shall be included in the Global Development Plan and the costs directly attributable or reasonably allocable to such establishment (but not the on-going supply costs) shall be shared as CMC Development Costs. If SGI does not exercise such option within such **[*]** period, or if SGI fails to establish such second or additional source Manufacturing within the time period mutually agreed by the Parties in the Global Development Plan, then Agensys shall have the right to (A) establish contracts and maintain arrangements with Third Parties approved by the JCMC (after conferring and discussing various potential Third Party manufacturers), for such second or additional source Manufacturing, or (B) conduct such second or additional source Manufacturing itself or through an Affiliate; *provided* , that any such party Manufacturing the Product (including Agensys or its Affiliates) and any such Manufacturing site must be qualified in accordance with the applicable terms and conditions of any quality agreement then in place between the Parties.

5.5.3 If the JSC does not agree to establish such a second or additional source of Manufacture, then (and in lieu of escalation pursuant to Section 2.9.4 or resolution pursuant to ARTICLE 14) each Party may establish a second or additional source for the sole purpose of Manufacturing the Product or components thereof for its Royalty Territory and Exclusive Profit Share Territory; *provided* , that the relevant activities and budget therefor shall not be included in the Global Development Plan, the costs with respect to such establishment shall not be shared as CMC Development Costs or otherwise, and such second or additional source shall not be available to the other Party for supply of Product or components unless such other Party agrees to reimburse **[*]** percent (**[*]** %) of the costs directly attributable or reasonably allocable to the establishment of such second or additional source.

5.5.4 In the event that either Party at any time elects to establish a second or additional source of Manufacture pursuant to this Section 5.5, the other Party and its Affiliates shall provide or cause their Third Party subcontractors to provide all assistance reasonably requested by the other Party to conduct a technical transfer of Manufacturing to such other Party or its designee, including by providing copies of such documents and information, access to relevant Manufacturing personnel and facilities, samples, materials, and other know-how, as are reasonably necessary to enable such Party or its designee to conduct such Manufacturing in accordance with Applicable Law. Such technical transfer shall be conducted in accordance with a technical transfer plan developed and approved by the JCMC.

5.5.5 If the JSC establishes any second or additional sources of supply of Product, the Parties agree to maintain Manufacturing volumes at existing Third Party Manufacturing sites at or above the minimum level necessary to maintain such Third Party Manufacturing sites and avoid the **[*]** (including any **[*]** or **[*]** for the Manufacture of the Product) against a Party or its Affiliate(s), except as otherwise agreed by the Parties.

5.6 Manufacturing Costs .

5.6.1 Within **[*]** after the Effective Date, the Parties, through the JFC and JCMC, shall establish a standard cost for the commercial Manufacture of a unit of Product for which Packaging and Labeling has not been completed (the " Standard Cost ") in accordance with the terms of this Agreement and the supply agreement, which Standard Cost shall be adjusted annually as described below. Prior to the end of each Year (starting with the first full Year following the first commercial sale of the Product anywhere in the Territory), the Parties, through the JFC and JCMC, shall update the Standard Cost for such Year as needed to account for the actual costs of Manufacture of unpackaged and unlabeled Product incurred during such Year, and such updated Standard Cost shall (a) serve as the basis for an annual reconciliation between projected Standard Cost and actual Standard Cost, which reconciliation shall be reflected in the calculation of the final payment made between the Parties with respect to such Year (or the following Quarter if data necessary to determine such reconciliation is not available in time to reflect in the final payment for such Year), and (b) apply for the Manufacture of Product in the upcoming Year prior to the annual reconciliation described above. A detailed mechanism for the calculation of Standard Cost and the reconciliation process will be set forth in the supply agreement. The applicable Standard Cost for each unit of Product shall be an Allowable Expense of the applicable Selling Party and used for purposes of calculating payments due from one Party to the other hereunder.

5.6.2 In addition, the Parties shall each track their respective inventory of Product (including components thereof) and their respective standard costs (without markup) of Manufacturing and cost of labeling and packaging as well as true up to Standard Costs on a Quarterly

basis. Each Party shall provide a report of such inventory and cost to the JFC and JCMC on a Quarterly basis or as otherwise determined by the JCMC.

ARTICLE 6
MEDICAL AFFAIRS ACTIVITIES

6.1 Overview . The Parties agree to collaborate with respect to the Medical Affairs Activities in support of the Product in the United States as provided in this ARTICLE 6 under the direction of the JMAC, and pursuant to the Global Medical Affairs Plan and US Medical Affairs Plan. Subject to the Global Medical Affairs Plan, each Party shall have the sole right and responsibility for Medical Affairs Activities in support of the Product in its Royalty Territory in accordance with this Agreement and as provided in this ARTICLE 6. Subject to the SGI Profit Share Territory Medical Affairs Plan (in the case of SGI) and the Agensys Profit Share Territory Medical Affairs Plan (in the case of Agensys), each Party shall have the sole right and responsibility for Medical Affairs Activities in support of the Product in its Exclusive Profit Share Territory and in accordance with this Agreement and as provided in this ARTICLE 6. Unless otherwise agreed by Joint Committee Consent of the JMAC, the Medical Affairs Activities for the Product in the United States shall be performed by SGI and Agensys using an equal FTE effort, but not necessarily an equal number of Medical Liaisons, managers or directors allocated to Product (*i.e.* , the Parties acknowledge that the respective Medical Liaisons, managers and directors will be responsible for multiple products and will ensure that the proportion of time each Medical Liaison, manager and director allocates to the Product is such that the total FTE effort of each Party's Medical Liaisons, managers and directors to the Product, taken as a whole, are equal). Each Party will **[*]** ; *provided* that **[*]** .

6.2 Global Medical Affairs Plan . The Medical Affairs Activities in support of the Product globally shall be described in a high-level plan including a budget for Global Medical Affairs Costs (a " Global Medical Affairs Plan "). The JMAC shall prepare the first draft of the Global Medical Affairs Plan for review and approval by the JSC. All Global Medical Affairs Plans with respect to the Product and subsequent revisions thereto will include (a) a high-level description of the strategy for Medical Affairs Activities for the Product globally (including the relative responsibilities of the Parties), (b) overall medical strategy, the medical narrative, all planned Voluntary Phase IV Studies, global advisory boards, publication plans and such information as the JMAC believes necessary for the successful medical affairs support of the Product, and (c) a budget for Global Medical Affairs Costs. **[*]** , or more often as the Parties deem appropriate, the JMAC shall prepare amendments to the then-current Global Medical Affairs Plan for approval by the JSC. In the event of any inconsistency between a Global Medical Affairs Plan and this Agreement, the terms of this Agreement shall prevail.

6.3 United States Medical Affairs .

6.3.1 US Medical Affairs Plan . The Medical Affairs Activities in support of the Product in the United States shall be described in a comprehensive plan and budget (such plan, a " US Medical Affairs Plan ") that describes the Medical Affairs Activities for the Product in the United States (including any proposed Voluntary Phase IV Studies, health economics and outcomes research, advisory boards, scientific publications, and medical education, including independent medical education), key plans for implementing those activities, the relative responsibilities of the Parties, and a budget for the associated activities. The initial US Medical Affairs Plan has been approved by the JSC, and updated plans shall be approved by the JSC on an annual basis. All US Medical Affairs Plans with respect to the Product in the United States and subsequent revisions thereto will contain such information as the JMAC believes necessary for the successful medical affairs support of the Product in the United States. **[*]** , or more often as the Parties deem appropriate, the JMAC shall prepare amendments to the then-current US Medical Affairs Plan(s) approval by the JSC. All decisions with respect to Medical Affairs Activities for the Product in the United States (other than matters set forth in an Approved Plan and Party Tactical Matters) shall require the joint approval of the Parties, through Joint Committee Consent of the JSC. In the event of any inconsistency between a US Medical Affairs Plan and this Agreement, the terms of this Agreement shall prevail.

6.3.2 Medical Affairs Reports for the United States . Each Party shall keep the JMAC fully informed regarding the progress and results of Medical Affairs Activities in support of the Product in the United States.

6.3.3 Supply of Product for Medical Affairs . SGI shall use Commercially Reasonable Efforts to make available to the Parties the quantities of Product (for which it has completed Packaging and Labeling for the United States) for use in connection with Medical Affairs Activities in the United States set forth in the US Medical Affairs Plan. The Commercial Packaging and Labeling Costs of either Party for such supply (as well as the Standard Costs of either Party for such supply, which will be reconciled in accordance with Section 5.6) shall be included as a Global Allowable Expense. The terms associated with such supply shall be described in the supply agreement under Section 5.3 or amendment thereto.

6.4 Exclusive Profit Share Territory Medical Affairs .

6.4.1 Exclusive Profit Share Territory Plan . The Medical Affairs Activities in support of the Product in the SGI Profit Share Territory shall be described in a high-level plan and budget (such plan, a " SGI Profit Share Territory Medical Affairs Plan ") and in the Agensys Profit Share Territory shall be described in a high-level plan and budget (such plan, an " Agensys Profit Share Territory Medical Affairs Plan "), in each case, that includes a high-level description of the strategy for Medical Affairs Activities for the Product in the corresponding Exclusive Profit Share

Territory (including the relative responsibilities of the applicable Party and a budget for the associated activities and in the case of the Agensys Profit Share Territory Medical Affairs Plan). All SGI Profit Share Territory Medical Affairs Plans, Agensys Profit Share Territory Medical Affairs Plans with respect to the Product and subsequent revisions thereto will contain such information as the JMAC believes necessary for the successful Medical Affairs Activities in support of the Product. **[*]** , or more often as the Parties deem appropriate, SGI prepare amendments to the then-current SGI Profit Share Territory Medical Affairs Plan and Agensys shall prepare amendments to the then-current Agensys Profit Share Territory Medical Affairs Plan, in each case for review by the JMAC and approval by the JSC. In the event of any inconsistency between a SGI Profit Share Territory Medical Affairs Plan and Agensys Profit Share Territory Medical Affairs Plan and this Agreement, the terms of this Agreement shall prevail.

6.4.2 Medical Affairs Reports for the Exclusive Profit Share Territory . **[*]** , each Party shall provide such information regarding the Medical Affairs Activities in support of the Product in its respective Exclusive Profit Share Territory as the JMAC may reasonably request.

6.5 Royalty Territory Medical Affairs

6.5.1 Medical Affairs Updates for the Royalty Territory . Each Party shall provide informational updates to the JMAC of its planned Medical Affairs Activities and recent results in support of Product in its Royalty Territory on an annual basis in a format agreed by Party Written Consent; and shall respond in a timely fashion to any reasonable requests of the other Party with respect to such activities and results. Each Party will consider in good faith the other Party's input; *provided* that each Party shall have final decision making authority with respect to Medical Affairs Activities in support of Product in its Royalty Territory.

6.5.2 Medical Affairs Costs in the Royalty Territory . Each Party shall be solely responsible for all costs and expenses incurred by or on behalf of such Party in its Royalty Territory for Medical Affairs Activities in support of Product in the Royalty Territory (other than Global Medical Affairs Costs).

6.6 Medical Affairs Materials . The Parties, through the JMAC, shall align on a process for the review, approval, revision, and re-approval of materials prepared in connection with Medical Affairs Activities in the United States.

6.7 Medical Affairs Standards of Conduct .

6.7.1 Diligence; Compliance . Each Party shall carry out the tasks assigned to it under the Medical Affairs Plans in a timely and effective manner and in material compliance with Applicable Law and applicable industry compliance standards.

6.7.2 Diligence Obligations . Each Party shall use Commercially Reasonable Efforts to perform Medical Affairs Activities in support of the Product in its Royalty Territory following obtaining Regulatory Approval therefor with respect to the applicable country.

ARTICLE 7
REGULATORY MATTERS

7.1 Clinical and Regulatory Matters .

7.1.1 Global Regulatory Plan . As part of the Global Development Plan, the Parties shall jointly prepare a global regulatory plan for the Product that describes the regulatory actions to be taken by each Party and how such activities shall be coordinated if necessary, including (a) the content of the Core Data Sheet for the Product (prepared in accordance with Section 7.1.6(b)) that will be used to support global submissions to Regulatory Authorities, (b) planned meetings with Regulatory Authorities regarding the Product, (c) plans for INDs, Drug Regulatory Approval Applications, Regulatory Approvals and related filings for the Product, and (d) the amount of annual fees projected to be assessed by Regulatory Authorities. Without limiting the foregoing, the JDC shall coordinate with the JCMC with respect to the regulatory aspects of CMC Development and the regulatory activities related to CMC Development that are addressed in the Global Development Plan.

7.1.2 Ownership . Notwithstanding Section 7.3.1 of the Collaboration Agreement, legal title to and legal ownership of all INDs, Drug Regulatory Approval Applications, Regulatory Approvals and related filings for the Product in the United States, the Agensys Profit Share Territory and the Agensys Royalty Territory shall be held by Agensys or its Affiliates, and SGI shall hold legal ownership in the SGI Profit Share Territory, and SGI Royalty Territory (such Party holding legal title to such INDs, Drug Regulatory Approval Applications, Regulatory Approvals in the applicable country or region being referred to as the " Lead Regulatory Party "). Agensys shall be the Lead Regulatory Party for global Clinical Trials (*i.e.* , Clinical Trials that occur in multiple countries that are not all in the SGI Profit Share Territory or SGI Royalty Territory), however, **[*]** ; *provided* that **[*]** . To the extent any INDs, Drug Regulatory Approval Applications, Regulatory Approvals, and related filings for the Product existing as of the Effective Date (or at any time during the Term) are not owned by the Lead Regulatory Party, the other Party hereby assigns to the applicable Lead Regulatory Party all of its right, title, and interest in and to all such INDs, Drug Regulatory Approval Applications, Regulatory Approvals and related filings for Product that it Controls. Such other Party shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary to effectuate such assignment.

7.1.3 Responsibilities. The Lead Regulatory Party shall (a) be responsible for the day-to-day implementation of the regulatory activities required to obtain and maintain Regulatory Approval of the Product in the applicable country, (b) subject to Sections 7.1.4, 7.1.5, and 7.1.7, take the lead with respect to communications with the Regulatory Authorities in such country, and (c) designate a representative to serve as the designated regulatory official for the Product in such country or jurisdiction for purposes of receiving communications from the FDA and other Regulatory Authorities. The other Party will cooperate with the Lead Regulatory Party and the costs thereof will be Development Costs.

7.1.4 Regulatory Authority Submissions and Correspondence. Subject to the Global Development Plan and Section 7.1.3, the Lead Regulatory Party shall be responsible for the preparation of all documents and other correspondence to be submitted to Regulatory Authorities (other than the Core Data Sheet, which is the responsibility of the JDC under Section 7.1.6(b)) pertaining to the Product, however, **[*]**. The **[*]** shall **[*]** and shall **[*]**. The Lead Regulatory Party shall as promptly as practicable (and in any event within **[*]** in the **[*]**, the **[*]**, **[*]**. and **[*]** and **[*]** elsewhere) provide the other Party with copies, of any documents or other correspondence received from or submitted to a Regulatory Authority pertaining to the Product. Neither Party shall be required to **[*]**.

7.1.5 Meetings with Regulatory Authorities. Subject to the Global Development Plan, the Lead Regulatory Party with respect to a country shall be responsible for conducting all meetings and telephone or video conferences related to the Product with Regulatory Authorities in such country, including all Product labeling discussions, but in the **[*]**, the **[*]**, **[*]**, and **[*]**, the Lead Regulatory Party shall consult with and shall take into consideration all reasonable views of the other Party in finalizing the strategy for such meetings. With respect to the **[*]**, the **[*]**, **[*]**, and **[*]**, the Lead Regulatory Party shall (a) provide the other Party with advance notice of all such scheduled meetings and conferences with the applicable Regulatory Authorities (including FDA advisory committee meetings and any other meeting of experts convened by the FDA concerning any topic relevant to the Product and foreign equivalents), and (b) in **[*]** use **[*]** to include **[*]** representatives of the other Party in all meetings and telephone discussions between representatives of the Lead Regulatory Party and such Regulatory Authority related to the Product; provided that, subject to the forgoing efforts, the final number of representatives (i.e., from each Party and both Parties combined) will be in the discretion of the applicable Lead Regulatory Party. For clarity, (i) Agensys shall take the lead with respect to discussions with the Regulatory Authorities in the **[*]**, the **[*]**, **[*]**, **[*]**, and the Agensys Royalty Territory, but SGI shall be entitled to have reasonable representation present at all such meetings with Regulatory Authorities in the **[*]**, the **[*]**, **[*]** and **[*]** (*provided* that SGI shall be entitled to actively participate in any such meetings in countries where SGI is conducting a clinical trial, if such meeting is about such clinical trial), and (ii) SGI will take the lead with respect to discussions with the Regulatory Authorities **[*]** and the SGI Royalty Territory, but Agensys shall be entitled to have reasonable representation present

at all such meetings concerning **[*]** . Agensys and SGI shall use reasonable efforts to agree in advance on the scheduling of such meetings and conferences, the objectives to be accomplished at such meetings and conferences, the agenda for such meetings and conferences and the briefing materials to be used at such meetings and conferences.

7.1.6 Regulatory Approval of DAAs and Core Data Sheet .

(a) The JDC in collaboration with the JCMC (or a joint Working Group of the JDC and JCMC) shall approve (i) the contents of any Drug Regulatory Approval Application for the Product in the **[*]** , the **[*]** , **[*]** and **[*]** , and all material correspondence submitted to the applicable Regulatory Authorities in the **[*]** , the **[*]** , **[*]** , and **[*]** , and (ii) the chemistry, manufacturing and controls components of any Drug Regulatory Approval Application in the Territory. If the chemistry, manufacturing and controls components of any Drug Regulatory Approval Application for the Product have previously been approved as set forth above, the Lead Regulatory Party may submit such components (or subset thereof) to the applicable Regulatory Authorities without seeking additional approval; *provided* that if any changes are made to such components or additional chemistry, manufacturing and controls information is required to be submitted together with such components, approval under this Section 7.1.6 shall be required.

(b) The JDC shall prepare, review and approve the Core Data Sheet for approval by the JSC for the Product, and such Core Data Sheet will be maintained and held by Agensys. Each Party shall be responsible for creating and updating the local product information for the Product in its Exclusive Profit Share Territory and Royalty Territory and shall submit such information to the JDC, which shall be subject to approval by the JDC if any deviations are made from the Core Data Sheet. Any changes to the local product information required by Applicable Law or a Governmental Authority shall be communicated by the applicable Party to the JDC in a timely manner.

7.1.7 Advertising and Promotion . Subject to Section 3.2.6, the Lead Regulatory Party in the applicable country shall be the point of contact and the responsible Party for Regulatory Authorities with respect to any Promotional material relating to the Product consistent with the Approved Plans and any guidance of the JCC.

7.1.8 Drug Naming Regulatory Approvals . Subject to Section 10.2.1, the Lead Regulatory Party in the applicable country will take the lead in drug naming procedures with the Governmental Authorities and Regulatory Authorities relating to the Product.

7.1.9 Rights of Reference . Each Party shall have the right to cross reference, file or incorporate by reference any regulatory submission or drug master file (and any data contained therein) for any Product, or any component thereof, made in any country in the Territory (including

all Regulatory Approvals) in order to support regulatory submissions that such Party is permitted or required to make under this Agreement for the Product and to enable either Party to fulfill its obligations, or exercise its rights, under this Agreement.

7.1.10 Notice of Inspection, Investigation or Inquiry . If any Governmental Authority, including any Regulatory Authority, (a) contacts a Party with respect to the alleged improper Development, Manufacture, or Commercialization of any Product in the Territory, (b) conducts, or gives notice of its intent to conduct, a non-routine inspection at such Party's facilities (or the facilities of any clinical trial site or vendor) to the extent related to the Product, or (c) takes, or gives notice of its intent to take, any other regulatory or enforcement action with respect to any activity of such Party that could reasonably be expected to adversely affect any Commercialization activities with respect to the Product in the Territory, then such Party shall promptly notify the other Party of such contact, inspection or notice. The contacted or inspected Party shall provide such other Party with copies of all pertinent information and documentation issued by any such Regulatory Authority immediately after receipt (and in any event within **[*]** of receipt), and the JDC in collaboration with the JCMC shall have the right to oversee the preparation of any responses that pertain to the Product other than responses to routine inspections; *provided* that (i) where the time limit for a response to the competent Regulatory Authorities would prevent the Parties from consulting the JDC and JCMC in advance, the Parties shall promptly notify the JDC and JCMC and send a copy of any response not later than **[*]** after the response to the competent Regulatory Authorities is submitted, and (ii) final decision-making authority with respect to such submissions shall be as set forth in the quality agreement; *provided* , *further* , that any such responses that relate to critical issues or significant non-compliance shall be escalated to the JSC for review and approval of such responses.

7.2 Pharmacovigilance; Adverse Event Reporting . The Parties entered into a Pharmacovigilance Agreement effective September 21, 2017 covering the management of safety information, adverse event reporting and the maintenance of a global safety database. Within **[*]** after the Effective Date (but in all cases prior to submission of the first BLA for Product), the Parties shall amend the existing pharmacovigilance agreement or enter into a new pharmacovigilance agreement to address the Commercialization and other activities contemplated by this Agreement. To the extent the terms and conditions of this Agreement conflict or are otherwise inconsistent with the terms of such pharmacovigilance agreement(s), the terms and conditions of this Agreement shall prevail except with respect to safety matters for which the pharmacovigilance agreement(s) shall prevail.

ARTICLE 8
COMPLIANCE

8.1 Compliance . In connection with all activities undertaken pursuant to this Agreement or otherwise relating to the Product, each Party hereby covenants and agrees to comply, and cause its Affiliates to comply, with (a) the **[*]** , (b) the **[*]** and the **[*]** , and (c) **[*]** . In particular:

8.1.1 Each Party shall (a) instruct its personnel **[*]** (b) maintain **[*]** , and (c) immediately notify the other Party of the substance of any such report in the event that (i) **[*]** , and (ii) such Party **[*]** .

8.1.2 In performing the activities contemplated by this Agreement, neither Party shall **[*]** . In addition, no Party shall **[*]** . No employee of a Party or its Affiliates shall **[*]** .

8.1.3 Each Party must track and report (a) **[*]** , and (b) **[*]** .

8.1.4 Agensys and SGI agree to abide by **[*]** in the course of their performance under this Agreement. The Parties shall **[*]** .

8.1.5 Agensys and SGI agree to abide by **[*]** .

8.1.6 Each Party agrees to **[*]** .

8.2 Export . This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries which may be imposed upon or related to SGI or Agensys from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental Regulatory Approval, without first obtaining the written consent to do so from the appropriate Governmental Authorities.

8.3 Harmonizing Policies . The Parties shall **[*]** . Neither Party shall be required to **[*]** . It is agreed and acknowledged that **[*]** .

ARTICLE 9
REPRESENTATIONS AND COVENANTS

9.1 Mutual Representations and Warranties . Each Party represents and warrants to the other as of the Effective Date that:

9.1.1 Corporate Power . It is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

9.1.2 Due Authorization . It is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action.

9.1.3 Binding Agreement . This Agreement is legally binding upon it and enforceable against it in accordance with its terms. Subject to compliance by such Party with its obligations under the agreements listed or referred to in Section 15.13.2, the execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any Governmental Authority having jurisdiction over it.

9.1.4 No Conflicts . The execution and delivery of this Agreement and the performance of such Party's obligations hereunder do not and will not (a) conflict with or violate in any material respect any requirement of Applicable Law or any judgment, decree, order, regulation, or rule of any Governmental Authority by which such Party is bound or subject; (b) conflict with or violate the organizational documents of such Party; or (c) result in a breach (or any event which, with notice or lapse of time or both, would constitute a breach) of any material term or provision of, or constitute a material default under any contractual obligations of, such Party or any of its Affiliates

9.2 No Debarment . In the course of the Development of the Product pursuant to the Collaboration Agreement each Party has not used, and during the Term will not use, any employee or consultant that is debarred, disqualified, or restricted by any Governmental Authority or Regulatory Authority or, to the best of such Party's knowledge, is the subject of debarment, disqualification, or restriction proceedings by any Governmental Authority or Regulatory Authority. If either Party learns that it or any employee or consultant performing services on its behalf under this Agreement has been debarred, disqualified, or restricted by any Governmental Authority or Regulatory Authority, or has become the subject of debarment, disqualification, or restriction proceedings by any Governmental Authority or Regulatory Authority, such Party shall promptly notify the other Party and in the case of an employee or consultant, shall prohibit such employee or consultant from performing on its behalf under this Agreement.

9.3 DISCLAIMER . NEITHER PARTY MAKES ANY EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 9 OR ELSEWHERE IN THIS AGREEMENT, INCLUDING ANY REPRESENTATION OR WARRANTY REGARDING THE VALIDITY OR SCOPE OF ITS PATENT RIGHTS OR THAT THE MANUFACTURE, USE OR SALE OF THE PRODUCT WILL NOT INFRINGE THE PATENT RIGHTS OF THIRD PARTIES, OR ANY REPRESENTATION OR WARRANTY AS TO THE VALUE, ADEQUACY, FREEDOM FROM FAULT OF, OR QUALITY, EFFICIENCY,

CHARACTERISTICS OR USEFULNESS OF, OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF, THE PRODUCT.

ARTICLE 10
INTELLECTUAL PROPERTY

10.1 Copyrights . All copyrights for Product-specific advertising, promotional, packaging and educational materials and all Product-specific training materials jointly prepared or authored by or for the Parties or their respective Affiliates in furtherance of the Collaboration shall be jointly owned by the Parties; *provided* that (a) such materials may not be used outside the Collaboration without the Party Written Consent of the other Party and (b) the foregoing shall not affect or constitute a waiver of any copyright rights that a Party may have in its individually owned materials that were incorporated into a jointly owned copyrighted material.

10.2 Product Trademarks .

10.2.1 Both Parties shall use the same brand name and associated trademarks for the Product in all countries in which the global trademark can reasonably be secured. The Product shall be sold under the same trademark and a generic or international non-proprietary name, and marketed using same logos, slogans, trade dress, domain names, and other intellectual property throughout the Territory to create a worldwide brand for the Products unless a Party has cause to use a different brand name (such as for regulatory or Third Party infringement reasons) in its territory and informs the JSC thereof (excepting the generic or international non-proprietary name, hereinafter, " Product Trademarks "); *provided* , that the Product Trademarks shall not use, be comprised of, or incorporate **[*]** (hereinafter, " Other Marks ") without SGI's or Agensys', as applicable, prior Party Written Consent. For clarity, "Other Marks" includes the Corporate Names. The Product Trademarks shall be initially jointly owned worldwide and the initial applications for registration for such Product Trademarks shall be filed and prosecuted by the Parties jointly using outside counsel mutually acceptable to the Parties (with the associated costs included in Trademark Costs). Upon registration of the Product Trademarks in the applicable Territory, the Parties shall assign such Product Trademarks (a) to **[*]** , (b) to **[*]** , and (c) **[*]** (the applicable Party, the " Trademark Owner "). All registrations for Product Trademarks shall be maintained by the Trademark Owner (at its expense; *provided* that costs for the Profit Share Territory shall be treated as Trademark Costs). Each Party agrees that it will use the trademark registration symbol ® or TM, as appropriate, in connection with the Product Trademarks. Agensys and SGI agree to cooperate with respect to execution and delivery of such additional instruments or documents as shall be necessary to ensure each Party's rights and interest in and to the Product Trademarks.

10.2.2 Each Party agrees to maintain suitable quality standards with respect to the Products it provides in connection with the Product Trademarks. Neither Party shall use outside

the Collaboration any trademark that is substantially the same as or deceptively or confusingly similar to the Product Trademarks.

10.3 Other Marks; Limited License .

10.3.1 Each Party hereby grants to the other Party a royalty-free, non-transferable, non-sublicensable (except to Affiliates or as the Parties may agree by Party Written Consent) right to use in the United States (and in the other Party's Royalty Territory and Exclusive Profit Share Territory to the extent required by Applicable Law) only its Other Marks relevant to the subject matter covered by this Agreement solely for use in connection with the Commercialization activities provided for in this Agreement. Except as specifically consented to by such Party in writing or as required by Applicable Law, this limited right to use the granting Party's Other Marks (including, for clarity, the granting Party's Corporate Name) relevant to the subject matter covered by this Agreement shall immediately cease (a) when the other Party's right to jointly Promote the Product in the United States is terminated (including as a result of transition of such activities pursuant to Section 12.3.1(a)), or (b) if the granting Party's Other Marks are used in a manner inconsistent with or in breach of the terms of this Agreement. Each Party hereby understands that no rights are granted under this Section 10.3.1 except those specifically set forth herein. All Product labeling, packaging and Promotional materials that bears any of a Party's Other Marks shall identify such Party as the owner and licensor of such Other Marks.

10.3.2 Each Party agrees to conform to the customary guidelines of the granting Party under Section 10.3.1 with respect to manner of use, and to maintain the quality standards of such granting Party with respect to the goods sold and services provided in connection with such granting Party's Other Marks. Each Party recognizes and agrees that no ownership rights are vested or created by the limited rights of use granted pursuant to Section 10.3.1, and that all goodwill developed by virtue of the use of Other Marks in accordance with Section 10.3.1 inures to the benefit of the respective owner of the Other Marks. Further, except when used in accordance with any usage guidelines provided by the owner of the Other Mark, each Party shall submit to the other Party any materials bearing the other Party's Other Marks for review and Regulatory Approval prior to the use thereof and shall make no use of the Other Marks of the other Party not expressly permitted by this Agreement without the other Party's Party Written Consent. Neither Party shall use outside the Collaboration any trademark that is substantially the same as or deceptively or confusingly similar to the Other Marks (including the Corporate Names).

10.3.3 Each Party shall execute any documents required in the reasonable opinion of the other Party to be entered as a recorded licensee of the other Party's Other Marks or to be removed as licensee thereof.

10.3.4 Each Party agrees to indemnify and to hold the other Party harmless in the event that such other Party incurs liability as a result of the use of the indemnifying Party's Other Marks; *provided* that indemnified Party's use of the Other Mark in question was in accordance with the provisions of this Section 10.3. The indemnified Party shall provide prompt notice to the indemnifying Party of any claim that the indemnifying Party's Other Marks infringe the rights of a Third Party, and the indemnified Party shall provide good faith cooperation in the defense of such claim. Any amounts paid as indemnification pursuant to this Section 10.3.4, shall not be included in Allowable Expenses and shall be borne solely by the indemnifying Party

10.3.5 Each Party shall have the sole right, but not the responsibility, to prosecute and maintain its Other Marks.

10.4 Infringement of Trademarks .

10.4.1 Defense of Third Party Claims . Each Party shall notify the other Party promptly upon learning of any actual or alleged infringement, or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods or like offenses or any such claims thereof relating to the Product Trademarks (hereinafter " Trademark Infringement Claims ") brought by a Third Party against a Party or any of its Affiliates. Upon learning of such Trademark Infringement Claim, the Party or Parties against which such claim is made shall take all reasonable and appropriate steps to resolve the Trademark Infringement Claim, and give reasonable consideration to the other Party's suggestions, regarding such Trademark Infringement Claim. All of the reasonable fees and expenses incurred for outside counsel and other reasonable direct costs incurred in bringing, maintaining and prosecuting any action described in this Section 10.4.1 shall be included in Trademark Costs if such Trademark Infringement Claim relates to the United States. The non-resolving Party shall cooperate with the resolving Party in connection with any Trademark Infringement Claims.

10.4.2 Enforcement of Product Trademarks . Each Party shall notify the other Party in writing promptly upon learning of any actual or alleged infringement by any Third Party of any Product Trademark of which they become aware. The Trademark Owner shall have the first right, but not the obligation, to control the prosecution of any such infringement. If the Trademark Owner does not initiate an infringement action within **[*]** after learning of the infringement, then the other Party shall have the right, but not the obligation, to bring such an action. In the case of a jointly owned trademark, neither Party shall have the right to settle any infringement action under this Section 10.4.2 in a manner that diminishes the rights or interests of the other Party or imposes any liability on the other Party without the prior Party Written Consent of such other Party. The expenses of defense, settlement and judgments in actions governed by this Section 10.4.2 shall be Trademark Costs (to the extent not reimbursed through recoveries from such litigation) if related to the Profit Share Territory. The costs and expenses of the Party bringing suit under this Section 10.4.2 shall be reimbursed first out of any damages or other monetary awards recovered in favor of Agensys or

SGI (if such recovery is less than the Parties' aggregate costs and expenses incurred in such action, such recovery shall be allocated between the Parties on a pro rata basis based on their relative costs and expenses incurred in such action). The Party that does not control the action or suit hereunder shall cooperate with the controlling Party in connection with such action or suit. Any damages or other monetary awards remaining after payment of the Parties' expenses shall be allocated between the Parties in the same proportion as they share in Net Profit/Net Loss hereunder. Any recovery shall be split as provided in this Section 10.4.2, shall not be applied to reduce Allowable Expenses (except as specifically provided above) and shall not be included in the calculation of Net Sales.

10.5 Other Intellectual Property .

10.5.1 All rights and obligations with respect to Patents will continue under the Collaboration Agreement, including each Party's obligation to fund fifty percent (50%) of the cost thereof in accordance with the terms thereunder.

10.5.2 Subject to Section 10.2.1, the Parties shall use a common domain name incorporating the same brand name for the Product worldwide. The Parties shall jointly select domain names and will coordinate filing and registering such names. All such registered domain names shall be jointly owned by the Parties.

10.6 No Implied Licenses . No right or license under any Agensys Technology or SGI Technology or any Product Trademark or Other Mark is granted or shall be granted by implication as a result of the respective rights of the Parties under this Agreement. All such rights or licenses are or shall be granted only as expressly provided in this Agreement (or the Collaboration Agreement).

10.7 Court or Government Order or Decree . Notwithstanding any other provision in this Agreement, neither Party shall be required to take any action pursuant to this ARTICLE 10 that it reasonably determines in its sole judgment and discretion conflicts with or violates any court or government order or decree or any agreement with any Governmental Authority that it is then subject to or otherwise may create legal liability on the part of it.

10.8 Competing Product .

10.8.1 During the Term and subject to the terms of this Agreement, including Section 10.9, each Party hereby covenants that neither it nor its Affiliates will, directly or indirectly, by itself or with a Third Party, **[*]** , **[*]** , **[*]** , **[*]** or **[*]** , except as permitted in Section 10.8.2, any Competing Product other than as a result of a Change in Control (which is addressed in Section 10.9). For clarity, this Section 10.8 shall not apply in the event that any Person that becomes an Affiliate of an Acquired Party as a result of a Change in Control of such Acquired Party or its

Affiliate owns or controls a Competing Product prior to such Change in Control, which circumstance is addressed in Section 10.9.

10.8.2 If a Party or any of its Affiliates, either as a result of (a) **[*]** or (b) **[*]** , then such Party or its Affiliate (the " Competing Party ") shall **[*]** notify the other Party **[*]** no later than the Required Notice Date that it is electing to:

(a) Divest itself of such Competing Product via a transaction in which such Party and its Affiliates no longer has an economic interest in the future sales of the Competing Product and notify the other Party in writing of such Divestiture, provided that such Divestiture must be completed within (i) **[*]** of the Required Notice Date in the case of a Competing Product that is already being offered for commercial sale, and (ii) prior to **[*]** , in the case of a Competing Product that is not then being offered for commercial sale (the " Divestment Period "); or

(b) refrain, and cause its Affiliates to refrain, directly or indirectly, by itself or with a Third Party, from **[*]** , **[*]** , **[*]** , **[*]** or **[*]** such Competing Product, or, in the case of any such Competing Product with respect to which first commercial sale has occurred prior to the Required Notice Date, cease engaging in such prohibited activities with respect to such Competing Product (in which event the Competing Party shall have a period of **[*]** after the Required Notice Date to sell off existing inventory or work-in-progress).

10.8.3 For clarity, in any circumstance when **[*]** , the Competing Party shall not be in breach of Section 10.8.1. Moreover, (a) in circumstances where **[*]** , and **[*]** , the Competing Party shall not be in breach of this Section 10.8 if it complies with foregoing Section 10.8.2(b) after **[*]** and (b) during **[*]** , the Competing Party shall not be in breach of Section 10.8.

10.9 Change in Control .

10.9.1 Notwithstanding anything to the contrary herein, any intellectual property Controlled by any Person that becomes an Affiliate of a Party (the " Acquired Party ") as a result of a Change in Control of such Acquired Party or its Affiliate shall not be Independent Technology (as defined in the Collaboration Agreement) unless (a) such technology or rights had been Controlled, prior to the Change in Control, by such Acquired Party or its Affiliate(s) that were Affiliate(s) prior to the Change in Control or (b) with respect to any of the foregoing technology covered by patent rights, at least one named inventor was employed by such Acquired Party or its then Affiliate(s) immediately prior to the public announcement of the transaction(s) giving rise to such Change in Control.

10.9.2 Following any Change in Control of Agensys or its Affiliates, in the event the applicable acquirer has, or has rights or an interest in, at the time of the Change of Control, a Competing Product, Agensys shall be required to, and to cause its Affiliates to: (a) **[*]** and (b) **[*]**

(collectively, the " SGI Sensitive Information ") beyond personnel of Agensys or its Affiliates who continue to actively perform obligations under this Agreement, and to control the dissemination of SGI Sensitive Information disclosed after the Change in Control of Agensys or its Affiliates with such acquirer. For clarity, the foregoing will not apply to any SGI Sensitive Information that is not treated as Confidential Information under Section 11.1. Notwithstanding the foregoing, following such Change in Control of Agensys or its Affiliates, Agensys will be allowed to provide information regarding the amount of financial payments (including the underlying reports provided hereunder) from SGI to Agensys hereunder to such acquirer or its Affiliates.

10.9.3 Following any Change in Control of SGI or its Affiliates, in the event the applicable acquirer has, or has rights or an interest in, at the time of the Change of Control, a Competing Product, SGI shall be required to, and to cause its Affiliates to (a) **[*]** and (b) **[*]** (collectively, the " Agensys Sensitive Information ") beyond personnel of SGI or its Affiliates who continue to actively perform obligations under this Agreement, and to control the dissemination of Agensys Sensitive Information disclosed after the Change in Control of SGI or its Affiliates with such acquirer. For clarity, the foregoing will not apply to any Agensys Sensitive Information that is not treated as Confidential Information under Section 11.1. Notwithstanding the foregoing, following such Change in Control of SGI or its Affiliates, SGI will be allowed to provide the information regarding the amount of financial payments (including the underlying reports provided hereunder) from Agensys to SGI hereunder to such acquirer or its Affiliates.

ARTICLE 11
CONFIDENTIALITY

11.1 Confidentiality .

11.1.1 Confidential Information . For purposes of this Agreement " Confidential Information " means all Information, documents (including unpublished patent applications), trade secrets, or materials supplied by the other Party under this Agreement, whether disclosed orally, visually, in writing or in any tangible or electronic form or media, that is confidential or proprietary and is marked or otherwise identified as "Confidential" or which the receiving party should reasonably recognize as being confidential. Confidential Information may be owned by the disclosing Party or its Affiliates or held by the disclosing Party or its Affiliates under an obligation of confidentiality to a Third Party. The terms of this Agreement and Information related to the Product shall be the Confidential Information of both Parties. Confidential Information of a Party may also include information relating to such Party's or its Affiliates' **[*]** . Information shall not be considered Confidential Information to the extent the receiving Party can demonstrate by competent evidence that such Information:

(a) has been published or otherwise entered the public domain other than by breach by the receiving Party or its Affiliates of this ARTICLE 11 or directly or indirectly under another agreement between the Parties that imposed obligations of confidentiality;

(b) has been disclosed to the receiving Party or its Affiliates by a Third Party, *provided* such Information was not obtained by such Third Party directly or indirectly from the disclosing Party or its Affiliates on a confidential basis;

(c) prior to disclosure by the disclosing Party under this Agreement, the Collaboration Agreement or directly or indirectly under another agreement between the Parties that imposed obligations of confidentiality, was already in the possession of the receiving Party or its Affiliates; or

(d) was developed independently of and without reference to the disclosing Party's or its Affiliates' Confidential Information.

11.1.2 Non-Disclosure Obligations . Except as otherwise provided in this ARTICLE 11, during the Term and for a period **[*]** thereafter, each Party shall maintain in confidence, and use only for purposes as expressly authorized and contemplated by this Agreement, all Confidential Information supplied by the other Party or its Affiliates under this Agreement. Each Party shall use at least reasonable care, and in no event less than the same standard of care as it uses to protect its own Confidential Information, to ensure that its and its Affiliates' employees, agents, consultants and clinical investigators only make use of the other Party's Confidential Information for purposes as expressly authorized and contemplated by this Agreement or the Collaboration Agreement and do not make any unauthorized use or disclosures of such Confidential Information.

11.1.3 Permitted Disclosures . Notwithstanding Section 11.1.1, Confidential Information may be disclosed by the receiving Party or its Affiliates solely to the extent such Confidential Information:

(a) is permitted to be disclosed by prior written consent of the other Party;

(b) is disclosed in the filing, prosecution or maintenance of patents solely in accordance with this Agreement or the Collaboration Agreement, *provided* that (i) such disclosure may be only to the extent reasonably necessary for such purpose and (ii) the receiving Party complies with the obligations set forth in Section 11.1.1 hereof;

(c) is disclosed to a Regulatory Authority in accordance with this Agreement or as required by the Applicable Law to gain or maintain a Regulatory Approval, *provided* that such disclosure may be only to the extent reasonably necessary for such purpose;

(d) is deemed necessary by the receiving Party to be disclosed to such Party's financial advisors, attorneys or independent accountants for the sole purpose of enabling such financial advisors, attorneys or independent accountants to provide professional advice to the receiving Party on the condition that such Third Parties are bound by confidentiality and non-use obligations customary for the type of professional and are advised that the information being disclosed is confidential;

(e) is deemed necessary by the receiving Party to be disclosed to accredited investors, lenders or potential acquirers or merger candidates in the context of due diligence investigations of such Party solely for the purpose of evaluating a potential business relationship, on the condition that such Third Parties are bound by confidentiality and non-use obligations (i) customary for the type of recipient in the case of all recipients who are not potential acquirers or merger candidates, and (ii) contained in this Agreement, in the case of potential acquirers or merger candidates, but in no event pursuant to (i) or (ii) for a term of less than **[*]** , and are advised that the information being disclosed is confidential;

(f) is deemed necessary by the receiving Party to be disclosed to such potential sublicensees as permitted hereunder, *provided* that any such potential sublicensee is bound by obligations of confidentiality and limitations on use of such Confidential Information contained herein;

(g) is disclosed to a potential or bona fide collaborator or manufacturing, or development or sales contractor or partner (including any Approved Subcontractor) but only to the extent directly relevant to the collaboration, partnership or contract, and *provided* that such collaborator, partner or contractor is bound by obligations of confidentiality and limitations on use of such Confidential Information contained herein; or

(h) is disclosed in accordance with Section 11.1.4.

Notwithstanding the disclosures permitted under subsections (a)-(h), such Confidential Information shall remain otherwise subject to the non-disclosure and non-use provisions of this ARTICLE 11.

11.1.4 Compelled Disclosure . If a Party is required by Applicable Law or the rules of any securities exchange to disclose Confidential Information of the other Party, the Party being compelled shall (if not prohibited from doing so) promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed pursuant to Applicable Law or the rules of any securities exchange shall remain otherwise subject to the non-disclosure and non-use provisions of this ARTICLE 11, and the Party disclosing Confidential Information pursuant to Applicable Law or the rules of any securities exchange shall take all steps reasonably necessary,

including seeking an order of confidentiality, to ensure the continued confidential treatment of such Confidential Information. Each Party agrees that it shall cooperate fully and in a timely manner with the other Party with respect to all disclosures to the Securities and Exchange Commission and any other governmental or regulatory agencies or securities exchange, including requests for confidential treatment of Confidential Information of either Party included in any such disclosure.

11.2 Publicity . Neither SGI nor Agensys will, without the prior written consent of the other, issue any press release or make any other public announcement or furnish any statement to any Person (other than either Parties' respective Affiliates) concerning the existence of this Agreement, its terms and the transactions contemplated hereby, except for disclosures made in compliance with Sections 14.3, 14.4 or 14.6 of the Collaboration Agreement.

11.3 Securities Filings . In the event either Party proposes to file with the **[*]** , the U.S. Securities and Exchange Commission or the securities regulators of any state or other jurisdiction under the Securities Act of 1933, as amended, the Exchange Act, or any other applicable securities law (the " Securities Exchanges ") a registration statement or any other disclosure document which describes or refers to the Collaboration or this Agreement, such Party shall notify the other Party of such intention and shall provide the other Party with a copy of relevant portions of the proposed filing not less than three (3) Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto relating to the Collaboration or this Agreement, and shall use reasonable efforts to obtain confidential treatment of any information concerning the other Party, the Collaboration, or this Agreement that the other Party requests be kept confidential, consistent with such Party's disclosure obligations under applicable securities laws.

11.4 Publications . Any publications or presentations of activities under this Agreement must comply with the publications charter (the " Publication Charter "), as may be amended by Joint Committee Consent of the JMAC from time to time. The Parties through the JMAC jointly prepared the initial Publication Charter on April 3, 2018 (which may be amended by Joint Committee Consent of the JMAC from time to time). The Publication Charter supersedes the publication provisions of the Collaboration Agreement.

11.5 Existing Confidentiality Agreement . The Parties acknowledge that Article 14 of the Collaboration Agreement contains confidentiality and non-use provisions that shall remain in full force and effect and the confidentiality provisions in this Agreement shall be in addition to, and are not intended to supersede, Article 14 of the Collaboration Agreement. Notwithstanding the foregoing, in the event of any conflict between the terms of Article 14 of the Collaboration Agreement and the terms of this Agreement, the terms of this Agreement shall control with respect to the matters addressed by this Agreement.

ARTICLE 12
TERM AND TERMINATION

12.1 Term . The term of this Agreement (the " Term ") shall become effective on the Effective Date and shall remain in effect until expired or terminated as provided in this ARTICLE 12.

12.2 Expiration . This Agreement shall expire (a) with respect to the Profit Share Territory, on country-by-country basis, on the date of complete cessation of Commercialization of Product in such country and (b) with respect to countries in the Royalty Territory, on country-by-country basis, on the date of the expiration of the Royalty Term with respect to Product in such country. For clarity, this Agreement shall expire in its entirety upon both (i) complete cessation of Commercialization of Product in all countries in the Profit Share Territory and (ii) expiration of all applicable Royalty Terms under this Agreement with respect to all countries in the Royalty Territory. Upon expiration of this Agreement pursuant to this Section 12.2, (A) the Collaboration Agreement will automatically terminate with respect to the Product, and (B) thereafter neither Party shall Commercialize the Product in the relevant country or countries without the prior written agreement of the other Party.

12.3 Material Breach .

12.3.1 If either Party (the " Non-Breaching Party ") believes that the other Party (the " Breaching Party ") has materially breached one (1) or more of its material obligations under this Agreement, then the Non-Breaching Party may deliver notice of such material breach to the Breaching Party (a " Default Notice "). If the Breaching Party **[*]** , then if the Breaching Party **[*]** to cure such breach, or **[*]** , within **[*]** after receipt of the Default Notice, or if such compliance cannot be fully achieved within such **[*]** period and the Breaching Party has failed to **[*]** or has failed to **[*]** , then, subject to Section 12.3.3, Section 12.3.1(a) or 12.3.1(b), as applicable, shall apply. If the Breaching Party disputes that **[*]** , the dispute shall be resolved pursuant to ARTICLE 14. If, as a result of the application of such dispute resolution procedures, the Breaching Party is determined to be in material breach of **[*]** (an " Adverse Ruling "), then if the Breaching Party fails to **[*]** , or if such compliance cannot be fully achieved within such **[*]** period and the Breaching Party has failed **[*]** , then, subject to Section 12.3.3, Section 12.3.1(a) or 12.3.1(b), as applicable, shall apply:

(a) If the material breach is with respect to the **[*]** , the Non-Breaching Party may, in its sole discretion, upon written notice to the Breaching Party **[*]** .

(b) If the material breach affects the Breaching Party's Royalty Territory as a whole or the Breaching Party's Exclusive Profit Share Territory as a whole (and

not solely a portion thereof), the Non-Breaching Party may, in its sole discretion, **[*]** , as applicable, and, **[*]** . Following the **[*]** .

12.3.2 For clarity, the Parties agree that this Agreement will not be terminated pursuant to this Section 12.3 and **[*]** .

12.3.3 Disfavored Remedy . The Parties agree that the remedies under foregoing Sections 12.3.1(a) and 12.3.1(b) are to be invoked **[*]** .

12.4 Termination of Co-Funding; Out-License of Product . For clarity, Section 5.9 of the Collaboration Agreement continues to apply to the Product; *provided* that (a) the Non-Continuing Party may terminate its co-funding obligation on a country-by-country basis, (b) the Opt-Out Date for the Product will be effective **[*]** after the Non-Continuing Party provides irrevocable, written notice to the other Party, and (c) the Continuing Party shall have the right to determine whether it will assume sole responsibility for Development and Commercialization on a country-by- country basis. If the Continuing Party so elects for a given terminated country, then, on and after the effective date of termination:

12.4.1 the Product shall be treated as an Agensys Product (if Agensys is the Continuing Party) or an SGI Product (if SGI is the Continuing Party) with respect to such country and the terms of the Collaboration Agreement shall apply with respect to Product in such country, including the payment of royalties pursuant to Article 11 of the Collaboration Agreement; and

12.4.2 for clarity, if the terminated country is in the Profit Share Territory, profits shall no longer be shared pursuant to Section 4.1 and if the terminated country is in the Royalty Territory, no royalties shall be paid pursuant to Section 4.2.

12.5 Termination for Insolvency; Bankruptcy .

12.5.1 Termination for Insolvency . Either Party may terminate this Agreement if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy . under Chapter 7 of the U.S. Bankruptcy Code, (b) such other Party shall be served with an involuntary petition in bankruptcy under Chapter 7 of the U.S. Bankruptcy Code against it, and such petition shall not be dismissed within **[*]** after the filing thereof, (c) such other Party shall propose or be a party to any dissolution or liquidation, other than a dissolution or liquidation for the purpose of completing a reorganization, consolidation or merger with another entity, or (d) such other Party shall make an assignment for the benefit of its creditors. All rights and licenses granted under this Agreement are, and shall be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(56) of the United States Bankruptcy Code. The Parties agree that, in the event of the commencement of a bankruptcy proceeding by or against

one Party hereunder under the United States Bankruptcy Code, the other Party shall be entitled to complete access to any such intellectual property, and all embodiments of such intellectual property, pertaining to the rights granted in the licenses hereunder of the Party by or against whom a bankruptcy proceeding has been commenced, subject, however, to payment of the fees, milestone payments and royalties set forth in this Agreement through the effective date of any termination hereunder .

12.5.2 Applicability of 11 U.S.C. §365(n) . All rights and licenses (collectively, the " Intellectual Property ") granted under or pursuant to this Agreement, including all rights and licenses to use improvements or enhancements developed during the Term, are intended to be, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the " Bankruptcy Code ") or any analogous provisions in any other country or jurisdiction, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that the licensee of such Intellectual Property under this Agreement shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code, including Section 365(n) of the Bankruptcy Code, or any analogous provisions in any other country or jurisdiction. All of the rights granted to either Party under this Agreement shall be deemed to exist immediately before the occurrence of any bankruptcy case in which the other Party is the debtor.

12.5.3 Rights of non-Debtor Party in Bankruptcy . If a bankruptcy proceeding is commenced by or against either Party under the Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the non-debtor Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any Intellectual Property and all embodiments of such Intellectual Property, which, if not already in the non-debtor Party's possession, shall be delivered to the non-debtor Party within **[*]** of such request; *provided* , that the debtor Party is excused from its obligation to deliver the Intellectual Property to the extent the debtor Party continues to perform all of its obligations under this Agreement and the Agreement has not been rejected pursuant to the Bankruptcy Code or any analogous provision in any other country or jurisdiction.

12.6 Remedies; Right of Set Off .

12.6.1 Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to one (1) or more countries or other jurisdiction(s)) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

12.6.2 Either Party may set-off the amount of any claim or damages that is subject to a court judgment hereunder against any payment otherwise due to the other Party under this Agreement; provided that, to the extent such claim or damage is being appealed, such set off amount shall be paid into an escrow fund to be designated by the such Party and reasonably acceptable to the other Party, and released once the claim or damage is non-appealable, as determined by a

responsible court or arbitrator, in accordance with the final determination of such claim or damage. Neither the exercise of nor the failure to exercise such right of setoff will constitute an election of remedies or limit any Party in any manner in the enforcement of any other remedies that may be available to it.

12.7 Accrued Rights; Surviving Obligations . Termination or expiration of this Agreement (either in its entirety or with respect to one (1) or more countries) for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, ARTICLE 1 (to the extent defined terms are used in any other surviving provisions), Section 2.9.4, Section 3.9, the last sentence of Section 3.10, Section 4.7 and, with respect to amounts accrued thereunder prior to termination or expiration of this Agreement, the remainder of ARTICLE 4, Section 9.3, Section 10.1, Section 10.2 (with respect to ownership of Product Trademarks), Section 10.4 (with respect to provisions regarding jointly owned trademarks), Section 10.6, ARTICLE 11, Section 12.2, Section 12.5, Section 12.6, Section 12.7, ARTICLE 13, ARTICLE 14, and ARTICLE 15 of this Agreement shall survive the termination or expiration of this Agreement for any reason. If this Agreement is terminated with respect to a terminated country but not in its entirety, then following such termination the foregoing provisions of this Agreement shall remain in effect with respect to the terminated country (to the extent they would survive and apply in the event the Agreement expires or is terminated in its entirety), and all provisions not surviving in accordance with the foregoing shall terminate upon termination of this Agreement with respect to the terminated country and be of no further force and effect (and, for purposes of clarity, all provisions of this Agreement shall remain in effect with respect to all countries in the Territory other than the terminated countries).

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification . Subject to Section 13.3, each Party shall defend, indemnify and hold harmless the other Party, its Affiliates and their respective directors, officers, employees and agents (collectively, such Party's " Indemnitees ") from and against all liabilities, losses, damages, and expenses, including reasonable attorneys' fees and costs, (collectively, " Losses ") resulting from all Third Party claims, suits, actions, or demands (collectively, the " Claims ") to the extent that such Losses are incurred, relate to or arise out of (a) the material breach of any provision of this Agreement or a Related Manufacturing Agreement by the indemnifying Party or its Affiliate (or the inaccuracy of any representation or warranty made by such Party in this Agreement or a Related Manufacturing Agreement), or (b) the negligence, recklessness or willful misconduct of the indemnifying Party or its Affiliate in connection with the performance of its obligations under this Agreement or a Related Manufacturing Agreement.

13.2 Indemnification Procedure .

13.2.1 A Party believing that it or its Indemnitees are entitled to indemnification under Section 13.1 (an " Indemnified Party ") shall give prompt written notification to the other Party (the " Indemnifying Party ") of the commencement of any Claim for which indemnification may be sought or, if earlier, upon the assertion of any such Claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third Party Claim as provided in this Section 13.2 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually materially prejudiced as a result of such failure to give notice). Subject to any written agreement by the Parties to the contrary, within **[*]** after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Claim with counsel reasonably satisfactory to the Indemnified Party. If a Party believes that a Claim presented to it for indemnification is one as to which the Party seeking indemnification is not entitled to indemnification under Section 13.1, it shall so notify the Party seeking indemnification.

13.2.2 If the Indemnifying Party elects to assume the defense of such Claim, the Indemnified Party may participate in such defense at its own expense; *provided* , that, if the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such Claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith.

13.2.3 In any event, the Indemnifying Party shall keep the other Party reasonably apprised of the status of such Claim and the defense thereof (including by providing copies of pleadings and such other documents, information, and correspondence reasonably requested by the Indemnified Party) and shall consider in good faith recommendations made by the Indemnified Party with respect thereto.

13.2.4 The Indemnified Party shall not agree to any settlement of such Claim without the prior Party Written Consent of the Indemnifying Party. The Indemnifying Party shall not agree to any settlement of such Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party or adversely affects the Indemnified Party without the prior Party Written Consent of the Indemnified Party, which shall not be unreasonably withheld, conditioned or delayed.

13.3 Treatment of Manufacturing Losses .

13.3.1 For purposes of this Agreement, the following terms shall have the following meanings:

(a) " Manufacturing Losses " shall mean (i) any and all Losses of a Party or both Parties resulting from (A) a Claim or (B) a claim for direct damages or (ii) any other Losses of a Party or both Parties not accounted for in Standard Costs shared by the Parties, in each case in connection with the Manufacturing of Product (including any claim related to or arising out of Product Liability, breach of Product warranty, the inaccuracy of any representation or warranty, failure to comply with Applicable Law or other breach of any provision of this Agreement or a Related Manufacturing Agreement in connection with the Manufacture of Product).

(b) " Cap " means **[*]** .

(c) " Related Manufacturing Agreement " means any supply or quality agreement entered into between the Parties or their Affiliates pursuant to this Agreement.

13.3.2 Notwithstanding anything to the contrary in this Agreement or any Related Manufacturing Agreement, the Parties shall share equally in the aggregate Manufacturing Losses of both Parties and such Manufacturing Losses shall be included as Allowable Expenses hereunder except that a Party shall be responsible for **[*]** percent (**[*]** %) of the aggregate Manufacturing Losses of both Parties during the Term up to the Cap (and such Manufacturing Losses shall not be included as Allowable Expenses hereunder) to the extent that such Manufacturing Losses are incurred, relate to or arise out such Party's or its Affiliate's (A) **[*]** of any provision of this Agreement or a Related Manufacturing Agreement (or the inaccuracy of any representation or warranty made by such Party in this Agreement or a Related Manufacturing Agreement) or (B) **[*]** . For clarity, any such Manufacturing Losses above the Cap shall be included as an Allowable Expense.

13.3.3 For clarity, (a) a Party shall not be responsible for the breach, negligence, recklessness or willful misconduct of any contract manufacturer of Product and any Manufacturing Losses incurred, related to or arising out of such breach, negligence, recklessness or willful misconduct will be shared equally by the Parties as an Allowable Expense (provided, that nothing in this Section 13.3.3(a) is intended to limit the extent to which a Party would otherwise be responsible under Article 13 for Manufacturing Losses incurred, related to or arising out of the breach, negligence, recklessness or willful misconduct of such Party and its Affiliates), and (b) Section 13.3.2 shall not apply (i.e., the Cap shall not apply) to the extent that such Manufacturing Losses are incurred, relate to or arise out of the **[*]** , **[*]** or **[*]** of such Party or its Affiliates (and such Manufacturing Losses shall not be included as Allowable Expenses hereunder).

13.4 No Consequential or Punitive Damages . EXCEPT **[*]** , NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL,

EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING BUSINESS INTERRUPTION, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT, A RELATED MANUFACTURING AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE USE OF THE PRODUCT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

13.5 Effect on Collaboration Agreement . For clarity, the provisions of this ARTICLE 13 shall supersede the provisions of Article 18 of the Collaboration Agreement with respect to any right to indemnification by either Party for Claims to the extent that such Claims relate to or arise out of this Agreement or the performance of obligations under this Agreement (or Related Manufacturing Agreement); provided that Section 18.2.2 of the Collaboration agreement shall continue to apply with respect to the sharing of Liabilities (as defined in the Collaboration Agreement) in connection with the defense or settlement of claims of infringement of Third Party patent rights.

13.6 Manufacturing Losses; Limitation of Liability . With respect to liability for Manufacturing Losses (whether incurred in connection with the Parties' performance of their respective obligations under this Agreement or a Related Manufacturing Agreement, or otherwise), the provisions of this ARTICLE 13 shall apply to the allocation of financial responsibility between the Parties. The allocation of financial responsibility for Manufacturing Losses set forth in this ARTICLE 13 shall apply regardless of whether such Manufacturing Losses arise in contract, tort (including negligence and strict product liability), indemnity, contribution, specific performance or otherwise, and irrespective of whether a party has been advised of, or otherwise might have anticipated the possibility of, any such Manufacturing Losses.

ARTICLE 14
DISPUTE RESOLUTION

14.1 Disputes . The Parties recognize that disputes as to certain matters may from time to time arise that relate to decisions to be made by one or more of the Committees provided for herein or to the Party's respective rights or obligations hereunder. It is the desire of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to arbitration or litigation. To accomplish this objective, the Parties agree that, except for disputes regarding Party Tactical Matters or other matters for which a Party has final decision-making authority, subject to Section 14.2, the dispute resolution procedures set forth in Section 23.3 of the Collaboration Agreement shall apply if and when a dispute arises under this Agreement; *provided* , that if such dispute is regarding a matter subject to Section 2.9.4, then the terms of Section 2.9.4 shall first apply; *provided* , *further* ,

that any dispute as to whether or not a matter (a) is a Party Tactical Matter, (b) requires Joint Committee Consent, or (c) is subject to a Party's final decision-making authority hereunder shall be resolved in accordance with Section 23.3 of the Collaboration Agreement.

14.2 Short Form Arbitration . If a JSC deadlock, Plan Dispute, Royalty Dispute or Financial Dispute arises under this Agreement, the dispute resolution procedures set forth in Section 23.4 of the Collaboration Agreement (rather than Section 23.3.4 of the Collaboration Agreement) shall apply; *provided* , that

14.2.1 if such dispute is regarding a matter subject to Section 2.9.4, then the terms of Section 2.9.4 shall first apply;

14.2.2 if the dispute is a Financial Dispute, the arbitrator shall be an independent auditor or independent qualified valuation expert mutually acceptable to the Parties (or, if the Parties are unable to agree on such auditor or expert, an independent auditor or independent qualified valuation expert selected by the AAA);

14.2.3 if the dispute is a Royalty Dispute, the last approved applicable royalty rate shall remain in full force and effect until the dispute is resolved by the Parties in accordance with Section 2.9.4 or by the arbitrator in accordance with Section 23.4 of the Collaboration Agreement; and

14.2.4 if the dispute is a Plan Dispute, the last approved version of the applicable Approved Plan shall remain in full force and effect, with the most recently approved budget(s) applying for the next Year, until the dispute is resolved by the Parties or the arbitrator in accordance with Section 2.9.4 or Section 23.4 of the Collaboration Agreement.

14.3 Definitions . For purposes of this Agreement, the following definitions shall apply:

14.3.1 " Financial Dispute " means any dispute raised by a Party regarding (a) any accounting, financial (including reporting and controls), or funds flow matters under the purview of the JFC, (b) a royalty report of a Party delivered pursuant to Section 4.2.4, or (c) calculating any payment due to the other Party, but, for clarity, not including any Plan Dispute or any other matter relating to the conduct or inclusion of any matter in any Approved Plan. For clarity, a Financial Dispute shall not include a Royalty Dispute.

14.3.2 " Plan Dispute " means any dispute relating to the contents proposed to be included in an Approved Plan, including any dispute raised by a Party claiming that the budget (or any part thereof) proposed to be included in an Approved Plan is not commercially reasonable.

14.3.3 " Royalty Dispute " means any dispute relating to a royalty rate determination or amendment to Schedule 4.2.1 pursuant to Section 4.2.1(b).

ARTICLE 15
MISCELLANEOUS

15.1 Nonsolicitation of Employees . Each Party agrees that during the Term neither it nor any of its Affiliates that participates in or is responsible for the Commercialization of any Product pursuant to this Agreement shall recruit, solicit or induce any employee of the other Party **[*]** to terminate his or her employment with such other Party and become employed by or consult for such other Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing, "recruit", "solicit" or "induce" shall not be deemed to mean (a) circumstances where an employee of one Party initiates contact with the other Party or any of its Affiliates with regard to possible employment or (b) general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements. This Section 15.1 shall not restrict either Party from recruiting, soliciting or hiring any employee of the other Party or any of its Affiliates who has been identified for termination in connection with any reduction in workforce by such other Party or its Affiliates.

15.2 Maintenance of Records . Each Party shall keep and maintain all records required by Applicable Law (including records for Patent purposes) with respect to the Product and shall make copies of such records available to the other Party upon request.

15.3 Force Majeure . No Party (or any of its Affiliates) shall be held liable or responsible to the other Party (or any of its Affiliates), or be deemed to have defaulted under or breached the Agreement, for failure or delay by such Party in fulfilling or performing any term of the Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party (or any of its Affiliates), including fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, acts of God, earthquakes, or omissions or delays in acting by any governmental authority (" Force Majeure "); *provided* , *however* , that the affected Party shall (i) promptly notify the other Party in writing of the existence of the Force Majeure, and (ii) exert all reasonable efforts to eliminate, cure or overcome any such Force Majeure and to resume performance of its covenants promptly. Notwithstanding the foregoing, to the extent that an event of Force Majeure continues for a period in excess of **[*]** , the affected Party shall promptly notify in writing the other Party of such event of Force Majeure and the Parties shall negotiate in good faith either (a) a resolution of the event of Force Majeure, if possible, (b) an extension by mutual agreement of the time period to resolve, eliminate, cure or overcome such event of Force Majeure, (c) an amendment of this Agreement to the extent reasonably possible, or (d) an early termination of this Agreement.

15.4 Assignment . This Agreement may not be assigned or otherwise transferred, in whole or in part, nor, except as expressly provided hereunder, may any right or obligations hereunder be

assigned or transferred, to any Third Party by either Party without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned, or delayed; *provided* , *however* , that either Party may, without such consent, assign this Agreement and its rights and obligations hereunder (a) to any of its Affiliates or (b) in connection with the transfer or sale of all or substantially all of its business or all or substantially all of its business or assets relating to the Product, or in the event of a Change in Control (in which case, for clarity, the provisions of Section 10.9 shall apply). Written notice of any permitted assignment of this Agreement shall be promptly provided to the non-assigning Party and any permitted assignee shall assume all rights and obligations of its assignor under this Agreement. Any attempted assignment of this Agreement not in accordance with this Section 15.4 shall be void and of no effect. This Agreement shall be binding on, and inure to the benefit of, each Party, its successors and permitted assigns.

15.5 Severability . Each Party hereby agrees that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties hereto shall substitute, by Party Written Consent, valid provisions for such invalid provisions, in their economic effect, are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement based on such valid provisions. In case such alternative provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provisions.

15.6 Insurance. The insurance provisions of Article 22 of the Collaboration Agreement shall apply and survive with respect to activities conducted hereunder during the Term for a period of at least **[*]** thereafter.

15.7 Notices . Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties hereto to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery, first class air mail or courier), first class air mail or courier, postage prepaid (where applicable), addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the address to the other Party in accordance with this Section 15.7 and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

For Agensys:

Agensys, Inc.
c/o Astellas Pharma Inc.
5-1 Nihonbashi-Honcho, 2-Chome

Chuo-ku, Tokyo 103-8411 Japan
Attention: Vice President, Business Development
Fax: **[*]**

With copies in each case to:

Astellas US LLC
1 Astellas Way
Northbrook, IL 60062
Attention: Vice President and Legal Head,
Business Development & Alliance Management
Fax: **[*]**

For SGI:

Seattle Genetics, Inc.
21823 30th Drive St
Bothell, WA 98021
Fax: **[*]**
Email: **[*]** Attention: General Counsel

Invoices to SGI: **[*]**

With copies of invoices to:

Accounts Payable
21823 – 30th Drive SE
Bothell, WA 98021

15.8 Governing Law . The Agreement shall be governed by and construed in accordance with the laws of the State of California, without regard to the conflict of law principles thereof that may dictate application of the laws of any other state.

15.9 Headings; Construction .

15.9.1 Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party hereto as being responsible for the wording or drafting of this

Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

15.9.2 The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall". The word "any" shall mean "any and all" unless otherwise clearly indicated by context. The word "or" is used in the inclusive sense (and/or) unless the context otherwise requires.

15.9.3 Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Applicable Laws herein shall be construed as referring to such Applicable Laws as from time to time enacted, repealed or amended, (c) any reference herein to any Person shall be construed to include the Person's successors and permitted assigns, (d) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (e) all references herein to Articles, Sections or Schedules, unless otherwise specifically provided, shall be construed to refer to Articles, Sections and Schedules of this Agreement. As used herein, the reference to an Article refers to all of the Sections under that Article (for example, Sections 15.1 through 15.15 in the case of this ARTICLE 15).

15.9.4 The headings of Articles and Sections of this Agreement are for ease of reference only and shall not affect the meaning or interpretation of this Agreement in any way.

15.10 No Third Party Beneficiaries . No Person other than Agensys, SGI and their respective Affiliates, successors and permitted assignees hereunder, shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

15.11 Entire Agreement; Amendment . This Agreement, together with the Schedules hereto, the Collaboration Agreement and the supply agreement, quality agreement, and pharmacovigilance agreements referenced herein, contains the entire understanding of the Parties with respect to the specific subject matter hereof. All other express or implied agreements and understandings, either oral or written, heretofore made are expressly superseded. To the extent the terms and conditions of this Agreement conflict or are otherwise inconsistent with the terms of the Collaboration Agreement or the supply agreement, quality agreement, and pharmacovigilance

agreements referenced herein, the terms and conditions of this Agreement shall prevail; *provided* that (a) with respect to the Collaboration Agreement, the terms and conditions of this Agreement shall only apply and prevail with respect to the Product and not any other product developed under the Collaboration Agreement, (b) the terms and conditions of such pharmacovigilance agreements shall prevail with respect to Product safety matters, and (c) the terms and conditions of such quality agreement shall prevail with respect to Product quality matters. Notwithstanding anything to the contrary, the Collaboration Agreement may not be terminated with respect to Product for so long as this Agreement continues to survive. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.

15.12 Independent Contractors . SGI and Agensys each acknowledge that they shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture, agency or any type of fiduciary relationship. Neither SGI nor Agensys shall have the authority to make any statements, representations or commitments of any kind, or take any action, which shall be binding on the other Party, without the prior consent of the other Party to do so.

15.13 Affiliates .

15.13.1 Either Party may perform any or all of its obligations under this Agreement through one or more Affiliates (or affiliates of Affiliates); provided that such Party shall remain fully liable for the obligations under this Agreement and any acts or omissions of such Affiliates. Each Party shall cause its respective Affiliates to comply fully with the provisions of this Agreement to the extent such provisions specifically relate to, or are intended to specifically relate to, such Affiliates, as though such Affiliates were expressly named as joint obligors hereunder. In addition, notwithstanding any limitations in the Collaboration Agreement, each Party shall have the right to extend the rights, licenses, immunities and obligations granted in this Agreement and the Collaboration Agreement to one or more of its Affiliates (but only for so long as such Person is and remains an Affiliate of such Party) and any such extension to Affiliates prior to the Effective Date is hereby deemed approved. All applicable terms and provisions of this Agreement and the Collaboration Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the extending Party.

15.13.2 To the extent required by Applicable Law, the Parties shall cause their relevant local Affiliates in any country in the Territory to enter into local agreements, to implement the arrangements provided for in this Agreement. Such implementing agreements shall be in forms mutually agreed by the Parties and shall be, in all material respects, consistent with the terms and conditions of this Agreement, including by having termination provisions that are not inconsistent with ARTICLE 12 of this Agreement.

15.14 No Waiver . Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

15.15 Counterparts . This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by delivery of electronically scanned copies of original signatures delivered by facsimile or electronic mail, and such signatures shall be deemed to bind each Party as if they were original signatures.

{Signature Pages Follow}

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

AGENSYS, INC.

By: /s/ Akihiko Iwai
Akihiko Iwai
President

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

SEATTLE GENETICS, INC.

By: /s/ Clay B. Siegall
Clay B. Siegall, Ph.D.
President and Chief Executive Officer

{Signature Page to Joint Commercialization Agreement}

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.

SCHEDULE 1.6
AMERICAS REGION

[*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.

SCHEDULE 4.2.1
ROYALTY RATES

[*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.

Exhibit 10.2

TWELFTH AMENDMENT
TO DEVELOPMENT AND SUPPLY AGREEMENT

Effective as of the date of the last signature below, AbbVie Inc. (the successor-in-interest to Abbott Laboratories), a Delaware corporation having a principal place of business at 1 N Waukegan Road, North Chicago, IL 60064 (" ***AbbVie*** "), and Seattle Genetics, Inc., a Delaware corporation having a principal place of business at 21823 – 30 th Drive Southeast in Bothell, Washington 98021 (" ***Seattle Genetics*** ") (individually the " ***Party*** " or collectively the " ***Parties*** ") agree to the following terms and conditions as set forth below (this " ***Twelfth Amendment*** "). Capitalized terms used but not defined herein shall have the meaning ascribed to them in the Agreement (as defined below).

WHEREAS, the Parties entered into a Development and Supply Agreement with an Effective Date of February 23, 2004 for the manufacture of a chimeric anti-CD30 AC10 monoclonal antibody known as cAC10 Bulk Drug Intermediate (the " ***Original Agreement*** "), which also constitutes the antibody component of SGN-35, and the Parties subsequently entered into eight amendments to the Original Agreement (collectively, the Original Agreement and those eight amendments are hereinafter referred to as the " ***Agreement*** ");

WHEREAS, Abbott Laboratories (" ***Abbott*** ") and AbbVie entered into a Separation and Distribution Agreement dated as of November 28, 2012 (the " ***Separation and Distribution Agreement*** "), which provided for, among other things, the separation of Abbott's research-based pharmaceuticals business from its other business by the contribution from Abbott to AbbVie of certain assets, the assumption of AbbVie of certain Liabilities (as defined in the Separation and Distribution Agreement) from Abbott, the distribution by Abbott of AbbVie common stock to Abbott shareholders, and the execution and delivery of certain agreements in order to facilitate and provide for the foregoing, in each case subject to the terms and conditions set forth therein;

WHEREAS , in connection with the Separation and Distribution Agreement, Abbott assigned, transferred and conveyed all of its rights and obligations under the Agreement to AbbVie and AbbVie accepted and assumed all rights and obligations of Abbott under the Agreement as further set forth below; and

WHEREAS , the Parties desire to further amend the Agreement as herein provided as of the date of the last signature below.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained here and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Incorporation of the Agreement . All capitalized terms which are used but not otherwise defined herein shall have the same meanings as set forth in the Agreement, and the Agreement, to the extent not inconsistent with this Twelfth Amendment, is incorporated herein by this reference as though the same was set forth in its entirety. To the extent any terms and provisions of the Agreement are

inconsistent with this Twelfth Amendment, such terms and provisions shall be deemed superseded by the Twelfth Amendment. Except as specifically set forth herein, the Agreement shall remain in full force and effect and its provisions shall be binding on the Parties.

2. Process Development Work. The Parties agree that AbbVie shall perform the Stage set forth in Attachment 1 hereto entitled "Stage 14: Stability Testing" pursuant to the terms and conditions of the Agreement and this Twelfth Amendment.

3. Payment Schedule. As compensation for the Stage to be performed by AbbVie pursuant to Attachment 1 hereto and the remaining compensation due to AbbVie pursuant to Stage 13A that was the subject of the Seventh Amendment to Development and Supply Agreement between the Parties, Seattle Genetics shall pay to AbbVie on the dates and in the amounts set forth in Attachment 2 hereto entitled "Updated Summarized Payment Schedule (Amendments 7 & 9)".

4. Project References. All references to the Project set forth in the Agreement shall also be deemed to apply to the Stage performed by AbbVie pursuant to this Twelfth Amendment.

5. Effectuation. The amendment to the Agreement contemplated by this Twelfth Amendment shall be deemed effective as of the last date written below upon the full execution of this Twelfth Amendment and without any further action required by the Parties hereto. There are no conditions precedent or subsequent to the effectiveness of this Twelfth Amendment. All terms and conditions set forth in the Agreement that are not amended hereby shall remain in full force and effect. Any term of this Twelfth Amendment may be amended with the written consent of both Parties. From the date hereof, any reference to the Agreement shall be deemed to refer to the Agreement as amended by this Twelfth Amendment.

6. Counterparts. This Twelfth Amendment may be executed in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. One or more counterparts of this Twelfth Amendment may be delivered by facsimile, with the intention that delivery by such means shall have the same effect as delivery of an original counterpart thereof.

7. Entire Agreement. This Twelfth Amendment is the product of both Parties, and together with the Agreement and exhibits thereto, constitute the entire agreement between the Parties pertaining to the subject matter hereof, and merge all prior negotiations and drafts of the Parties with regard to the transactions contemplated herein.

IN WITNESS WHEREOF, the Parties have caused this Twelfth Amendment to be executed by their duly authorized officers as of the date of the last signature set forth below.

ABBVIE INC.	**SEATTLE GENETICS, INC.**
By: /s/ Jennifer Cannon	By: /s/ Vaughn Himes
Name: Jennifer Cannon	Name: Vaughn Himes
Title: VP, Operations Contract Manufacturing	Title: Chief Technical Officer
Date: 4/25/2019	Date: 4/23/2019

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.

Attachment 1

STAGE 14: STABILITY TESTING

[*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.

Attachment 2

UPDATED SUMMARIZED PAYMENT SCHEDULE (Amendments 9, 11 and 12)

[*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.

Exhibit 10.3

EXECUTIVE EMPLOYMENT AGREEMENT

THIS EXECUTIVE EMPLOYMENT AGREEMENT (" Agreement ") is made and entered into as of the 20th day of May, 2019, by and between SEATTLE GENETICS, INC., a Delaware corporation (" Company ") and Robin Taylor (" Executive ").

RECITALS:

A. The Company desires that Executive perform services as Chief Commercial Officer of the Company, having been duly appointed to such position.

B. Executive desires to accept such engagement.

C. This Agreement contains other provisions applicable to the employment of Executive by the Company.

In consideration of the above Recitals and the provisions of this Agreement, the Company and Executive agree as follows:

I. DUTIES

1.1 *Title and Responsibilities.* Executive shall serve as Chief Commercial Officer of the Company, which title may be changed at any time in the sole discretion of the Company. Executive's responsibilities and duties shall include those inherent in Executive's position with the Company and shall further include such other managerial responsibilities and executive duties consistent with such position as may be assigned to Executive from time to time by the Chief Executive Officer of the Company, and as applicable, the executive officer to whom Executive reports. Executive shall devote Executive's best efforts and full business time to the business and interests of the Company. During the term of Executive's employment with the Company, Executive may serve on the board of directors of other companies, manage personal investments, and engage in civic and charitable activities, provided that such activities shall not represent a conflict of interest with the Company and do not materially detract from fulfilling Executive's responsibilities and duties to the Company.

II. COMPENSATION

2.1 *Base Salary.* Executive shall be paid a base salary (" Base Salary ") by the Company during the term of Executive's employment at the rate determined by the Compensation Committee of the Board of Directors (the " Compensation Committee "), or as applicable, any individual authorized to approve the terms of employment of Executive, which is currently $500,000 per year. Executive's Base Salary shall be reviewed annually and evaluated based on performance and any other factors determined appropriate by the Compensation Committee, or as applicable, any individual authorized to approve the terms of employment of Executive, in its or their sole discretion. Based upon such evaluation and review, Executive's Base Salary may be adjusted from time to time as determined by the Compensation Committee, or as applicable, any

individual authorized to approve the terms of employment of Executive, in its or their sole discretion.

2.2 *Bonus.* In addition to Base Salary, Executive may be eligible to receive an annual bonus (" Annual Bonus "), currently targeted at fifty percent (50%) of Executive's Base Salary, based upon performance criteria as determined by the Compensation Committee, or as applicable, any individual authorized to approve the terms of employment of Executive.

2. 3 *Equity Awards* . Executive may be eligible to receive grants of stock options or other equity awards from time to time in the future, on such terms and subject to such conditions as the Compensation Committee, or as applicable, any individual authorized to approve the terms of employment of Executive, shall determine as of the date of any such grant and pursuant to the existing equity plan(s) of the Company.

2.4 *Other Benefits.*

(i) Executive shall be entitled to such employee benefits generally available to full-time salaried employees of the Company, including without limitation, health insurance, paid vacation of not less than four (4) weeks per year, retirement plans and other similar benefits; provided, that Company reserves the right to amend, modify, terminate or make any other changes in such benefits generally available to full-time salaried employees of the Company at any time in its sole discretion.

(ii) The Company shall pay or reimburse Executive for all travel and entertainment expenses incurred by Executive in connection with Executive's duties on behalf of the Company, subject to the reasonable approval of the Company. Executive shall only be entitled to reimbursement to the extent that Executive follows the procedures set forth in the Company's travel and expense policy, as then in effect, which will include, but will not be limited to, providing satisfactory evidence of such expenditures.

III. TERMINATION OF EMPLOYMENT

3.1 *Termination of Employment and Severance Benefits* **.**

(a) *Termination of Employment* **.** This Agreement may be terminated upon the occurrence of any of the following events:

(i) The Company's determination in good faith that it is terminating Executive for Cause (as defined in Section 3.3 below) (" Termination for Cause ");

(ii) The Company's determination that it is terminating Executive without Cause, which determination may be made by the Company at any time at the Company's sole discretion, for any or no reason (" Termination Without Cause ");

(iii) The effective date of a written notice sent to the Company from Executive stating that Executive is electing to terminate Executive's employment with the Company (" Voluntary Termination ");

(iv) A change in Executive's status such that a Constructive Termination (as defined in Section 3.2(d) below) has occurred; or

(v) Following Executive's death or Disability (as defined in Section 3.4 below).

3.2 *Severance Benefits* **.** Executive shall be entitled to receive severance benefits upon termination of employment only as set forth in this Section 3.2 contingent upon resignation from all positions held by Executive and only if Executive executes a full release and waiver of claims within thirty (30) days of Executive's termination (and allows it to become effective in accordance with its terms):

(a) Voluntary Termination **.** If Executive's employment terminates by Voluntary Termination, then Executive shall not be entitled to receive payment of any severance benefits. Executive will receive payment(s) for all salary and unpaid vacation accrued as of the date of Executive's termination of employment and Executive's benefits will be continued under the Company's then existing benefit plans and policies in accordance with such plans and policies in effect on the date of termination and in accordance with applicable law.

(b) Involuntary Termination **.** If Executive's employment is terminated under Section 3.1(a)(ii) (Termination Without Cause) or 3.1(a)(iv) (Constructive Termination) above (such termination, an " Involuntary Termination "), Executive will be entitled to receive payment of severance benefits equal to Executive's regular monthly salary (the " Salary Payment Amount ") for twelve (12) months (the " Severance Period "); provided that if such Involuntary Termination occurs immediately prior to or within twelve (12) months after a Change of Control (as defined below), such Severance Period shall be for a period of eighteen (18) months and such payment shall not be less than the amount that would result from using Executive's regular monthly salary in effect immediately prior to the Change of Control. Executive will also be entitled to receive a payment equal to the target Annual Bonus established for Executive for the fiscal year in which the termination occurs (the " Bonus Payment Amount "); provided that if such Involuntary Termination occurs immediately prior to or within twelve (12) months after a Change of Control, then Executive shall be entitled to receive a payment equal to 1.5 times the Bonus Payment Amount and such payment shall not be less than the amount that would result from using Executive's regular monthly salary and target bonus percentage in effect immediately prior to the Change of Control. Such Salary Payment Amount and Bonus Payment Amount shall be paid, at the Company's option, in a lump sum within sixty (60) days after the date of Executive's Involuntary Termination or periodically over the Severance Period according to the Company's standard payroll schedule, provided that such payments may not extend beyond two and one-half (2 ½) months following the end of the calendar year in which the date of Involuntary Termination occurs. Executive will receive payment(s) for all salary and unpaid vacation accrued as of the date of Executive's termination of employment and health insurance benefits will be continued through payment of Executive's COBRA health insurance premiums

by the Company over the Severance Period so long as Executive timely elects to continue Executive's health insurance coverage under COBRA and subject to COBRA's terms, conditions and requirements.

(c) Termination for Cause **.** If Executive's employment is terminated for Cause, then Executive shall not be entitled to receive payment of any severance benefits. Executive will receive payment(s) for all salary and unpaid vacation accrued as of the date of Executive's termination of employment and Executive's benefits will be continued under the Company's then existing benefit plans and policies in accordance with such plans and policies in effect on the date of termination and in accordance with applicable law.

(d) Constructive Termination **.** " Constructive Termination " shall be deemed to occur if (A) there is a material reduction or change in job duties, responsibilities and requirements inconsistent with Executive's position with the Company and prior duties, responsibilities and requirements, provided that neither a mere change in title alone nor reassignment to a position that is substantially similar to the position held prior to the change in terms of job duties, responsibilities or requirements shall constitute a material reduction in job responsibilities; or (B) there is a reduction in Executive's then-current base salary by at least twenty percent (20%), provided that an across-the-board reduction in the salary level of all other senior executives by the same percentage amount as part of a general salary level reduction shall not constitute such a salary reduction; or (C) Executive refuses to relocate to a facility or location more than 50 miles from the Company's current location; provided, however, that in each case above, Executive must first provide notice of the existence of the circumstances giving rise to a Constructive Termination within ninety (90) days of the initial existence of such circumstances and the Company must be provided with a period of thirty (30) days from the date of receipt of such notice to cure the circumstances giving rise to a Constructive Termination; provided further that the Company may notify Executive at any time prior to expiration of the cure period that it will not cure the circumstances, in which case the cure period shall end immediately upon such notification.

(e) Termination by Reason of Death or Disability **.** In the event that Executive's employment with the Company terminates as a result of Executive's death or Disability (as defined in Section 3.4 below), Executive or Executive's estate or representative will receive all salary and unpaid vacation accrued as of the date of Executive's death or Disability and any other benefits payable under the Company's then existing benefit plans and policies in accordance with such plans and policies in effect on the date of death or Disability and in accordance with applicable law. In addition, Executive's estate or representative will receive the amount of Executive's target Annual Bonus for the fiscal year in which the death or Disability occurs, as determined by the Board of Directors or its Compensation Committee, which will be paid prior to two and one-half (2 ½) months following the year of Executive's death or Disability (subject to Executive's termination as a result of such Disability).

3.3 *Definition of Cause* **.** For purposes of this Agreement, " Cause " for Executive's termination will exist at any time after the happening of one or more of the following events:

(a) An action or omission of Executive which constitutes a willful and intentional material breach of this Agreement or the Confidentiality Agreement (defined below), including without limitation, Executive's theft or other misappropriation of the Company's proprietary information;

(b) Executive's commitment of fraud, embezzlement, misappropriation of funds or breach of trust in connection with Executive's employment; or

(c) Executive's conviction of any crime which involves dishonesty or a breach of trust, or gross negligence in connection with the performance of the Executive's duties.

3.4. *Definition of Disability* **.** For purposes of this Agreement " Disability " shall mean any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than twelve (12) months and renders Executive unable to perform the duties of Chief Commercial Officer.

IV. STOCK ACCELERATION

4.1 *Accelerated Vesting* . Unless specifically provided otherwise in the applicable equity award agreement, in addition to any other right of acceleration that may be provided pursuant to any equity award plan or agreement pursuant to which Executive has been granted an equity award by the Company, if Executive's employment is terminated due to an Involuntary Termination, the vesting of any equity awards granted by the Company to Executive shall accelerate such that such equity awards shall become vested as to an additional twelve (12) months, effective as of the date of such Involuntary Termination, to the extent that such equity awards are outstanding and unvested as of the date of such Involuntary Termination; provided that if such Involuntary Termination occurs immediately prior to or within twelve (12) months after a Change of Control (as defined below), then the vesting of all such equity awards shall be accelerated completely so that such equity awards shall become fully vested, effective as of the date of such Involuntary Termination, to the extent that such equity awards are outstanding and unvested as of the date of such Involuntary Termination. For the avoidance of any doubt, this Section shall prevail over any provision in an equity award agreement providing that unvested equity awards shall terminate or be forfeited as of the date of such termination, and any such provision shall be inoperative to the extent it is in conflict with this Section.

4.2 *Definition of Change of Control.* For purposes of this Agreement, " Change of Control " shall mean the occurrence of any of the following events: (i) an acquisition of the Company by another entity by means of any transaction or series of related transactions (including, without limitation, any reorganization, merger or consolidation but excluding any merger effected exclusively for the purpose of changing the domicile of the Company), or (ii) a sale of all or substantially all of the assets of the Company (collectively, a " Merger "), so long as in either case the Company's stockholders of record immediately prior to such Merger will, immediately after such Merger, hold less than fifty percent (50%) of the voting power of the surviving or acquiring entity.

V. RESTRICTIVE COVENANTS

5.1 *Confidentiality Agreement* **.** Executive shall sign, or has signed the Company's form of Proprietary Information and Inventions Agreement (the " Confidentiality Agreement "). Executive hereby represents and warrants to the Company that Executive has complied with all obligations under the Confidentiality Agreement and agrees to continue to abide by the terms of the Confidentiality Agreement and further agrees that the provisions of the Confidentiality Agreement shall survive any termination of this Agreement or of Executive's employment relationship with the Company, including the noncompetition provisions of the Confidentiality Agreement.

VI. OTHER PROVISIONS

6.1 *Limitation on Change of Control Payments and Benefits* . In the event that any payment or benefit that Executive would receive from the Company or otherwise in connection with a Change of Control or other similar transaction (a " 280G Payment ") (i) would constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the " Code ") and (ii) but for this Section 6.1, would be subject to the excise tax imposed by Section 4999 of the Code, then any such 280G Payment shall be payable either:

(a) in full, or

(b) as to such lesser amount which would result in no portion of such payments and benefits being subject to excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Executive on an after-tax basis, of the greatest amount of payments and benefits notwithstanding that all or some portion of such payments and benefits may be taxable under Section 4999 of the Code. Any determination required under this Section 6.1 shall be made in writing by independent public accountants appointed by Executive and reasonably acceptable to the Company (the " Accountants "), whose determination shall be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required by this Section 6.1, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section 6.1. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 6.1. If a reduced amount is to be paid under this Section 6.1, reductions in payments and/or benefits shall occur in the following order: (1) reduction of cash payments, (2) cancellation of accelerated vesting of stock awards other than stock options, (3) cancellation of accelerated vesting of stock options and (4) reduction of other benefits (if any) paid to the Executive.

6.2 *Code Section 409A* . This Agreement shall be interpreted to avoid any penalty sanctions under Section 409A of the Code and the final regulations and any guidance promulgated thereunder (" Section 409A "). If any payment or benefit cannot be provided or made at the time specified herein without incurring sanctions under Section 409A, then such benefit or payment shall be provided in full at the earliest time thereafter when such sanctions will not be imposed. All payments to be made upon a termination of employment under this Agreement may be made only upon a "separation of service" under Section 409A. Notwithstanding anything to the contrary in this Agreement, if at the time of Executive's termination of employment, Executive is a "specified employee" within the meaning of Section 409A, and the deferral of the commencement of any severance payments or benefits otherwise payable pursuant to this Agreement as a result of such termination of employment is necessary in order to prevent any accelerated income recognition or additional tax under Section 409A(a)(1), then the Company will not commence any payment of any such severance payments or benefits otherwise required hereunder (but without any reduction in such payments or benefits ultimately paid or provided to Executive) that (a) will not and may not under any circumstances, regardless of when such termination occurs, be paid in full by March 15 of the year following Executive's termination (or two and one half (2 ½) months after the close of the Company's fiscal year, if later), and (b) are in excess of the lesser of (i) two (2) times Executive's then annual compensation or (ii) two (2) times the limit on compensation set forth in Section 401(a)(17) of the Code for the year in which Executive's employment is terminated and will not be paid by the end of the second calendar year following the year in which the termination occurs, until the first payroll date that occurs after the date that is six (6) months following Executive's "separation of service" with the Company (as defined under Code Section 409A). If any payments are delayed due to such requirements, such amounts will be paid in a lump sum to Executive on the earliest of (x) Executive's death following the date of Executive's termination of employment with the Company or (y) the first payroll date that occurs after the date that is six (6) months following Executive's "separation of service" with the Company. For these purposes, each severance payment or benefit is designated as a separate payment or benefit and will not collectively be treated as a single payment or benefit. This provision is intended to comply with the requirements of Code Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. The Company and Executive agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Executive under Section 409A. Notwithstanding anything to the contrary set forth in this Agreement, to the extent that any amendment to this Agreement with respect to the payment of any severance payments or benefits would constitute under Section 409A a delay or acceleration in a payment or a change in the form of payment, then such amendment must be done in a manner that complies with Section 409A(a)(4)(C).

6.3 *Indemnification* . The Company hereby agrees to indemnify and hold the Executive harmless, to the fullest extent permitted by law and as set forth in the Amended and Restated Certificate of Incorporation of the Company, from and against any expenses, including legal fees, and all judgments, fines and amounts paid in settlement and reasonably incurred in connection with legal, administrative or investigative proceedings to which the Executive is made, or

threatened to be made, a party by reason of the fact the Executive is or was a director or officer of the Company.

6.4 *Entire Agreement.* This Agreement, the Confidentiality Agreement, the indemnification agreement between Executive and the Company and any agreement pertaining to Executive's equity awards contain the entire agreement and understanding of the parties with respect to Executive's employment by the Company and compensation payable to Executive by the Company and supersede all prior understandings, agreements and discussions. This Agreement may only be amended or modified by a written instrument executed by Executive and the Company pursuant to authorization by any individual or individuals authorized to approve the compensation and other terms of employment of Executive.

6.5 *Notices.* Any and all notices permitted or required to be given under this Agreement must be in writing. Notices will be deemed given (i) on the first business day after having been sent by commercial overnight courier with written verification of receipt, or (ii) on the third business day after having been sent by registered or certified mail from a location on the United States mainland, return receipt requested, postage prepaid, whichever occurs first, at the address set forth below or at any new address, notice of which will have been given in accordance with this Section 6.5:

If to the Company: Seattle Genetics, Inc.
21823 30 th Drive SE
Bothell, WA 98021
Attn: General Counsel

If to Executive: Robin Taylor
c/o Seattle Genetics, Inc.
21823 30 th Drive SE
Bothell, WA 98021

6.6 *Non-Waiver.* Failure to enforce at any time any of the provisions of this Agreement shall not be interpreted to be a waiver of such provisions or to affect either the validity of this Agreement or the right of either party thereafter to enforce each and every provision of this Agreement.

6.7 *Separability.* If one or more provisions of this Agreement is finally determined to be invalid or unenforceable, such provision will not affect or impair the other provisions of this Agreement, all of which will continue to be in effect and will be enforceable, provided, however, that any such invalid provisions shall, to the extent possible, be reformed so as to implement insofar as practicable the intentions of the parties.

6.8 *Term.* The employment of Executive under this Agreement shall be for an unspecified term. The Company and Executive acknowledge and agree that Executive's employment is and shall continue to be at-will, as defined under applicable law, and that Executive's employment with the Company may be terminated by either party at any time for

any or no reason, and with or without notice. If Executive's employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages award or compensation other than as provided in this Agreement.

6.9 *Law.* This Agreement shall be interpreted in accordance with the laws of the State of Washington.

6 . 10 *No Duty to Mitigate* **.** Executive shall not be required to mitigate the amount of any payment contemplated by this Agreement (whether by seeking new employment or in any other manner), nor, except as otherwise provided in this Agreement, shall any such payment be reduced by any earnings that Executive may receive from any other source.

6.11 *Legal Fees.* In the event either party breaches this Agreement, the nonbreaching party shall be entitled to recover from the breaching party any and all damages, costs and expenses, including without limitation, attorneys' fees and court costs, incurred by the nonbreaching party as a result of the breach.

6 . 12 *Counterparts* . This Agreement may be executed in counterparts which when taken together will constitute one instrument. Any copy of this Agreement with the original signatures of all parties appended will constitute an original.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

COMPANY:

SEATTLE GENETICS, INC.

By: /s/ Christopher Pawlowicz

Name: Christopher Pawlowicz

Title: EVP – HR

EXECUTIVE

/s/ Robin Taylor
Robin Taylor

Exhibit 31.1

CERTIFICATIONS

I, Clay B. Siegall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Seattle Genetics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Clay B. Siegall

Clay B. Siegall

Chief Executive Officer

(Principal Executive Officer)

Date: July 16, 2019

Exhibit 31.2

CERTIFICATIONS

I, Todd E. Simpson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Seattle Genetics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Todd E. Simpson

Todd E. Simpson

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: July 16, 2019

Exhibit 32.1

SEATTLE GENETICS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Seattle Genetics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Clay B. Siegall, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Clay B. Siegall

Clay B. Siegall
Chief Executive Officer
(Principal Executive Officer)

Date: July 16, 2019

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Seattle Genetics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

SEATTLE GENETICS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Seattle Genetics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Todd E. Simpson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Todd E. Simpson

Todd E. Simpson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: July 16, 2019

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Seattle Genetics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.