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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2020

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

SEAGEN INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

91-1874389
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

As of October 27, 2020, there were 180,306,390 shares of the registrant's common stock outstanding.

Seagen Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 2020

INDEX

	Page
PART I. FINANCIAL INFORMATION (Unaudited)	
Item 1.	Condensed Consolidated Financial Statements
	Condensed Consolidated Balance Sheets
	Condensed Consolidated Statements of Comprehensive Income (Loss)
	Condensed Consolidated Statements of Stockholders' Equity
	Condensed Consolidated Statements of Cash Flows
	Notes to Condensed Consolidated Financial Statements
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations
Item 3.	Quantitative and Qualitative Disclosures About Market Risk
Item 4.	Controls and Procedures
PART II. OTHER INFORMATION	
Item 1.	Legal Proceedings
Item 1A.	Risk Factors
Item 6.	Exhibits
SIGNATURE	80

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

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

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 919,454	\$ 274,562
Short-term investments	798,921	536,493
Accounts receivable, net	293,416	236,001
Inventories	96,727	85,932
Prepaid expenses and other current assets	57,521	43,653
Total current assets	2,166,039	1,176,641
Property and equipment, net	192,867	155,491
Operating lease right-of-use assets	64,282	65,230
Long-term investments	—	57,283
Intangible assets, net	289,484	25
In-process research and development	—	300,000
Goodwill	274,671	274,671
Other non-current assets	17,618	176,525
Total assets	\$ 3,004,961	\$ 2,205,866
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 68,650	\$ 52,292
Accrued liabilities and other	274,038	207,065
Deferred revenue	250,450	—
Total current liabilities	593,138	259,357
Long-term liabilities:		
Operating lease liabilities, long-term	65,003	67,607
Other long-term liabilities	88,790	2,615
Total long-term liabilities	153,793	70,222
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; 175,188 shares issued and outstanding at September 30, 2020 and 171,994 shares issued and outstanding at December 31, 2019	175	172
Additional paid-in capital	3,293,668	3,359,124
Accumulated other comprehensive income	850	229
Accumulated deficit	(1,036,663)	(1,483,238)
Total stockholders' equity	2,258,030	1,876,287
Total liabilities and stockholders' equity	\$ 3,004,961	\$ 2,205,866

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Net product sales	\$ 267,494	\$ 167,582	\$ 706,473	\$ 461,563
Royalty revenues	35,924	27,261	87,520	66,218
Collaboration and license agreement revenues	758,313	18,420	780,250	99,128
Total revenues	<u>1,061,731</u>	<u>213,263</u>	<u>1,574,243</u>	<u>626,909</u>
Costs and expenses:				
Cost of sales	78,296	10,827	155,962	32,024
Research and development	217,670	196,119	610,945	518,313
Selling, general and administrative	127,579	96,101	375,470	258,703
Total costs and expenses	<u>423,545</u>	<u>303,047</u>	<u>1,142,377</u>	<u>809,040</u>
Income (loss) from operations	638,186	(89,784)	431,866	(182,131)
Investment and other income (loss), net	1,223	(2,129)	17,951	(2,349)
Income (loss) before income taxes	639,409	(91,913)	449,817	(184,480)
Provision for income taxes	(3,242)	—	(3,242)	—
Net income (loss)	<u>\$ 636,167</u>	<u>\$ (91,913)</u>	<u>\$ 446,575</u>	<u>\$ (184,480)</u>
Net income (loss) per share - basic	<u>\$ 3.65</u>	<u>\$ (0.55)</u>	<u>\$ 2.58</u>	<u>\$ (1.13)</u>
Net income (loss) per share - diluted	<u>\$ 3.50</u>	<u>\$ (0.55)</u>	<u>\$ 2.47</u>	<u>\$ (1.13)</u>
Shares used in computation of per share amounts - basic	<u>174,460</u>	<u>168,109</u>	<u>173,409</u>	<u>163,428</u>
Shares used in computation of per share amounts - diluted	<u>181,877</u>	<u>168,109</u>	<u>180,939</u>	<u>163,428</u>
Comprehensive income (loss):				
Net income (loss)	\$ 636,167	\$ (91,913)	\$ 446,575	\$ (184,480)
Other comprehensive income (loss):				
Unrealized gain (loss) on securities available-for-sale, net of tax	(790)	(177)	441	297
Foreign currency translation gain (loss)	172	(7)	180	45
Total other comprehensive income (loss)	<u>(618)</u>	<u>(184)</u>	<u>621</u>	<u>342</u>
Comprehensive income (loss)	<u>\$ 635,549</u>	<u>\$ (92,097)</u>	<u>\$ 447,196</u>	<u>\$ (184,138)</u>

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

Seagen Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
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
Net loss	—	—	—	—	(91,913)	(91,913)
Other comprehensive loss	—	—	—	(184)	—	(184)
Issuance of common stock for employee stock purchase plan	85	—	5,452	—	—	5,452
Stock option exercises	513	—	17,854	—	—	17,854
Restricted stock vested during the period, net	658	1	(1)	—	—	—
Issuance of common stock	8,214	8	548,683	—	—	548,691
Share-based compensation	—	—	27,875	—	—	27,875
Balances as of September 30, 2019	<u>171,108</u>	<u>\$ 171</u>	<u>\$ 3,288,196</u>	<u>\$ 302</u>	<u>\$ (1,509,068)</u>	<u>\$ 1,779,601</u>
Balances as of December 31, 2019	171,994	\$ 172	\$ 3,359,124	\$ 229	\$ (1,483,238)	\$ 1,876,287
Net loss	—	—	—	—	(168,402)	(168,402)
Other comprehensive income	—	—	—	3,249	—	3,249
Issuance of common stock for employee stock purchase plan	133	—	8,513	—	—	8,513
Stock option exercises	442	1	13,272	—	—	13,273
Restricted stock vested during the period, net	67	—	—	—	—	—
Share-based compensation	—	—	32,698	—	—	32,698
Balances as of March 31, 2020	172,636	173	3,413,607	3,478	(1,651,640)	1,765,618
Net loss	—	—	—	—	(21,190)	(21,190)
Other comprehensive loss	—	—	—	(2,010)	—	(2,010)
Stock option exercises	858	1	31,484	—	—	31,485
Restricted stock vested during the period, net	371	—	—	—	—	—
Share-based compensation	—	—	40,174	—	—	40,174
Balances as of June 30, 2020	173,865	174	3,485,265	1,468	(1,672,830)	1,814,077
Net income	—	—	—	—	636,167	636,167
Other comprehensive loss	—	—	—	(618)	—	(618)
Premium for commitment to sell common stock	—	—	(250,150)	—	—	(250,150)
Issuance of common stock for employee stock purchase plan	75	—	6,948	—	—	6,948
Stock option exercises	352	—	12,554	—	—	12,554
Restricted stock vested during the period, net	896	1	(1)	—	—	—
Share-based compensation	—	—	39,052	—	—	39,052
Balances as of September 30, 2020	<u>175,188</u>	<u>\$ 175</u>	<u>\$ 3,293,668</u>	<u>\$ 850</u>	<u>\$ (1,036,663)</u>	<u>\$ 2,258,030</u>

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

Seagen Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2020	2019
Operating activities:		
Net income (loss)	\$ 446,575	\$ (184,480)
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities		
Share-based compensation	107,458	79,747
Depreciation	26,219	17,885
Amortization of intangible assets	10,541	11
Amortization of right-of-use assets	7,945	7,257
Amortization of premiums, accretion of discounts, and (gains) losses on debt securities	(426)	(3,750)
(Gains) losses on equity securities	(11,604)	10,258
Changes in operating assets and liabilities		
Accounts receivable, net	(57,166)	(44,037)
Inventories	(10,795)	(38,795)
Prepaid expenses and other assets	(16,792)	3,414
Lease liability	(8,223)	(4,633)
Deferred revenue	300	(26,572)
Other liabilities	173,392	31,809
Net cash provided (used) by operating activities	<u>667,424</u>	<u>(151,886)</u>
Investing activities:		
Purchases of securities	(811,274)	(666,120)
Proceeds from maturities of securities	587,000	375,000
Proceeds from sales of securities	194,733	—
Purchases of property and equipment	(65,899)	(51,763)
Net cash used by investing activities	<u>(95,440)</u>	<u>(342,883)</u>
Financing activities:		
Net proceeds from issuance of common stock	—	548,691
Proceeds from exercise of stock options and employee stock purchase plan	72,773	61,358
Net cash provided by financing activities	<u>72,773</u>	<u>610,049</u>
Effect of exchange rate changes on cash and cash equivalents	135	—
Net increase in cash and cash equivalents	644,892	115,280
Cash and cash equivalents at beginning of period	274,562	78,186
Cash and cash equivalents at end of period	<u>\$ 919,454</u>	<u>\$ 193,466</u>

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

Seagen 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 Seagen Inc. and its wholly-owned subsidiaries (collectively “Seagen,” “we,” “our,” or “us”). In October 2020, we changed our corporate name from Seattle Genetics, Inc. to Seagen Inc., reflecting the global expansion of our operations. All intercompany transactions and balances have been eliminated. 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, 2019 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, 2019, as filed with the SEC.

The preparation of financial statements in accordance with GAAP requires us to make estimates, assumptions, and judgments that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The results of our operations for the three and nine month periods ended September 30, 2020 are not necessarily indicative of the results to be expected for the full year or any other interim period.

Reclassification

We combined cost of sales with cost of royalty revenues during the current period, and reclassified the prior year cost of royalty revenues amount on our condensed consolidated statements of comprehensive income (loss) to conform the current year presentation. This reclassification had no effect on our total costs and expenses or net income (loss) on our condensed consolidated statements of comprehensive income (loss).

We reclassified the prior year amortization of premiums and accretion of discounts on debt securities on our condensed consolidated statements of cash flows to conform to our current year presentation. This reclassification had no effect on our net cash used by operating activities or our condensed consolidated statements of comprehensive income (loss).

Non-cash activities

We had \$8.8 million and \$11.1 million of accrued capital expenditures as of September 30, 2020 and December 31, 2019, respectively. Accrued capital expenditures are treated as a non-cash investing activity and, accordingly, have not been included in the condensed consolidated statement of cash flows until such amounts have been paid in cash. During the nine months ended September 30, 2020 and 2019, we recorded \$7.0 million and \$39.2 million, respectively, of right-of-use assets in exchange for lease liabilities, which are treated as a non-cash operating activity. See Note 3 for additional information. As of September 30, 2020, we recorded \$250.1 million in deferred revenue associated with a stock purchase agreement with a subsidiary of Merck & Co., Inc. or Merck, which was treated as a non-cash operating activity and was not included in the condensed consolidated statement of cash flows. See Note 2 for additional information.

Investments

We held certain equity securities that we acquired in connection with strategic agreements, which were 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. Accrued interest receivable as of September 30, 2020, was \$1.9 million, and was included in prepaid expenses and other current assets. 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 Codification, or ASC, Topic 842--Leases on January 1, 2019, resulting in a change to our accounting policy for leases. We recorded a liability to make lease payments and a right-of-use asset representing our right to use the underlying assets for the applicable lease terms in our condensed consolidated balance sheet. We used the modified retrospective method transition option.

We elected the "package of practical expedients", which permitted us not to reassess 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 adoption of the standard had a material impact on our condensed consolidated balance sheet, did not have an impact on our condensed consolidated statement of comprehensive income (loss), and there was no cumulative-effect adjustment to the opening accumulated deficit in the period of adoption. See 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. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants. Variable lease cost primarily includes building operating expenses as charged to us by our landlords.

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, which generally occurs when FDA approval is obtained, the carrying value of the related intangible asset is amortized to cost of sales on a straight-line basis over the estimated useful life of the asset beginning in the period in which the project is completed. We periodically evaluate when facts or circumstances indicate that the carrying value of these assets may not be recoverable. 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 period in which the costs are incurred. The results of operations of the acquired business are included in the consolidated financial statements from the acquisition date.

Intangible assets, net

Our intangible assets are primarily comprised of acquired TUKYSA™ (tucatinib) technology from the acquisition of Cascadian Therapeutics, Inc. in 2018. Upon FDA approval and commercial launch of TUKYSA in April 2020, we reclassified in-process research and development costs related to the acquired TUKYSA technology to finite-lived intangible assets. Prior to 2020, our finite-lived intangible assets consisted of certain in-licensed ADCETRIS technology. Amortization expense of \$5.8 million and \$10.5 million related to acquired TUKYSA technology costs for the three and nine months ended September 30, 2020, respectively, was included in cost of sales in our condensed consolidated statements of comprehensive income (loss). The gross carrying value and accumulated amortization of our finite-lived intangible assets was \$305.7 million and \$16.2 million as of September 30, 2020, respectively, and \$5.7 million and \$5.6 million as of December 31, 2019, respectively. The weighted average useful life of our finite-lived intangible assets was 13 years as of September 30, 2020, and estimated future amortization expense related to TUKYSA is \$5.8 million for the three months ending December 31, 2020, and \$23.1 million for each of the years ending December 31, 2021 through December 31, 2025.

Long-term incentive plans

We have established Long-Term Incentive Plans, or LTIPs. The LTIPs provide eligible employees with the opportunity to receive performance-based incentive compensation, which may be comprised of cash, stock options, and/or restricted stock units, 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. In April 2020, an LTIP milestone was achieved related to FDA approval of TUKYSA based on our HER2CLIMB trial, which triggered vesting of performance-based stock awards previously granted to eligible participants, and an RSU grant to eligible participants. As of September 30, 2020, the estimated unrecognized compensation expense related to all LTIPs was approximately \$58 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, PADCEV and TUKYSA 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, PADCEV, and TUKYSA through a limited number of specialty distributors and specialty pharmacies. We and our collaboration partner Astellas Pharma, Inc. or Astellas jointly promote PADCEV in the U.S. Under the joint promotion in the U.S., we record net sales of PADCEV and are responsible for all distribution through a limited number of specialty distributors. The delivery of our products represents a single performance obligation for these transactions and we record net product sales at the point in time when title and risk of loss pass. The transaction price for net 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.

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 our products. 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 payor mix and our experience to-date.

We have a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of our products. 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 our products. Under these agreements, distributors process a chargeback to us for the difference between wholesale acquisition cost and the applicable discounted price. We 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 a specified number of days prior to or past expiration date or that is damaged. We estimate product returns based on our experience to-date using the expected value approach. We provide financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance through our patient support programs. 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.

Royalty revenues

Royalty revenues primarily reflect amounts earned under the ADCETRIS collaboration with Takeda Pharmaceutical Company Limited, or 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 annual net sales tiers. Takeda bears a portion of low single digit third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenues. Amounts owed to our third-party licensors related to Takeda's sales of ADCETRIS are recorded in cost of sales. These amounts are recognized in the period in which the related sales by Takeda occur. Royalty revenues also reflect amounts from Genentech, Inc., a member of the Roche Group, or Genentech, earned on net sales of Polivy under our ADC collaboration with Genentech.

Collaboration and license agreement revenues

We have collaboration and license agreements for our technology with a number of biotechnology and pharmaceutical companies. Under these agreements, we typically receive or are entitled to receive upfront cash payments and progress- and sales-dependent milestones for the achievement by our licensees of certain events, and annual maintenance fees and support fees for research and development services and materials provided under the agreements. We also are entitled to receive royalties on net sales of any resulting products incorporating our technology.

Collaboration and license agreements 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 future reversal of cumulative revenue and, therefore, should be included in the transaction price. 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 collaboration and license agreements, 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.

When no performance obligations are required of us, or following the completion of the performance obligation period, such amounts are recognized 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.

We have several active collaboration and license agreements entered into prior to 2015. Our licensees are solely responsible for research, product development, manufacturing and commercialization of any product candidates under these collaborations, which includes the achievement of the potential milestones. Since we do not take a substantive role or control the research, development or commercialization of any products generated by our licensees, 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 licensees. As such, the potential future milestone payments associated with our collaboration and license agreements involve a substantial degree of uncertainty and risk that they may never be received.

We have concluded that the license of intellectual property in certain collaboration and license agreements is not distinct from the perspective of our customers at the time of initial transfer, since we often 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 may 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 certain ADC collaboration and license agreements as evaluated at contract inception were not distinct and represented a single performance obligation. For those agreements, 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. Each of these agreements is beyond the initial performance period, and we have no remaining performance obligations. We may receive license maintenance fees and potential milestones and royalties based on collaborator development and regulatory progress, which are recorded in the period achieved in the case of milestones, and during the period of the related sales for royalties.

Recent accounting pronouncements 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. We adopted this standard on January 1, 2020 using the modified retrospective transition method. The adoption of this ASU had no impact on our current or previously reported 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. We adopted this standard on January 1, 2020 on a prospective basis. The adoption of this ASU did not have a material impact on our financial condition, results of operations, cash flows, and financial statement disclosures. Capitalized implementation costs are included in prepaid expenses and other current assets or other non-current assets.

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 ASC Topic 808--Collaborative Arrangements and ASC Topic 606--Revenue from Contracts with Customers. Currently, ASC 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 ASC Topic 606 have resulted in uncertainty in practice about the effect of the revenue standard on the accounting for collaborative arrangements. We adopted this standard on January 1, 2020 on a retrospective basis to contracts that were not completed. The adoption of this ASU did not change the way we previously accounted for any of our collaboration arrangements under ASC Topic 808, thus had no impact on our current or previously reported financial condition, results of operations, cash flows, and financial statement disclosures.

Recent accounting pronouncements not yet adopted

In December 2019, the FASB issued “ASU 2019-12, Simplifying the Accounting for Income Taxes.” The objective of the standard is to improve areas of GAAP by removing certain exceptions permitted by ASC Topic 740-- Income Taxes and clarifying existing guidance to facilitate consistent application. The standard will become effective for us beginning on January 1, 2021. We are currently evaluating the new standard to determine the potential impact on our financial condition, results of operations, cash flows, and financial statement disclosures.

2. Revenue from contracts with customers

Substantially all of our product revenues are recorded in the U.S. Royalty revenues primarily reflect royalties earned under the ADCETRIS collaboration with Takeda, and, to a lesser extent, amounts from Genentech earned on net sales of Polivy.

Collaboration and license agreement revenues by collaborator are summarized as follows:

(dollars in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Merck	\$ 725,000	\$ —	\$ 725,000	\$ —
Takeda	7,013	17,720	22,925	89,859
Other	26,300	700	32,325	9,269
Collaboration and license agreement revenues	\$ 758,313	\$ 18,420	\$ 780,250	\$ 99,128

We recognized collaboration and license agreement revenues of \$0.0 million and \$27.5 million during the nine months ended September 30, 2020 and 2019, respectively, that were included in deferred revenue as of the beginning of the respective years. For the nine months ended September 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.

We estimate an allowance for doubtful accounts based on our assessment of the collectability of customer accounts. We regularly review the allowance by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer’s ability to pay. As of September 30, 2020, we recognized no year-to-date bad debt expense.

Merck LV and TUKYSA license and collaboration agreements, and stock purchase agreement

In September 2020, we entered into two license and collaboration agreements, and a stock purchase agreement, with subsidiaries of Merck.

Under one of the license and collaboration agreements, referred to as the LV Agreement, we will pursue a broad joint development program evaluating ladiratuzumab vedotin, or LV, as monotherapy and in combination with Merck’s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in triple-negative breast cancer, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors. Pursuant to the LV Agreement, we granted to Merck a co-exclusive worldwide development and commercialization license for LV, and agreed to jointly develop and commercialize LV on a worldwide basis. We received an upfront cash payment of \$600.0 million, and we are eligible to receive up to \$850.0 million in milestone payments upon the initiation of certain clinical trials and regulatory approval in certain major markets, and up to an additional \$1.75 billion in milestone payments upon the achievement of specified annual global net sales thresholds of LV. Each company is responsible for 50% of global costs to develop and commercialize LV and will receive 50% of potential future profits. In connection with the LV Agreement, we entered into a stock purchase agreement with Merck, referred to as the Purchase Agreement, pursuant to which we agreed to issue and sell, and Merck agreed to purchase 5,000,000 newly-issued shares of our common stock, at a purchase price of \$200 per share, for an aggregate purchase price of \$1.0 billion.

Under the other license and collaboration agreement, referred to as the TUKYSA Agreement, we granted Merck exclusive rights to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Pursuant to the TUKYSA Agreement, Merck is responsible for marketing applications for approval in its territory, supported by the positive results from the HER2CLIMB clinical trial. We retained commercial rights in the U.S., Canada and Europe, where we will record sales. Merck is also co-funding a portion of the TUKYSA global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers. We will continue to lead ongoing TUKYSA global development operational execution. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territories. We received an upfront cash payment from Merck of \$125.0 million and also received \$85.0 million in prepaid research and development funding to be applied to Merck's global development cost sharing obligations. We are eligible to receive progress-dependent milestone payments of up to \$65.0 million, and are entitled to receive tiered royalties on sales of TUKYSA by Merck that begin in the low twenty percent range and escalate based sales volume by Merck in its territory.

We determined that these agreements are within the scope of ASC 808. Pursuant to ASC 808, we considered other authoritative guidance for distinct units of account related to these agreements, including ASC 606. Our performance obligations within the scope of ASC 606 consisted of the delivery of the LV license and transfer of regulatory information to enable the LV collaboration, the delivery of the TUKYSA license and transfer of regulatory materials for use by Merck in its territory, and supply of commercial TUKYSA inventory to Merck for use in its territory. The LV license and TUKYSA license are functional intellectual property and distinct from the other promises made under the contract. Since we also determined that Merck can benefit from the LV license and the TUKYSA licenses at the time of conveyance, the related performance obligations were satisfied at that point in time. Therefore, we recognized the license revenue under ASC 606 of \$725.0 million in collaboration and license agreement revenues during the three and nine months ended September 30, 2020.

Potential development, regulatory, and sales-based milestones, and royalties, will be accounted for as variable transaction price related to the LV or TUKYSA licenses under ASC 606. Given the uncertain nature of these payments, we determined they were fully constrained as of September 30, 2020 and not included in the transaction price. We will re-evaluate the transaction price at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

We and Merck will share equally in LV global development costs, and Merck is co-funding a portion of the TUKYSA global development plan. We consider the collaborative activities associated with the global development and commercialization of LV, and the global development of TUKYSA, to be units of account within the scope of ASC 808. We recognize development cost sharing proportionately with the performance of the underlying activities, and record Merck's reimbursement of our expenses as a reduction of research and development expenses. Reimbursements from Merck for the LV Agreement and TUKYSA Agreement were not material during the three and nine months ended September 30, 2020. Merck's prepayment of \$85.0 million towards the TUKYSA global development plan was recorded as a co-development liability in other long-term liabilities on our condensed consolidated balance sheet as of September 30, 2020. As joint development expenses are incurred, we recognize the portion of Merck's prepayment as a reduction of our research and development expenses on our condensed consolidated statements of comprehensive income (loss). As of September 30, 2020, \$84.5 million was recorded as the remaining co-development liability. Sales of TUKYSA drug product supplied to Merck will be included in collaboration and license agreement revenues.

The fair market value of 5,000,000 shares of our common stock was \$749.9 million, based on the closing price of the last trading day prior to the Purchase Agreement being executed. We accounted for the associated premium of \$250.1 million as a freestanding equity-linked instrument under ASC 815. The premium was determined to be variable consideration in the calculation of the total transaction price related to the LV license, and recorded in deferred revenue as of September 30, 2020, due to the substantive contingency associated with closing of the sale of shares under the Purchase Agreement. The closing of the sale of the shares pursuant to the Purchase Agreement occurred in October 2020. Upon closing, we recorded the fair market value of the shares issued in stockholders' equity on our condensed consolidated balance sheet. The variable consideration restraint was removed upon the closing of the sale of shares pursuant to the Purchase Agreement, and the premium will be recognized in collaboration and license agreement revenues in the quarter and year ending December 31, 2020.

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. During the nine months ended September 30, 2020 and 2019, we recorded \$7.0 million and \$39.2 million of right-of-use assets in exchange for lease liabilities, respectively. 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 September 30, 2020.

Supplemental operating lease information was as follows:

(dollars in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease cost	\$ 3,832	\$ 3,479	\$ 10,967	\$ 10,066
Variable lease cost	998	691	2,972	2,120
Total lease cost	\$ 4,830	\$ 4,170	\$ 13,939	\$ 12,186
Cash paid for amounts included in measurement of lease liabilities	\$ 3,327	\$ 2,732	\$ 10,223	\$ 7,129
	As of September 30,			
	2020	2019		
Weighted average remaining lease term	6.3 years	7.3 years		
Weighted average discount rate	5.2 %	5.4 %		

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

(dollars in thousands)	September 30, 2020	December 31, 2019
Accrued liabilities and other	\$ 12,326	\$ 9,445
Operating lease liabilities, long-term	65,003	67,607
Total	\$ 77,329	\$ 77,052

4. Net income (loss) per share

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

(dollars in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income (loss)	\$ 636,167	\$ (91,913)	\$ 446,575	\$ (184,480)
Shares used in computation of per share amounts - basic	174,460	168,109	173,409	163,428
Dilutive potential common shares	7,417	—	7,530	—
Weighted average common shares outstanding - diluted	181,877	168,109	180,939	163,428
Net income (loss) per share - basic	\$ 3.65	\$ (0.55)	\$ 2.58	\$ (1.13)
Net income (loss) per share - diluted	\$ 3.50	\$ (0.55)	\$ 2.47	\$ (1.13)

Potential shares of common stock excluded from the computation of diluted net income (loss) per share because their effect would have been antidilutive totaled approximately 437,000 and 12,618,000 for the three months ended September 30, 2020 and 2019, respectively, and approximately 310,000 and 12,758,000 for the nine months ended September 30, 2020 and 2019, respectively.

5. Common stock

In July 2019, we completed an underwritten public offering of 8,214,286 shares of our common stock at a public offering price of \$70.00 per share. The offering resulted in net proceeds to us of \$548.7 million, after deducting underwriting discounts, commissions, and other offering expenses. The primary use of the net proceeds was to fund our ADCETRIS and PADCEV commercialization efforts and our research and development efforts, as well as general corporate purposes, including working capital.

6. 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:			Total
	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
(dollars in thousands)				
September 30, 2020				
Short-term investments—U.S. Treasury securities	\$ 798,921	\$ —	\$ —	\$ 798,921
December 31, 2019				
Short-term investments—U.S. Treasury securities	\$ 536,493	\$ —	\$ —	\$ 536,493
Long-term investments—U.S. Treasury securities	57,283	—	—	57,283
Other non-current assets—equity securities	163,936	—	—	163,936
Total	\$ 757,712	\$ —	\$ —	\$ 757,712

Our short- and long-term investments portfolio only contains investments in U.S. Treasury and other U.S. government-backed securities. We review our portfolio based on the underlying risk profile of the securities and have a zero loss expectation for these investments. We also regularly review the securities in an unrealized loss position and evaluate the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. During the three and nine months ended September 30, 2020, we recognized no year-to-date credit loss related to our short- and long-term investments, and had no allowance for credit loss recorded as of September 30, 2020.

In April 2020, we sold our Immunomedics common stock holdings for \$174.7 million, and, accordingly, recognized the associated realized gain in our condensed consolidated statements of comprehensive income (loss) for the three and nine months ended September 30, 2020.

Our debt securities consisted of the following:

(dollars in thousands)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
September 30, 2020				
U.S. Treasury securities	\$ 798,269	\$ 670	\$ (18)	\$ 798,921
Contractual maturities (at date of purchase):				
Due in one year or less	\$ 670,578			\$ 670,663
Due in one to two years	127,691			128,258
Total	\$ 798,269			\$ 798,921
December 31, 2019				
U.S. Treasury securities	\$ 593,565	\$ 236	\$ (25)	\$ 593,776
Contractual maturities (at date of purchase):				
Due in one year or less	\$ 466,439			\$ 466,547
Due in one to two years	127,126			127,229
Total	\$ 593,565			\$ 593,776

7. Investment and other income (loss), net

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

(dollars in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Gain (loss) on equity securities	\$ —	\$ (5,690)	\$ 11,604	\$ (10,258)
Investment and other income, net	1,223	3,561	6,347	7,909
Total investment and other income (loss), net	\$ 1,223	\$ (2,129)	\$ 17,951	\$ (2,349)

Gain (loss) on equity securities includes the realized and unrealized holding gains and losses on our equity securities.

8. Inventories

Inventories consisted of the following:

(dollars in thousands)	September 30, 2020	December 31, 2019
Raw materials	\$ 74,783	\$ 78,285
Finished goods	21,944	7,647
Total	\$ 96,727	\$ 85,932

We capitalize our commercial inventory costs. 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.

9. Income taxes

For the three and nine months ended September 30, 2020, we recorded an income tax provision of \$3.2 million. Our effective tax rate of approximately 1% differed from the federal statutory rate primarily because we maintain a full valuation allowance. The income tax provision recorded is related to estimated state tax liabilities, for which there were limitations on the use of existing state carryforwards against estimated taxable income. We have existing federal tax carryforwards sufficient to offset estimated taxable income.

Included in the estimated effective tax rate, we have forecasted a valuation allowance release due to expected utilization of tax attributes in 2020. It also reflected a discrete benefit of \$52.1 million primarily offset by a valuation allowance release for stock-based compensation windfalls during the nine months ended September 30, 2020. We have provided a full valuation allowance against the remaining deferred tax assets because based on the weight of available evidence, it is more likely than not some or all of the deferred tax assets will not be realized in the future.

10. Legal matters

We are engaged in a dispute with Daiichi Sankyo Co. Ltd., or Daiichi Sankyo, regarding the ownership of certain technology used by Daiichi Sankyo in its metastatic breast cancer drug ENHERTU and certain product candidates. We believe that the linker and other ADC technology used in ENHERTU and these drug candidates are improvements to our ADC technology, the ownership of which we contend was assigned to us under the terms of a 2008 collaboration agreement between us and Daiichi Sankyo. On November 4, 2019, Daiichi Sankyo filed a declaratory judgment action in the United States District Court for the District of Delaware, alleging that we are not entitled to the intellectual property rights under dispute, in an attempt to have the case heard in federal court. On November 12, 2019, we submitted an arbitration demand to the American Arbitration Association seeking, among other remedies, a declaration that we are the owner of the intellectual property rights under dispute, monetary damages, and a running royalty. On March 25, 2020, a District of Delaware magistrate judge issued a stay of Daiichi Sankyo's court action pending determination by the arbitrator of whether the suit should be heard in court or arbitration. On April 8, 2020, Daiichi Sankyo filed objections to the magistrate judge's order. On October 27, 2020, the presiding District Court Judge overruled Daiichi Sankyo's objections and affirmed the magistrate judge's stay of the Daiichi Sankyo court action. On April 27, 2020, the arbitrator confirmed the dispute should be resolved in arbitration and that the arbitration process should progress.

Separately from the on-going arbitration against Daiichi Sankyo described above, on October 19, 2020, we filed a complaint in the United States District Court for the Eastern District of Texas to commence an action for infringement of our U.S. Patent No. 10,808,039, or the '039 Patent, by Daiichi Sankyo's importation into, offer for sale, sale, and use in the United States of ENHERTU. This action is seeking, among other remedies, a judgment that Daiichi Sankyo infringed one or more valid and enforceable claims of the '039 Patent, monetary damages and a running royalty.

As a result of these disputes, we have incurred and will continue to incur litigation expenses. In addition, from time to time, we may become involved in other 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, and they may subject us to claims which may result in liabilities or require us to take or refrain from certain actions. 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.

11. Subsequent event

On October 27, 2020, we closed the sale of the shares pursuant to the Purchase Agreement, and issued 5,000,000 shares of our common stock to Merck at a purchase price of \$200 per share, for proceeds of \$1.0 billion. As a result, upon closing, we recorded \$749.9 million in stockholders' equity on our consolidated balance sheet, and will recognize the \$250.1 million premium attributed to the Purchase Agreement in collaboration and license agreement revenues for the quarter and year ending December 31, 2020.

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

Seagen is a biotechnology company that develops and commercializes therapies targeting cancer. We are commercializing ADCETRIS[®], or brentuximab vedotin, for the treatment of certain CD30-expressing lymphomas, PADCEV[®], or enfortumab vedotin-ejfv, for the treatment of certain metastatic urothelial cancers, and TUKYSA[®], or tucatinib, for treatment of certain metastatic HER2-positive breast cancers. 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 and PADCEV, 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. In October 2020, we changed our corporate name from Seattle Genetics, Inc. to Seagen Inc., reflecting the global expansion of our operations.

ADCETRIS[®] (brentuximab vedotin)

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 collaborate 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, and 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 a potentially registration-enabling trial evaluating treatment with ADCETRIS in Hodgkin lymphoma and PTCL patients who are unfit for combination chemotherapy, and a potentially registration-enabling trial evaluating retreatment with ADCETRIS in Hodgkin and T-cell lymphoma patients who progress after a prior response, including in the frontline setting. We have also initiated a phase 3 clinical trial evaluating ADCETRIS in combination with lenalidomide and rituxan in patients with relapsed or refractory diffuse large B-cell lymphoma. In addition, we are evaluating ADCETRIS in combination with nivolumab 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 April 2020, we and BMS agreed to co-fund an additional cohort in an ongoing trial that will evaluate the combination of ADCETRIS, nivolumab and chemotherapy as first-line therapy in stage I and II Hodgkin lymphoma.

PADCEV[®] (enfortumab vedotin-ejfv)

Our second marketed product, PADCEV, is being co-developed and jointly commercialized with Astellas Pharma, Inc., or Astellas. In the U.S., we and Astellas are jointly promoting PADCEV. In the U.S., we record net sales of PADCEV and are responsible for all distribution activities. We and Astellas each bear the costs of our own sales organizations in the U.S., equally share certain other costs associated with commercializing PADCEV in the U.S., and equally share in any profits realized in the U.S.

PADCEV was granted accelerated approval by the FDA in December 2019 for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1 or PD-L1 inhibitor and a platinum-containing chemotherapy before (neoadjuvant) or after (adjuvant) surgery or in a locally advanced or metastatic setting. FDA approval of PADCEV was supported by data from the first cohort of patients in a single-arm pivotal phase 2 clinical trial called EV-201. The trial enrolled 125 patients with locally advanced or metastatic urothelial cancer who received prior treatment with a PD-1 or PD-L1 inhibitor and a platinum-based chemotherapy. It is the first FDA approved treatment for these patients. Continued approval may be contingent upon verification and description of clinical benefit in a required confirmatory trial.

In September 2020, we announced that the global phase 3 clinical trial called EV-301, which compared PADCEV to chemotherapy in adult patients with locally advanced or metastatic urothelial cancer who were previously treated with platinum-based chemotherapy and a PD-1/L1 inhibitor, met its primary endpoint of overall survival, or OS. We plan to submit the EV-301 results to the FDA as the confirmatory trial following PADCEV's accelerated approval in December 2019. EV-301 is also intended to support global registrations. In the trial, PADCEV significantly improved OS, with a 30 percent reduction in risk of death (Hazard Ratio [HR]=0.70; [95 percent Confidence Interval (CI): 0.56, 0.89]; p=0.001). PADCEV also significantly improved progression-free survival, or PFS, a secondary endpoint, with a 39 percent reduction in risk of disease progression or death (HR=0.61 [95 percent CI: 0.50, 0.75]; p<0.00001). For patients in the PADCEV arm of the trial, adverse events were consistent with those listed in the U.S. Prescribing Information, with rash, hyperglycemia, decreased neutrophil count, fatigue, anemia and decreased appetite as the most frequent Grade 3 or greater adverse event(s) occurring in more than 5 percent of patients.

In October 2020, we announced positive topline results from the second cohort of patients in the pivotal phase 2 EV-201 trial. The cohort is evaluating PADCEV for patients with locally advanced or metastatic urothelial cancer who have been previously treated with a PD-1/L1 inhibitor and have not received a platinum-containing chemotherapy and are ineligible for cisplatin. Results showed a 52 percent objective response rate, or ORR, [95 percent Confidence Interval (CI): 40.8, 62.4] per blinded independent central review and a median duration of response of 10.9 months. The most frequently reported treatment-related adverse events Grade 3 or greater that occurred in more than 5 percent of patients were: neutropenia, rash, fatigue, increased lipase, diarrhea, decreased appetite, anemia and hyperglycemia. We expect to discuss the data from the second cohort with regulatory authorities.

PADCEV is also being investigated in frontline metastatic urothelial cancer and earlier stages of bladder cancer. We and Astellas are conducting a phase 1b/2 clinical trial, called EV-103, that is a multi-cohort, open-label trial of PADCEV alone or in combination with the anti-PD-1 therapy pembrolizumab and/or chemotherapy. The trial is evaluating safety, tolerability and activity in locally advanced and first- and second-line metastatic urothelial cancer, and was expanded to include muscle invasive bladder cancer, or MIBC. In February 2020, updated results from the trial in patients with previously untreated locally advanced or metastatic urothelial cancer who were ineligible for treatment with cisplatin-based chemotherapy were presented at the 2020 Genitourinary Cancers Symposium.

In February 2020, based on the positive initial results of the EV-103 trial, the FDA granted Breakthrough Therapy designation for PADCEV in combination with pembrolizumab for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are unable to receive cisplatin-based chemotherapy in the first-line setting. In April 2020, we announced that based on discussions with the FDA, data from the randomized cohort K in the EV-103 trial, along with other data from the EV-103 trial, could potentially support registration under the FDA's accelerated approval pathway. The primary outcome measures are objective response rate and duration of response.

In addition to the potential accelerated approval pathway based on the EV-103 trial, we are conducting a global, registrational phase 3 trial, called EV-302, in frontline metastatic urothelial cancer in collaboration with Astellas and a subsidiary of Merck & Co., Inc., or Merck. We, Astellas and Merck are jointly funding EV-302 and the trial is being led by us. EV-302 is an open-label, randomized phase 3 clinical trial evaluating the combination of PADCEV and pembrolizumab versus chemotherapy alone in patients with previously untreated locally advanced or metastatic urothelial cancer. The trial includes metastatic urothelial cancer patients who are either eligible or ineligible for cisplatin-based chemotherapy and is expected to enroll 760 patients. The first patient was dosed in the trial in April 2020. The trial has dual primary endpoints of progression-free survival and overall survival and is intended to support global registrations and potentially serve as a confirmatory trial if accelerated approval is granted based on EV-103.

In April 2020, we and Astellas entered into an agreement with Merck to evaluate PADCEV in MIBC. Merck has amended its ongoing phase 3 KEYNOTE-905/EV-303 registrational trial in cisplatin-ineligible patients with MIBC to include an arm evaluating PADCEV in combination with pembrolizumab. In October 2020, we and Astellas entered into an agreement with Merck to evaluate PADCEV in combination with pembrolizumab in a phase 3 trial to be conducted by Merck in cisplatin-eligible patients with MIBC.

In January 2020, we and Astellas also initiated a phase 2 clinical trial, called EV-202, to evaluate PADCEV monotherapy in solid tumors that have high-levels of Nectin-4 expression, including non-small cell lung, head and neck, gastric/esophageal and breast cancers. In March 2020, the first patient was dosed in the trial.

TUKYSA® (tucatinib)

In April 2020, TUKYSA received approval from the FDA in combination with trastuzumab and capecitabine for the treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. TUKYSA is an oral, small molecule tyrosine kinase inhibitor, or TKI, that is highly selective for HER2, a growth factor receptor overexpressed in many cancers.

The FDA reviewed the application for approval under the Oncology Center of Excellence's, or OCE's, Real Time Oncology Review, or RTOR, pilot program. We are also participating in the Project Orbis initiative of the FDA OCE which provides a framework for concurrent submission and review of oncology products among international partners. Under this program we have received approval from the following countries participating in the FDA's Project Orbis initiative: U.S., Canada, Australia, Singapore, and Switzerland. In January 2020, we submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, and the submission was validated, which confirmed it was sufficiently complete to begin the formal review process.

FDA approval of TUKYSA was supported by data from the HER2CLIMB trial. HER2CLIMB is a randomized trial evaluating TUKYSA in combination with trastuzumab and capecitabine versus trastuzumab and capecitabine alone in patients with HER2-positive unresectable locally advanced or metastatic breast cancer, including patients with brain metastases. Patients had to have previously received, either separately or in combination, trastuzumab, pertuzumab, and ado-trastuzumab emtansine, or T-DM1. In December 2019, positive results from the HER2CLIMB trial were published in the *New England Journal of Medicine* and TUKYSA was granted Breakthrough Therapy designation by the FDA.

We are conducting a broad clinical development program of TUKYSA including ongoing and planned trials in earlier lines of breast cancer and in other HER2-positive cancers. In October 2019, we initiated a phase 3 randomized trial, called HER2CLIMB-02, evaluating TUKYSA versus placebo, each in combination with T-DM1, for patients with unresectable locally advanced or metastatic HER2-positive breast cancer, including those with brain metastases, who have had prior treatment with a taxane and trastuzumab.

We are also conducting a phase 2 trial, called MOUNTAINEER, evaluating TUKYSA in combination with trastuzumab in patients with HER2-positive, RAS wild-type metastatic colorectal cancer after treatment with first- and second-line standard-of-care therapies. Initial results from 23 patients were presented at the ESMO 2019 Congress that demonstrated encouraging antitumor activity. We believe the trial could potentially support an application for accelerated approval in the U.S.

We are conducting a phase 2/3 trial, called MOUNTAINEER-02, in combination with trastuzumab, ramucirumab and paclitaxel in second-line HER2-positive metastatic gastroesophageal cancer. We have also initiated a phase 1b trial evaluating TUKYSA in combination with trastuzumab and oxaliplatin based chemotherapy in first-line HER2-positive unresectable or metastatic colorectal, gastric, esophageal and gallbladder cancers.

In September 2020, we entered into a license and collaboration agreement with a subsidiary of Merck, or the TUKYSA Agreement, that granted exclusive rights to Merck to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. The collaboration is intended to accelerate global availability of TUKYSA. Please refer to Note 2 of the Notes to Our Condensed Consolidated Financial Statements included in Part 1 Item 1 of this Quarterly Report on Form 10-Q for additional information.

Tisotumab Vedotin

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 innovaTV 204, evaluating single-agent tisotumab vedotin for patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment. In September 2020, data from the innovaTV 204 trial were presented at the European Society for Medical Oncology, or ESMO, Virtual Congress 2020. Results from the trial showed a 24 percent confirmed objective response rate [95 percent Confidence Interval (CI): 15.9 percent-33.3 percent], including 7 patients (7 percent) with a complete response and 17 patients (17 percent) with a partial response by independent central review. After a median follow-up of 10 months, the median DOR was 8.3 months (95 percent CI: 4.2, not reached). The most common treatment-related adverse events (greater than or equal to 20 percent) included alopecia (Grade 1/2 at 38 percent), epistaxis (nose bleeds, Grade 1/2 at 30 percent), nausea (Grade 1/2 at 27 percent), conjunctivitis (Grade 1/2 at 26 percent), fatigue (Grade 1/2 at 24 percent, Grade 3 or higher at 2 percent) and dry eye (Grade 1/2 at 23 percent). Most treatment-related adverse events were Grade 1 or 2 and no new safety signals were reported. One death due to septic shock was considered by the investigator to be related to tisotumab vedotin. Pre-specified adverse events of interest with tisotumab vedotin treatment included ocular events, bleeding and peripheral neuropathy. Ocular adverse events considered to be related to therapy that occurred in patients were mostly mild to moderate (Grade 1 at 25 percent, Grade 2 at 27 percent, Grade 3 at 2 percent) of which a majority of the events resolved (86 percent) and were managed with an eye care plan. Bleeding events considered to be related to therapy that occurred in patients were mostly mild (Grade 1 at 34 percent, Grade 2 at 3 percent, Grade 3 at 2 percent) of which a majority of the events resolved (90 percent). The most common bleeding events included Grade 1 epistaxis (28 percent). Peripheral neuropathy events considered to be related to therapy were mostly mild to moderate (Grade 1 at 17 percent, Grade 2 at 9 percent, Grade 3 at 7 percent) and managed with dose modifications. Resolution of peripheral neuropathy was limited by follow-up period. Based on the positive results, the companies plan to submit a Biologics License Application, or BLA, to the FDA under the FDA's accelerated approval pathway.

We are also conducting a phase 2 clinical trial, called innovaTV 205, evaluating tisotumab vedotin as monotherapy and in combination with certain other anti-cancer agents for first-line treatment of patients with recurrent or advanced cervical cancer. Additionally, we are conducting a phase 2 clinical trial, called innovaTV 207, for patients with relapsed, locally advanced or metastatic solid tumors and a phase 2 clinical trial, called innovaTV 208, for patients with platinum-resistant ovarian cancer.

Ladiratumab Vedotin

Our pipeline also includes ladiratumab vedotin, or LV, 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 breast cancer and select solid tumors with high LIV-1 expression. In September 2020, we and a subsidiary of Merck entered into a license and collaboration agreement, or the LV Agreement, under which the companies will jointly develop and share future costs and profits worldwide for LV. Merck made an upfront payment to us of \$600.0 million, and in October 2020, Merck made a \$1.0 billion equity investment in 5,000,000 shares of our common stock at \$200 per share. In addition, we are eligible to receive up to \$850.0 million in milestone payments upon the initiation of certain clinical trials and regulatory approval in certain major markets, and up to an additional \$1.75 billion in milestone payments upon the achievement of specified annual global net sales thresholds of LV, for an aggregate \$2.6 billion. Please refer to Note 2 of the Notes to Our Condensed Consolidated Financial Statements included in Part 1 Item 1 of this Quarterly Report on Form 10-Q for additional information.

Other clinical and early-stage product candidates

We are advancing multiple earlier stage programs that employ our proprietary technologies. In June 2020, the first patient was dosed in a phase 1 clinical trial of our investigational agent SEA-TGT, also known as SGN-TGT, an anti-TIGIT antibody for patients with solid tumors and lymphomas. TIGIT (T-cell immune receptor with Ig and ITIM domains) is an inhibitory immune receptor that is emerging as a clinically relevant immuno-oncology target. SEA-TGT is a nonfucosylated human IgG1 antibody that uses our proprietary Sugar Engineered Antibody, or SEA, technology. We also announced the dosing of the first patient in a phase 1 clinical trial evaluating our investigational agent SGN-B6A, an ADC targeting integrin beta-6, which is overexpressed in numerous solid tumors and has been demonstrated to be a negative prognostic indicator across a diverse range of cancers.

Antibody-Drug Conjugate technology license agreements

We have active technology license agreements for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd., or AbbVie; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; and Progenics Pharmaceuticals Inc, as well as collaboration agreements with Astellas and Genmab. Genentech and GSK have ADCs using our technology in late-stage clinical trials. In June 2019, Genentech received accelerated approval from the FDA and, in January 2020, received conditional marketing authorization from the European Commission for Polivy[®] (polatuzumab vedotin-piic), an ADC that uses our technology, to treat patients with relapsed or refractory diffuse large B-cell lymphoma. In August 2020, GSK received accelerated approval from the FDA and conditional marketing authorization from the European Commission for Blenrep[™] (belantamab mafodotin-blmf), an ADC developed by GSK that uses our technology, for treatment of patients with relapsed or refractory multiple myeloma who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor and an immunomodulatory agent. Under our ADC license agreements with Genentech and GSK, these events triggered milestone payments to us and we are also entitled receive royalties on net sales of Polivy and Blenrep worldwide.

COVID-19

We are continuing to closely monitor the impact of the evolving effects of the COVID-19 pandemic on our business and are taking proactive efforts designed to protect the health and safety of our workforce, patients and healthcare professionals, and to continue our business operations and advance our goal of bringing important medicines to patients as rapidly as possible.

We have implemented measures designed to protect the health and safety of our workforce, including a mandatory work-from-home policy for employees who can perform their jobs offsite. We are continuing essential research, manufacturing, and laboratory activities on site and maintain a number of additional precautionary measures designed to protect these onsite employees, such as temperature checks, screening protocols, masks, social distancing, contact tracing and making testing available. In the conduct of our business activities, we are also taking actions designed to protect the safety of patients and healthcare professionals. Among other actions, our field-based personnel have paused most in-person customer interactions in healthcare settings and have been using primarily electronic communications to support healthcare professionals and patients. In addition, following guidance from relevant authorities, our field-based personnel are engaging in limited in-person interactions where state and local laws and regulations allow, the institution or office is accepting in-person interactions and our field-based personnel are comfortable engaging in-person with healthcare providers. We believe that the measures we have implemented are appropriate and are helping to reduce transmission of COVID-19, and we will continue to monitor conditions and related guidance from governmental authorities and adjust our activities as appropriate.

Outlook

While we anticipate that sales of ADCETRIS will continue to increase, we expect lower sales growth for ADCETRIS in 2020 as compared to sales growth in 2019. In addition, impacts associated with the COVID-19 pandemic appear to be reducing the rate of Hodgkin lymphoma diagnoses, and we are also experiencing an increase in gross-to-net deductions that we believe is due to a shift in the locations where ADCETRIS is administered, which has increased the proportion of ADCETRIS sales through the federal 340B drug discount program. All of these factors appear to be contributing to the slower growth of ADCETRIS sales in 2020 as compared to 2019. We expect that, going forward, our ability to maintain or continue to grow our 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 its approved indications, including in the frontline Hodgkin lymphoma indication, and the extent to which physicians make prescribing decisions with respect to ADCETRIS. Other important factors affecting our ADCETRIS sales include the incidence flow of patients eligible for treatment in ADCETRIS' approved indications, the extent to which coverage and adequate levels of reimbursement for ADCETRIS are available from governments and other third-party payors, the impact of any healthcare reform measures that may be adopted in the future, including measures that could potentially result in more rigorous coverage criteria and additional downward pressure on the price that we receive for ADCETRIS, increasing competition from competing therapies including pembrolizumab in multiple indications, including in the relapsed or refractory classical Hodgkin lymphoma indication, impacts resulting from the evolving effects of the COVID-19 pandemic including lower diagnosis rates, and the potential future approval of ADCETRIS in any additional indications. For these reasons, we cannot assure you that ADCETRIS sales will continue to grow or that we can maintain sales of ADCETRIS at or near current levels. In addition, as a result of these and other factors, our future ADCETRIS product sales can be difficult to accurately predict from period to period.

Our ability to realize the anticipated benefits from our investment in PADCEV is subject to a number of risks and uncertainties, including our and Astellas' ability to successfully jointly market and commercialize PADCEV in the U.S. in its approved indication, the extent to which we and Astellas are able to obtain regulatory approvals of PADCEV in additional indications in the U.S., including in the frontline metastatic urothelial cancer setting, and in territories outside the U.S., our ability and Astellas' ability to successfully comply with rigorous post-marketing requirements, including obtaining the FDA's agreement as to the confirmation of clinical benefit of PADCEV based on the results of the EV-301 clinical trial, the acceptance of PADCEV by the medical community and patients, the extent to which physicians make prescribing decisions with respect to PADCEV, the incidence flow of patients eligible for treatment in PADCEV's approved indication, the duration of therapy for patients receiving PADCEV, the extent to which coverage and adequate levels of reimbursement for PADCEV are available from governments and other third-party payors, the impact of any healthcare reform measures that may be adopted in the future, including measures that could potentially result in more rigorous coverage criteria and additional downward pressure on the price that we receive for PADCEV, potential competition from competing therapies, the impact of conducting launch activities virtually during the COVID-19 pandemic and other impacts resulting from the evolving effects of the COVID-19 pandemic including potential negative impacts of reduced cancer diagnosis rates. In addition, due to the lack of significant historical sales data and these factors, PADCEV sales are currently difficult to predict from period to period.

Our ability to realize the anticipated benefits of our investment in TUKYSA is subject to a number of risks and uncertainties, including our and Merck's ability to successfully launch, market and commercialize TUKYSA in our respective territories in its approved indication, the extent to which we and Merck are able to obtain regulatory and other required governmental and pricing and reimbursement approvals of TUKYSA in additional territories, including in the European Union, the extent to which we and Merck are able to obtain regulatory approvals of TUKYSA in additional indications, including earlier lines of breast cancer and other HER2-positive cancers, the acceptance of TUKYSA by the medical community and patients, competition from other therapies, our and Merck's ability to accurately predict and supply product demand, the extent to which coverage and reimbursement will be available from governments and other third-party payors, our capacity to effectively commercialize a product outside of the U.S., the impact of conducting launch activities virtually during the COVID-19 pandemic and other impacts resulting from the evolving effects of the COVID-19 pandemic including potential negative impacts of reduced cancer diagnosis rates. In addition, due to the lack of significant historical sales data and these factors, TUKYSA sales are currently difficult to predict from period to period.

The biopharmaceutical industry and the markets in which we operate are intensely competitive. Many of our competitors are working to develop or have commercialized products similar to those we market or are developing. Drug prices are under significant scrutiny and we expect drug pricing and other healthcare costs to continue to be subject to intense political and societal pressures on a global basis. For example, in July 2020, President Trump announced four Executive Orders related to reducing prescription drug prices and we expect that drug pricing will continue to be subject to close scrutiny by federal, state and foreign governments. In addition to pricing actions and other measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, our sales and operations could also be affected by other risks of doing business internationally.

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, our PADCEV collaboration with Astellas, and our TUKYSA and LV collaborations with Merck, as well as by entering into potential new collaboration and license agreements.

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, and we will require significant financial resources and additional personnel in order to advance the development of, to pursue, obtain and maintain regulatory approvals for, and to commercialize our products and product candidates, and expand our pipeline. 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. As a result, we may need to raise additional capital, and our operating expenses may fluctuate as a result of such activities. We may also incur milestone payment obligations to certain of our licensors as our product candidates progress through clinical trials towards potential commercialization.

We are closely evaluating the impacts of the evolving effects of the COVID-19 pandemic on our ability and the ability of our collaborators to effectively market, sell and distribute our products and to develop our products and product candidates. While our field-based personnel are engaging in limited in-person interactions, our field-based personnel are primarily using electronic communication, such as emails, phone calls and video conferences. Many healthcare professionals that we normally call on are working a greater proportion of their working schedule from home and are facing additional demands on their time during the ongoing COVID-19 pandemic. We are experiencing increased competition for virtual appointments with healthcare professionals and are experiencing a significant reduction in the number of interactions our sales personnel are having with physicians. We expect the different quality of electronic interactions as compared with in-person interactions, as well as the reduced quantity of interactions during the COVID-19 pandemic, to reduce the effectiveness of our sales personnel, as well as those of our collaborators, which could negatively affect our product sales and those of our collaborators, as well as physician awareness of our products. With respect to PADCEV and TUKYSA specifically, we have not launched a product using primarily virtual communication channels in the past and cannot predict the effects that this approach will ultimately have on demand for TUKYSA or PADCEV. However, we believe that the need to conduct these activities virtually is negatively impacting our ability to connect with key customers, including those familiar with competitive products, and our ability to conduct payor engagements. We face a number of challenges that will limit our ability to fully resume in-person interactions for the foreseeable future, including increasing COVID-19 infection rates in many states, the potential for more severe outbreaks, the need to navigate varying restrictions for entering healthcare facilities and employee childcare obligations during virtual school sessions. In addition, the effects of the COVID-19 pandemic continue to evolve rapidly, and we may subsequently be forced to, or subsequently determine that we should, resume a more restrictive remote work model, whether as a result of further spikes or surges in COVID-19 infection, positivity or hospitalization rates or otherwise. Moreover, the long-term effects of the COVID-19 pandemic are also unknown and it is possible that following the pandemic, healthcare institutions could alter their policies with respect to in person visits by pharmaceutical company representatives. COVID-19 related restrictions could also present product distribution challenges as we utilize recently initiated distribution channels for TUKYSA. We also expect that the conversion of medical conferences to a virtual format may reduce our ability to effectively disseminate scientific information about our products, which may result in decreased physician awareness of our products, their approved indications and their efficacy and safety. The evolving effects of the COVID-19 pandemic may also negatively affect our product sales due to challenges in patient access to healthcare settings, significant increases in unemployment and the resulting loss of individual health insurance coverage, and inability to access government healthcare programs due to backlogs or inability of government agencies to process additional applications, some or all of which appear to be affecting diagnosis rates and may affect side effect management and course of treatment and increase enrollment in our patient support programs. With respect to ADCETRIS specifically, impacts associated with the COVID-19 pandemic appear to be reducing the rate of Hodgkin lymphoma diagnoses, which appears to be contributing to the slower growth of ADCETRIS sales in 2020 as compared to 2019. In addition, we have observed lower than expected levels of our research and development spending, in part as a result of the COVID-19 pandemic. This includes some delays in clinical trial enrollment as well as reduced travel due to the conversion of medical and scientific meetings to virtual format. While we do not at this time anticipate the need to revise our publicly reported projected clinical milestone dates as a result of the effects of the COVID-19 pandemic, there may be some impacts to our clinical study timelines, which, depending upon the duration and severity of the evolving effects of the COVID-19 pandemic, could ultimately delay data availability. In addition, many of our non-essential on site research activities are currently significantly reduced as a result of the COVID-19 pandemic, which may negatively impact the number of investigational new drug application, or IND, candidates entering our clinical pipeline in future years. The extent to which the risks and evolving effects of the COVID-19 pandemic impact our business, our ability to generate sales of and revenues from our approved products, and our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements in the U.S. and in other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and in other countries to contain and treat the disease. For more information on the risks and uncertainties associated with the evolving effects of the COVID-19 pandemic on our business, our ability to generate sales of and revenues from our approved products, and our clinical development and regulatory efforts, see “Part II Item 1A—Risk Factors.”

Because of the above and other factors, our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and should not be relied upon as being indicative of our future performance.

Financial summary

For the nine months ended September 30, 2020, our total revenues increased to \$1.6 billion, compared to \$626.9 million for the same period in 2019. This growth was driven by \$725.0 million upfront license revenue recognized in the third quarter of 2020 related to the LV and TUKYSA agreements with Merck, the U.S. launches of PADCEV beginning in December 2019 and TUKYSA in April 2020, respectively, as well as higher ADCETRIS net product sales and royalty revenues.

For the nine months ended September 30, 2020, total costs and expenses increased to \$1.1 billion, compared to \$809.0 million for the same period in 2019. This reflected higher cost of sales, higher selling, general and administrative expenses, and higher research and development expenses.

As of September 30, 2020, we had \$1.7 billion in cash, cash equivalents and investments and \$2.3 billion in total stockholders' equity.

Results of operations

Net product sales

(dollars in thousands)	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	% Change	2020	2019	% Change
ADCETRIS	\$ 163,263	\$ 167,582	(3) %	\$ 494,851	\$ 461,563	7 %
PADCEV	61,849	—	NM	153,485	—	NM
TUKYSA	42,382	—	NM	58,137	—	NM
Net product sales	\$ 267,494	\$ 167,582	60 %	\$ 706,473	\$ 461,563	53 %

NM: No amount in comparable period or not a meaningful comparison.

Our net product sales grew 60% and 53% during the three and nine months ended September 30, 2020, respectively, compared to the prior year periods. We began commercializing PADCEV and TUKYSA following FDA approvals in December 2019 and April 2020, respectively. ADCETRIS net product sales declined slightly for the three months ended September 30, 2020 from the comparable period in 2019. ADCETRIS net product sales increased for the nine months ended September 30, 2020 from the comparable period in 2019, due to higher sales volumes and the effect of price increases during the current year period.

While we expect growth in net product sales in 2020 from 2019, primarily driven by the recent launches of PADCEV and TUKYSA, as well as continued growth in ADCETRIS net product sales, we also expect lower net product sales growth for ADCETRIS in 2020 as compared to growth in 2019. Refer to "Overview—Outlook" above for additional information.

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, 2019	\$ 38,116	\$ 7,538	\$ 45,654
Provision related to current period sales	256,777	21,126	277,903
Adjustment for prior period sales	(1,244)	—	(1,244)
Payments/credits for current period sales	(226,997)	(12,664)	(239,661)
Payments/credits for prior period sales	(30,119)	(1,666)	(31,785)
Balance as of September 30, 2020	\$ 36,533	\$ 14,334	\$ 50,867

Government-mandated rebates and chargebacks are the most significant component of our total gross-to-net deductions and the discount percentage has been increasing. These discount percentages increased during the nine months ended September 30, 2020 as a result of price increases for ADCETRIS that we instituted that exceeded the rate of inflation. The most significant portion of our gross-to-net accrual balances as of September 30, 2020 and 2019 was for Medicaid rebates. 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 2020 as compared to 2019, driven by anticipated growth in our gross product sales.

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 annual net sales tiers. Takeda bears third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenues. Royalty revenues also reflect, to a lesser extent, amounts from Genentech earned on net sales of Polivy beginning in 2019.

(dollars in thousands)	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	% Change	2020	2019	% Change
Royalty revenues	\$ 35,924	\$ 27,261	32 %	\$ 87,520	\$ 66,218	32 %

Royalty revenues increased for the three and nine months ended September 30, 2020 from the comparable period in 2019, primarily due to growth in Takeda net sales of ADCETRIS in its territories, as well as higher Roche net sales of Polivy, which began in the second quarter of 2019.

We expect that royalty revenues will decrease in 2020 as compared to 2019, reflecting the recognition in the fourth quarter of 2019 of a \$40.0 million sales-based milestone earned from Takeda based on its achievement of an annual ADCETRIS net sales milestone. We expect higher anticipated royalties for ADCETRIS and Polivy in 2020 as compared to 2019.

Collaboration and license agreement revenues

Collaboration and license agreement revenues reflect amounts earned under certain of our license and collaboration agreements. These revenues reflect the earned portion of payments received by us for technology access and maintenance fees, milestone payments and reimbursement payments for research and development support that we provide to our collaborators.

Collaboration and license agreement revenues by collaborator were as follows:

(dollars in thousands)	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	% Change	2020	2019	% Change
Merck	\$ 725,000	\$ —	NM	\$ 725,000	\$ —	NM
Takeda	7,013	17,720	(60) %	22,925	89,859	(74) %
Other	26,300	700	NM	32,325	9,269	249 %
Total collaboration and license agreement revenues	\$ 758,313	\$ 18,420	NM	\$ 780,250	\$ 99,128	NM

NM: No amount in comparable period or not a meaningful comparison.

Collaboration and license agreement revenues from Merck included license revenues of \$725.0 million related to the LV Agreement and the TUKYSA Agreement for the three and nine months ended September 30, 2020. In October 2020, upon closing of the sale of the shares to Merck under the stock purchase agreement we entered into with Merck in connection with the LV Agreement, we will record additional Merck collaboration and license revenues for \$250.1 million for the quarter and year ending December 31, 2020. Refer to Note 2 for additional information.

Collaboration and license agreement revenues from Takeda fluctuate based on changes in reimbursement funding under the ADCETRIS collaboration, which are impacted by the activities each party is performing under the collaboration agreement at a given time. 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. Collaboration revenues from Takeda for the three and nine months ended September 30, 2020 decreased compared to the comparable periods in 2019, primarily as a result of regulatory milestones achieved by Takeda in 2019 totaling \$37.5 million during the nine months ended September 30, 2019, respectively, and the completion of the Takeda performance period in November 2019.

Other collaboration and license agreement revenues increased for the three and nine months ended September 30, 2020 as compared to the comparable periods in 2019 primarily due to recognition of two regulatory milestones achieved by GlaxoSmithKline in the third quarter of 2020.

We expect our collaboration and license agreement revenues in 2020 to increase substantially compared to 2019, driven by the revenue recognized from the Merck agreements. 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, the timing of milestones achieved and our ability to enter into potential additional collaboration and license agreements.

Collaboration agreements

Takeda ADCETRIS collaboration

We have an agreement with Takeda for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. We have commercial rights for ADCETRIS in the U.S. and its territories and in Canada. Takeda has commercial rights in the rest of the world. Under the collaboration, we and Takeda can each conduct development activities and equally co-fund the cost of certain mutually agreed development activities. We recognize payments from Takeda, including progress-dependent development and regulatory milestone payments, reimbursement for drug supplied, and net development cost reimbursement payments, as collaboration and license agreement revenues upon transfer of control of the goods or services over the development period. When the performance of development activities under the collaboration results in us making a reimbursement payment to Takeda, that payment reduces collaboration and license agreement revenues. We also recognize royalty revenues based on a percentage of Takeda's net sales of ADCETRIS in its territories, ranging from the mid-teens to the mid-twenties based on annual net sales tiers, as well as sales-based milestones. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS, which is included in royalty revenues. Costs associated with co-development activities are included in research and development expense.

As of September 30, 2020, we had achieved milestone payments totaling \$157.5 million related to regulatory and commercial progress by Takeda. As of September 30, 2020, total future potential milestone payments to us under this collaboration could total \$77.0 million. Of that amount, up to approximately \$7.0 million relates to the achievement of development milestones, up to \$70.0 million relates to the achievement of regulatory milestones. In addition, we recognize royalty revenues, where royalties are based on a percentage of Takeda's net sales of ADCETRIS in its licensed territories, with percentages ranging from the mid-teens to the mid-twenties based on annual net sales tiers, and sales-based milestones. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS, which is included in royalty revenues.

Astellas PADCEV collaboration

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 PADCEV. We rely on Astellas to supply PADCEV for commercial sales and for our clinical trials, and Astellas oversees the manufacturing supply chain for PADCEV. 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 PADCEV:

- In the U.S., we and Astellas jointly promote PADCEV. We record sales of PADCEV in the U.S. and are responsible for all U.S. distribution activities. The companies each bear the costs of their own sales organizations in the U.S., equally share certain other costs associated with commercializing PADCEV in the U.S., and equally share 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 the rest of the world, including Europe, Asia, Australia and Africa. The agreement is intended to provide that we and Astellas will effectively equally share 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.

Astellas or its affiliates are responsible for manufacturing PADCEV for development and commercial use. However, we are responsible for packaging and labeling in countries in which we sell PADCEV. In addition, if the parties determine that a second source is required, we will be responsible for establishing such second source whether internally or through a third party.

Genmab tisotumab vedotin collaboration

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. In October 2020, we and Genmab entered into a joint commercialization agreement to govern the global commercialization of tisotumab vedotin, if we are successful in obtaining any regulatory approvals of tisotumab vedotin:

- In the U.S., we and Genmab will co-promote tisotumab vedotin. We will record sales of tisotumab vedotin in the U.S. and are responsible for leading U.S. distribution activities. The companies will each hire and maintain 50% of the sales representatives and medical science liaisons, equally share those and certain other costs associated with commercializing tisotumab vedotin in the U.S., individually bear the costs of certain other personnel in the U.S., and equally share in any profits realized in the U.S.
- Outside the U.S., we have commercialization rights in the rest of the world except for Japan, where Genmab has commercialization rights. In Europe, China, and Japan, we and Genmab equally share 50% of the costs associated with commercializing tisotumab vedotin as well as any profits realized in these markets. In markets outside the U.S. other than Europe, China, and Japan, aside from certain costs specified in the agreement, we are solely responsible for all costs associated with commercializing tisotumab vedotin and will pay Genmab a royalty based on a percentage of aggregate net sales ranging from the mid-teens to mid-twenties.

Costs associated with co-development activities are included in research and development expense.

Merck LV collaboration

In September 2020, we entered into the LV Agreement with a subsidiary of Merck. We will pursue a broad joint development program evaluating LV as monotherapy and in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in triple-negative breast cancer, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors. Under the terms of the LV Agreement, we granted Merck a co-exclusive worldwide development and commercialization license for LV, and agreed to jointly develop and commercialize LV on a worldwide basis. We received an upfront cash payment of \$600.0 million, and we are eligible to receive up to \$850.0 million in milestone payments upon the initiation of certain clinical trials and regulatory approval in certain major markets, and up to an additional \$1.75 billion in milestone payments upon the achievement of specified annual global net sales thresholds of LV. Each company is responsible for 50% of global costs to develop and commercialize LV and will receive 50% of potential future profits. In connection with the LV Agreement, we entered into a stock purchase agreement with Merck in September 2020, pursuant to which we agreed to issue and sell, and Merck agreed to purchase 5,000,000 newly-issued shares of our common stock, at a purchase price of \$200 per share, for an aggregate purchase price of \$1.0 billion, referred to as the Purchase Agreement. We closed the Purchase Agreement on October 27, 2020 following the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

We recognized license revenue of \$600.0 million during the three and nine months ended September 30, 2020 associated with the LV Agreement, and we recognize such cost sharing proportionately with the performance of the underlying activities, while recording Merck's reimbursement of our expenses as a reduction of research and development expenses.

Merck TUKYSA collaboration

In September 2020, we entered into the TUKYSA Agreement with a subsidiary of Merck. We granted exclusive rights to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Under the terms of the TUKYSA Agreement, Merck is responsible for marketing applications for approval in its territory, supported by the positive results from the HER2CLIMB clinical trial. We retained commercial rights in, and will record sales in, the U.S., Canada and Europe. Merck is also co-funding a portion of the TUKYSA global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers. We will continue to lead ongoing TUKYSA global development operational execution. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territories. We received an upfront cash payment from Merck of \$125.0 million and also received \$85.0 million in prepaid research and development funding to be applied to Merck's global development cost sharing obligations. We are eligible to receive progress-dependent milestone payments of up to \$65.0 million, and are entitled to receive tiered royalties on sales of TUKYSA by Merck that begin in the low twenty percent range and escalate based sales volume by Merck in its territory.

We recognized license revenue of \$125.0 million during the three and nine months ended September 30, 2020 associated with the TUKYSA Agreement, and we recognize such cost sharing proportionately with the performance of the underlying activities, while recording Merck's reimbursement of our expenses as a reduction of research and development expenses. Sales of TUKYSA drug product supplied is included in collaboration and license agreement revenues. The prepayment received for global development cost-sharing was recorded as a co-development liability in other long-term liabilities on our condensed consolidated balance sheet as of September 30, 2020. As joint development expenses are incurred, we recognize the portion of Merck's prepayment as a reduction of our research and development expenses on our condensed consolidated statements of net income (loss). As of September 20, 2020, \$84.5 million was recorded as the remaining co-development liability.

Other technology collaboration and license agreements

We have other active collaboration and license agreements for our technology with a number of biotechnology and pharmaceutical companies entered into prior to 2015. We typically receive upfront cash payments and progress- and sales-dependent milestones for the achievement by our licensees of certain events, and 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 if the license is determined not to be distinct from other goods and services provided, or, if there is no performance obligation, upon transfer of control of the goods or services to the customer. Each of these agreements is beyond the initial performance period, and we have no remaining performance obligations. We may receive license maintenance fees and potential milestones and royalties based on collaborator development and regulatory progress, which are recorded in the period achieved in the case of milestones, and during the period of the related sales for royalties.

Cost of sales

Cost of sales includes manufacturing and distribution costs of product sold, gross profit share with Astellas pursuant to our collaboration, amortization of technology license costs, royalties owed on certain net product sales, as well as royalties owed to our third-party licensors related to Takeda's sales of ADCETRIS.

(dollars in thousands)	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	% Change	2020	2019	% Change
Cost of sales	\$ 78,296	\$ 10,827	623 %	\$ 155,962	\$ 32,024	387 %

Cost of sales increased for the three and nine months ended September 30, 2020 from the comparable periods in 2019, driven by the Astellas gross profit share related to PADCEV net product sales, a payment owed to a third-party technology licensor resulting from the TUKSYA Agreement, amortization expense associated with TUKSYA, and in-licensing royalties owed on PADCEV and TUKYSA net product sales. We and Astellas launched PADCEV in the U.S. in December 2019. The gross profit share with Astellas totaled \$29.1 million and \$72.6 million for the three and nine months ended September 30, 2020, respectively. We recorded amortization expense of \$5.8 million and \$10.5 million for acquired TUKYSA technology costs during the three and nine months ended September 30, 2020, respectively, which began following FDA approval of TUKYSA in April 2020.

We expect cost of sales to substantially increase in 2020 as compared to 2019 as a result of the net product sales growth of our commercial-stage drugs, and the payment owed to a third-party technology licensor resulting from the TUKYSA Agreement. This includes cost of product sales for PADCEV and the gross profit share with Astellas under our collaboration. Growth will also be driven by the cost of product sales for TUKYSA and the amortization of acquired technology costs. The increase in cost of sales will also reflect expected growth in ADCETRIS net product sales. Product costs of sales includes a low-single digit royalty on ADCETRIS sales, a mid-single digit royalty on PADCEV sales, and a low double-digit royalty on TUKYSA sales, and royalties on Merck's potential TUKYSA net sales and development milestones related to licensed technology applicable to the drug. Cost of sales for PADCEV and TUKYSA in 2020 will be partially reduced by the use of product inventory that was manufactured prior to FDA approval, and previously charged to research and development expense.

Research and development

(dollars in thousands)	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	% Change	2020	2019	% Change
Research and clinical development	\$ 155,693	\$ 136,000	14 %	\$ 426,079	\$ 352,131	21 %
Process sciences and manufacturing	61,977	60,119	3 %	184,866	166,182	11 %
Total research and development	\$ 217,670	\$ 196,119	11 %	\$ 610,945	\$ 518,313	18 %

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

Research and clinical development expenses include 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 nine months ended September 30, 2020 from the comparable periods in 2019 primarily reflected increases in employee-related costs and external development costs mainly to support our early- and late-stage pipeline of product candidates.

Process sciences and manufacturing expenses include personnel and occupancy expenses, 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 nine months ended September 30, 2020 from the comparable periods in 2019 primarily reflected increases in employee-related costs and external development costs primarily to support our early- and 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 milestone payments for in-licensed technology for our products 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, as well as personnel, facilities, manufacturing, and other indirect costs not directly charged to development programs.

(dollars in thousands)	Three months ended September 30,		Nine months ended September 30,		Five years ended September 30, 2020
	2020	2019	2020	2019	
ADCETRIS (brentuximab vedotin)	\$ 16,669	\$ 11,539	\$ 39,771	\$ 33,318	\$ 290,409
TUKYSA (tucatinib)	18,799	23,441	56,768	67,269	181,784
PADCEV (enfortumab vedotin-ejfv)	13,639	10,243	27,450	23,437	115,968
Tisotumab vedotin	8,412	9,746	21,513	24,420	80,211
Ladiratumab vedotin	4,564	5,260	13,577	15,940	85,040
Other clinical stage programs	7,566	7,739	22,892	21,328	267,746
Total third-party costs for clinical stage programs	69,649	67,968	181,971	185,712	1,021,158
Other costs and overhead	148,021	128,151	428,974	332,601	1,785,079
Total research and development	\$ 217,670	\$ 196,119	\$ 610,945	\$ 518,313	\$ 2,806,237

Third-party costs for ADCETRIS increased for three and nine months ended September 30, 2020 from the comparable periods in 2019, primarily due to increased activities associated with our ongoing ADCETRIS clinical trials.

Third-party costs for TUKYSA decreased for the three and nine months ended September 30, 2020, as compared to the comparable periods in 2019, primarily due to lower clinical supply expenses. Following the approval of TUKYSA in April 2020, we began capitalizing inventory costs manufactured for commercial sale.

Third-party costs for PADCEV increased for the three and nine months ended September 30, 2020 from the comparable periods in 2019, primarily due to increased activities associated with our ongoing PADCEV clinical trials.

Third-party costs for tisotumab vedotin decreased for the three and nine months ended September 30, 2020, from the comparable periods in 2019, due to the timing of our and Genmab's ongoing clinical trials.

Third-party costs for ladiratumab vedotin decreased for the three and nine months ended September 30, 2020, as compared to the comparable periods in 2019, primarily due to lower research and clinical development expenses.

Other costs and overhead include third-party costs of our preclinical programs and costs associated with personnel and facilities. These costs increased for the three and nine months ended September 30, 2020 from the comparable periods in 2019, due to the addition of new preclinical programs and higher employee-related expenses from headcount growth.

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. We will also need to conduct additional clinical trials in order to expand labeled indications of use for our commercial products. The outcome of our clinical trials is uncertain. The cost of clinical trials may vary significantly as a result of a variety of factors, including the number of patients enrolled, patient site costs, quantity and source of drug supply required, safety and efficacy of the product candidate, and extent of regulatory efforts, among others.

We anticipate that our total research and development expenses in 2020 will increase compared to 2019, primarily due to higher costs for the continued development of our approved products and product candidates.

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 these risk and uncertainties, 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 our products in any additional approved indications or of any of our product candidates.

Selling, general and administrative

(dollars in thousands)	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	% Change	2020	2019	% Change
Selling, general and administrative	\$ 127,579	\$ 96,101	33 %	\$ 375,470	\$ 258,703	45 %

Selling, general and administrative expenses increased for the three and nine months ended September 30, 2020 from the comparable periods in 2019 primarily due to increased field sales personnel for our recently commercialized products, and higher infrastructure costs to support our continued growth.

We anticipate that selling, general and administrative expenses will increase in 2020 as compared to 2019 as we support the launches of PADCEV and TUKYSA, and invest in infrastructure to support our continued growth.

Investment and other income (loss), net

(dollars in thousands)	Three months ended September 30,			Nine months ended September 30,		
	2020	2019	% Change	2020	2019	% Change
Gain (loss) on equity securities	\$ —	\$ (5,690)	(100) %	\$ 11,604	\$ (10,258)	(213) %
Investment and other income, net	1,223	3,561	(66) %	6,347	7,909	(20) %
Total investment and other income (loss), net	\$ 1,223	\$ (2,129)	(157) %	\$ 17,951	\$ (2,349)	(864) %

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 included common stock holdings in Immunomedics prior to the sale of these securities in April 2020), realized gains and losses on equity and debt securities, and amounts earned on our investments in U.S. Treasury securities.

The gain on equity securities in the nine months ended September 30, 2020 was primarily driven by a realized gain in April 2020 from the sale of our equity securities, offset in part by an unrealized loss on equity securities during the three months ended March 31, 2020. In April 2020, we sold our Immunomedics common stock holdings for \$174.7 million, and, accordingly, recognized the associated realized gain in our condensed consolidated statements of comprehensive income (loss) for the nine months ended September 30, 2020.

Investment and other income, net reflects amounts earned on our investments in U.S. Treasury securities. Investment and other income, net decreased for the three and nine months ended September 30, 2020 compared to the comparable periods in 2019, due to lower average yields on our investment portfolio during the 2020 periods.

Provision for income taxes

We recorded a provision for income taxes of \$3.2 million for the three and nine months ended September 30, 2020. We utilized deferred tax assets to offset a Federal tax liability, however, we incurred certain state tax liabilities due to the apportionment of income to some states in which there were limitations of the utilization of net operating losses to offset the respective tax liability.

Liquidity and capital resources

(in thousands)	September 30, 2020	December 31, 2019
Cash, cash equivalents, and investments	\$ 1,718,375	\$ 868,338
Working capital	1,572,901	917,284
Stockholders' equity	2,258,030	1,876,287

(in thousands)	Nine months ended September 30,	
	2020	2019
Cash provided (used) by:		
Operating activities	\$ 667,424	\$ (151,886)
Investing activities	(95,440)	(342,883)
Financing activities	72,773	610,049

The change in net cash from operating activities was primarily due to the change in our net income (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, proceeds from sales of securities, and amounts reinvested. The change in net cash from financing activities was driven by differences in proceeds from stock option exercises and our employee stock purchase plan.

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

Our cash, cash equivalents, and investments are held in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate securities, taxable municipal bonds, commercial paper and money market accounts. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs. However, if our liquidity needs should be accelerated for any reason in the near term, or investments do not pay at maturity, we may be required to sell investment securities in our portfolio prior to their scheduled maturities, which may result in a loss. As of September 30, 2020, we had \$1.7 billion 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 sales, royalty revenues, and the 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, and support our development, commercialization, and planned global expansion, which may require us to raise 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. 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. In this regard, our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the evolving effects of the COVID-19 pandemic. 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, our business and operations may be adversely affected.

Commitments

Our future minimum contractual commitments were reported in our Annual Report on Form 10-K for the year ended December 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 nine months ended September 30, 2020 were consistent with those in Part II Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2019, except for the following updates:

Revenue recognition

Net product sales: We sell ADCETRIS, PADCEV, and TUKYSA through a limited number of specialty distributors and specialty pharmacies. We and our collaboration partner Astellas Pharma, Inc. or Astellas jointly promote PADCEV in the U.S. Under the joint promotion in the U.S., we record net sales of PADCEV and are responsible for all distribution through a limited number of specialty distributors. The delivery of our products represents a single performance obligation for these transactions and we record net product sales at the point in time when title and risk of loss pass. The transaction price for net 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.

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 our products. 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 payor mix and our experience to-date.

We have a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of our products. 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 our products. Under these agreements, distributors process a chargeback to us for the difference between wholesale acquisition cost and the applicable discounted price. We 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 a specified number of days prior to or past expiration date or that is damaged. We estimate product returns based on our experience to-date using the expected value approach. We provide financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance through our patient support programs. 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.

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, which generally occurs when FDA approval is obtained, the carrying value of the related intangible asset is amortized to cost of sales on a straight-line basis over the estimated useful life of the asset beginning in the period in which the project is completed. We periodically evaluate when facts or circumstances indicate that the carrying value of these assets may not be recoverable. 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 period in which the costs are incurred. The results of operations of the acquired business are included in the consolidated financial statements from the acquisition date.

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, 2019.

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 September 30, 2020 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 I 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 success depends on our ability to effectively commercialize our products. If we and our collaborators are unable to effectively commercialize our products and to expand their utilization, our ability to generate significant revenue and our prospects for profitability will be adversely affected.

Our three marketed products are ADCETRIS[®], or brentuximab vedotin, PADCEV[®], or enfortumab vedotin-ejfv, which received accelerated approval from the U.S. Food and Drug Administration, or FDA, in December 2019, and TUKYSA[®], or tucatinib, which received approval from the FDA in April 2020. Our ability to generate revenue from product sales and our prospects for profitability are substantially dependent on our and our collaborators’ ability to effectively commercialize ADCETRIS, PADCEV and TUKYSA and expand their utilization. We may not be able to fully realize the commercial potential of our products, or commercial sales of our products may be lower than our projections, for a number of reasons, including:

- we and our collaborators may be unable to effectively commercialize our products, including in any new markets or in any new indications for which we receive marketing approval;
- we may not be able to establish or demonstrate in the medical community the safety, efficacy or value of our products and their potential advantages compared to existing and future therapeutics in their approved indications, including, with respect to ADCETRIS, in the newly diagnosed, previously untreated Stage III and IV classical Hodgkin lymphoma indication, or the frontline Hodgkin lymphoma indication;
- we and our collaborators may not be able to obtain and maintain regulatory and other required governmental approvals to market our products for their currently approved indications in any additional territories or for any additional indications, including any additional approvals for PADCEV or TUKYSA, which would limit the sales and commercial potential of the applicable product;
- new competitive therapies in ADCETRIS’ approved indications, including immuno-oncology agents such as PD-1 inhibitors (e.g., pembrolizumab and nivolumab) and other novel agents (e.g., mogamulizumab), in PADCEV’s approved indication, including antibody drug conjugates (e.g., sacituzumab govitecan) and other targeted agents (e.g., erdafitinib for patients with select fibroblast growth factor receptor, or FGFR, genetic alterations), and in TUKYSA’s approved indication, including HER2-targeting agents (e.g., fam-trastuzumab deruxtecan-nxki, neratinib, margetuximab and SYD985), have been approved by regulatory authorities or may be submitted in the near term to regulatory authorities for approval, and these competitive products could negatively impact commercial sales of ADCETRIS, PADCEV or TUKYSA, respectively;
- there may be changes to the labeling for our products, including the boxed warning in the ADCETRIS label, that further restrict how we market and sell our products, including as a result of data collected from any of the clinical trials that we and our collaborators are conducting or may in the future conduct for our products, including the post-approval confirmatory studies that our collaborator, Takeda Pharmaceutical Company Limited, or Takeda, is required to conduct as a condition to the conditional marketing authorization of ADCETRIS granted by the European Commission, or the EC, and the confirmatory post-marketing study that we and our collaborator, Astellas Pharma, Inc., or Astellas, are required to conduct as a condition to the accelerated approval of PADCEV by the FDA, or as a result of investigator-sponsored studies;
- the estimated incidence rate of new patients or the duration of therapy in the approved indications for our products may be lower than our projections;
- there may be adverse results or events reported in any of the clinical trials that we or our collaborators are conducting, or may conduct in the future, for our products;

- we and our collaborators may be unable to continue to effectively market, sell and distribute our products;
- the negative impacts to our commercialization efforts, and those of our collaborators, resulting from the risks and evolving effects of the COVID-19 pandemic may increase or become more severe;
- in the case of PADCEV, our joint commercialization efforts in the U.S. with Astellas may be unsuccessful or we may encounter challenges in joint decision making and joint execution that adversely affect PADCEV product sales;
- our products 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 our products may be higher than alternative treatment options, and therefore their reimbursement may be limited by private and governmental insurers;
- physicians may be reluctant to prescribe our products due to side effects associated with their 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 our products; and
- we may not be able to obtain adequate commercial supplies of our products to meet demand or at an acceptable cost.

We have 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. We also have agreements with Astellas to develop and commercialize PADCEV, under which we and Astellas jointly promote PADCEV in the U.S., we have commercialization rights in the other countries in North and South America, and Astellas has commercialization rights in the rest of the world. In addition, we have an agreement with a subsidiary of Merck & Co., Inc., or Merck, to develop and commercialize TUKYSA, under which we retain commercial rights in the United States and its territories, Canada and Europe, and Merck has been granted commercial rights in the rest of the world. The success of these collaborations and the activities of our collaborators will significantly impact the development and commercialization of our products. We cannot control the amount and timing of resources that our collaborators dedicate to the development and commercialization of ADCETRIS, PADCEV or TUKYSA, or to their marketing and distribution. Our ability to generate royalty revenues from ADCETRIS and TUKYSA product sales by Takeda and Merck depends on their respective abilities to obtain regulatory approvals for ADCETRIS and TUKYSA in their territories, and to achieve market acceptance of, and to otherwise effectively market, ADCETRIS and TUKYSA in their territories. Our ability to generate revenues from PADCEV product sales in the U.S. and in Astellas' territories depends on our and Astellas' ability to effectively jointly commercialize PADCEV in the U.S. and on Astellas' ability to obtain regulatory approvals for, achieve market acceptance of, and otherwise effectively market, PADCEV in Astellas' territories. Moreover, foreign sales of our products 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 separation from the European Union, commonly referred to as Brexit, escalating global trade and political tensions, the evolving effects of the COVID-19 pandemic or otherwise.

We are closely evaluating the impacts of the evolving effects of the COVID-19 pandemic on our ability and the ability of our collaborators to effectively market, sell and distribute our products and to develop our products and product candidates. While our field-based personnel are engaging in limited in-person interactions, our field-based personnel are primarily using electronic communication, such as emails, phone calls and video conferences. Many healthcare professionals that we normally call on are working a greater proportion of their working schedule from home and are facing additional demands on their time during the ongoing COVID-19 pandemic. We are experiencing increased competition for virtual appointments with healthcare professionals and are experiencing a significant reduction in the number of interactions our sales personnel are having with physicians. We expect the different quality of electronic interactions as compared with in-person interactions, as well as the reduced quantity of interactions during the COVID-19 pandemic, to reduce the effectiveness of our sales personnel, as well as those of our collaborators, which could negatively affect our product sales and those of our collaborators, as well as physician awareness of our products. With respect to PADCEV and TUKYSA specifically, we have not launched a product using primarily virtual communication channels in the past and cannot predict the effects that this approach will ultimately have on demand for TUKYSA or PADCEV. However, we believe that the need to conduct these activities virtually is negatively impacting our ability to connect with key customers, including those familiar with competitive products, and our ability to conduct payor engagements. We face a number of challenges that will limit our ability to fully resume in-person interactions for the foreseeable future, including increasing COVID-19 infection rates in many states, the potential for more severe outbreaks, the need to navigate varying restrictions for entering healthcare facilities and employee childcare obligations during virtual school sessions. In addition, the effects of the COVID-19 pandemic continue to evolve rapidly, and we may subsequently be forced to, or subsequently determine that we should, resume a more restrictive remote work model, whether as a result of further spikes or surges in COVID-19 infection, positivity or hospitalization rates or otherwise. Moreover, the long-term effects of the COVID-19 pandemic are also unknown and it is possible that following the pandemic, healthcare institutions could alter their policies with respect to in person visits by pharmaceutical company representatives. COVID-19 related restrictions could also present product distribution challenges as we utilize recently initiated distribution channels for TUKYSA. We also expect that the conversion of medical conferences to a virtual format may reduce our ability to effectively disseminate scientific information about our products, which may result in decreased physician awareness of our products, their approved indications and their efficacy and safety. The evolving effects of the COVID-19 pandemic may also negatively affect our product sales due to challenges in patient access to healthcare settings, significant increases in unemployment and the resulting loss of individual health insurance coverage, and inability to access government healthcare programs due to backlogs or inability of government agencies to process additional applications, some or all of which appear to be affecting diagnosis rates and may affect side effect management, and course of treatment and increase enrollment in our patient support programs. With respect to ADCETRIS specifically, impacts associated with the COVID-19 pandemic appear to be reducing the rate of Hodgkin lymphoma diagnoses, which appears to be contributing to the slower growth of ADCETRIS sales in 2020 as compared to 2019. In addition, we have observed lower than expected levels of our research and development spending, in part as a result of the COVID-19 pandemic. This includes some delays in clinical trial enrollment as well as reduced travel due to the conversion of medical and scientific meetings to virtual format. While we do not at this time anticipate the need to revise our publicly reported projected clinical milestone dates as a result of the effects of the COVID-19 pandemic, there may be some impacts to our clinical study timelines, which, depending upon the duration and severity of the evolving effects of the COVID-19 pandemic, could ultimately delay data availability. In addition, many of our non-essential on site research activities are currently significantly reduced as a result of the COVID-19 pandemic, which may negatively impact the number of investigational new drug application, or IND, candidates entering our clinical pipeline in future years. The extent to which the risks and evolving effects of the COVID-19 pandemic impact our business, our ability to generate sales of and revenues from our approved products, and our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements in the U.S. and in other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and in other countries to contain and treat the disease.

While we anticipate that sales of ADCETRIS will continue to increase, we expect lower sales growth for ADCETRIS in 2020 as compared to sales growth in 2019. In addition, impacts associated with the COVID-19 pandemic appear to be reducing the rate of Hodgkin lymphoma diagnoses, and we are also experiencing an increase in gross-to-net deductions that we believe is due to a shift in the locations where ADCETRIS is administered, which has increased the proportion of ADCETRIS sales through the federal 340B drug discount program. All of these factors appear to be contributing to the slower growth of ADCETRIS sales in 2020 as compared to 2019. We expect that, going forward, our ability to maintain or continue to grow our 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 its approved indications, including in the frontline Hodgkin lymphoma indication, and the extent to which physicians make prescribing decisions with respect to ADCETRIS. Other important factors affecting our ADCETRIS sales include the incidence flow of patients eligible for treatment in ADCETRIS' approved indications, the extent to which coverage and adequate levels of reimbursement for ADCETRIS are available from governments and other third-party payors, the impact of any healthcare reform measures that may be adopted in the future, including measures that could potentially result in more rigorous coverage criteria and additional downward pressure on the price that we receive for ADCETRIS, increasing competition from competing therapies including pembrolizumab in multiple indications, including in the relapsed or refractory classical Hodgkin lymphoma indication, impacts resulting from the evolving effects of the COVID-19 pandemic including lower diagnosis rates, and the potential future approval of ADCETRIS in any additional indications. For these reasons, we cannot assure you that ADCETRIS sales will continue to grow or that we can maintain sales of ADCETRIS at or near current levels. In addition, as a result of these and other factors, our future ADCETRIS product sales can be difficult to accurately predict from period to period.

Our ability to realize the anticipated benefits from our investment in PADCEV is subject to a number of risks and uncertainties, including our and Astellas' ability to successfully jointly market and commercialize PADCEV in the U.S. in its approved indication, the extent to which we and Astellas are able to obtain regulatory approvals of PADCEV in additional indications in the U.S., including in the frontline metastatic urothelial cancer setting, and in territories outside the U.S., our ability and Astellas' ability to successfully comply with rigorous post-marketing requirements, including obtaining the FDA's agreement as to the confirmation of clinical benefit of PADCEV based on the results of the EV-301 clinical trial, the acceptance of PADCEV by the medical community and patients, the extent to which physicians make prescribing decisions with respect to PADCEV, the incidence flow of patients eligible for treatment in PADCEV's approved indication, the duration of therapy for patients receiving PADCEV, the extent to which coverage and adequate levels of reimbursement for PADCEV are available from governments and other third-party payors, the impact of any healthcare reform measures that may be adopted in the future, including measures that could potentially result in more rigorous coverage criteria and additional downward pressure on the price that we receive for PADCEV, potential competition from competing therapies, the impact of conducting launch activities virtually during the COVID-19 pandemic and other impacts resulting from the evolving effects of the COVID-19 pandemic including potential negative impacts of reduced cancer diagnosis rates. In addition, due to the lack of significant historical sales data and these factors, PADCEV sales are currently difficult to predict from period to period.

Our ability to realize the anticipated benefits of our investment in TUKYSA is subject to a number of risks and uncertainties, including our and Merck's ability to successfully launch, market and commercialize TUKYSA in our respective territories in its approved indication, the extent to which we and Merck are able to obtain regulatory and other required governmental and pricing and reimbursement approvals of TUKYSA in additional territories, including in the European Union, the extent to which we and Merck are able to obtain regulatory approvals of TUKYSA in additional indications, including earlier lines of breast cancer and other HER2-positive cancers, the acceptance of TUKYSA by the medical community and patients, competition from other therapies, our and Merck's ability to accurately predict and supply product demand, the extent to which coverage and reimbursement will be available from governments and other third-party payors, our capacity to effectively commercialize a product outside of the U.S., the impact of conducting launch activities virtually during the COVID-19 pandemic and other impacts resulting from the evolving effects of the COVID-19 pandemic including potential negative impacts of reduced cancer diagnosis rates. In addition, due to the lack of significant historical sales data and these factors, TUKYSA sales are currently difficult to predict from period to period.

Our ability to grow our product sales in future periods is also dependent on price increases, and we periodically increase the price of our products. Price increases on our products and negative publicity regarding drug pricing and price increases generally, whether on our products or products distributed by other pharmaceutical companies, could negatively affect market acceptance of, and sales of, our products. 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 our product sales.

Our success also depends on our ability to obtain regulatory approvals for our product candidates and for our current products in additional territories, as well as our ability to expand the labeled indications of use for our current products, and, if the requisite approvals are obtained, our ability to successfully launch and commercialize our products in their approved indications. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Neither we nor our collaborators are permitted to market our product candidates in the United States or foreign countries until we obtain marketing approvals from the FDA and foreign regulatory authorities, and we or our collaborators may never receive regulatory approval for the commercial sale of any of our product candidates. Likewise, we and our collaborators are required to obtain marketing approvals from applicable regulatory authorities in order to market our products in additional territories and to expand the labeled indications of use for our current products.

We have made and are continuing to make significant investments in a number of product candidates, including tisotumab vedotin, and in seeking additional regulatory approvals for ADCETRIS, PADCEV and TUKYSA. However, obtaining marketing approval is a lengthy, expensive and uncertain process, approval is never assured, and we have limited experience in preparing and submitting the applications necessary to gain regulatory approvals. As an organization, we did not have any experience applying for regulatory approvals or pricing and reimbursement approvals in jurisdictions outside the U.S. and Canada prior to our foreign TUKYSA regulatory submissions. Further, the FDA and other regulatory agencies have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for our products and product candidates, including any regulatory approvals for ADCETRIS, PADCEV or TUKYSA in additional indications or in additional territories. In this regard, even if we believe the data collected from preclinical studies or clinical trials of our products and product candidates are promising, the FDA or any foreign regulatory authority or their respective advisors may disagree with our interpretations of this data. For example, we reported positive results from the pivotal clinical trial comparing TUKYSA added to trastuzumab and capecitabine versus trastuzumab and capecitabine alone in patients with locally advanced or metastatic HER2-positive breast cancer who were previously treated with trastuzumab, pertuzumab and ado-trastuzumab emtansine, or T-DM1, which we refer to as the HER2CLIMB trial. Although we submitted a Marketing Authorization Application, or MAA, for TUKYSA to the European Medicines Agency, or EMA, based on the results from the HER2CLIMB trial, the EMA or their advisors may disagree with our interpretation of the data from the HER2CLIMB trial and may otherwise determine not to approve the MAA we submitted for TUKYSA in a timely manner or at all. In addition, in September 2020, we and Astellas reported that the global phase 3 clinical trial called EV-301, which compared PADCEV to chemotherapy in adult patients with locally advanced or metastatic urothelial cancer who were previously treated with platinum-based chemotherapy and a PD-1/L1 inhibitor, met its primary endpoint of overall survival. Further, in October 2020, we and Astellas announced positive topline results from the second cohort of patients in the pivotal phase 2 EV-201 trial. The cohort is evaluating PADCEV for patients with locally advanced or metastatic urothelial cancer who have been previously treated with a PD-1/L1 inhibitor, have not received a platinum-containing chemotherapy and are ineligible for cisplatin. Although EV-301 is intended to serve as the confirmatory trial following PADCEV's accelerated approval by the FDA and to support global registrations, and although we plan to discuss the results of the EV-201 trial with regulatory authorities, regulatory authorities, including the FDA, or their advisors may disagree with our interpretation of the data from these trials. The FDA may not convert PADCEV's accelerated approval to regular approval in the U.S., and regulatory authorities may not accept or approve any other regulatory applications for PADCEV, in a timely manner or at all. In addition, although the FDA granted Breakthrough Therapy designation to PADCEV in combination with pembrolizumab, for treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are unable to receive cisplatin-based chemotherapy in the first-line setting, this Breakthrough Therapy designation does not increase the likelihood that PADCEV will receive marketing approval in this indication or will otherwise receive any additional marketing approvals. Likewise, although we reported positive results from the pivotal phase 2 trial, called innovaTV 204, evaluating single-agent tisotumab vedotin for patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment, and we and Genmab A/S, or Genmab, plan to submit a Biologics License Application, or BLA, to the FDA to support accelerated approval for tisotumab vedotin based on the innovaTV 204 trial, we cannot be certain that the data from the innovaTV 204 trial will be sufficient to support accelerated approval. We may experience delays in preparing and submitting the BLA that we and Genmab plan to submit for tisotumab vedotin based on the innovaTV 204 trial. In addition, we cannot predict whether this BLA will be accepted or approved in a timely manner or at all. We also cannot assure you that any of our product candidates will receive any marketing approvals. In fact, it is possible that none of our product candidates will ever become commercial products. As a result, we may not realize the anticipated benefits of our investments in our product candidates. In addition, failure to obtain regulatory approval of TUKYSA from the EMA would negatively impact our plans to build a commercial infrastructure, and commercialize TUKYSA, in Europe.

Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our products in any additional indications or territories, or of any future approved product. Regulatory agencies also may approve a product 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. In addition, our products and product candidates could take a significantly longer time to gain new or initial regulatory approvals than we expect or may never gain new or initial regulatory approvals, which could delay or eliminate any potential product revenue from sales of our product candidates or of our products in any additional indications or territories and significantly delay or prevent us from achieving profitability. In this regard, part of our growth strategy is to continue to explore the use of ADCETRIS in different CD30-expressing lymphomas, to seek approval for PADCEV in our territories outside the U.S., to continue to seek approval for TUKYSA from the EMA and to continue to explore the use of PADCEV and TUKYSA in additional indications. However, we and/or our collaborators may be unable to obtain any regulatory approvals for the commercial sale of any of our products in any additional indications or territories in a timely manner or at all. For example, as part of the 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 target action dates, and if the FDA were to fail to meet its PDUFA target action date in the future for any of our future regulatory applications, the commercialization of the affected product candidate, or of the affected product in any additional indications, could be delayed or impaired. In addition, while regulatory authorities have not to date notified us of any delays in their review of our regulatory applications and we have not yet experienced any obvious delays as a result of the effects of the COVID-19 pandemic, it is possible that we could experience delays in the timing of regulatory review and/or our interactions with regulatory authorities due to reduced working hours of governmental employees or by the diversion of authorities' efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay any approval decisions with respect to our or Merck's regulatory applications for TUKYSA outside of the U.S., or our progress in advancing our development efforts with respect to other products and product candidates. Our interactions with regulatory authorities in other jurisdictions and across multiple products and product candidates continue but we cannot rule out the possibility of negative impacts on such interactions in the future as the effects of the pandemic continue to evolve.

Even if approved for commercial sale, our ability to realize the anticipated benefits from our investments in our product candidates and our efforts to expand the labeled indications of use and territories for our current products is subject to a number of risks and uncertainties, including our and our collaborators' ability to successfully launch, market and commercialize our products, our reliance, in the case of PADCEV and tisotumab vedotin, on Astellas and Genmab, respectively, to effectively jointly launch and commercialize PADCEV and any potential future approved tisotumab vedotin product with us, our and our collaborators' ability to successfully comply with rigorous post-marketing requirements, including confirmation of clinical benefit of PADCEV based on the results of the Phase 3 confirmatory trial, EV-301, that we and Astellas are required to complete as a result of the accelerated approval of PADCEV by the FDA, the acceptance of our approved products by the medical community and patients, and 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. For example, although PADCEV was launched in the U.S. in December 2019 and although TUKYSA was launched in the U.S. in April 2020, the launch and commercialization of these products are at an early stage and may not be successful. In addition, the impacts of the evolving effects of the COVID-19 pandemic, including potential negative impacts of reduced cancer diagnosis rates, could limit our ability to continue to effectively launch PADCEV and TUKYSA and restrictions on in-person interactions with healthcare providers will likely negatively impact our ability to connect with key customers, including those familiar with competitive products, and our ability to conduct payor engagements. If we are unable to successfully continue to launch and commercialize PADCEV jointly with Astellas in the U.S., or to successfully continue to launch and commercialize TUKYSA in the U.S., our growth prospects and our prospects for profitability would be adversely affected. Likewise, although TUKYSA received regulatory approvals in Australia, Singapore and Switzerland and we have submitted an MAA for TUKYSA to the EMA, we have no prior experience as an organization launching or commercializing a product outside the U.S. and Canada, which could adversely affect our ability to maximize the commercial potential of TUKYSA. Further, while our TUKYSA collaboration with Merck is intended to accelerate global availability of TUKYSA, we are wholly reliant on Merck's ability to effectively launch and commercialize TUKYSA in territories outside of the U.S., Canada and Europe, and we have limited control of Merck's actions. In addition, in many countries, the proposed pricing for a drug must be approved before it may be lawfully marketed, and in some cases there are additional individual country requirements, which will delay entry of a product into a market or, if pricing is not approved, will prevent us from selling a product in a country where we have received regulatory approval. The launch of a newly approved product or of an existing product in a new market, including the launch of TUKYSA in Australia, Canada, Singapore and any other markets where it may receive regulatory approval, if any, could be delayed due to a variety of factors, including supply constraints, delays in arranging a commercial infrastructure, delays in negotiating pricing and reimbursement approvals or other factors, any of which risks could be heightened by the risks and the evolving effects of the COVID-19 pandemic. If we or Merck experience delays or unforeseen difficulties due to any of these factors, planned launches in the countries in question would be delayed, which could negatively impact anticipated revenue from TUKYSA. In addition, if we or Merck is unable to obtain favorable pricing and reimbursement approvals in territories that represent significant potential markets, including the European Union, our anticipated revenue from and growth prospects for TUKYSA in Europe and other regions could be negatively affected.

If we or our collaborators are unable to obtain and maintain necessary or desirable regulatory approvals for our products and product candidates, including for ADCETRIS, PADCEV and TUKYSA, in a timely manner, if at all, if the FDA or other regulatory authorities do not approve product labeling that is necessary or desirable for the successful commercialization of an approved product, or if sales of an approved product do not reach the levels we expect, then our anticipated revenue from our products and 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 our products or product candidates could delay or prevent us from obtaining or maintaining regulatory approvals or could negatively impact sales of our products or the prospects for our product candidates.

Reports of adverse events or safety concerns involving our products could interrupt, delay or halt clinical trials of our products, including the post-approval confirmatory studies that regulatory agencies have required us or our collaborators to complete. In addition, reports of adverse events or safety concerns involving our products could result in regulatory authorities requiring that we update the applicable product's prescribing information, or limiting, denying or withdrawing approval of our products for any or all indications, including previously approved indications. There are no assurances that patients receiving our products will not experience serious adverse events in the future, whether the serious adverse events are disclosed in the prescribing information or are newly reported. Further, there are no assurances that patients receiving our products 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 our products. We may be required to further update the prescribing information for our products, including boxed warnings, limitations of use, contraindications, warnings and precautions, and adverse reactions, based on reports of adverse events or safety concerns, or implement a Risk Evaluation and Mitigation Strategy, or REMS, which could adversely affect the acceptance of our products in the market, make competition easier or make it more difficult or expensive for us to distribute our products. For example, the prescribing information for ADCETRIS has been revised over time to include warnings and precautions for various toxicities, 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 for our products, including ADCETRIS, PADCEV and TUKYSA, which could negatively impact sales of our products or adversely affect our products' acceptance in the market.

Likewise, reports of adverse events or safety concerns involving our product candidates could interrupt, delay or halt clinical trials of our product candidates, or could result in our or our collaborators' inability to obtain regulatory approvals for any of our product candidates. Although we announced positive results from the innovaTV 204 trial, data continues to be generated in this trial and in other tisotumab vedotin trials. There may still be important new or evolving facts about the safety, efficacy, and risk versus benefit of each of our product candidates, including tisotumab vedotin, which may negatively impact our ability to develop and commercialize these product candidates. For example, in response to prior safety events observed in our clinical trials of PADCEV and tisotumab vedotin, including serious side effects and 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 or other trials that could delay or prevent us from advancing the clinical development of, or obtaining regulatory approvals for, our products and product candidates or require us to alter the approved labeling of our products, and may adversely affect our business, results of operations and prospects.

Concerns regarding the safety of our products or 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 our products or the product candidates. Undesirable side effects caused by our products or 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, implementation of a REMS or the inclusion of unfavorable information in our product labeling, and in turn delay or prevent us from commercializing the applicable product or 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 our products or product candidates or result in potential product liability claims. Any of these events could prevent us from developing or commercializing the applicable product or 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 any future approved 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 any future approved products.

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, PADCEV and TUKYSA in each of their 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 our current and any future approved products. For example, the FDA's accelerated approval of PADCEV included a requirement for a confirmatory trial, EV-301, to confirm the clinical benefit and provide additional long-term efficacy data that may inform product labeling. If the FDA does not agree with our interpretation of the data from this post-marketing study, it could withdraw approval of PADCEV or require the inclusion of unfavorable safety information in our product labeling, which could seriously harm our business. Moreover, in connection with PADCEV's accelerated approval, the labeling and advertising and promotion of PADCEV are subject to additional regulatory requirements, which entail significant expense and could negatively impact the commercialization of PADCEV. In addition, the use of any of our products may uncover additional adverse events that limit or prevent that product's widespread use or that result in the withdrawal of that product from the market. Any problems with a product or any violation of ongoing regulatory obligations could result in restrictions on the applicable product, including the withdrawal of the applicable product from the market.

ADCETRIS is approved under conditional marketing authorization in relapsed Hodgkin lymphoma, relapsed cutaneous T-cell lymphoma, and in both relapsed and frontline sALCL in the European Union 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. Takeda is subject to certain post-approval requirements, including the requirement to conduct clinical trials to confirm clinical benefit. 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. 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. We and Takeda have a collaboration with Ventana Medical Systems, Inc., or Ventana, under which Ventana is working to develop, manufacture and commercialize a companion diagnostic test to measure CD30 expression levels in tissue specimens. If Ventana develops an in-vitro diagnostic device that we are able to clinically validate, the FDA or another regulatory authority may revise our label for the frontline PTCL indication or in connection with any future approvals to require the use of the in-vitro test as a companion diagnostic. This may limit our ability to commercialize ADCETRIS in the applicable treatment setting due to potential label requirements, prescriber practices, constraints on availability of the diagnostic, or other factors. If Ventana is unable to successfully develop the CD30 in-vitro diagnostic, or experiences delays in doing so, or we experience delays in clinical validation of the diagnostic, we will likely need to renegotiate the timing or content of our post-marketing commitment regarding the in-vitro diagnostic device with the FDA.

We and the manufacturers of our current and any future approved products 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 our products and 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 our current or any future approved products, including adverse events of unanticipated severity or frequency, or problems with the facilities where our current or any future approved products are manufactured, including potential staffing shortages, production slowdowns and the extensive reliance on virtual oversight of third-party manufacturing in connection with the COVID-19 pandemic, may result in restrictions on the marketing of our current or any such future approved products, 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, delays in regulatory timelines 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, PADCEV or TUKYSA in any additional indications or territories, 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 our current or any future approved products 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 and our collaborators are currently conducting multiple clinical trials for our products and product candidates and plan to commence additional trials of our products and product candidates in the future. In this regard, we have initiated a phase 3 clinical trial evaluating ADCETRIS in combination with lenalidomide and rituxan in patients with relapsed or refractory diffuse large B-cell lymphoma. In addition, we and Astellas are conducting a phase 1b/2, multi-cohort, open-label trial of PADCEV alone or in combination with the anti-PD-1 therapy pembrolizumab and/or chemotherapy, called the EV-103 trial, in locally advanced and first- and second-line metastatic urothelial cancer and muscle invasive bladder cancer, which includes a randomized cohort, cohort K, that we believe, along with other data from the EV-103 trial, could potentially support registration under accelerated approval regulations in the U.S. We, Astellas and Merck are also conducting an open-label, randomized phase 3 trial, called the EV-302 trial, evaluating the combination of PADCEV and pembrolizumab versus chemotherapy alone in patients with previously untreated locally advanced or metastatic urothelial cancer. Under an agreement with Merck, Merck has amended its ongoing phase 3 KEYNOTE-905/EV-303 registrational trial in cisplatin-ineligible patients with muscle invasive bladder cancer to include an arm evaluating PADCEV in combination with pembrolizumab. Additionally, we are conducting a phase 3 randomized trial of TUKYSA vs. placebo, in combination with T-DM1 for patients with unresectable locally advanced or metastatic HER2-positive breast cancer, including those with brain metastases, who have had prior treatment with a taxane and trastuzumab, which we refer to as HER2CLIMB-02, and a phase 2 trial evaluating TUKYSA in combination with trastuzumab in patients with HER2-positive, RAS wild-type metastatic colorectal cancer after treatment with first- and second-line standard-of-care therapies, which we call MOUNTAINEER. Each of these trials was initiated based on only limited clinical data and we cannot be certain that the design or conduct of, or data collected from, these trials will be sufficient to support FDA or any foreign regulatory approvals. 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 outcome of these trials is uncertain. Later-stage clinical trials may differ in significant ways from earlier stage clinical trials and may have different outcomes. Differences in earlier- and later-stage clinical trials may include changes to inclusion and exclusion criteria, efficacy endpoints and statistical design. In this regard, despite the positive initial results we and Astellas reported from the EV-103 trial, we cannot be certain that PADCEV will demonstrate sufficient efficacy in other trials, including in the EV-302 trial, other cohorts of the EV-103 trial or any future trials or cohorts. Moreover, despite the positive initial data from the EV-103 trial, PADCEV may not demonstrate sufficient efficacy in any other clinical trials in a frontline setting and may never be approved for use in any frontline setting, which would significantly delay or prevent us from achieving profitability. Likewise, despite the positive results we reported from the HER2CLIMB trial, we cannot be certain that TUKYSA will demonstrate sufficient efficacy in other trials, including the HER2CLIMB-02 trial, and, despite the positive results we reported from the innovaTV 204 trial, we cannot be certain that tisotumab vedotin will demonstrate sufficient efficacy in other 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 PADCEV, TUKYSA and tisotumab vedotin that are not known to us at this time which may negatively impact our ability to develop and commercialize PADCEV, TUKYSA or tisotumab vedotin as single agents or in combination with other agents. In this regard, in the first cohort of the EV-201 trial, there was one death due to interstitial lung disease, which occurred outside the safety-reporting period of the trial and was confounded by prolonged high-dose steroid use and suspected pneumonia, and in the initial results of the EV-103 trial, there was one death deemed to be treatment-related by the investigator, attributed to multiple organ dysfunction syndrome. There was also one death deemed to be treatment-related by the investigator in the innovaTV 204 trial. In addition, in response to prior safety events observed in our clinical trials of PADCEV and tisotumab vedotin, including serious side effects and 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 PADCEV, TUKYSA 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 PADCEV and TUKYSA. If we or our collaborators fail to produce positive results in our ongoing or planned clinical trials of PADCEV, TUKYSA, tisotumab vedotin or any of our other product candidates, the development timeline and regulatory approval and commercialization prospects for PADCEV, TUKYSA, tisotumab vedotin and our other product candidates, and, correspondingly, our business, financial condition, results of operations and growth prospects, would be materially adversely affected.

The timing of the commencement, continuation and completion of each of our clinical trials may be subject to 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. In the context of the COVID-19 pandemic, we are working to advance our clinical trial activities, while also actively assessing and seeking to mitigate risks to our patients, partners, employees and clinical trial site personnel. Some of the sites participating in our clinical trials are affected by site closings, reduced capacity or other effects of the COVID-19 pandemic. We are actively monitoring all clinical activities and currently are experiencing impacts to our ability to monitor patients, activate sites, screen and enroll patients, complete site monitoring and manage samples. The extent of the impact of these factors on a particular clinical trial depends on the current stage of activities at a given site, for example, study start up versus post-enrollment, and the impact on a clinical trial depends on the number of impacted sites participating in that clinical trial. In addition, we believe that rates of cancer diagnoses are lower than they would otherwise be as a result of the impacts of the COVID-19 pandemic, which may also negatively impact enrollment. While we do not at this time anticipate the need to revise our publicly reported projected clinical milestone dates as a result of the effects of the COVID-19 pandemic, there may be some impacts to our clinical study timelines, which, depending upon the duration and severity of the evolving effects of the COVID-19 pandemic, could ultimately delay data availability. In addition, our ability to recruit and retain principal investigators and site staff could be adversely impacted by the risks of exposure to COVID-19 and by the conversion of medical conferences to virtual format. Further, due to the suspension of data monitoring activities at sites that do not currently allow remote monitoring, as well as impacts on the ability to monitor patients, maintain patient treatment according to the trial protocols and to manage samples, there is also the potential of negative impacts on data quality. While we are actively utilizing digital monitoring measures and other mitigations designed to prevent negative data quality impacts, if there were in fact a negative impact on data quality, we or our collaborators could be required to repeat, extend the duration of, or increase the size of clinical trials, which could significantly delay potential commercialization and require greater expenditures. We expect that similar factors will impact clinical studies operationalized by our collaborators. We cannot at this time fully forecast the scope of impacts that the evolving effects of the COVID-19 pandemic may have on our ability to initiate trial sites, enroll and assess patients, handle the operational aspects of trials such as drug and sample management, run studies in accordance with the protocol and best practices and report trial results.

Additionally, beyond impacts related to the evolving effects of the COVID-19 pandemic, 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. From time to time we have experienced enrollment-related delays in clinical trials, including in connection with the COVID-19 pandemic, and we will likely continue to experience similar delays in our current and future trials.

Many of our future and ongoing clinical trials are being or will be coordinated or conducted with Takeda, Astellas, Merck, Genmab, Bristol-Myers-Squibb Company, or BMS, and other collaborators, which may delay the commencement or adversely affect the continuation or completion of these trials. In addition, our collaborators have operational control over some of the studies we conduct jointly and we do not have full visibility into these studies run by our collaborators. We also depend on medical institutions to conduct 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, whether due to the risks and evolving effects of the COVID-19 pandemic or otherwise, 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 and additional regulatory requirements, as well as expose us to risks associated with 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. In addition, conducting clinical trials in foreign countries that are experiencing heightened impact from the evolving effects of the COVID-19 pandemic may exacerbate these risks.

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 our products or 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 our products or any of our product candidates, for numerous reasons, including:

- ADCETRIS, PADCEV, TUKYSA 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, PADCEV, TUKYSA 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, PADCEV, TUKYSA or the applicable product candidate may not appear to be more effective than current therapies;
- the quality or stability of ADCETRIS, PADCEV, TUKYSA 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, PADCEV, TUKYSA 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 trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different 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 clinical research organizations 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;
- 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; or
- the risks and evolving effects of the COVID-19 pandemic.

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, including tisetumab vedotin, or to market ADCETRIS, PADCEV or TUKYSA and/or expand ADCETRIS, PADCEV or TUKYSA into additional indications and territories. In addition, clinical trial results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. For example, even though we reported positive results from the HER2CLIMB trial and submitted an MAA for TUKYSA to the EMA, the EMA or its advisors may disagree with our interpretation of the data from the HER2CLIMB trial and may otherwise determine not to approve the MAA we submitted for TUKYSA in a timely manner or at all. Similarly, we and Astellas reported that the EV-301 trial met its primary endpoint of overall survival and reported positive topline results from the second cohort of patients in the EV-201 trial. However, despite these results and although EV-301 is intended to serve as the confirmatory trial following PADCEV's accelerated approval by the FDA and to support global registrations, and although we and Astellas plan to discuss the results of the EV-201 trial with regulatory authorities, regulatory authorities, including the FDA, or their advisors may disagree with our interpretation of the data from these trials. As a result, the FDA may not convert PADCEV's accelerated approval to regular approval in the U.S., and regulatory authorities may not accept or approve any other regulatory applications for PADCEV, in a timely manner or at all. Further, although we announced positive results from the innovaTV 204 trial and we and Genmab plan to submit a BLA to the FDA to support accelerated approval for tisetumab vedotin based on the results of the innovaTV 204 trial, the FDA, or its advisors, may disagree with our interpretation of the data from the innovaTV 204 trial and may otherwise determine not to accept or approve the BLA that we and Genmab plan to submit for tisetumab vedotin in a timely manner or at all. Likewise, although we reported positive results in our ECHELON-2 trial, regulatory agencies outside of the territories where ADCETRIS has been approved in the ECHELON-2 treatment setting, 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. Moreover, 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, PADCEV or TUKYSA, result in our failure to expand ADCETRIS, PADCEV or TUKYSA into additional indications and territories, adversely affect our ability to market ADCETRIS, PADCEV or TUKYSA, 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 utility 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.

Although we announced positive results from the innovaTV 204 trial of our late-stage product candidate, tisetumab vedotin and we and Genmab plan to submit a BLA to the FDA to support accelerated approval for tisetumab vedotin based on the results of the innovaTV 204 trial, we cannot be certain that the data from the innovaTV 204 trial will be sufficient to support accelerated approval. We cannot predict whether the BLA that we and Genmab plan to submit for tisetumab vedotin based on the innovaTV 204 trial will be accepted or approved in a timely manner or at all. Our clinical pipeline also includes ladiratuzumab vedotin, which is in phase 2 clinical development, and other product candidates that are in phase 1 clinical development. 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, potentially obtain and maintain regulatory approvals for, and to potentially commercialize tisetumab 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. 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, any encouraging or positive results from clinical trials of our product candidates in earlier stage trials may not be replicated in subsequent later-stage trials. For example, although we reported positive results from the innovaTV 204 trial of tisotumab vedotin, we cannot be certain that tisotumab vedotin will demonstrate sufficient efficacy in other trials. In addition, we are developing products and 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 a product or product candidate in one or more indications 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 products and product candidates only to learn that a product or product candidate is not an effective treatment or is not superior to existing approved therapies in the applicable indication, or has an unacceptable safety profile. Any of these results could prevent or significantly delay regulatory approval for the applicable product in any additional indications or of the applicable product candidate or could cause us to discontinue or limit the further development of such product or product candidate. If we or our collaborators fail to produce positive results in our ongoing or planned clinical trials of tisotumab vedotin or any of our other product candidates, the development timeline and regulatory approval and commercialization prospects for that product candidate, and our ability to recoup our investment in that product candidate, 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. In addition, many of our non-essential on site research activities are currently significantly reduced as a result of the COVID-19 pandemic, which may negatively impact the number of investigational new drug application, or IND, candidates entering our clinical pipeline in future years.

The successful commercialization of our products 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 our current 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 and our collaborators will achieve and continue to have coverage available for our products and any product candidates that we or our collaborators commercialize and, if available, that the reimbursement rates will be adequate. If we or our collaborators are unable to obtain coverage and adequate levels of reimbursement for our current and any future approved products that we or our collaborators commercialize, their marketability will be negatively and materially impacted. For example, we cannot be certain that third-party payors will continue to 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, we cannot be certain that third-party payors will provide coverage and adequate reimbursement for PADCEV or TUKYSA based on their relative price and perceived benefits as compared to alternative treatment options or otherwise, which may materially harm our and our collaborators' ability to successfully commercialize PADCEV and TUKYSA. In addition, depending on the ultimate duration and severity of the evolving effects of the COVID-19 pandemic, we may experience a shift from commercial payor coverage to government payor coverage, which would lead to higher gross-to net revenue reductions. We are currently seeking regulatory approval of TUKYSA from the EMA. In many jurisdictions, including the European Union, the proposed pricing for a drug must be approved before it may be lawfully marketed, which could delay entry of a product into a market or, if pricing is not approved, may prevent us or our collaborators from selling a product in a country where we or our collaborators have received regulatory approval. The launch of TUKYSA outside of the U.S. could be delayed due to a variety of factors, including supply constraints, delays in arranging a commercial infrastructure, delays encountered by our collaborator, Merck, delays in negotiating pricing and reimbursement approvals or other delays related to regulatory requirements. If we or Merck experiences delays or unforeseen difficulties due to any of these factors, planned launches in the countries in question would be delayed, which could negatively impact anticipated revenue from TUKYSA. In addition, if we or Merck is unable to obtain favorable pricing and reimbursement approvals in the countries that represent significant potential markets, our anticipated revenue from and growth prospects for TUKYSA in Europe and other regions could be negatively affected.

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 our current and any future approved 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 our products or the pricing of pharmaceutical products generally, the prices that we charge for our current and any future approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our current 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 our current and any future approved products. 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 any 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 our current or any future approved products are not included or positioned favorably in such treatment guidelines and pathways, the full utilization potential of our products may not be reached, which may harm our ability to successfully commercialize our current or any future approved 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, PADCEV and TUKYSA 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 several 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 replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, several 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, the 2020 federal spending package permanently repealed, effective January 1, 2020, the PPACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device taxes, and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” In December 2018, CMS published a new final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, although it is unclear when a decision will be made. It is also unclear how recent changes to the composition of the United States Supreme Court may impact its review of this case, as well as other future cases. We cannot be sure whether additional legislative changes will be enacted, or whether existing regulations, guidance or interpretations will be changed, or what the impact of such changes may be on our business, if any. The ultimate content, timing or effect of any such changes on the United States healthcare industry and our business remains unknown. Given the current political environment, we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products, which could result in reduced demand for our products or additional pricing pressure.

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 our current and any future approved products 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 our current or any future approved products, which may harm our business. For example, increased discounts and rebates may be mandated by governmental entities, or requested by private insurers, or fee caps and pricing pressures could be enacted by industry organizations or state and federal governments, any of which could significantly affect the revenue generated by sales of our current 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. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. In March 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses and place limits on pharmaceutical price increases. Moreover, in May 2018, the Trump administration previously released its "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," or the Blueprint. The Blueprint contained 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. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. 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. Additionally, in July 2020, President Trump announced Executive Orders related to reducing prescription drug prices that attempt to implement several of the Trump administration's proposals, including a proposal that would tie Medicare Part B drug prices to international drug prices; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; and one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for plans, pharmacies and pharmaceutical benefit managers. In September 2020, President Trump released the text of the previously announced Executive Orders regarding international drug pricing, which requires HHS to test payment model(s) where CMS pays no more than the lowest price among countries with similar gross domestic products for certain Part B drugs. They additionally called for an extension of the model to Part D drugs where insufficient competition exists. While some of these and other measures may require additional authorization 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 our current or any future approved products. Our commercial opportunity would be negatively impacted by legislative or executive action that controls pricing, mandates price negotiations, or increases government discounts and rebates.

Also, price increases on our products and negative publicity regarding drug pricing and price increases generally, whether on our products or products distributed by other pharmaceutical companies, could negatively affect market acceptance of, and sales of, our products. 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 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, Recovery and Economic Security Act, or the CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020 and extended the sequester by one year through 2030. The CARES Act also expands requirements for reporting drug shortages and supply chain interruptions to the FDA. 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 our current or any future approved products earlier than otherwise would have occurred. Increased competition may negatively impact coverage and pricing of our products, which could negatively affect our financial condition or results of operations.

We also expect to experience pricing pressures in connection with the sale of our products 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 Health 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, effective January 1, 2019, is the effective date of the 2018 final rule that set forth the calculation of the ceiling price and application of civil monetary penalties. Pursuant to the 2018 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. Further, the Centers for Medicare & Medicaid Services issued a final rule in 2018 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 since announced the same change for physician-based practices under 340B in 2019 and 2020. Such cuts to the 340B drug discount program have been the subject of ongoing litigation. In the November 2019 final rule that set forth the cuts in 2020, CMS noted that, in light of ongoing litigation, CMS would collect drug acquisition cost data for 2018 and 2019 to be used to set the payment amount for drugs acquired by 340B hospitals for cost years going forward and to develop a potential remedy for 2018 and 2019 in the event that such cuts are deemed unlawful. However, in July 2020, the U.S. Court of Appeals for the District of Columbia Circuit court held that CMS's decision to lower 340B drug reimbursement rates was within the agency's statutory authority, and cuts to the 340B drug discount program could remain. The full extent to which this decision may impact our business is unclear. While the appellate court's holding may be appealed, any such appeal, if granted, will likely involve a lengthy process prior to full resolution. A significant portion of purchases of our products 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, will likely have a negative impact on our net sales of our products.

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. It is possible that additional governmental action is taken in response to the evolving effects of the COVID-19 pandemic. 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 our current and or potential future 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.

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 our products and some of our product candidates and for the development and commercialization of other 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 our products, develop and commercialize our 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 our products and some of our current and future product candidates. Because control of development and commercialization is shared with our collaborators under these collaborations, we do not have sole discretion and control over the development and commercialization of the applicable products and 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, and we entered into a collaboration agreement with Merck in September 2020 that granted Merck rights to develop and commercialize TUKYSA outside of the United States, Canada and Europe. In addition, we have entered into collaborations with Astellas for the development and commercialization of PADCEV, with Genmab for the development and commercialization of tisotumab vedotin, and with Merck for the development and commercialization of ladiratumab vedotin. Our collaborations also include clinical trial collaborations to develop, in combination, our product or product candidates and the products or product candidates of one or more third parties. For example, we have clinical trial collaborations with BMS to evaluate the combination of nivolumab with ADCETRIS in various settings and with Merck to evaluate the combination of pembrolizumab in combination with PADCEV in various settings.

We also have antibody-drug conjugate, or ADC, license agreements 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, to allow them to use our proprietary ADC technology, and our ADC licensees conduct all research, product development, manufacturing and commercialization of any product candidates under these agreements.

Our dependence on collaborative arrangements to assist in the development and commercialization of our products and some of our product candidates and on license arrangements for the development and commercialization of other 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 and licensees devote to the development or commercialization of products and product candidates under a collaboration or license agreement, including ADCETRIS, PADCEV, TUKYSA and tisotumab vedotin;
- disputes may arise between us and our collaborators or licensees 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, our PADCEV collaboration with Astellas, our TUKYSA collaboration with Merck, and our collaboration with 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 development or commercialization plans or co-promotion activities, which may delay or otherwise harm the research, development, launch or commercialization of the applicable products and product candidates, including ADCETRIS, PADCEV, TUKYSA and tisotumab vedotin;
- our current and potential future collaborators and licensees 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, use standards or processes for conducting clinical trials that differ from ours 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 and licensees 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 and licensees to effectively commercialize these product candidates;
- our relationships with our collaborators and licensees 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 and licensees may not pursue regulatory approvals in a timely manner, may not be successful in their efforts to obtain regulatory approvals, or may not launch or commercialize a product in their territories in a timely manner;
- our current and potential future collaborators and licensees may receive regulatory sanctions relating to other aspects of their business, or could take actions with respect to our jointly-developed product, that could adversely affect the development, approval or commercialization of the applicable products or product candidates or our reputation with regulatory agencies;
- our current and potential future collaborators and licensees 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 or licensee's business strategy may adversely affect such party's willingness or ability to complete its obligations under any arrangement;
- a collaborator or licensee 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 or licensee either independently or in collaboration with others, including our competitors;
- our current and potential future collaborators and licensees may experience financial difficulties; and
- our collaboration or license agreements may be terminated, breached or allowed to expire, or our collaborators or licensees 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 and license 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 or Merck were to terminate the ADCETRIS collaboration or the TUKYSA collaboration, respectively, which they 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 or for TUKYSA outside the United States, Canada and Europe. As a result of any such termination, we may have to engage another collaborator to complete the ADCETRIS or TUKYSA development process and to commercialize ADCETRIS or TUKYSA in our collaborators' current territories, or to complete the development process and undertake commercializing ADCETRIS or TUKYSA in our collaborators' current territories ourselves, either of which could significantly delay the continued development and commercialization of ADCETRIS or TUKYSA and increase our costs. Similarly, Astellas, Genmab and Merck each have the right to opt out of their co-development obligations relating to PADCEV, tisotumab vedotin and ladiratuzumab vedotin, respectively. If Astellas, Genmab or Merck were to opt out of their co-development collaborations with us, this would significantly delay the commercialization and development of PADCEV or the development of tisotumab vedotin or ladiratuzumab vedotin, as applicable, 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 the applicable product or product candidate, which would otherwise be co-funded by our collaboration partners. Moreover, in the case of PADCEV and tisotumab vedotin, the success of PADCEV and any approved tisotumab vedotin product will depend, in part, on our ability to effectively jointly commercialize PADCEV and tisotumab vedotin with Astellas and Genmab, respectively, in accordance with our joint commercialization obligations and 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 commercialization of PADCEV and the potential future commercialization of an approved tisotumab vedotin product, respectively. The product candidates being developed under our collaboration and license agreements are in various stages of development and we cannot guarantee that any of the product candidates under our collaborations will be successful. In this regard, certain of our ADC licensees 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 assist in commercializing any future products in regions outside the United States, and we may lack the capital and resources necessary to market these products in certain regions outside the United States 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 and Merck's pembrolizumab are approved for the treatment of certain patients with relapsed or refractory classical Hodgkin lymphoma, and Celgene's romidepsin and Acrotech Biopharma's pralatrexate and belinostat are approved for relapsed or refractory sALCL among other T-cell lymphomas. Kyowa Kirin's mogamulizumab 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 with ADCETRIS. An interim analysis of this clinical trial demonstrated a statistically significant improvement in progression-free survival for pembrolizumab compared with ADCETRIS, and we expect increased competition from pembrolizumab in this indication. We are also aware of multiple investigational agents currently being studied that, 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 PADCEV, other treatments in pre-treated metastatic urothelial cancer include checkpoint inhibitor monotherapy, generic chemotherapy or, for patients with select FGFR genetic alterations, Janssen's erdafitinib. There are other investigational agents that, if approved, could be competitive with PADCEV, such as Immunomedics' sacituzumab govitecan, which is in a pivotal phase 2 study. Treatment in front line metastatic urothelial cancer has traditionally been treated with chemotherapy alone but is evolving to include two recently approved checkpoint inhibitor therapies for cisplatin-ineligible patients with high PD-L1 expression or patients who are ineligible for platinum therapy. Several trials of investigational agents in combination with chemotherapy or other novel agents are ongoing. Continued development of PD-(L)1 targeted therapies across early stage bladder cancer and in metastatic bladder cancer in frontline combinations with chemotherapy, in frontline maintenance with the recent announcement of positive phase 3 data of avelumab, and in pretreated disease, could potentially impact PADCEV usage and enrollment to PADCEV clinical trials.

With respect to TUKYSA, there are multiple marketed products which target HER2, including the antibodies trastuzumab and pertuzumab and the antibody drug conjugate T-DM1. In addition, lapatinib is an EGFR/HER2 oral kinase inhibitor for the treatment of metastatic breast cancer, and neratinib is an irreversible pan-HER kinase inhibitor indicated for extended adjuvant treatment and has been recently approved for patients who have received two or more prior anti-HER2-based regimens in the metastatic setting. Daiichi Sankyo and AstraZeneca have fam-trastuzumab deruxtecan-nxki that was recently approved for patients who have received two or more prior anti-HER2-based regimens in the metastatic setting. Byondis has an antibody drug conjugate, SYD985, in a pivotal study in this patient population and MacroGenics has a HER2 targeted, Fc-optimized antibody, margetuximab, also in a pivotal study in this patient population for which positive data were reported and a BLA was submitted in late 2019.

With respect to tisotumab vedotin, in June 2018, Merck's pembrolizumab 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, Sanofi-Aventis 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, Roche, and Zymeworks, 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, PADCEV, TUKYSA, 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, PADCEV, TUKYSA, 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, PADCEV, TUKYSA, tisotumab vedotin or our other product candidates.

Our business is currently being adversely affected and could be materially and adversely affected in the future by the evolving effects of the COVID-19 pandemic as a result of the current and potential future impacts on our commercialization efforts, supply chain, regulatory and clinical development activities and other business operations, in addition to the impact of a global economic slowdown.

Our business is currently being adversely affected and could be materially and adversely affected in the future by the evolving effects of the COVID-19 pandemic. In accordance with guidance issued by the Centers for Disease Control and Prevention, the World Health Organization and local authorities, beginning in March 2020, we implemented a mandatory work-from-home policy for employees who can perform their jobs offsite. Our essential research, manufacturing and laboratory activities are ongoing, and we maintain a number of additional precautionary measures to protect these onsite employees, such as temperature checks, screening protocols, masks, social distancing, contact tracing and making testing available. However, if we are unable to obtain adequate supplies of personal protective equipment due to shortages or encounter other challenges related to the evolving COVID-19 pandemic, we may have to place or may experience additional limitations on our in person activities. In addition, our increased reliance on personnel working from home may negatively impact productivity or disrupt, delay or otherwise adversely impact our business. This could also increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. In addition, our oversight of third-party manufacturers is currently being conducted by virtual means, which may increase the chance of a manufacturing quality issue. Impacts related to the COVID-19 pandemic could materially and adversely affect our business, our ability to generate sales of and revenues from our approved products, and our ability to advance the development of our products and product candidates, as described elsewhere in this "Risk Factors" section. The magnitude of such impacts will depend, in large part, on the ultimate duration and severity of the evolving effects of the COVID-19 pandemic.

The effects of the COVID-19 pandemic continue to rapidly evolve. These effects have increased market volatility and could result in a significant long-term disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, the current recession or additional market corrections resulting from the effects of the COVID-19 pandemic could materially affect our business and the value of our common stock. The extent to which the evolving effects of the COVID-19 pandemic impact our business, our ability to generate sales of and revenues from our approved products, and our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements in the U.S. and in other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and in other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, sales of our products, our clinical and regulatory activities, our research programs, healthcare systems or the global economy as a whole. However, these effects could materially and adversely affect our business, financial condition, results of operations and growth prospects. In addition, to the extent the evolving effects of the COVID-19 pandemic adversely affect our business, financial condition, results of operations and growth prospects, they may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section. It is also possible that future global pandemics could also occur and also materially and adversely affect our business, financial condition, results of operations and growth prospects.

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 product sales guidance from time to time, you should not rely on product 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 product sales for newly-approved products or in indications for existing products for which we have recently received marketing approval. Moreover, our product sales have, on occasion, been below the expectations of securities analysts and investors and have been below prior period sales, and our sales 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 our products, which may vary significantly from period to period;
- the overall level of demand for our products, including the impact of any competitive or biosimilar products and the duration of therapy for patients treated with our products;
- the extent to which coverage and reimbursement for our products 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 our products and their potential advantages compared to existing and future therapies in their approved indications, including in ADCETRIS' frontline Hodgkin lymphoma and frontline PTCL indications, PADCEV's FDA approved indication and TUKYSA's FDA approved indication;
- 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 our products at the discounted government price or to obtain government-mandated rebates on purchases of our products;
- changes in our cost of sales due to potential new product launches, royalties owed under technology license agreements or write-offs of inventory;
- the incidence rate of new patients in the approved indications for our products;
- the evolving effects of the COVID-19 pandemic, including those leading to current and potential future reductions in the rate of cancer diagnoses;
- the timing, cost and level of investment in our sales and marketing efforts to support our products sales;
- the timing, cost and level of investment in our research and development, pre-commercialization and other activities involving ADCETRIS, PADCEV, TUKYSA, tisotumab vedotin and our other product candidates by us or our collaborators; 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, even if we and/or our collaborators are able to obtain regulatory approvals for our product candidates, due to the lack of any historical sales data from the commercialization of any of our product candidates, sales of a newly-approved product such as PADCEV or TUKYSA will be difficult to predict from period to period. As a result, sales results or trends for PADCEV, TUKYSA or any of our future approved products in any period may not necessarily be indicative of future performance. In any event, if we are unable to obtain and maintain necessary or desirable regulatory approvals for our products and product candidates, including for ADCETRIS, PADCEV and TUKYSA, in a timely manner, if at all, if the FDA or other regulatory authorities do not approve product labeling that is necessary or desirable for the successful commercialization of an approved product, or if sales of an approved product do not reach the levels we expect, our anticipated revenue from our products and 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.

Moreover, we have entered into collaboration and license 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, our PADCEV collaboration with Astellas and our ladiratuzumab vedotin and TUKYSA collaborations with Merck, 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.

For these and other reasons, it is difficult for us to accurately forecast future sales of our current or any future approved products, 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 sustained 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 our products and product candidates as well as commercializing our products for the treatment of patients in their approved indications. In addition, we expect to make substantial expenditures to further develop and potentially commercialize 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, even though we reported net income for the three and nine months ended September 30, 2020 due to the upfront license revenue recognized in the third quarter of 2020 related to the LV Agreement and TUKYSA Agreement with Merck, we nonetheless expect to continue to incur net losses and may not achieve sustained profitability in the future for some time, if at all. Although we recognize revenue from product sales and we continue to earn amounts under our collaboration agreements, our revenue and profit potential is unproven and our future operating results are 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.

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 transition into a multi-product oncology company, our operation of a manufacturing facility and our continuing international expansion. In this regard, the anticipated continued growth of ADCETRIS, the continued launch and commercialization of PADCEV and TUKYSA in the U.S., and the potential launch and commercialization of TUKYSA in Canada and Europe and of any other future approved products may require expansion of our sales force and commercial organization, and we may need to commit significant additional funds, management and other resources to the growth of our commercial organization. We may not be able to achieve any necessary growth in a timely or cost-effective manner or realize a positive return on our investment, and we may not have the financial resources to achieve the necessary growth in a timely manner or at all, any of which could negatively impact our ability to successfully launch and commercialize a newly-approved product and harm the commercial potential of our current and any future approved products. In any event, this rapid growth and additional complexity 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. In particular, we are using new distribution channels for TUKYSA that require us to implement additional control systems to monitor inventory that has been purchased by specialty pharmacies and not yet dispensed to patients. A failure to correctly implement and monitor these new control systems could result in a control failure or error in our financial accounting. In addition, this growth places significant demands on our third party suppliers and they may not have the resources and personnel to adequately support our commercial plans and launch needs, including in regions outside the United States. 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, control deficiencies or other problems. We expect that we may need to increase our management personnel to oversee our expanding operations, and recruiting and retaining qualified individuals is difficult. Likewise, we could experience limitations on our ability to recruit, hire and retain personnel at all levels of the organization as a result of the COVID-19 pandemic, and without reductions in the pace, scale or complexity of our business, this could result in strain on our staff, loss of talent, failure to capitalize fully on opportunities, control deficiencies and other challenges, which could adversely affect our business, financial condition, results of operations and prospects. 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 and retaining qualified management personnel, our business, financial condition, results of operations and prospects may be adversely affected.

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

We are expanding our operations internationally. We have an expanding number of subsidiaries in foreign jurisdictions, including multiple subsidiaries in Europe, and we plan to build a commercial infrastructure in Europe and expand our commercial infrastructure in Canada. Consequently, we are, and will increasingly 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, drug safety, drug supply, 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 and different languages;
- reliance on vendors who are located far from our headquarters and with whom we have not worked previously;

- 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 and expanding commercial infrastructure in Canada, our business and corporate structure has and will become substantially more complex. In addition, as a business, we do not have experience conducting operations outside of the United States and Canada. There can be no assurance that we will effectively manage the increased complexity and broader scope of our operations without experiencing operating inefficiencies, control deficiencies or other problems. Significant management time and effort will be required to effectively manage the increasing complexity and broader scope of our operations, 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 United Kingdom, or U.K., is derived from European Union directives and regulations, Brexit, which occurred on January 31, 2020, 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, PADCEV, TUKYSA and our product candidates. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the European Union, the U.K. will be subject to a transition period through December 31, 2020, or the Transition Period, during which European Union rules will continue to apply. Negotiations between the U.K. and the European Union are expected to continue in relation to the customs and trading relationship between the U.K. and the European Union following the expiry of the Transition Period. Under the formal withdrawal arrangements between the U.K. and the EU, the parties had until June 30, 2020 to agree to extend the Transition Period if required. No such extension was agreed prior to such date. No agreement has yet been reached between the U.K. and the EU and it may be the case that no formal customs and trading agreement will be reached prior to the expiry of the Transition Period on December 31, 2020. We or our collaborators may face new costs and challenges as result of Brexit, in particular following the Transition Period, that could have an adverse effect on our operations, including potential stresses and constraints on the capacity of service providers providing product release services in new locations outside of the U.K., potential challenges with releasing clinical product supplies into the U.K. and potential challenges or inefficiencies in obtaining approvals to commercialize our current or potential future products in the U.K., any of which could negatively impact our current and planned clinical trials and regulatory and commercial activities, and those of our collaborators, 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 and Astellas. Moreover, following the Transition Period, there is currently considerable uncertainty in relation to U.K. financial and banking markets as well as the pharmaceutical regulatory process in the U.K. In addition, the U.K. is likely to lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers and could make it more difficult for us and our collaborators to do business in the U.K., including to obtain and maintain regulatory approvals of products. 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 our collaborators' 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.

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 our products and 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. We rely on Astellas to supply PADCEV for our clinical trials and for commercial sale, and Astellas oversees the manufacturing supply chain for PADCEV. With respect to TUKYSA, we rely on multiple contract manufacturers and other third parties to perform manufacturing services for us including Sterling Pharma Solutions Limited for production of the starting materials for TUKYSA, Esteve Quimica to produce the active pharmaceutical ingredient, Hovione to complete spray drying and Corden Plankstadt to produce the tablets for TUKYSA. We have entered into commercial supply agreements with each of Sterling, Esteve Quimica and Corden, and are in the process of negotiating a commercial supply agreement with Hovione. 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 and TUKYSA, and on Astellas and other third parties to produce and store sufficient quantities of PADCEV, for use in our clinical trials and for commercial sale. If our contract manufacturers, collaborators or other third parties fail to deliver our products 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 our products. With respect to TUKYSA specifically, we have limited prior experience as an organization manufacturing TUKYSA and small molecule drug products generally, and have relatively new working relationships with many of the third-party manufacturers involved in TUKYSA 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. Moreover, there are a limited number of facilities in which each of our products can be produced, and any interruption of the operation of those facilities due to the risks and evolving effects of the COVID-19 pandemic or other 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 product supply, or limit our or our collaborators' ability to sell our products. Further, we and our collaborators depend on outside vendors for the supply of raw materials used to produce our products. If the third-party suppliers were to cease production or otherwise fail to supply us or our collaborators with quality raw materials and we or our collaborators were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have our products manufactured to meet clinical and commercial requirements would be adversely affected. While we believe that the existing supplies of PADCEV and Astellas' contract manufacturing relationships will be sufficient to accommodate current clinical and commercial needs, we or Astellas may need to obtain additional manufacturing arrangements or increase manufacturing capability to meet potential future commercial needs with respect to PADCEV, which could require additional capital investment by us or cause us potential delays if Astellas encounters challenges in negotiating commercially reasonable arrangements with these manufacturers. While we believe that the existing supplies of TUKYSA will be sufficient to accommodate current clinical and forecasted commercial needs at this time, we expect that we will need to put in place additional manufacturing arrangements or expand our current 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. Forecasting demand for a new product can be challenging and in the event demand for TUKYSA exceeds our estimates or in the event that our commercial manufacturers of TUKYSA encounter unexpected failures or setbacks in completing manufacturing services in accordance with applicable quality standards, our TUKYSA launch in the U.S. could be negatively impacted by short-term product supply challenges, which would adversely impact our TUKYSA revenues and could negatively affect our relationships with patients and healthcare professionals. In addition, any failures or delays in manufacturing adequate product supplies and in putting in place or expanding our manufacturing and supply infrastructure could delay or impede our and Merck's ability to launch and commercialize TUKYSA in any markets outside the U.S. where TUKYSA has obtained regulatory approval and any additional markets where it may obtain regulatory approval, if any. While we do not currently anticipate disruptions to the supply of our products due to the evolving effects of the COVID-19 pandemic, if the COVID-19 pandemic continues for an extended period of time or the effects of the COVID-19 pandemic become more severe, or any of the parties in our supply chain are adversely impacted by the evolving effects of the COVID-19 pandemic, such as staffing shortages, production slowdowns and/or disruptions in delivery systems, then there could be disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products. Any supply disruptions would adversely impact our ability to generate sales of and revenues from our products, and our business, financial condition, results of operations and growth prospects could be materially adversely affected. Further, in connection with the COVID-19 pandemic and in an effort to increase the wider availability of needed medical and other supplies and products, we and our third-party suppliers may elect to or governments may require us or our third-party suppliers to allocate manufacturing capacity (for example pursuant to the U.S. Defense Production Act) in a way that adversely affects our ability to have our products manufactured to meet clinical and commercial requirements.

For the clinical supply of our product candidates, we rely, and expect for the foreseeable future to continue to rely, on multiple contract manufacturers and other third parties to perform manufacturing services for us. If these third-party manufacturers 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, delays and an adverse effect on our business. With respect to tisotumab vedotin, we currently rely on drug product supply provided by Genmab and have little control over their supply chains or the contract manufacturers they utilize. For the near-term, we expect to continue to rely on Genmab for manufacturing of clinical supplies of tisotumab vedotin. Under the commercialization agreement we entered into with Genmab in October 2020, we will be responsible for overseeing the clinical and commercial manufacturing supply chain of tisotumab vedotin following a transition period. We will need to obtain appropriate manufacturing arrangements and increase manufacturing capability to meet potential future commercial needs, which will require additional capital investment by us and cause potential delays if we encounter challenges in negotiating commercially reasonable arrangements with manufacturers or in transitioning oversight of the manufacturing process from Genmab to us.

In order to obtain regulatory approval of any product candidate or regulatory approval for any product in a new jurisdiction, we or our supplier or suppliers for that product or product candidate must obtain approval to manufacture and supply product, in some cases based on qualification data provided as part of a BLA, a New Drug Application, or NDA, or another application for regulatory approval. In addition, the manufacturing facilities utilized to manufacture the product or product candidate will be subject to pre-approval regulatory inspections. Any delay in generating, or failure to generate, data required in connection with submission of the chemistry, manufacturing and controls, or CMC, portions of any BLA, NDA or other application for regulatory approval, or challenges in the regulatory inspection process, could negatively impact our ability to meet our anticipated submission dates, result in delay in any approval decisions and/or negatively affect our ability to obtain regulatory approval at all. Any failure of us, our collaborators or a manufacturer to obtain approval from a regulatory authority to manufacture and supply product or any delay in obtaining and distributing adequate supplies of a newly-approved product, including PADCEV and TUKYSA, on a timely basis or in accordance with applicable specifications and local requirements could negatively impact our ability to successfully launch and commercialize the applicable product or product candidate and to generate sales of that product or product candidate at the levels we expect. We or our collaborators may also encounter difficulties in meeting the regulatory requirements applicable to the manufacturing process for these agents, in managing the additional complexity of manufacturing for a number of markets outside the U.S. or in responding to changes in the amount or timing of supply needs. Any failures or delays to meet these requirements could substantially delay or impede our ability to obtain regulatory approvals for and to market these agents, which could negatively impact our operating results and adversely affect our business.

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

We actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses. Any potential 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 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 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 to market ADCETRIS outside of the United States and Canada. Likewise, even though we market TUKYSA in the United States, our revenues will still depend in part on Merck's ability and willingness to market TUKYSA outside of the United States, Canada and Europe. In addition, under our agreements with Astellas, we and Astellas bear the costs of their own sales organizations in the U.S., equally share certain other costs associated with commercializing PADCEV in the U.S. and equally share in any profits realized in the U.S. The loss of our collaborators, especially Takeda or Astellas, 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.

We sell ADCETRIS and PADCEV through a limited number of specialty distributors. Healthcare providers order ADCETRIS and PADCEV through these distributors. We receive orders from distributors and generally ship product directly to the healthcare provider. We sell TUKYSA through a distribution network of specialty pharmacies, integrated delivery network hospitals and practices that dispense in the office. These distributors and distribution network partners do not set or determine demand for our products; however, our ability to effectively commercialize our products will depend, in part, on their performance. Although we believe we can find alternative distributors and partners on relatively short notice, the loss of a major distributor or partner could materially and adversely affect our results of operations and financial condition. In addition, business disruptions arising from the COVID-19 pandemic could negatively affect the ability of some of our distributors or distribution network partners to pay amounts owed to us in a timely manner or at all.

We are subject to various state and federal and foreign laws and regulations, including healthcare, data protection and privacy 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 civil monetary penalties statute, the federal Health Insurance Portability and Accountability Act, or HIPAA, the federal Health Information Technology for Economic and Clinical Health Act, or HITECH, and the federal transparency requirements under the PPACA. These laws may impact, among other things, the sales, marketing and education programs for ADCETRIS, PADCEV, TUKYSA 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. 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 would otherwise be lawful in businesses outside of the healthcare industry.

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 codified case law that 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. Similar to the Anti-Kickback Statute, PPACA also 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.

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 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.

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 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, as defined by such law, and teaching hospitals, and physician ownership and investment interests. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year.

Many states and foreign jurisdictions have similar laws and regulations, such as anti-kickback, anti-bribery and corruption, false claims, privacy and data protection 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 European Union is governed by the provisions of the European Union 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 European Union, 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 all types of personal data that we process, 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. Moreover, one of the primary safeguards allowing U.S. companies to import personal information from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, the Court of Justice of the EU recently invalidated the EU-U.S. Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal information transfers from Europe to the United States or most other countries. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. Where appropriate, we rely on individuals' explicit consent to transfer their personal information from Europe to the United States and other countries. In addition, we rely on inter-company Standard Contractual Clauses to provide appropriate safeguards for such transfers. Authorities in Switzerland, whose data protection laws are similar to those of the EU, also invalidated use of the Swiss-U.S. Privacy Shield. Authorities in the U.K. may similarly invalidate use of the EU-U.S. Privacy Shield. Brexit has created additional uncertainty with regard to data protection regulation in the U.K., as it is unclear whether the U.K. and EU will be able to negotiate a mutually agreeable data protection agreement that regulates data transfers between the U.K. and EU and what impact this will have on our business. If we are unable to rely on explicit consent to transfer individuals' personal information from Europe, which can be revoked, or if, upon review by authorities, our existing compliance solutions are found to be insufficient, we will face increased exposure to substantial fines under European data protection laws as well as injunctions against processing personal information from persons resident in Europe. The inability to import personal information from the European Economic Area, U.K. or Switzerland could restrict our clinical trial activities in Europe, limit our ability to collaborate with contract research organizations, service providers, contractors and other companies subject to European data protection laws, interfere with our ability to hire employees in Europe and require us to increase our data processing capabilities in Europe at significant expense. In any event, our failure or alleged failure (including as a result of deficiencies in our policies, procedures or measures relating to privacy, data protection, marketing or communications) to comply with laws, regulations, policies, legal or contractual obligations, industry standards or regulatory guidance relating to privacy or data protection, 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 privacy and data protection (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018, which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States, and we cannot determine the impact such new laws, regulations and standards may have on our business. We may also be subject to state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or other reporting and registration requirements related to our business activities. Many of these state laws differ from each other in significant ways, thus complicating compliance efforts.

The FDA and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. In recent years, private whistleblowers have also pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of off-label promotion. If we are found to have promoted an approved product for off-label uses we may be subject to significant liability, including significant civil and administrative financial penalties and other remedies as well as criminal 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. Further, as we expand our footprint and activities outside of the United States and Canada, our exposure to compliance risks under the FCPA and other similar laws will likewise increase.

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. We also actively work to revise and evolve our compliance program to keep pace with evolving compliance risks and the growing scale of our business. 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 significant 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, or reduced working hours of governmental employees or by the diversion of the efforts and attention of governmental agencies to approval of other therapeutics or other activities related to the COVID-19 pandemic, could 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. With respect to the COVID-19 pandemic, it is possible that we could experience delays in the timing of regulatory review and/or our interactions with regulatory authorities due to reduced working hours or absenteeism of governmental employees or by the diversion of authorities' efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay any approval decision with respect to the MAA we submitted to the EMA for TUKYSA, or our progress in advancing our development efforts with respect to other products and product candidates. Our interactions with regulatory authorities in other jurisdictions and across multiple products and product candidates continue but we cannot rule out the possibility of negative impacts on such interactions in the future as the pandemic continues to evolve.

Disruptions at the FDA and other agencies may 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 a number of 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 setbacks in our ADC development program would negatively affect our business and financial position.

ADCETRIS, PADCEV and our 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 license agreements with AbbVie, Astellas, Genentech, GSK, and Progenics, and our collaboration agreements with Takeda, Astellas, and Genmab. Certain of our ADC product candidates include additional proprietary technologies that have not yet been proven in late stage clinical development. Any failures or 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 our products in their 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, which could result in substantial damages and may divert management's time and attention from our business.

We are engaged in a dispute with Daiichi Sankyo regarding the ownership of certain technology used by Daiichi Sankyo in its metastatic breast cancer drug ENHERTU and certain product candidates and previously submitted an arbitration demand related to the dispute. We have also separately filed an action for patent infringement against Daiichi Sankyo relating to Daiichi Sankyo's importation into, offer for sale, sale, and use in the United States of ENHERTU. As a result of these disputes, we have incurred and will continue to incur litigation expenses. In addition, from time to time, we may become involved in other 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 other 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 course of these and potential future litigations, we may be subject to additional claims and counterclaims that may result in liabilities or require us to take or refrain from certain actions, and we may not prevail. Monitoring, defending against and pursuing 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. Successful challenges to our patent or other intellectual property rights 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. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price.

We may need to raise 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, and support our development, manufacturing, commercialization, and planned global expansion, which may require us to raise additional capital. 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 our products, 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 may require us to raise 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. 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, PADCEV, TUKYSA or of any future approved products;
- the time and costs involved in obtaining regulatory approvals of our products in additional indications or territories, if any, and potentially of 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, revenue generated under our collaboration with Astellas and anticipated royalty revenue generated by commercial sales of TUKYSA by Merck;
- the cost of establishing and maintaining clinical supplies of our products and product candidates and commercial supplies of our current and any future approved products;
- the extent of our investment in development, manufacturing and commercialization outside the U.S.;
- the costs associated with acquisitions or licenses of additional technologies, products, or companies as well as licenses we may need to commercialize our current or any future approved 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 or our undertaking of additional programs, business activities or entry into additional strategic transactions, including potential future acquisitions of products, technologies or businesses. Moreover, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

During the past several years, domestic and international financial markets have experienced extreme disruption from time to time, including, among other things, high volatility and significant declines in stock prices and severely diminished liquidity and credit availability for both borrowers and investors. Such adverse capital and credit market conditions could make it more difficult to obtain additional capital on favorable terms, or at all, which could have a material adverse effect on our business and growth prospects. For example, our ability to raise additional capital may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the evolving effects of the COVID-19 pandemic.

We and our collaborators rely on license agreements for certain aspects of our products and 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 our products and 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. In addition, Astellas has agreements to license technology for use in PADCEV. We rely on Astellas to maintain these license agreements. If Astellas fails to maintain these license agreements, if our licensors terminate our license agreements or if we or our collaborators are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize our products or product candidates. Further, we have had in the past, and we or our collaborators may in the future have, disputes with our licensors, which may impact our ability to develop and commercialize our products or product candidates or require us to enter into additional licenses. An adverse result in potential future disputes with our or our collaborators' licensors may impact our ability to develop and commercialize our products and 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 our products and 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 our products or any 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. In addition, we rely on external agents to perform certain activities to maintain our patents. Although we carefully select and oversee these agents, the failure of an agent to properly perform these maintenance activities, whether through mistake or otherwise, could adversely affect our intellectual property rights.

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 our products 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 our products or future commercialization of our product candidates. 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 our products 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 our products or 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 TUKYSA. 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 our products, 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, and with increasing reliance on remote work arrangements, the geographic market in which we compete for talent is expanding. Our failure to compete effectively in this area could negatively affect our sales of our current and any future approved products. 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 effectively commercialize PADCEV and TUKYSA, to build a commercial infrastructure in Europe or to support the potential launch and commercialization of our product candidates, alone or jointly with our collaborators, if we receive regulatory approval. If our commercial organization is not appropriately sized or equipped to adequately market our current and any future approved products, the commercial potential of our current and any future approved products may be diminished, and our business and prospects for profitability may be adversely affected.

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, commercial sales data and corporate records, communicate with staff and external parties and operate other critical functions. The effects of the COVID-19 pandemic have intensified our dependence on information technology systems as many of our critical business activities are currently being conducted remotely and our increased reliance on personnel working from home could increase our cybersecurity risk. 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 our products and 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.

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 our products and product candidates by us and our corporate collaborators in clinical trials and the sale of our products, 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. In addition, 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 our products could materially adversely affect our business by rendering us unable to sell our products for some time and by adversely affecting our reputation.

Changes in tax laws or regulations may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, result in significant one-time charges, increase our future tax expense or otherwise have a material adverse effect on our business, cash flow, financial condition or results of operations.

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 our products. 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.

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 our products and product candidates or about the diseases that our products 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 intangible assets and goodwill may negatively affect our results of operations and financial position.

As of September 30, 2020, we recorded \$564.2 million of intangible assets, net and goodwill on our condensed consolidated balance sheet. Our intangible assets 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 intangible assets 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 nine months ended September 30, 2020, our closing stock price fluctuated between \$95.75 and \$195.69 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 levels of ADCETRIS, PADCEV and TUKYSA product sales;
- announcements of FDA or foreign regulatory approval or non-approval of our products, including TUKYSA, or any of our product candidates or specific label indications for or restrictions, warnings or limitations in its use, or delays in the regulatory review or approval process;
- announcements regarding the results of discovery efforts and preclinical, clinical and commercial activities by us, or those of our competitors;
- announcements regarding the results of the clinical trials we and our collaborators are conducting or may in the future conduct for our products and product candidates;
- announcements regarding, or negative publicity concerning, adverse events or safety concerns associated with the use of ADCETRIS, PADCEV, TUKYSA 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, or establishment of new collaborations or licensing arrangements;
- our failure to achieve the perceived benefits of our strategic transactions 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, including with respect to our disputes with Daiichi Sankyo;
- developments regarding any future 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, including in connection with the COVID-19 pandemic, which has resulted in decreased market prices, notwithstanding the lack of a fundamental change in the underlying business models or prospects of those companies. In this regard as a result of the risks and evolving effects of the COVID-19 pandemic, Brexit and/or significant changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade and healthcare 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 market price of our common stock. In this regard, worsening economic conditions and other adverse impacts or developments relating to the evolving effects of the COVID-19 pandemic may negatively affect the market price of our common stock, regardless of our actual operating performance.

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

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

Sales of a substantial number of shares of our common stock into the public market, including sales by members of our management or board of directors or entities affiliated with such members, could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-related securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of September 30, 2020, we had 175,188,320 shares of common stock outstanding, all of which shares are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144. In addition, we may issue a substantial number of shares of our common stock or equity-related securities, including convertible debt, to meet our capital needs, including in connection with funding potential future acquisition or licensing opportunities, capital expenditures or product development costs, which issuances could be substantially dilutive and could adversely affect the market price of our common stock. Likewise, future issuances by us of our common stock upon the exercise, conversion or settlement of equity-based awards or other equity-related securities would dilute existing stockholders' ownership interest in our company and any sales in the public market of these shares, or the perception that these sales might occur, could also adversely affect the market price of our common stock.

Moreover, we have in the past and may in the future grant rights to some of our stockholders that require us to register the resale of our common stock or other securities on behalf of these stockholders and/or facilitate public offerings of our securities held by these stockholders, including in connection with potential future acquisition or capital-raising transactions. For example, in connection with our September 2015 public offering of common stock, we entered into a registration rights agreement with entities affiliated with Baker Bros. Advisors LP, or the Baker Entities, that together, based on information available to us as of September 30, 2020, collectively beneficially owned approximately 27% 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 September 30, 2020, our executive officers and directors and holders of greater than five percent of our outstanding common stock beneficially owned approximately 64% of our voting power as of September 30, 2020. 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.

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 Seagen 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 Seagen 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 Seagen, 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 Seagen.

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 Seagen Inc. (f/k/a 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 Seagen Inc. (f/k/a 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 Seagen Inc. (f/k/a Seattle Genetics, Inc.)	8-K	000-32405	3.3	5/26/2011
3.3	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seagen Inc. (f/k/a Seattle Genetics, Inc.)	8-K	000-32405	3.1	10/8/2020
3.4	Amended and Restated Bylaws of Seagen Inc. (f/k/a Seattle Genetics, Inc.)	8-K	000-32405	3.1	1/16/2020
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 Seagen Inc. (f/k/a 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 Seagen Inc. (f/k/a Seattle Genetics, Inc.) and the persons listed on Schedule A attached thereto	8-K	000-32405	10.1	9/11/2015
10.1+†	License and Collaboration Agreement relating to ladiratuzumab vedotin dated September 13, 2020 between Seagen Inc. (f/k/a Seattle Genetics, Inc.) and Merck Sharp & Dohme Corp.	—	—	—	—
10.2+†	Stock Purchase Agreement dated September 13, 2020 between Seagen Inc. (f/k/a Seattle Genetics, Inc.) and Merck Sharp & Dohme Corp.	—	—	—	—
10.3+*	Form of Performance-Based Stock Unit Grant Notice and Stock Unit Agreement under the Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan (approved August 16, 2020)	—	—	—	—
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	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, formatted in Inline XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Comprehensive Income (Loss), (iii) Condensed Consolidated Statements of Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text and including detailed tags.	—	—	—	—
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).	—	—	—	—

+ 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.

[*] = 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

LICENSE AND COLLABORATION AGREEMENT

by and between

MERCK SHARP & DOHME CORP.

and

SEATTLE GENETICS, INC.

Dated as of: September 13, 2020

TABLE OF CONTENTS

Page

Table of Contents

ARTICLE 1 DEFINITIONS	1
ARTICLE 2 OVERVIEW OF COLLABORATION; LICENSE GRANTS	34
2.1 Overview of Collaboration	34
2.2 License Grants to Merck	34
2.3 License Grants to SeaGen	37
2.4 No Implied Licenses; Retained Rights	38
2.5 Third Party In-License Agreements	39
2.6 Sublicense Rights by Licensee; Further Grants of Licenses by Licensor	39
2.7 Use of Subcontractors	40
2.8 No Outside Development, Manufacture or Commercialization of Licensed Compounds and the Licensed Product	41
2.9 Exclusivity	42
ARTICLE 3 GOVERNANCE	45
3.1 Committees	45
3.2 Joint Steering Committee	46
3.3 Joint Development Committee	52
3.4 Joint Manufacturing Committee	55
3.5 Joint Commercialization Committee	57
3.6 Financial Managers; Joint Finance Committee	60
3.7 Meetings of Subcommittees	61
3.8 Decision Making of Subcommittees	62
3.9 Alliance Managers	62
ARTICLE 4 ALLOCATION OF RESPONSIBILITIES	63
4.1 General	63
4.2 Technology Transfers to Enable Collaboration	64
ARTICLE 5 DEVELOPMENT	65
5.1 Development	65
5.2 Development Plans for the Licensed Product	65
5.3 Development Reports; Development Data and Records	70
5.4 Lead Study Party; Conduct of Clinical Trials	71
5.5 Regulatory and Safety Responsibility for the Licensed Product	72
ARTICLE 6 COMMERCIALIZATION	78
6.1 Commercialization	78
6.2 Commercialization Plan	78
6.3 Commercialization Reports	82
6.4 Lead Distribution Party	82
6.5 Promotional Materials; Other Field-Based Materials	83
6.6 Promotion for the Licensed Product	86
6.7 Unsolicited Requests for Medical Information	87
6.8 Recalls	87
ARTICLE 7 MANUFACTURE	88

TABLE OF CONTENTS
(continued)

	Page
7.1 Manufacture Generally	88
7.2 Manufacturing Plan for the Licensed Product.....	89
7.3 Development Supply for Licensed Product.....	90
7.4 Commercial Supply for Licensed Product.....	91
7.5 Continuity of Supply for Licensed Compounds and the Licensed Product.....	94
7.6 Compliance for Licensed Compounds and the Licensed Product.....	94
7.7 Audits and Oversight of Manufacturing Facilities for Licensed Compounds and the Licensed Product.....	95
7.8 Changes to Specifications and Manufacturing Process for Licensed Compound or Licensed Product.....	96
7.9 Supply Agreements for Supply of Licensed Product	96
7.10 Supply of Proprietary Product for Clinical Trial of Proprietary Combination.....	97
ARTICLE 8 COMPLIANCE.....	97
8.1 Compliance with Applicable Law and Ethical Business Practices	97
8.2 Safety or Legal Issues.....	100
8.3 Data Privacy.....	100
ARTICLE 9 CONFIDENTIALITY AND PUBLICATION	101
9.1 Nondisclosure Obligation.....	101
9.2 Permitted Disclosure.....	102
9.3 Disclosures Required by Applicable Law	103
9.4 Program Know-How.....	104
9.5 Publication.....	104
9.6 Publicity/Use of Names.....	105
ARTICLE 10 PAYMENTS.....	106
10.1 Upfront Payment.....	106
10.2 Development Milestones	106
10.3 Commercial Milestones.....	112
10.4 Sharing of Costs and Revenues for Licensed Compounds and the Licensed Product Generally.....	114
10.5 Payment Terms.....	117
10.6 Recordkeeping and Audit.....	118
10.7 Taxes	119
ARTICLE 11 REPRESENTATIONS, WARRANTIES AND COVENANTS	119
11.1 Representations and Warranties of Each Party.....	119
11.2 Additional SeaGen Representations and Warranties.....	120
11.3 Additional SeaGen Representations and Warranties with Respect to the Licensed Compound and the Licensed Product.....	123
11.4 Additional Covenants of SeaGen.....	125
11.5 Additional Covenants of Merck.....	125
11.6 Non-Solicitation.....	126
11.7 Disclaimer.....	126



TABLE OF CONTENTS
(continued)

	Page
ARTICLE 12 INTELLECTUAL PROPERTY	127
12.1 Intellectual Property Operating Committee.....	127
12.2 Disclosure of Program Know-How	128
12.3 Ownership of Intellectual Property.....	128
12.4 Filing, Prosecution and Maintenance of Patent Rights.....	129
12.5 Patent Term Extension and Supplementary Protection Certificate	132
12.6 Common Ownership Under Joint Research Agreements	133
12.7 Administrative Proceedings.....	133
12.8 Invalidity or Unenforceability Defenses or Actions.....	134
12.9 Patent Listings	135
12.10 Enforcement of Patents and Know-How.....	137
12.11 SeaGen Existing In-Licenses.....	142
12.12 Trademarks.....	143
ARTICLE 13 INDEMNIFICATION; LIMITATION ON LIABILITY	146
13.1 General Indemnification by SeaGen.....	146
13.2 General Indemnification by Merck.....	146
13.3 Shared Liability Claims; Product Liability Actions for Proprietary Combinations; [
*].....	147
13.4 Additional Indemnification by SeaGen.....	150
13.5 Claims for Indemnification.....	150
13.6 Disclaimer of Liability.....	152
13.7 Insurance.....	152
ARTICLE 14 TERM AND TERMINATION.....	152
14.1 Term	152
14.2 Unilateral Termination of Agreement in its Entirety by Merck	152
14.3 Termination by Mutual Agreement	152
14.4 Termination for Cause.....	153
14.5 Termination For Bankruptcy	153
14.6 Termination for Patent Challenge.....	154
14.7 Effects of Termination.....	155
14.8 Milestone Payments.....	165
14.9 Effect of Expiration or Termination; Survival.....	165
ARTICLE 15 TAX MATTERS.....	166
15.1 Tax Partnership.....	166
15.2 Tax Information Sharing.....	166
15.3 Tax Returns of Tax Partnership.....	166
15.4 Additional Matters.....	167
ARTICLE 16 MISCELLANEOUS	167
16.1 Use of Affiliates.....	167
16.2 Interpretation.....	167
16.3 Force Majeure.....	168



TABLE OF CONTENTS
(continued)

	Page
16.4 Assignment.....	168
16.5 Severability.....	176
16.6 Notices	176
16.7 Applicable Law.....	177
16.8 Dispute Resolution	177
16.9 Entire Agreement; Amendments	179
16.10 Export Controls.....	179
16.11 Headings.....	179
16.12 Independent Contractors.....	179
16.13 Third-Party Beneficiaries.....	179
16.14 Waiver	180
16.15 Cumulative Remedies.....	180
16.16 Waiver of Rule of Construction.....	180
16.17 Business Day Requirements	180
16.18 Counterparts.....	180
16.19 Further Actions.....	180

Table of Contents
(continued)

Schedules and Exhibits

Schedule 1.26: European Collaboration Territory
Schedule 1.39: Cost of Goods Manufactured
Schedule 1.133: SeaGen Existing CMO Agreements
Schedule 1.134: SeaGen Existing In-Licenses
Schedule 1.139: SeaGen Patents
Schedule 1.152: SGN-LIV-1-A
Schedule 1.153: SGN-LIV-1-B
Schedule 1.154: SGN-LIV-1-C
Schedule 2.7: Permitted Distributor Countries
Schedule 2.9.2: Next Generation Compound Criteria - SGN-LIV-1-C
Schedule 6.8: Certain Costs of Recalls
Schedule 7.9: Certain Terms for Supply Agreements
Schedule 9.6.1: Press Release
Schedule 11.2: SeaGen Disclosure Schedules
Schedule 11.3.1: Regulatory Documentation
Schedule 13.4: [*]
Schedule 14.7.6: Continuing Product Payment Reductions
Schedule 15.3: Partnership Tax Related Provisions
Exhibit A: Initial Development Plan

LICENSE AND COLLABORATION AGREEMENT

This License and Collaboration Agreement (this "Agreement") is entered into as of September 13, 2020 (the "Effective Date"), by and between Merck Sharp & Dohme Corp., a company organized and existing under the laws of New Jersey ("Merck"), and Seattle Genetics, Inc., a company organized and existing under the laws of Delaware ("SeaGen"). Merck and SeaGen are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS:

WHEREAS, SeaGen is a global biopharmaceutical company engaged in the research, development and commercialization of biopharmaceutical products, including antibody drug conjugates, and owns or controls certain patents and other intellectual property relating to antibody drug conjugates, including SGN-LIV-1-A (as defined below, and which is also known as ladiratuzumab vedotin (LV));

WHEREAS, Merck and its Affiliates possess expertise in the research, development and commercialization of pharmaceutical products;

WHEREAS, the Parties (or their respective Affiliates) are currently parties to that certain Clinical Trial Collaboration and Supply Agreement having an Effective Date of September 8, 2017 (the "CTC") relating to the use of SeaGen's proprietary antibody drug conjugate SGN-LIV-1-A and Merck's proprietary product "KEYTRUDA" in concomitant or sequential use for the treatment of certain tumor types; and

WHEREAS, Merck and SeaGen desire to enter into a collaboration to develop, manufacture, commercialize and otherwise jointly exploit Licensed Compounds and the Licensed Product upon the terms and conditions set forth herein, including as a monotherapy and in combination (including concomitant or sequential therapy) with other pharmaceutical products.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency of which are hereby acknowledged, Merck and SeaGen hereby agree as follows:

ARTICLE 1 DEFINITIONS

Whenever used in this Agreement with an initial capital letter, the terms defined in this Article 1 and elsewhere in this Agreement, and any cognates or correlatives thereof, whether used in the singular or plural, shall have the specified meanings.

1.1 "Accounting Standards" means GAAP or IAS/IFRS or equivalent standards adopted by a Party from time to time, as applicable, as consistently applied by such Party or its Affiliates in maintaining its books and records.

1.2 "Act" means, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as such may be amended from time to time.



1.3 “Action” means any claim, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), arbitration or other proceedings brought or asserted by any Third Party (including any Governmental Authority) against a Party (or any other Indemnified Party).

1.4 “Affiliate” means any entity directly or indirectly controlled by, controlling, or under common control with, a Party to this Agreement, regardless of whether such entity is or becomes an Affiliate on or after the Effective Date, but only for so long as such control exists. For purposes of this definition, “control” (including, with correlative meanings, “controlled by”, “controlling” and “under common control with”) means (a) possession, direct or indirect, of the power to direct or cause direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise), or (b) beneficial ownership of fifty percent (50%) or more (or the maximum ownership interest permitted by Applicable Law giving control) of the voting securities or other ownership or general partnership interest (whether directly or indirectly) or other comparable equity interests in an entity.

1.5 “Allowable Commercialization Costs” means, with respect to the Commercialization of the Licensed Product for the Territory in a given period, the sum of the following with respect to such Licensed Product in such period, but solely to the extent (a) incurred by a Party (or its Affiliate) on or after the Effective Date as a cost or expense in accordance with the applicable Party’s Accounting Standards, (b) directly attributable or reasonably allocable to the Commercialization of such Licensed Product for the Territory, including, for clarity, those that are directly attributable or reasonably allocable to the Commercialization of a Proprietary Combination pursuant to this Agreement and the Commercialization Plan (and, for clarity, costs associated with the Commercialization of a Proprietary Combination pursuant to this Agreement and the Commercialization Plan shall be fully allocated to the Licensed Product hereunder), including, for example, Promotional Materials for the Licensed Product that reference a Proprietary Combination (but excluding for clarity any Merck Proprietary Combination Outside Promotional Materials and SeaGen Proprietary Combination Outside Promotional Materials) and (c) within the scope of the activities set forth in the Commercialization Plan and in accordance with the Commercialization Budget (plus any Permitted Commercialization Overage):

1.5.1 [*];

1.5.2 [*];

1.5.3 [*]; provided that, (i) if SeaGen is [*], this Section 1.5.3 shall exclude [*], but shall include [*] and (ii) if Merck is [*], this Section 1.5.3 shall exclude [*], but shall include [*];

1.5.4 such costs and expenses incurred [*];

1.5.5 [*] payable as a result of [*]; and

1.5.6 [*] costs and expenses [*] incurred by or on behalf of [*] in carrying out [*].

1.6 “Allowable Development Costs” means, with respect to the Development of the Licensed Product in a given period, the Development Costs incurred by a Party (or its Affiliate) for the Development of such Licensed Product pursuant to this Agreement, but solely to the extent (a) incurred by a Party (or its Affiliate) on or after the Effective Date as a cost or expense in accordance with the applicable Party’s Accounting Standards, (b) directly attributable or reasonably allocable to such Licensed Product (provided that, for clarity, costs associated with the Development of a Proprietary Combination pursuant to this Agreement and the Development Plan shall be fully allocated to the Licensed Product, including, for example, subject to Section 5.2.6(b), Clinical Trials for a Proprietary Combination to the extent set forth in the Development Plan), including, for example, Other Field-Based Materials for the Licensed Product that reference a Proprietary Combination (but excluding for clarity any Merck Proprietary Combination Outside Other Field-Based Materials and SeaGen Proprietary Combination Outside Other Field-Based Materials), and (c) within the scope of the activities set forth in the Development Plan and in accordance with the Development Budget (plus any Permitted Development Overage).

1.7 “Allowable Field Force FTE Costs” means the aggregate Field Force FTE Costs of a Party or its Affiliates pursuant to the Commercialization Plan that are directly attributable or reasonably allocable to Promotional activities for the Licensed Product for the Territory conducted by a Party’s (or its Affiliate’s) field force.

1.8 “Allowable Joint IP Costs” means Joint Patent Costs, Joint Trademark Costs and Joint IP Action Costs, in each case, incurred by or on behalf of a Party or its Affiliates in accordance with this Agreement.

1.9 “Allowable Promotion FTE Costs” means the aggregate Promotion FTE Costs of a Party or its Affiliates pursuant to the Commercialization Plan that are directly attributable or reasonably allocable to Promotion activities for the Licensed Product for the Territory.

1.10 “Ancillary Agreement” means any Merck Supply Agreement, SeaGen Supply Agreement, Promotion Agreement, European Collaboration Territory Distribution Agreement, Pharmacovigilance Agreement, Regulatory Agreement, [*], and any other agreement (including quality agreements) entered into by and between the Parties or their Affiliates specifically related to the Development, Manufacture or Commercialization of a Licensed Compound or Licensed Product. For clarity, no Third Party shall be a party to an Ancillary Agreement.

1.11 “Applicable Law” means, as applicable, (a) any United States federal, state or local law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, (b) any national, provincial, state or local or multinational law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation in any country or region in the Territory outside the United States, (c) any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any Governmental Authority in the Territory, or (d) any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law, including as applicable (i) cGLPs, cGCPs and cGMPs and (ii) all applicable data protection and privacy laws, rules and regulations, including the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act,

as any of the foregoing may be amended from time to time. Regarding Personal Data (as defined herein), Applicable Laws means any applicable 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 of any kind, including HIPAA, General Data Protection Regulation (Regulation (EU) 2016/679) (GDPR), Brazilian General Data Protection Law (Federal Law no. 13,709/2018), the Act on the Protection of Personal Information of Japan, and any equivalent Applicable Laws in any other jurisdiction, as any of the foregoing may be amended from time to time (collectively, "Data Protection Laws").

1.12 "Biomarker Test" means, in relation to a Licensed Compound or the Licensed Product, any diagnostic test designed to objectively measure or evaluate samples of blood, other body fluids or tissue as an indicator of biological processes, pathogenic processes or pharmacologic responses and may include next generation sequencing (NGS) tests or immunohistochemistry (IHC) tests, as applicable, in each case, to determine if a Licensed Compound or the Licensed Product may be useful for a given patient or patient population.

1.13 "Business Day" means a day other than a Saturday, Sunday, or any other day when banks are authorized or required by law to be closed in New York, New York, or Seattle, Washington.

1.14 "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that the first Calendar Quarter of the Term shall begin on the Effective Date and end on the last day of the then-current Calendar Quarter and the last Calendar Quarter of the Term shall begin on the first day of such Calendar Quarter and end on the last day of the Term.

1.15 "Calendar Year" means each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, however, that the first Calendar Year of the Term shall begin on the Effective Date and end on December 31 of the then-current Calendar Year and the last Calendar Year of the Term shall begin on the first day of such Calendar Year and end on the last day of the Term.

1.16 "CEOs" means, respectively, [*] (or the officer or employee of Merck then serving in a substantially equivalent capacity) or his or her designee and [*] (or the officer or employee of SeaGen then serving in a substantially equivalent capacity) or his or her designee, provided that any such designee must have decision-making authority on behalf of the applicable Party.

1.17 "cGCP" or "current Good Clinical Practice" means the applicable then-current standards for clinical activities for pharmaceuticals or biologicals, as set forth in the Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with, with respect to work performed in a country other than the United States, any similar standards of good clinical practice as are required by any Regulatory Authority in such country.

1.18 "cGLP" or "current Good Laboratory Practice" means the applicable then-current standards for laboratory activities for pharmaceuticals or biologicals, as set forth in the Act

and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with, with respect to work performed in a country other than the United States, any similar standards of good laboratory practice as are required by any Regulatory Authority in such country.

1.19 "cGMP" or "current Good Manufacturing Practice" means the applicable then-current standards for conducting Manufacturing activities for pharmaceuticals or biologicals (or active pharmaceutical ingredients) as are required by any applicable Regulatory Authority in the Territory.

1.20 "Change of Control" with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Effective Date:

(a) any Third Party "person" or "group" (as such terms are defined below) (i) is or becomes, through one or a series of transactions, the "beneficial owner" (as defined below), directly or indirectly, of the then-outstanding shares of common stock of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) representing fifty percent (50%) or more of the total then-outstanding common stock (or foreign equivalent thereof) (the "Outstanding Common Stock"), (ii) is or becomes, through one or a series of transactions, the "beneficial owner", directly or indirectly, of shares of securities, capital stock or other interests (including partnership interests) of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) then-outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions ("Outstanding Voting Stock") of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) representing fifty percent (50%) or more of the total voting power of all Outstanding Voting Stock of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) or (iii) has the power, directly or indirectly, to elect a majority of the members of the Party's (or any direct or indirect parent entities or ultimate parent entities of such Party) board of directors (or similar governing body); or

(b) such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) enters into a merger, consolidation or similar transaction with a Person (whether or not such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) is the surviving entity) (a "Business Combination"), in each case, unless, following such Business Combination, (i) the individuals and entities who were the beneficial owners, respectively, of the Outstanding Common Stock and Outstanding Voting Stock of such Party (and the ultimate parent entity thereof) immediately prior to such Business Combination beneficially own, directly or indirectly, fifty percent (50%) or more of, respectively, (1) the then-outstanding shares of common stock (or foreign equivalent thereof) and (2) the combined voting power of the then-outstanding voting securities entitled to vote generally in the election of directors, of the corporation or other entity resulting from such Business Combination (and the ultimate parent entity thereof) and (ii) fifty percent (50%) or more of the members of the board of directors (or similar governing body) of the corporation or other entity resulting from such Business Combination (and ultimate parent entity thereof, as applicable) were members of the board of directors (or similar governing body) of such Party (or ultimate parent entity of such Party, as applicable) at the time of the execution of the initial agreement, or became members of the board

of directors of such corporation or other entity by virtue of the action of the board of directors (or similar governing body) of such Party (or ultimate parent entity), providing for such Business Combination; or

(c) such Party (and its Affiliates) sells, exchanges or otherwise transfers to any Third Party, directly or indirectly (including through the transfer of shares (or other ownership interests) in Affiliates), in one or a series of transactions, the properties and assets representing all or substantially all of such Party's total assets (together with all or substantially all of the properties and assets of its Affiliates).

For the purpose of this definition of Change of Control, (x) "person" and "group" have the meanings given such terms under Sections 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term "group" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the aforesaid Act; (y) a "beneficial owner" shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (z) the terms "beneficially owned" and "beneficially own" shall have meanings correlative to that of "beneficial owner."

1.21 "China" means the People's Republic of China[*].

1.22 "Clinical Trial" means a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial or Phase IV Clinical Trial.

1.23 "CMC" means chemistry, manufacturing and controls.

1.24 "CMC Development" means the CMC-related Development activities related to the composition, manufacture, and specification of a Licensed Compound or the Licensed Product intended to assure the proper identification, quality, purity and strength thereof, including test method development and stability testing, process development, process improvements (improving product robustness or manufacturing efficiencies), drug substance development, process qualification, process and method validation, process scale-up, formulation development, delivery system development, QA and QC development.

1.25 "Co-Exclusive" means, as between the licensor Party and the licensee Party, a license that is exclusive to the licensee Party (with the right to grant sublicenses thereof in accordance with Section 2.6.1); provided that the licensor Party reserves full rights for itself to exploit the licensed intellectual property for the licensed purposes (with the right to grant further licenses thereof in accordance with Section 2.6.2).

1.26 "Collaboration Territory" means each of (a) the United States of America, including its territories and possessions (the "US Collaboration Territory"), and (b) (i) the countries within the European Union, (ii) the countries within the European Free Trade Association and (iii) the United Kingdom ((i), (ii) and (iii), collectively, the "European Collaboration Territory"). The countries within the European Collaboration Territory as of the Effective Date are set forth on Schedule 1.26. For clarity, (x) if a given country was a member of the European Union or the European Free Trade Association during the Term, but thereafter is no longer part of the European Union or the European Free Trade Association, as applicable, such



country shall remain as part of the European Collaboration Territory for purposes of this Agreement and (y) in the event that a country that was not, as of the Effective Date, part of the European Union or the European Free Trade Association, but thereafter becomes a member state of the European Union or European Free Trade Association during the Term, such country shall be, as of the effective date thereof, part of the European Collaboration Territory for purposes of this Agreement, and the Parties shall work in good faith to transition such country to the European Collaboration Territory on transition terms to be discussed by the JSC and agreed to by the Parties.

1.27 “Combination Product” means a Licensed Product containing a Licensed Compound in combination with one or more additional pharmaceutically active ingredients and combined in (i) a single formulation or (ii) separate formulations but in a single package and sold for a single price, in each case, that the Parties determine to Develop hereunder pursuant to a Development Plan. For clarity, a Proprietary Combination is not a Combination Product unless it meets the foregoing definition.

1.28 “Combination Therapy” means, with respect to a Licensed Compound or the Licensed Product, the use of or method of using a Licensed Compound or the Licensed Product with any other pharmaceutical product(s) (whether a Third Party product, Merck Proprietary Product or SeaGen Proprietary Product (and including, in each case, marketed products or pipeline products)) in concomitant or sequential administration, that the Parties determine to Develop hereunder pursuant to a Development Plan. For clarity, “sequential administration” shall not include separate but sequential lines of therapy.

1.29 “Commercialization Budget” means the budget for the Commercialization of the Licensed Product for the Territory, as set forth in the applicable Commercialization Plan, as the same may be amended from time to time in accordance with this Agreement. For clarity, the Commercialization Budget may be broken down into regions.

1.30 “Commercialization Plan” shall have the meaning given to such term in Section 6.2.1. For clarity, (a) each Commercialization Plan shall include a Commercialization Budget and (b) the Commercialization Plan may be broken down into regions, including pursuant to the Regional Commercialization Sub-Plans, as applicable.

1.31 “Commercialize” means to promote, market, distribute, import, sell, offer for sale and provide commercial-related product support for the Licensed Product, and “Commercializing” and “Commercialization” shall have correlative meanings. Commercialization may also include the foregoing activities, if any, with respect to a Companion Diagnostic for the Licensed Product, which activities, if any, shall be set forth in the relevant Commercialization Plan with respect to a Companion Diagnostic for the Licensed Product, as applicable.

1.32 “Commercially Reasonable Efforts” means, with respect to the efforts to be expended by a Party with respect to any objective, the reasonable, diligent, good faith efforts to accomplish such objective as a similarly situated biopharmaceutical company would normally use to accomplish a similar objective under similar circumstances. It is understood and agreed that with respect to the Development, Manufacture and Commercialization of a Licensed Compound or Licensed Product by either Party (or its Affiliate), such efforts shall be substantially equivalent

to those efforts and resources commonly used by such Party (or its Affiliate) for pharmaceutical products owned by it or to which it has rights (and which are not subject to co-development or co-commercialization rights of a Third Party), which product is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products (the sale of which such Party and its Affiliates do not profit from) in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the Regulatory Authority involved, the profitability of the product including the amounts payable to licensors of patent or other intellectual property rights (but not including any amounts payable to or shared with the other Party or its Affiliates hereunder or under any Ancillary Agreements) and other relevant factors. With respect to Licensed Compounds and the Licensed Product, Commercially Reasonable Efforts shall be determined on a country-by-country basis for a particular Licensed Compound or for the Licensed Product, as applicable, and it is anticipated that the level of effort will be different for different markets, and will change over time, reflecting changes in the status of the applicable Licensed Compound or the Licensed Product and the market(s) involved.

1.33 “Committee” means the Joint Steering Committee (and each Subcommittee of the JSC) and the Intellectual Property Operating Committee.

1.34 “Companion Diagnostic” or “CDx” means (a) a Class III PMA-approved (or foreign equivalent) Biomarker Test that is clinically linked to a Licensed Compound or the Licensed Product to determine its applicability to a specific patient or patient population or (b) any other Biomarker Test for a Licensed Compound or the Licensed Product to determine its applicability to a specific patient or patient population, in each case, that the Parties determine to Develop hereunder pursuant to a Development Plan.

1.35 “Competing Product” means any product containing or comprising, in any form, formulation, presentation or dosage strength, any [*]. For clarity, any product containing or comprising [*]. For clarity, any product containing or comprising [*] are Competing Products.

1.36 “Confidential Information” means any and all confidential or proprietary information and data, including all Merck Know-How, all SeaGen Know-How, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by or on behalf of one Party to the other Party in connection with this Agreement or any Ancillary Agreement.

1.37 “Control”, “Controls” or “Controlled by” means, subject to Section 16.4.2, with respect to any intellectual property right, information, documents or materials, the possession of the right (whether by ownership or license, other than pursuant to this Agreement or any Ancillary Agreement) or the ability of a Party or its Affiliate to grant access to, or a license or sublicense of, such intellectual property right, information, documents or materials as provided for herein without violating any Applicable Law or the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.



1.38 “Corporate Marks” means, (a) in the case of Merck, the corporate Trademarks owned by Merck or its Affiliates as Merck may designate in writing to SeaGen from time to time (each, a “Merck Corporate Mark”) and (b) in the case of SeaGen, the corporate Trademarks owned by SeaGen or its Affiliates as SeaGen may designate in writing to Merck from time to time (each, an “SeaGen Corporate Mark”), including for the purposes of both clause (a) and (b), any translation or derivation of any of the foregoing, either alone or in combination with other words and all marks, trade dress, logos, monograms, domain name registrations and other source identifiers confusingly similar to or embodying any of the foregoing either alone or in combination with other words.

1.39 “Cost of Goods Manufactured” means the cost to produce a given quantity of Licensed Product by a Party or its Affiliate, as calculated in accordance with Schedule 1.39, including taking into account in such calculation any other capital expenditure, costs and expenses approved as Cost of Goods Manufactured under Section 3.4.2(o).

1.40 “Develop” means (a) to research, develop, analyze, test and conduct non-clinical, preclinical (including GLP Tox Studies), clinical and all other regulatory studies and trials for a Licensed Compound or the Licensed Product, as applicable, including new indications and new combinations, (b) all activities pertaining to CMC Development and formulation development (including new formulations), (c) all other activities related to securing and maintaining Marketing Authorization for a Licensed Compound or the Licensed Product, as applicable, and regulatory activities in connection therewith and (d) medical affairs activities for the Licensed Product. Development may also include the foregoing activities, if any, with respect to any Companion Diagnostic, which activities, if any, shall be set forth in the relevant Development Plan with respect to a Companion Diagnostic for a Licensed Compound or the Licensed Product, as applicable. “Developing” and “Development” shall have correlative meanings.

1.41 “Development Budget” means the budget for the Development of the Licensed Product for the Territory, as set forth in the applicable Development Plan, as the same may be amended from time to time in accordance with this Agreement.

1.42 “Development Costs” means the sum of (a) Development FTE Costs and Medical Affairs FTE Costs and (b) out-of-pocket costs and expenses, incurred by a Party or any of its Affiliates in connection with the Development of a Licensed Compound or the Licensed Product in the Territory, in each case, that are (i) incurred on or after the Effective Date, (ii) incurred as an expense in accordance with the applicable Party’s Accounting Standards of such Party and (iii) directly attributable or reasonably allocable to a Licensed Compound or the Licensed Product for the Territory, including, for clarity, those that are directly attributable or reasonably allocable to the Development of a Proprietary Combination pursuant to this Agreement and the Development Plan (and, for clarity, any such costs associated with the Development of a Proprietary Combination pursuant to this Agreement and the Development Plan shall be fully allocated to the Licensed Product hereunder), including, for example, subject to Section 5.2.6(b), Clinical Trials for a Proprietary Combination to the extent included in the Development Plan). Development Costs shall include:

1.42.1 such costs and expenses that are [*] activities for [*];



- 1.42.2 such costs and expenses that are [*] activities for [*];
- 1.42.3 such costs and expenses incurred [*], including the cost of [*];
- 1.42.4 the [*] for use in [*];
- 1.42.5 such costs and expenses for [*] such as [*];
- 1.42.6 such costs and expenses [*], including [*];
- 1.42.7 such costs and expenses [*], including [*];
- 1.42.8 costs and expenses [*]; and
- 1.42.9 any [*] as a result of [*].

1.43 “Development Data” means any data generated from Development activities hereunder with respect to a Licensed Compound or the Licensed Product, including from Development of a Proprietary Combination.

1.44 “Development FTE Cost” means, for any period, the Development FTE Rate multiplied by the number of FTEs in such period performing Development activities that are directly attributable or reasonably allocable to the Licensed Product (including for use in a Proprietary Combination) for the Territory.

1.45 “Development FTE Rate” means the rate of [*] for one (1) full FTE per full calendar year; provided that, starting January 1, 2021, such rate shall adjust on January 1 of each Calendar Year by [*]. Notwithstanding the foregoing, the Parties may mutually agree in writing on alternative Development FTE Rates for the conduct of Development activities in the Territory (which rate may be different for different regions in the Territory).

1.46 “Development Plan” shall have the meaning given to such term in Section 5.2.1. For clarity, each Development Plan shall include a Development Budget.

1.47 “Distributor” means any Third Party(ies) appointed by the Lead Distribution Party or any of its Affiliates (or their respective (sub)licensees) in accordance with the terms of this Agreement to distribute and sell Licensed Product(s), with or without packaging rights, in one or more countries in the Territory, in circumstances where such Third Party purchases its requirements of Licensed Product(s) from such Party or its Affiliates (or their respective sublicensees) but does not otherwise make any royalty or other similar payment to such Party or its Affiliates (or their respective sublicensees) with respect to such Third Party’s sale of such Licensed Product(s). For clarity, a “Distributor” shall not be considered a sublicensee for purposes of this Agreement (even if ancillary licenses are granted to such Distributor for purposes of conducting its activities (specifically, distributing and selling the Licensed Product)).

1.48 “EMA” means the European Medicines Agency and any successor Regulatory Authority having substantially the same function.



1.49 "European Free Trade Association" means the organization of the member states of the European Free Trade Association, as it may be constituted from time to time during the Term.

1.50 "European Union" means the organization of member states of the European Union, as it may be constituted from time to time during the Term.

1.51 "FDA" means the United States Food and Drug Administration and any successor Regulatory Authority having substantially the same function.

1.52 "Field" means any and all uses and purposes, including diagnostic, prophylactic and therapeutic uses in humans and animals.

1.53 "Field Force FTE Cost" means, for any period, the Field Force FTE Rate multiplied by the number of field force FTEs in such period conducting Promotional activities for the Licensed Product in accordance with this Agreement (and, in the Collaboration Territory, in accordance with the applicable Promotion Agreement) that are directly attributable or reasonably allocable to conducting such Promotional activities for the Licensed Product (including conducting calls for the Licensed Product, including for use in a Proprietary Combination) for the Territory by a Party's (or its Affiliate's) field force, but subject to any further allocation to the Licensed Product as set forth in a Promotion Agreement, as applicable.

1.54 "Field Force FTE Rate" means the rate per FTE for the Territory as set forth in the applicable Commercialization Plan or as otherwise agreed to by the Parties for the conduct of Promotional activities for the Licensed Product in accordance with this Agreement (and the applicable Promotion Agreement, if any) in the Territory by a Party's (or its Affiliate's) field force (which rate may be different for different regions in the Territory), as such rate may be adjusted by mutual written agreement of the Parties on an annual basis. If the Parties are unable to agree on the Field Force FTE Rate in a given Commercialization Plan, but have previously agreed to the Field Force FTE Rate in a different Commercialization Plan, then such previously agreed to Field Force FTE Rate shall be used.

1.55 "First Commercial Sale" means, with respect to the Licensed Product in a country, the first sale to a Third Party for end use or consumption of such Licensed Product in such country after receipt of all Marketing Authorizations for such Licensed Product in such country, excluding, however, any sale or other distribution for use in a Clinical Trial.

1.56 "FTE" means the equivalent of the work of one (1) individual employee full time for one (1) full calendar year (consisting of a total of [*] hours per calendar year) of work directly related to Development, Promotion or other Commercialization activities under this Agreement. Any person who devotes fewer than [*] hours per calendar year shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked divided by [*].

1.57 "GAAP" means accounting principles generally accepted in the United States, consistently applied.

1.58 “GLP Tox Study” means a pre-clinical study conducted in a species using applicable cGLP for the purposes of assessing the onset, severity, and duration of toxic effects and their dose dependency with the goal of establishing a safety profile required for a regulatory submission supporting the dosing of human subjects. For the avoidance of doubt, preliminary toxicology studies are not regarded as a GLP Tox Study.

1.59 “Governmental Authority” or “Government” means any United States (federal, state or local) government (or political subdivision thereof), or any foreign government (or political subdivision thereof), or any multinational governmental organization or authority, or any governmental authority, agency or commission, in each case, entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.60 “IAS/IFRS” means International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board, consistently applied.

1.61 “Incidence” means, with respect to any type or subtype of cancer (including a separate and distinct tumor type), for the Calendar Year preceding the applicable Calendar Year for which the “Incidence” is being measured, an incidence in the US of over 10,000 patient population (taking into account all stages of the applicable type or subtype) according to the incidence published by the Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute (<https://seer.cancer.gov/>) or its substitute or successor statistic program as agreed to by the Parties, to establish the size of the treatable population in the US.

1.62 “IND” means an investigational new drug application, clinical trial authorization application, or similar application or submission (including any supplements of any of the foregoing) for approval to conduct human clinical investigations of a product filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.63 [*]

1.64 “Initial Merck Proprietary Product” means Merck’s (or its Affiliate’s) product pembrolizumab, a humanized anti-human PD-1 monoclonal antibody, that is primarily marketed as of the Effective Date under the tradename KEYTRUDA®, in any form, formulation, presentation or dosage strength.

1.65 “Initiated” or “Initiation” means, with respect to a Clinical Trial, the administration of the first dose of the Licensed Product being studied to the first human subject in such Clinical Trial.

1.66 “Joint IP Action Costs” means, with respect to the Licensed Product, any costs and expenses which are deemed to be “Joint IP Action Costs” pursuant to Article 12 with respect to such Licensed Product, but only to the extent such costs and expenses are incurred on or after the Effective Date.

1.67 "Joint Patent Costs" means any costs and expenses which are deemed to be "Joint Patent Costs" pursuant to Article 12, but only to the extent such costs and expenses are incurred on or after the Effective Date.

1.68 "Joint Program Copyright" means all Program Copyrights other than copyrights in any (a) Merck Proprietary Combination Outside Promotional Materials, Merck Proprietary Combination Outside Other Field-Based Materials, Merck Licensed Product Combination Promotional Materials, Merck Licensed Product Combination Other Field-Based Materials or other content owned by Merck as set forth in Section 12.3.4(a), and (b) SeaGen Proprietary Combination Outside Promotional Materials, SeaGen Proprietary Combination Outside Other Field-Based Materials, SeaGen Licensed Product Combination Promotional Materials, SeaGen Licensed Product Combination Other Field-Based Materials or other content owned by SeaGen as set forth in Section 12.3.4(b).

1.69 "Joint Program Know-How" means all Program Know-How that is not SeaGen Program Know-How or Merck Program Know-How. For clarity, Joint Program Know-How shall include all Program Know-How that (a) specifically relates to the use of or method of using a Licensed Compound or the Licensed Product in any Combination Therapy (including the use of or method of using the Licensed Product with a SeaGen Proprietary Product or Merck Proprietary Product in a Combination Therapy), or (b) relates to a Biomarker Test or Companion Diagnostic (this clause (b) "Biomarker Joint Program Know-How").

1.70 "Joint Program Patents" means all Patent Rights that claim Joint Program Know-How, but that do not (subject to Section 12.4.3(b)) claim SeaGen Program Know-How or Merck Program Know-How.

1.71 "Joint Trademark Costs" means any costs and expenses that are deemed to be "Joint Trademark Costs" pursuant to Article 12, but only to the extent such costs and expenses are incurred on or after the Effective Date.

1.72 "Know-How" means any and all proprietary or confidential inventions, discoveries, developments, data (including pre-clinical, clinical and regulatory data), information, trade secrets, specifications, formulae, instructions, processes, methods, protocols, expertise and other technology, including any of the foregoing applicable to formulations, compositions or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them, and all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, and manufacturing data relevant to any of the foregoing. "Know-How" excludes Patent Rights, Trademarks and physical substances.

1.73 "Lead Distribution Party" means (a) with respect to the Licensed Product for sale in the US Collaboration Territory, SeaGen (unless otherwise determined by the JCC), (b) with respect to the Licensed Product for sale in the European Collaboration Territory, SeaGen (unless otherwise determined by the JCC), (c) with respect to the Licensed Product for sale in the SeaGen Territory, SeaGen (unless otherwise determined by the JCC), and (d) with respect to the Licensed Product for sale in the Merck Territory, Merck (unless otherwise determined by the JCC), in each case (a), (b), (c) and (d), except as otherwise expressly set forth in this Agreement.



1.74 “Lead Manufacturing Party” means, with respect to the Licensed Product, SeaGen (unless otherwise determined by the JSC or otherwise expressly set forth in this Agreement); provided that (a) where a Party acts as a second source for supply in accordance with Section 7.4.4 or otherwise takes over responsibility for Manufacturing Licensed Product in accordance with this Agreement (or the applicable Ancillary Agreement), and, as such, Manufactures the Licensed Product, such Party shall be the “Lead Manufacturing Party” with respect to the quantities of Licensed Product Manufactured by it and (b) without limiting the foregoing sub-clause (a), certain specific Manufacturing responsibilities for the Licensed Product as set forth in the Manufacturing Plan (e.g., secondary packaging and labeling) may be designated to the other Party, in which case such other Party shall be the “Lead Manufacturing Party” to the extent of such assigned responsibilities as set forth in the Manufacturing Plan.

1.75 “Lead Patent Party” means, (a) SeaGen, with respect to the SeaGen Product-Specific Patents and Joint Program Patents, and (b) Merck, with respect to the Merck Product-Specific Patents, in each case, except as otherwise expressly set forth in this Agreement.

1.76 “Lead Regulatory Party” means, (a) with respect to the Licensed Product in the US Collaboration Territory, SeaGen (unless otherwise determined by the JSC), (b) with respect to the Licensed Product in the European Collaboration Territory, Merck (unless otherwise determined by the JSC), (c) with respect to the Licensed Product in the SeaGen Territory, SeaGen (unless otherwise determined by the JSC), and (d) with respect to the Licensed Product in the Merck Territory, Merck (unless otherwise determined by the JSC), in each case (a), (b), (c) and (d), except as otherwise expressly set forth in this Agreement.

1.77 “Lead Study Party” means, with respect to a given Clinical Trial for the Licensed Product, the Party that is designated by the JSC as the “Lead Study Party” for such Clinical Trial as set forth in the Development Plan, in each case, except as otherwise expressly set forth in this Agreement.

1.78 “Lead Trademark Party” means, with respect to a given country in the Territory, unless otherwise determined by the JCC, the Party that is the “Lead Distribution Party” for such country, as set forth in this Agreement.

1.79 “Licensed Compound” means (a) SGN-LIV-1-A, (b) any Next Generation Compound for which Merck has delivered (or is deemed to have delivered) a Licensed Compound Notice pursuant to Section 2.9.2 or (c) any Acquired Competing Product that the non-Acquiring Competing Product Party elects to include as a “Licensed Compound” pursuant to an offer to do so from the Acquiring Competing Product Party pursuant to Section 2.9.3(c). For clarity, (i) as of the Effective Date, SGN-LIV-1-A is the only Licensed Compound; and (ii) the Parties may Develop one or more Licensed Compounds hereunder at any one time.

1.80 “Licensed Product” means a product containing or comprising a Licensed Compound, in any form, formulation, presentation or dosage strength. For clarity, (a) each Licensed Product containing or comprising the same Licensed Compound, in any form, formulation, presentation or dosage strength, including, for clarity, (i) for monotherapy use or in Combination Therapy with any product (including a Proprietary Product) or (ii) in any Combination Product, shall be considered the same Licensed Product for purposes of this

Agreement [*]; provided that, notwithstanding the foregoing, [*], (b) Licensed Products shall include Combination Products (in any form, formulation, presentation or dosage strength), and (c) if there is more than one Licensed Compound hereunder (e.g., a Next Generation Compound for which Merck has delivered (or is deemed to have delivered) a Licensed Compound Notice pursuant to Section 2.9.2), then a product containing or comprising a different Licensed Compound (in any form, formulation, presentation or dosage strength) will be considered a different Licensed Product for purposes of this Agreement, but each such product will be deemed to be one of the Licensed Products hereunder.

1.81 "Licensed Product Net Revenues" means, with respect to a given Licensed Product in a given period, the sum of: (a) all Licensed Product Net Sales in such period, and (b) all net sales (calculated in the same manner as the calculation of Licensed Product Net Sales, *mutatis mutandis*) of such Licensed Product sold in such period to Third Parties for the Territory by each sublicensee (but excluding, for clarity, any Distributor) of each Party (and their respective Affiliates), as reported by the applicable sublicensee, as applicable, to the applicable Party (or its Affiliate), in each case (a) and (b), for such Licensed Product.

1.82 "Licensed Product Net Sales" means, with respect to Licensed Product sold to Third Parties (including to Distributors) for the Territory by a Party or its Affiliates, the gross amount invoiced (not including value added taxes, consumption taxes, sales taxes, or similar taxes) for sales of such Licensed Product for the Territory during a given period during the Term, less the following normal and customary deductions that are related to such Licensed Product sold during the Term and not otherwise deducted in computing other amounts hereunder (without duplication):

[*]

Licensed Product Net Sales shall be determined from the applicable Party's (or its Affiliate's) books and records maintained in accordance with the applicable Party's (or its Affiliate's) Accounting Standards (in each case, to the extent reasonably practicable when determining amounts at a product level) consistently applied. It is understood that any accruals of amounts reflected in Licensed Product Net Sales shall be periodically (but at least once a Calendar Quarter) true-up by the Parties consistent with their customary practices and in accordance with the applicable Party's Accounting Standards (to the extent reasonably practicable when determining amounts at a product level), and Licensed Product Net Sales shall be adjusted to reflect such true-up amounts.

Any of the deductions listed above that involves a payment by a Party or its Affiliates shall be taken as a deduction in the Calendar Quarter in which the payment is accrued by such entity. For purposes of determining Licensed Product Net Sales, a Licensed Product shall be deemed to be sold when invoiced. Notwithstanding the foregoing, a "sale" shall not include transfers or dispositions of such Licensed Product for pre-clinical or clinical purposes or as samples, in each case, without charge.

In the event that the Licensed Compound is sold as part of a Combination Product in a country in the Territory, Licensed Product Net Sales for such Combination Product shall be calculated [*].



Subject to the above, Licensed Product Net Sales shall be calculated in accordance with the standard internal policies and procedures of the applicable Party and its Affiliates, which must be in accordance with the Accounting Standards.

1.83 "LIV-1" means [*].

1.84 "Manufacture" or "Manufacturing" means, with respect to a compound or product (including a Licensed Compound and the Licensed Product), the receipt, handling and storage of active pharmaceutical ingredients and other materials, the manufacturing, processing, packaging and labeling, holding (including storage), quality assurance and quality control testing (including release) of such compound or product and shipping of such compound or product. Manufacturing may also include the foregoing activities, if any, with respect to any Companion Diagnostic for a Licensed Compound or the Licensed Product, which activities, if any, shall be set forth in the relevant Manufacturing Plan.

1.85 "Marketing Authorization Application" or "MAA" means a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the Act, or similar application or submission for Marketing Authorization of a product filed with a Regulatory Authority to obtain marketing approval for such product in that country or in that group of countries, or any supplements to any of the foregoing.

1.86 "Marketing Authorization" means all approvals from the relevant Regulatory Authority necessary to market and sell a product in any country or group of countries. For clarity, with respect to the Licensed Product, Marketing Authorization shall include [*].

1.87 "Medical Affairs FTE Cost" means, for any period, the Medical Affairs FTE Rate multiplied by the number of medical affairs FTEs in such period performing medical affairs activities that are directly attributable or reasonably allocable to the Licensed Product (including for use in a Proprietary Combination) for the Territory.

1.88 "Medical Affairs FTE Rate" means the rate per FTE for the Territory as set forth in the applicable Development Plan or as otherwise agreed to by the Parties for the conduct of medical affairs activities for the Territory (which rate may be different for different regions in the Territory), as such rate may be adjusted by mutual written agreement of the Parties on an annual basis. If the Parties are unable to agree on the Medical Affairs FTE Rate in a given Development Plan, but have previously agreed to the Medical Affairs FTE Rate in a different Development Plan, then such previously agreed to Medical Affairs FTE Rate shall be used.

1.89 "Merck General Know-How" means any Merck Know-How other than Merck Product-Specific Know-How.

1.90 "Merck General Patents" means any Merck Patents other than Merck Product-Specific Patents.

1.91 "Merck Know-How" means all Know-How Controlled by Merck or its Affiliates as of the Effective Date or at any time thereafter until the end of the Term that is necessary or

reasonably useful for the Development, Manufacture, or Commercialization of any Licensed Compound or the Licensed Product, whether as a monotherapy or for use in any Combination Therapy, or any Companion Diagnostic, and that is either (a) Merck Program Know-How (but excluding, for clarity, Joint Program Know-How), or (b) other Know-How Controlled by Merck that Merck discloses to SeaGen and that the Parties mutually agree to use (through the JDC), and is actually used, in the Development of the Licensed Product under this Agreement (and in accordance with the Development Plan) or any Ancillary Agreement (the Know-How in this clause (b), "Other Merck Contributed Know-How"), but in each case, excluding any Acquiring Person Intellectual Property.

1.92 "Merck Patents" means all Patent Rights Controlled by Merck or its Affiliates as of the Effective Date or at any time thereafter until the end of the Term, that cover or claim, or are otherwise necessary or reasonably useful for the Development, Manufacture or Commercialization of, any Licensed Compound or the Licensed Product, whether as a monotherapy or for use in any Combination Therapy, or any Companion Diagnostic, and that are either (a) Merck Program Patents (but excluding, for clarity, Joint Program Patents), (b) other Patent Rights Controlled by Merck that claim the use or method of using a Merck Proprietary Product in a Merck Proprietary Combination that the Parties have agreed to Develop hereunder pursuant to a Development Plan or (c) other Patent Rights Controlled by Merck that claim the Other Merck Contributed Know-How; but in each case, excluding any Acquiring Person Intellectual Property.

1.93 "Merck Product-Specific Know-How" means all [*] Know-How that is [*], but excluding [*].

1.94 "Merck Product-Specific Patents" means all [*] Patents that claim or cover (a) [*], or (b) any [*]; but excluding (in each case (a) and (b)) any [*] Patents that claim or cover [*].

1.95 "Merck Program Know-How" means (a) all [*] Know-How [*] that is [*] but, for clarity, not (i) [*] or (ii) [*] (this clause (a), a "Merck Proprietary Product Program Invention") and (b) all [*] Know-How that is [*].

1.96 "Merck Program Patents" means all Patent Rights that claim Merck Program Know-How and do not claim SeaGen Program Know-How or Joint Program Know-How.

1.97 "Merck Proprietary Combination" means a Proprietary Combination in which a Merck Proprietary Product is the Proprietary Product. For clarity, the Proprietary Combination of the Licensed Product and the Initial Merck Proprietary Product shall be a Merck Proprietary Combination for purposes of this Agreement.

1.98 "Merck Proprietary Combination Mark" means the Trademarks, if any, jointly developed and agreed to by the Parties that combines a Merck Proprietary Product Mark and a Collaboration Mark for use in connection with the Merck Proprietary Combination as permitted in the Agreement.

1.99 “Merck Proprietary Product” means any product that is owned by, or exclusively or co-exclusively licensed to Merck, or any of its Affiliates, including the Initial Merck Proprietary Product, but not including any Licensed Compound or the Licensed Product.

1.100 “Merck Proprietary Product Marks” means the Trademarks of Merck or its Affiliates with respect to any Merck Proprietary Product for use in a Merck Proprietary Combination, which Merck shall designate in writing to SeaGen from time to time.

1.101 “Merck Supply Agreement” means any and all supply agreements (including related quality agreements) entered into by the Parties (or their respective Affiliates) with respect to the Manufacture and supply of Licensed Product by or on behalf of Merck (or its Affiliate) to SeaGen (or its Affiliate) for use in the Commercialization of such Licensed Product in accordance with this Agreement. Each such Merck Supply Agreement for supply shall be on terms to be mutually agreed to by the Parties in good faith.

1.102 “Merck Technology” means the Merck Patents, Merck Know-How and Merck’s (and its Affiliates’) interest in the Joint Program Patents and Joint Program Know-How.

1.103 “Merck Territory” means those portions of the Territory other than the Collaboration Territory and the SeaGen Territory.

1.104 [*]

1.105 “Ongoing Clinical Trials” means all Clinical Trials of the Licensed Product that have been Initiated and are ongoing by SeaGen as of the Effective Date (and are included in the Initial Development Plan (and related initial Development Budget)) [*]. For clarity, with respect to such Clinical Trials, (x) updates to the protocol for any such Clinical Trial are subject to the approval of the JDC in accordance with Sections 3.3.2(d) and 5.4.1; and (y) any amendment to the Development Plan (and related Development Budget) with respect thereto are subject to the approval of the JSC in accordance with Section 3.2.3(e).

1.106 “Other Field-Based Materials” means, with respect to the Licensed Product, all written, printed, electronic or graphic field-based materials [*] used by or on behalf of (a) either or both Parties in the Collaboration Territory, (b) SeaGen in the SeaGen Territory, or (c) Merck in the Merck Territory; in each case ((a), (b) and (c)), [*] for the Licensed Product (including for use as a monotherapy or in any Combination Therapy) conducted hereunder.

1.107 “Patent Rights” means any and all patents and patent applications (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates and the like of any such patents and patent applications, and any and all foreign equivalents of the foregoing.

1.108 “Person” means an individual, Governmental Authority, Public Official, corporation, partnership, limited liability company, trust, business trust, association, joint stock

company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization or any other form of entity not specifically listed herein.

1.109 "Phase I Clinical Trial" means a human clinical trial in any country that would satisfy the requirements of 21 C.F.R. § 312.21(a).

1.110 "Phase II Clinical Trial" means a human clinical trial in any country that would satisfy the requirements of 21 C.F.R. § 312.21(b).

1.111 "Phase III Clinical Trial" means a human clinical trial in any country that would satisfy the requirements of 21 C.F.R. § 312.21(c).

1.112 "Phase IV Clinical Trial" means any human clinical trial (other than a Phase I Clinical Trial, Phase II Clinical Trial or Phase III Clinical Trial) in any country that is conducted on the Licensed Product for an indication in the Field after Marketing Authorization of the Licensed Product has been obtained from an appropriate Regulatory Authority in such country for such indication.

1.113 [*]

1.114 "Pricing Approval" means, with respect to any country or jurisdiction in which one or more Governmental Authorities determine or approve the pricing at which the Licensed Product will be charged to, or reimbursed by, public or private payors, the approval, agreement, determination or decision by such applicable Governmental Authority(ies) establishing the pricing and reimbursement status for such Licensed Product for any such payor or group of payors.

1.115 "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 (including as a result of participating in a Clinical Trial), whether based on negligence, strict product liability or any other product liability theory.

1.116 "Program Copyright" means copyright in Promotional Materials (and other content) created in connection with the Development, Manufacturing and Commercialization of the Licensed Product (a) by or on behalf of a Party or its Affiliate or sublicensee in the conduct of activities under this Agreement or any Ancillary Agreement, or (b) jointly by or on behalf of the Parties or their respective Affiliates or sublicensees in the conduct of activities under this Agreement or any Ancillary Agreement.

1.117 "Program Know-How" means any and all Know-How (including Development Data) conceived, developed, generated or reduced to practice during the Term (a) by or on behalf of a Party or its Affiliate or sublicensee in the conduct of activities under this Agreement or any Ancillary Agreement, or (b) jointly by or on behalf of the Parties or their respective Affiliates or sublicensees in the conduct of activities under this Agreement or any Ancillary Agreement. For clarity, notwithstanding anything to the contrary, any and all Know-How conceived, developed, generated or reduced to practice by or on behalf of SeaGen or its Affiliates or sublicensees in the conduct of pre-clinical development activities under Section 2.9.2 with respect to Next Generation Compounds prior to Merck delivering a Licensed Compound Notice with respect to the applicable



Next Generation Compound (which activities shall, for purposes of the definition of SeaGen Linker Technology at Section 1.138, be independent of the activities under this Agreement) (i) shall be solely owned by SeaGen; (ii) shall not be Program Know-How for purposes of this Agreement; and (iii) with effect from and after delivery (or deemed delivery) of a Licensed Compound Notice (if any) from Merck pursuant to Section 2.9.2, will be SeaGen Know-How for purposes of this Agreement.

1.118 "Program Patents" means the Merck Program Patents, SeaGen Program Patents and Joint Program Patents.

1.119 "Promote" means, with respect to a given country in the Territory, any activities undertaken by Merck (or its Affiliates) or SeaGen (or its Affiliates) in such country, or by both Merck (or its Affiliates) and SeaGen (or its Affiliates) in such country jointly (such joint activities in a given country, "Co-Promotion"), in each case, aimed at encouraging the use of the Licensed Product in such country, including marketing, promoting, conducting calls and details, contract administration, key account management, advertising (including educating, speaking programs and promotional symposia), but excluding any Distribution activities, Manufacturing activities or Development activities. "Promotion" shall have a correlative meaning.

1.120 "Promotion FTE Cost" means, for any period, the Promotion FTE Rate multiplied by the number of FTEs in such period performing Promotion activities that are directly attributable or reasonably allocable to the Licensed Product (including for use in a Proprietary Combination) for the Territory, but subject to any further allocation to the Licensed Product as set forth in a Promotion Agreement, as applicable. For the avoidance of doubt, Promotion FTE Costs shall exclude Field Force FTE Costs.

1.121 "Promotion FTE Rate" means the rate per FTE for the Territory as set forth in the applicable Commercialization Plan or otherwise agreed to by the Parties for the conduct of Promotion for the Territory (which rate may be different for different regions in the Territory), as such rate may be adjusted by mutual written agreement of the Parties on an annual basis. If the Parties are unable to agree on the Promotion FTE Rate in a given Commercialization Plan, but have previously agreed to the Promotion FTE Rate in a different Commercialization Plan, then such previously agreed to Promotion FTE Rate shall be used.

1.122 "Promotional Materials" means, with respect to the Licensed Product, all written, printed, electronic or graphic material (including the content of Licensed Product specific websites) used (a) by or on behalf of either or both Parties in connection with the Promotion of the Licensed Product in the Collaboration Territory conducted hereunder; (b) by or on behalf of SeaGen in connection with the Promotion of the Licensed Product in the SeaGen Territory conducted hereunder; or (c) by or on behalf Merck in connection with the Promotion of the Licensed Product in the Merck Territory conducted hereunder. Promotional Materials may include such materials for use in connection with the Promotion of the Licensed Product in a Proprietary Combination.

1.123 "Proprietary Combination" means any Combination Therapy of the Licensed Product and one or more Proprietary Product(s) as Developed by the Parties pursuant to a Development Plan following addition of such Proprietary Combination to the Development Plan



by approval of the JSC under Section 5.2.4(b) (provided that, for clarity, the Proprietary Combination of the Licensed Product and the Initial Merck Proprietary Product shall be a Proprietary Combination for purposes of this Agreement and shall not require approval by the JSC under Section 5.2.4(b)).

1.124 "Proprietary Product Party" means, with respect to a Proprietary Combination, the Party that owns or controls the Proprietary Product used in such Proprietary Combination; specifically: (a) in the case of a Merck Proprietary Combination, Merck; and (b) in the case of a SeaGen Proprietary Combination, SeaGen.

1.125 "Proprietary Product" means any SeaGen Proprietary Product or Merck Proprietary Product that the Parties agree, via the JSC under Section 5.2.4(b), to Develop pursuant to this Agreement for use in a Proprietary Combination.

1.126 "Proprietary Triple Combination Therapy" means any Combination Therapy involving the use of the Licensed Product, a Merck Proprietary Product and a SeaGen Proprietary Product, as Developed by the Parties pursuant to a Development Plan following addition of such Combination Therapy to the Development Plan by approval of the JSC under Section 5.2.4(b).

1.127 "Public Official" means (i) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (ii) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary, laboratory or medical facility; (iii) any officer, employee or representative of any public international organization, such as the African Union, the International Monetary Fund, the United Nations or the World Bank; and (iv) any person acting in an official capacity for any government or government entity, enterprise or organization identified above.

1.128 "Regulatory Authority" means any applicable Governmental Authority involved in granting approvals (including Pricing Approvals) for the manufacturing, development or marketing of a product (including the Licensed Product), including Marketing Authorizations therefor, in the Territory.

1.129 "Regulatory Documentation" means, with respect to a Licensed Compound or the Licensed Product, all submissions, documents and other correspondence submitted to applicable Regulatory Authorities in connection with the Development, Manufacture or Commercialization thereof, including INDs, MAAs and Marketing Authorizations (including product labeling and in connection with Pricing Approvals and health technology assessments) and the US Certificate of Pharmaceutical Product, and amendments and supplements thereto.

1.130 "Related Party" means, as applicable, (a) each of Merck and its Affiliates and their respective sublicensees (which term does not include Distributors) and (b) each of SeaGen and its Affiliates and their respective sublicensees (which term does not include Distributors).

1.131 "Safety Issue" means, with respect to the Licensed Product, that (a) a Regulatory Authority or safety data review board for a Clinical Trial of such Licensed Product has required termination or suspension of a Clinical Trial of such Licensed Product, (b) a Party reasonably



believes in good faith that (i) the Initiation of a Clinical Trial of such Licensed Product is not warranted, or (ii) termination or suspension of a Clinical Trial of such Licensed Product is warranted, in each case because of a material safety concern with respect to the use of such Licensed Product in such Clinical Trial; provided that such Party has provided reasonable evidence to the other Party documenting such material safety concern, or (c) a Party reasonably believes in good faith that the continued Commercialization of such marketed Licensed Product poses a material safety concern; provided that such Party has provided reasonable evidence to the other Party documenting such material safety concern.

1.132 "Sales and Marketing Expenses" means, for the Licensed Product, those costs and expenses (other than those deducted as part of the calculation of Licensed Product Net Sales) incurred by a Party or its Affiliates that are directly attributable or reasonably allocable to the market development or Promotion of such Licensed Product for the Territory consistent with the Commercialization Plan, whether before or after the First Commercial Sale of such Licensed Product. Sales and Marketing Expenses shall include: [*] for the [*] under the [*], including [*] to a [*] related to [*] and other [*], and [*] with [*] and [*] in connection with the [*] in connection with the [*] related to [*] and [*] that directly relate to the [*]. Sales and Marketing Expenses will specifically [*] for any of the [*] associated with [*] for the [*] without being [*] (other than the [*] that such [*] in this [*] and such other [*] where the applicable [*] and such other [*] with the [*] to this Agreement [*] shall be [*] to the [*] to the [*] are set forth in the [*] and in [*]. Sales and Marketing Expenses will also specifically exclude [*] such as [*] to the [*], and [*].

1.133 "SeaGen Existing CMO Agreements" means those contract manufacturing agreements between SeaGen or its Affiliate and a Third Party set forth on Schedule 1.133.

1.134 "SeaGen Existing In-Licenses" means those license agreements between SeaGen or its Affiliate and a Third Party set forth on Schedule 1.134.

1.135 "SeaGen General Know-How" means any SeaGen Know-How other than SeaGen Product-Specific Know-How.

1.136 "SeaGen General Patents" means any SeaGen Patents other than SeaGen Product-Specific Patents.

1.137 "SeaGen Know-How" means all Know-How Controlled by SeaGen or its Affiliates as of the Effective Date or at any time thereafter until the end of the Term that is necessary or reasonably useful for the Development, Manufacture, or Commercialization of any Licensed Compound or the Licensed Product, whether as a monotherapy or for use in any Combination Therapy, or any Companion Diagnostic, (a) including the SeaGen Program Know-How (but excluding, for clarity, Joint Program Know-How), but (b) excluding any Acquiring Person Intellectual Property.

1.138 "SeaGen Linker Technology" means, [*].

1.139 "SeaGen Patents" means all Patent Rights Controlled by SeaGen or its Affiliates as of the Effective Date or at any time thereafter until the end of the Term, that cover or claim, or

are otherwise necessary or reasonably useful for; the Development, Manufacture or Commercialization of, any Licensed Compound or the Licensed Product, whether as a monotherapy or for use in any Combination Therapy, or any Companion Diagnostic, (a) including all SeaGen Program Patents (but excluding, for clarity, Joint Program Patents), but (b) excluding any Acquiring Person Intellectual Property. The SeaGen Patents as of the Effective Date include those set forth on Schedule 1.139; provided that with respect to the SeaGen Linker Technology, Schedule 1.139 lists only those SeaGen Patents within the SeaGen Linker Technology that are relevant to SGN-LIV-1-A; provided further that SeaGen will update Schedule 1.139 to list SeaGen Patents within the SeaGen Linker Technology that are relevant to SGN-LIV-1-B, SGN-LIV-1-C or any other Next Generation Compound, respectively, upon Merck's delivery (or deemed delivery) of a Licensed Compound Notice with respect thereto pursuant to Section 2.9.2.

1.140 "SeaGen Product-Specific Know-How" means all [*] Know-How that is [*], but excluding (a) any [*] ("SeaGen Linker Product-Specific Know-How"), and (b) any [*].

1.141 "SeaGen Product-Specific Patents" means all [*] Patents that claim or cover (i) [*], or (ii) [*]; but excluding (in each case (i) and (ii)) (a) any [*] Patents that claim or cover [*] ("SeaGen Linker Product-Specific Patents"), and (b) s[*] Patents that claim or cover [*].

1.142 "SeaGen Program Know-How" means (a) all [*] Know-How [*] but, for clarity, not (i) [*] or (ii) [*] (this clause (a), a "SeaGen Proprietary Product Program Invention"), and (b) all [*] Know-How that is [*].

1.143 "SeaGen Program Patents" means all Patent Rights that claim SeaGen Program Know-How and do not claim Merck Program Know-How or Joint Program Know-How.

1.144 "SeaGen Proprietary Combination" means a Proprietary Combination in which a SeaGen Proprietary Product is the Proprietary Product.

1.145 "SeaGen Proprietary Combination Mark" means the Trademarks, if any, jointly developed and agreed to by the Parties that combines a SeaGen Proprietary Product Mark and a Collaboration Mark for use in connection with the SeaGen Proprietary Combination as permitted in the Agreement.

1.146 "SeaGen Proprietary Product" means any product that is owned by, or exclusively or co-exclusively licensed to, SeaGen or any of its Affiliates, including SeaGen's (or its Affiliate's) product known as [*], but not including any Licensed Compound (or Next Generation Compound) or the Licensed Product.

1.147 "SeaGen Proprietary Product Marks" means the Trademarks of SeaGen or its Affiliates with respect to any SeaGen Proprietary Product for use in a SeaGen Proprietary Combination, which SeaGen shall designate in writing to Merck from time to time.

1.148 "SeaGen Supply Agreement" means any and all supply agreements (including related quality agreements) entered into by the Parties (or their respective Affiliates) with respect to the Manufacture and supply of Licensed Product by or on behalf of SeaGen (or its Affiliate) to Merck (or its Affiliate) for use in the Development and Commercialization of such Licensed

Product in accordance with this Agreement. Each such SeaGen Supply Agreement for supply shall be on terms to be mutually agreed to by the Parties in good faith.

1.149 "SeaGen Technology" means the SeaGen Patents, SeaGen Know-How and SeaGen's (and its Affiliates') interest in the Joint Program Patents and Joint Program Know-How.

1.150 "SeaGen Territory" means Canada.

1.151 "Senior Executives" means, (a) with respect to Merck, (i) the [*], (ii) the [*], (iii) the [*] or (v) the [*] (or, in each case of (a)(i), (ii), (iii), (iv) or (v), as applicable, a person in an equivalent position at Merck), as the case may be and depending on the nature of the dispute at issue, and (b) with respect to SeaGen, (i) the Chief Medical Officer, (ii) the Executive Vice President, Commercial, (iii) the Chief Technical Officer or (iv) the Senior Vice President, Intellectual Property (or, in each case of (b)(i), (ii), (iii) or (iv), as applicable, a person in an equivalent position at SeaGen), as the case may be and depending on the nature of the dispute at issue.

1.152 "SGN-LIV-1-A" means [*].

1.153 "SGN-LIV-1-B" means [*].

1.154 "SGN-LIV-1-C" means [*].

1.155 "Subcommittees" means the JDC, JMC, JCC, the JFC and any other subcommittee of the JSC (but excluding, for clarity, the JSC itself) formed in accordance with Article 3. For clarity, the IPOC shall not be a Subcommittee.

1.156 "Sublicensee Revenues" means, with respect to the Licensed Product for the Territory, any payments (net of any VAT on such payments and any withholding tax deducted from such payments that cannot be claimed as a credit or otherwise utilized by a Party or its Affiliates) received by a Party or any its Affiliates during the Term from its or their respective Third Party (sub)licensee(s) or Distributors [*] for the [*], to the [*] to the [*] in the [*] or the [*] in the [*]; provided that Sublicensee Revenues shall exclude any amounts included in Licensed Product Net Sales. Notwithstanding the foregoing, the following shall apply:

1.156.1 if the applicable agreement giving rise to Sublicensee Revenues includes (i) products other than the applicable Licensed Product (including any Proprietary Product), or (ii) intellectual property other than intellectual property covering or claiming the applicable Licensed Product, the Parties shall mutually agree upon a fair and reasonable allocation of the Sublicensee Revenues to the Licensed Product for the Territory, and in the event that the Parties are unable to agree, the dispute shall be resolved pursuant to Section 16.8;

1.156.2 in the case where Licensed Compound is sold as part of a Combination Product, Sublicensee Revenues for such Combination Product shall be calculated as mutually determined by the Parties prior to the time the Development commences in relation to such Combination Product in order to allocate the Sublicensee Revenues between the Licensed

Compound contained therein and the other active pharmaceutical ingredients contained therein; and

1.156.3 for clarity, Sublicensee Revenues shall not include any payments in consideration for (i) a Change of Control transaction with respect to a given Party, or (ii) other transaction in which a Party assigns this Agreement to a Third Party as permitted hereunder.

1.157 "Territory" means all of the countries in the world, and their territories and possessions.

1.158 "Third Party" means a Person other than Merck, SeaGen or their respective Affiliates.

1.159 "Third Party In-License Agreements" means, subject to the provisions of Section 2.5.2 or 2.5.3, a license or other similar agreement between a Party (or its Affiliate) and a Third Party pursuant to which such Party (or its Affiliates) obtains a license or similar right in any (a) Know-How necessary or reasonably useful for the Development, Manufacture or Commercialization of a Licensed Compound or the Licensed Product under this Agreement; or (b) Patent Right that claims or covers a Licensed Compound or the Licensed Product or the Development, Manufacture or Commercialization of a Licensed Compound or the Licensed Product. Third Party In-License Agreements shall include the SeaGen Existing In-Licenses.

1.160 "Third Party Payments" means, with respect to Licensed Compound or the Licensed Product, any upfront payment, milestone payment, royalty or any other similar payment paid to any Third Party by a Party (or its Affiliates) during the Term under any Third Party In-License Agreement, which payments are directly attributable to or reasonably allocable to (a) the Development (including Manufacture for purposes of Development) or (b) the Commercialization (including Manufacture for purposes of Commercialization), of Licensed Compound or the Licensed Product for the Territory in accordance with this Agreement (including for use in a Proprietary Combination); provided that, for clarity, "Third Party Payments" shall exclude [*]. Third Party Payments shall also include the foregoing payments directly attributable to or reasonably allocable to the Development or Commercialization of any Companion Diagnostic as set forth in the Development Plan or Commercialization Plan, as applicable. Notwithstanding the foregoing, if the applicable Third Party In-License Agreement giving rise to Third Party Payments includes or applies to any (i) products other than Licensed Compound or the Licensed Product, or (ii) intellectual property other than intellectual property covering or claiming Licensed Compound or the Licensed Product, then, in each case ((i) and (ii)), the Parties shall mutually agree upon a fair and reasonable allocation of the applicable payments to the Licensed Compound or the Licensed Product (including any Proprietary Combination that is being Developed or Commercialized pursuant to this Agreement and the Development Plan or Commercialization Plan, as applicable, which allocation, as calculated as aforesaid, shall be fully allocated to the Licensed Product) in the Territory for purposes of including in Third Party Payments, and in the event that the Parties are unable to agree, the dispute shall be resolved pursuant to Section 16.8.

1.161 "Trademarks" means any and all trademarks, service marks, brand names, certification marks, collective marks, logos, symbols, trade dress, assumed names, company



names, fictitious names, trade names, and other indicia of origin, together with all goodwill associated therewith and symbolized thereby.

1.162 "U.S. Pivotal Trial" means a clinical trial of the Licensed Product conducted on a sufficient number of human subjects that satisfies each of the following ((a), (b) and (c)):

(a) such trial is designed to establish that the Licensed Product has an acceptable safety and efficacy profile for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, and is intended to support Marketing Authorization of the Licensed Product by the FDA; and

(b) such trial is a registration trial that is expected to generate results and data sufficient to obtain Marketing Authorization from the FDA for the Licensed Product; and

(c) such clinical trial is mutually agreed to by the Parties, prior to the Initiation thereof, to be the "U.S. Pivotal Trial" and such clinical trial is identified as the "U.S. Pivotal Trial" in the Development Plan (provided that, for clarity, if the Parties are conducting a given clinical trial pursuant to the Development Plan that was not initially designated as the "U.S. Pivotal Trial", but following Initiation thereof, such clinical trial is materially amended, in accordance with this Agreement, in a manner such that the Parties mutually agree that such clinical trial would then be the "U.S. Pivotal Trial", then the Parties may designate such clinical trial as the "U.S. Pivotal Trial" in the Development Plan following Initiation thereof).

1.163 "VAT" means (a) any tax imposed in compliance with the Council Directive of 28 November 2006 on the common system of value added tax (EC Directive 2006/112), and (b) any other tax of a similar or equivalent nature, imposed by any other jurisdictions.

1.164 "Violation" means that a Party or any of its officers or directors or any other personnel of such Party (or other permitted agents of such Party performing activities hereunder, including any of such Party's Affiliates, sublicensees or Third Party contractors and their respective officers and directors) has been: (a) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. § 1320a-7(a) (<http://oig.hhs.gov/exclusions/authorities.asp>); (b) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (<http://exclusions.oig.hhs.gov/>) or the U.S. General Services Administration's list of Parties Excluded from Federal Programs (<http://www.epls.gov/>); or (c) listed by any U.S. federal agency as being suspended, debarred, excluded or otherwise ineligible to participate in federal procurement or non-procurement programs, including under 21 U.S.C. § 335a (http://www.fda.gov/ora/compliance_ref/debar/) (each of (a), (b) and (c), collectively, the "Exclusions Lists").

1.165 Additional Definitions. Each of the following terms has the meaning described in the corresponding section of this Agreement indicated below:

<u>Definition:</u>	<u>Section:</u>
"6221(b) election"	15.3
"AAA"	16.8.2(b)



<u>Definition:</u>	<u>Section:</u>
"Acquired Competing Product"	2.9.3
"Acquiring Competing Product Party"	2.9.3
"Acquiring Person Intellectual Property"	16.4.2(a)
"Acquiror PDx Product"	16.4.2(b)
"Actual COGS"	7.4.5(a)
"Agreement"	Preamble
"Alliance Manager"	3.9.1
"Anti-Corruption Laws"	8.1.5(a)
"Applicable Percentage"	14.7.6(a)(i)
[*]	[*]
"Bankruptcy Party"	14.5.1
"BBA"	15.3
"Biomarker Joint Program Know-How"	1.69
"Biosimilar Application"	12.10.3(b)
"Business Combination"	1.20(b)
[*]	[*]
[*]	[*]
"CMO Recovered Amounts"	13.3.3(c)
"Code"	15.3
"Collaboration Marks"	12.12.1
"Commercial Milestone Event"	10.3.1
"Commercial Milestone Payment"	10.3.1
"Commercialization Cost Report"	10.4.2(a)
"Commercialization Guidelines"	3.5.2(b)
"Commercialization Plan"	6.2.1
"Competitive Infringement"	12.10.1
"Continuing Party"	14.7.6(a)(ii)
"Continuing Payment Term"	14.7.6(a)(iii)
"Continuing Product"	14.7.6(a)(iv)
"Continuing Product Payments"	14.7.6(a)
"Controlling Party"	12.10.3(a)(i)
"Co-Promotion"	1.119
"Core Data Sheet"	5.5.1(b)
"Cost Reconciliation Report"	10.4.2(b)
"Cost Reports"	10.4.2(a)
"CTC"	Recitals
"Data Protection Laws"	1.11
"Development Cost Report"	10.4.2(a)
"Development Milestone Event"	10.2.1
"Development Milestone Payment"	10.2.1
"Development Plan"	5.2.1
"Dispute"	16.8.1
"Distribution"	6.4.1

<u>Definition:</u>	<u>Section:</u>
"DPA"	8.3.2
"Effective Date"	Preamble
"Electronic Delivery"	16.18
"Estimated COGS"	7.4.5(a)
"European Collaboration Territory"	1.26
"European Collaboration Territory Distribution Agreement"	6.4.3
"Excluded Claim"	16.8.2(e)
"Exclusions Lists"	1.164
"Existing CDA"	16.9
"Existing DPA"	8.3.2
"Existing PDx Combination Trial"	16.4.2(b)(ii)
"Existing Regulatory Materials"	4.2.2
"Existing SeaGen CMO"	7.7.2
"Financial Manager"	3.6.1
"Force Majeure"	16.3
"Global Publication Strategy"	3.3.2(a)
[*]	[*]
"Indemnified Party"	13.5.1
"Indemnifying Party"	13.5.1
"Independent Patent Counsel"	12.5.1(b)
"Infringement Action"	12.10.2(a)
"Initial Commercialization Plan"	6.2.2
"Initial Development Plan"	5.2.2
"Initial Manufacturing Plan"	7.2.1
"Insolvency Event"	14.5.1
"Interim Permitted Competing Activities"	2.9.4
"IPOC"	12.1.1
"JCC" or "Joint Commercialization Committee"	3.5.1
"JDC" or "Joint Development Committee"	3.3.1
"JFC" or "Joint Finance Committee"	3.6.2
"JMC" or "Joint Manufacturing Committee"	3.4.1
"Joint Other Field-Based Materials"	6.5.2(a)
"Joint Promotional Materials"	6.5.2(a)
"JSC" or "Joint Steering Committee"	3.2.1
"Licensed Compound Notice"	2.9.2
"Licensee Party"	2.5.1
"Licensor Party"	2.5.1
[*]	[*]
"Losses"	13.1
"Manufacturing Data"	7.1.1
"Manufacturing Plan"	7.1.1
"MCI"	5.2.4(d)

<u>Definition:</u>	<u>Section:</u>
"Merck"	Preamble
"Merck Agreements"	11.5.3
[*]	[*]
"Merck Collaboration Mark"	12.12.1
"Merck Continuing Combinations"	14.7.7
"Merck Corporate Mark"	1.38
"Merck Indemnified Parties"	13.1
"Merck Licensed Product Combination Other Field-Based Materials"	6.5.3(a)
"Merck Licensed Product Combination Promotional Materials"	6.5.3(a)
[*]	[*]
"Merck Proprietary Combination Outside Other Field-Based Materials"	6.5.4(a)
"Merck Proprietary Combination Outside Promotional Materials"	6.5.4(a)
"Merck Proprietary Product Program Invention"	1.95
"Milestone Event"	10.3.1
"Milestone Payment"	10.3.1
"Next Generation Compound"	2.9.2
"Next Generation Compound Notice"	2.9.2
[*]	[*]
"Non-Controlling Party"	12.10.3(a)(i)
"Ongoing Merck Proprietary Combination Trial"	14.7.4
"Other Field-Based Materials Guidelines"	3.3.2(k)
"Other Merck Contributed Know-How"	1.91
"Outstanding Common Stock"	1.20(a)
"Outstanding Voting Stock"	1.20(a)
"Patent Listings"	12.9.1(a)
"Patent Term Extension"	12.5.1
"Party" or "Parties"	Preamble
"Payee"	10.7.2
"Paying Party"	10.7.2
[*]	[*]
"Permitted Commercialization Overage"	6.2.6(b)
"Permitted Development Overage"	5.2.6(c)
"Personal Data"	8.3.1
"Pharmacovigilance Agreement"	5.5.7(a)
[*]	[*]
[*]	[*]
[*]	[*]
"Pricing Guidelines"	3.5.2(g)
"Promotion"	1.120

<u>Definition:</u>	<u>Section:</u>
"Promotion Agreement"	6.6.1(b)
"Promotional Materials Guidelines"	3.5.2(c)
"Proprietary Product Regulatory Documentation"	5.5.5(a)
"Recall"	6.8.1(a)
[*]	[*]
"Recalling Party"	6.8.1(b)
"Recoupment Amount"	14.7.6(a)(v)
"Regional Commercialization Sub-Plan"	6.2.4
"Regulatory Agreement"	5.5.8
"Regulatory Plan"	5.5.2(a)
"Relevant Infringement IP"	12.10.2(a)(i)
"Relevant Linker Infringement IP"	12.10.2(a)(i)
"Restricted Employee"	11.6
"Revenue Reconciliation Report"	10.4.2(d)
"Revenue Report"	10.4.2(c)
"Reversion Product"	14.7.5(e)
"SeaGen"	Preamble
"SeaGen Acquiror"	16.4.2(b)
"SeaGen Agreements"	11.4.3
[*]	[*]
"SeaGen Combo Patent"	2.2.3
"SeaGen Continuing Combinations"	14.7.5(e)
"SeaGen Collaboration Mark"	12.12.1
"SeaGen Corporate Mark"	1.38
"SeaGen Disclosure Schedules"	11.2
"SeaGen Indemnified Parties"	13.2
"SeaGen Licensed Product Combination Other Field-Based Materials"	6.5.3(b)
"SeaGen Licensed Product Combination Promotional Materials"	6.5.3(b)
"SeaGen Linker Product-Specific Know-How"	1.140
"SeaGen Linker Product-Specific Patents"	1.141
[*]	[*]
[*]	[*]
[*]	[*]
"SeaGen Product-Specific Technology"	11.2.3
"SeaGen Proprietary Combination Outside Other Field-Based Materials"	6.5.4(b)
"SeaGen Proprietary Combination Outside Promotional Materials"	6.5.4(b)
"SeaGen Proprietary Product Program Invention"	1.142
"Sensitive Information"	16.4.2(b)(i)
[*]	[*]

<u>Definition:</u>	<u>Section:</u>
[*]	[*]
[*]	[*]
“Shared Liability Action”	13.3.1(a)
[*]	[*]
“Soliciting Party”	11.6
“Tax Partnership”	15.1
“Term”	14.1
[*]	[*]
“Trademark Clearance Party”	12.12.1
“Transition Lead”	4.2.3
“Transition Plan”	4.2.3
[*]	[*]
[*]	[*]
“US Collaboration Territory”	1.26

ARTICLE 2 OVERVIEW OF COLLABORATION; LICENSE GRANTS

2.1 Overview of Collaboration. The Parties intend and have agreed to undertake a collaboration under this Agreement to Develop and Manufacture the Licensed Compounds, and Develop, Manufacture and Commercialize the Licensed Product, including as a monotherapy as well as for use in any Combination Therapy, in each case, as more particularly described herein.

2.2 License Grants to Merck. Subject to the terms and conditions of this Agreement, the following shall apply:

2.2.1 Grants under SeaGen Technology for use with the Licensed Compounds and the Licensed Product. SeaGen shall, and hereby does, grant on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant) to Merck a Co-Exclusive (with SeaGen and its Affiliates) right and license, with the right to grant sublicenses through multiple tiers (subject to Section 2.6), under the SeaGen Technology to research, develop (including Develop), make (including Manufacture), have made (including have Manufactured), import, use, sell and offer to sell (including Commercialize) and otherwise exploit the Licensed Compounds and the Licensed Product, whether as a monotherapy or for use in any Combination Therapy, and any Companion Diagnostic, in the Field in the Territory in accordance with this Agreement, which license shall be payment-bearing pursuant to Section 10.4.2 during the Term with respect to the Licensed Product. For clarity, the foregoing license grant, with respect to the Licensed Product for use in a Combination Therapy or Combination Products, as applicable, or any Companion Diagnostic, only extends to those Combination Therapies and Combination Products and Companion Diagnostics, in each case, that the Parties have mutually agreed, via the JSC, to Develop pursuant to a Development Plan. In particular, the foregoing license grant, with respect to the Licensed Product for use in a Combination Therapy with any SeaGen Proprietary Product, is only for use with those SeaGen Proprietary Combinations that the Parties have mutually agreed, via the JSC, to Develop pursuant to a Development Plan, and, in such case, (a) is limited to the right for Merck and (subject to Section 2.6) its Affiliates and sublicensees to (i) conduct those

Development activities for the applicable SeaGen Proprietary Combination that are assigned to Merck pursuant to a Development Plan, including, as applicable, if Merck is the Lead Regulatory Party, submitting Regulatory Documentation for a label indication for the Licensed Product for use in the SeaGen Proprietary Combination, and (ii) Promote and otherwise Commercialize the Licensed Product for use in the SeaGen Proprietary Combination, in each case ((i) and (ii)), solely in accordance with this Agreement, and (b) excludes the right for Merck and its Affiliates and sublicensees to (i) Develop any SeaGen Proprietary Product (other than the Development of the use of a SeaGen Proprietary Product in the corresponding SeaGen Proprietary Combination in accordance with the Development Plan and this Agreement), or (ii) Manufacture, Promote or otherwise Commercialize any SeaGen Proprietary Product (other than the Promotion or other Commercialization of the Licensed Product for use in the applicable SeaGen Proprietary Combination in accordance with this Agreement). In addition, SeaGen shall, and hereby does, grant on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant) to Merck a right of reference to any INDs, MAAs, Marketing Authorizations and other Regulatory Documentation for the Licensed Product that are Controlled by SeaGen or any of its Affiliates, which right of reference shall be solely for use in connection with Merck and its Affiliates' and sublicensees' Development, Manufacture and Commercialization of the Licensed Product, including as a monotherapy as well as for use in any Combination Therapy, in the Field for the Territory in accordance with this Agreement. At the request of Merck, SeaGen shall provide to Merck a cross-reference letter or similar communication to the applicable Governmental Authority to effectuate such right of reference.

2.2.2 Grant under SeaGen Corporate Marks, SeaGen Collaboration Marks and SeaGen Proprietary Product Marks for use with the Licensed Product. SeaGen shall, and hereby does, grant on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant) to Merck a fully-paid, royalty-free right and license (which license shall be (x) non-exclusive with respect to the SeaGen Corporate Marks and SeaGen Proprietary Product Marks, and (y) Co-Exclusive (with SeaGen and its Affiliates) with respect to the SeaGen Collaboration Marks), with the right to grant sublicenses through multiple tiers (subject to Section 2.6), to use (a) the SeaGen Corporate Marks, the SeaGen Collaboration Marks and the SeaGen Proprietary Product Marks in Promotional Materials and Other Field-Based Materials for the Licensed Product, (b) the SeaGen Collaboration Marks in the packaging and labeling for the Licensed Product, and (c) any Program Copyright owned by SeaGen or its Affiliate, in each case of (a), (b) and (c), solely for the purposes of Promoting and otherwise Commercializing the Licensed Product in the Field in the Territory (including Promoting the Licensed Product for use in any Combination Therapy or Combination Product, or with any Companion Diagnostic, in each case, that the Parties have mutually agreed, via the JSC, to Develop pursuant to a Development Plan), in all cases solely in accordance with this Agreement (provided, however, that notwithstanding the foregoing, (i) the SeaGen Proprietary Product Marks and (ii) any Program Copyrights for the SeaGen Proprietary Combinations, may only be used for Promoting and otherwise Commercializing the Licensed Product solely for use in the applicable SeaGen Proprietary Combination in accordance with this Agreement and as approved by SeaGen); provided that such rights shall be exercised in accordance with the Promotional Materials Guidelines and Other Field-Based Materials Guidelines and, with respect to the SeaGen Corporate Marks and SeaGen Proprietary Product Marks, SeaGen quality standards and branding guidelines established by SeaGen (which are consistently applied) as notified by SeaGen to Merck from time to time. In all cases, SeaGen or its Affiliate shall remain



the owner of the SeaGen Corporate Marks, SeaGen Collaboration Marks and SeaGen Proprietary Product Marks (and of all trademark rights therein and all trademark registrations and applications therefor) and the goodwill pertaining thereto. Should Merck (or its Related Parties) acquire any ownership rights in any SeaGen Corporate Mark, SeaGen Collaboration Mark or SeaGen Proprietary Product Mark, Merck shall (and shall procure that its Related Parties will), and hereby does, assign any such rights to SeaGen (or its applicable Affiliate), to the extent legally permissible, and, to the extent not legally permissible, waive such rights.

2.2.3 Grant under SeaGen Technology for use with Merck Proprietary Products in a Merck Proprietary Combination. SeaGen shall, and hereby does, grant on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant) to Merck a fully-paid, royalty-free, Co-Exclusive (with SeaGen and its Affiliates) right and license, with the right to grant sublicenses through multiple tiers (subject to Section 2.6), under any SeaGen Patent that claims or covers the applicable Merck Proprietary Combination (each such SeaGen Patent, a "SeaGen Combo Patent") and under any SeaGen Know-How that is necessary or reasonably useful for the applicable Merck Proprietary Combination, to seek and obtain regulatory approval for, import, use, sell and offer to sell (including Commercialize) and otherwise exploit the applicable Merck Proprietary Product for use in the corresponding Merck Proprietary Combination. In addition, SeaGen shall, and hereby does, grant on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant) to Merck a right of reference to any INDs, MAAs, Marketing Authorizations and other Regulatory Documentation for any Licensed Product that are Controlled by SeaGen or any of its Affiliates, which right of reference shall be for use in connection with the applicable Merck Proprietary Product for use in the corresponding Merck Proprietary Combination in the Field for the Territory. At the request of Merck, SeaGen shall provide to Merck a cross-reference letter or similar communication to the applicable Governmental Authority to effectuate such right of reference. For clarity, the foregoing license grant and right of reference only extends to those Merck Proprietary Combinations that the Parties have mutually agreed, via the JSC, to Develop pursuant to a Development Plan.

2.2.4 Grant under SeaGen Corporate Marks and SeaGen Collaboration Marks for use with Merck Proprietary Products in a Merck Proprietary Combination. Subject to Section 6.5.4, SeaGen shall, and hereby does, grant on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant) to Merck a fully-paid, royalty-free right and license (which license shall be (x) non-exclusive with respect to the SeaGen Corporate Marks, and (y) Co-Exclusive (with SeaGen and its Affiliates) with respect to the SeaGen Collaboration Marks), with the right to grant sublicenses through multiple tiers (subject to Section 2.6), to use (a) the SeaGen Corporate Marks and the SeaGen Collaboration Marks, and (b) any Program Copyright owned by SeaGen or its Affiliate, in each case of (a) and (b), in Merck Proprietary Combination Outside Promotional Materials and Merck Proprietary Combination Outside Other Field-Based Materials for Merck Proprietary Products for the purposes of promoting the Merck Proprietary Products solely for use in a Merck Proprietary Combination in the Field in the Territory; provided that such rights shall be exercised in accordance with the quality standards and branding guidelines established by SeaGen (which are consistently applied) as notified by SeaGen to Merck from time to time. In all cases, SeaGen or its Affiliate shall remain the owner of the SeaGen Corporate Marks and SeaGen Collaboration Marks (and of all trademark rights therein and all trademark registrations and applications therefor) and the goodwill pertaining thereto. Should Merck (or its



Related Parties) acquire any ownership rights in any SeaGen Corporate Mark or SeaGen Collaboration Mark, Merck shall (and shall procure that its Related Parties will), and hereby does, assign any such rights to SeaGen (or its applicable Affiliate), to the extent legally permissible, and, to the extent not legally permissible, waive such rights.

2.3 License Grants to SeaGen. Subject to the terms and conditions of this Agreement, the following shall apply:

2.3.1 Grants under Merck Technology for use with the Licensed Compounds and the Licensed Product. Merck shall, and hereby does, grant on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant) to SeaGen a Co-Exclusive (with Merck and its Affiliates) right and license, with the right to grant sublicenses through multiple tiers (subject to Section 2.6), under the Merck Technology to research, develop (including Develop), make (including Manufacture), have made (including have Manufactured), import, use, sell and offer to sell (including Commercialize) and otherwise exploit the Licensed Compounds and the Licensed Product, whether as a monotherapy or for use in any Combination Therapy, and any Companion Diagnostic, in the Field in the Territory in accordance with this Agreement, which license shall be payment-bearing pursuant to Section 10.4.2 during the Term with respect to the Licensed Product. For clarity, the foregoing license grant, with respect to the Licensed Product for use in a Combination Therapy or Combination Products, as applicable, or any Companion Diagnostic, only extends to those Combination Therapies and Combination Products and Companion Diagnostics, in each case, that the Parties have mutually agreed, via the JSC, to Develop pursuant to a Development Plan. In particular, the foregoing license grant, with respect to the Licensed Product for use in a Combination Therapy with any Merck Proprietary Product, is only for use with those Merck Proprietary Combinations that the Parties have mutually agreed, via the JSC, to Develop pursuant to a Development Plan, and, in such case, (a) is limited to the right for SeaGen and (subject to Section 2.6) its Affiliates and sublicensees to (i) conduct those Development activities for the applicable Merck Proprietary Combination that are assigned to SeaGen pursuant to a Development Plan, including, as applicable, if SeaGen is the Lead Regulatory Party, submitting Regulatory Documentation for a label indication for the Licensed Product for use in the Merck Proprietary Combination, and (ii) Promote and otherwise Commercialize the Licensed Product for use in the Merck Proprietary Combination, in each case ((i) and (ii)), solely in accordance with this Agreement, and (b) excludes the right for SeaGen and its Affiliates and sublicensees to (i) Develop any Merck Proprietary Product (other than the Development of the use of a Merck Proprietary Product in the corresponding Merck Proprietary Combination in accordance with the Development Plan and this Agreement), or (ii) Manufacture, Promote or otherwise Commercialize any Merck Proprietary Product (other than the Promotion or other Commercialization of the Licensed Product for use in the applicable Merck Proprietary Combination in accordance with this Agreement). In addition, Merck shall, and hereby does, grant on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant) to SeaGen a right of reference to any INDs, MAAs, Marketing Authorizations and other Regulatory Documentation for the Licensed Product that are Controlled by Merck or any of its Affiliates, which right of reference shall be solely for use in connection with SeaGen and its Affiliates' and sublicensees' Development, Manufacture and Commercialization of the Licensed Product, including as a monotherapy as well as for use in any Combination Therapy, in the Field for the Territory in accordance with this Agreement. At the



request of SeaGen, Merck shall provide to SeaGen a cross-reference letter or similar communication to the applicable Governmental Authority to effectuate such right of reference.

2.3.2 Grant under Merck Corporate Marks, Merck Collaboration Marks and Merck Proprietary Product Marks for use with the Licensed Product. Merck shall, and hereby does, grant on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant) to SeaGen a fully-paid, royalty-free right and license (which license shall be (x) non-exclusive with respect to the Merck Corporate Marks and Merck Proprietary Product Marks, and (y) Co-Exclusive (with Merck and its Affiliates) with respect to the Merck Collaboration Marks), with the right to grant sublicenses through multiple tiers (subject to Section 2.6), to use (a) the Merck Corporate Marks, the Merck Collaboration Marks and the Merck Proprietary Product Marks in Promotional Materials and Other Field-Based Materials for the Licensed Product, (b) the Merck Collaboration Marks in the packaging and labeling for the Licensed Product, and (c) any Program Copyright owned by Merck or its Affiliate, in each case of (a), (b) and (c), solely for the purposes of Promoting and otherwise Commercializing the Licensed Product in the Field in the Territory (including Promoting the Licensed Product for use in any Combination Therapy or Combination Product, or with any Companion Diagnostic, in each case, that the Parties have mutually agreed, via the JSC, to Develop pursuant to a Development Plan), in all cases solely in accordance with this Agreement (provided, however, that notwithstanding the foregoing, (i) the Merck Proprietary Product Marks and (ii) any Program Copyrights for the Merck Proprietary Combinations, may only be used for Promoting and otherwise Commercializing the Licensed Product solely for use in the applicable Merck Proprietary Combination in accordance with this Agreement and as approved by Merck); provided that such rights shall be exercised in accordance with the Promotional Materials Guidelines and Other Field-Based Materials Guidelines and, with respect to the Merck Corporate Marks and Merck Proprietary Product Marks, Merck quality standards and branding guidelines established by Merck (which are consistently applied) as notified by Merck to SeaGen from time to time. In all cases, Merck or its Affiliate shall remain the owner of the Merck Corporate Marks, Merck Collaboration Marks and Merck Proprietary Product Marks (and of all trademark rights therein and all trademark registrations and applications therefor) and the goodwill pertaining thereto. Should SeaGen (or its Related Parties) acquire any ownership rights in any Merck Corporate Mark, Merck Collaboration Mark or Merck Proprietary Product Mark, SeaGen shall (and shall procure that its Related Parties will), and hereby does, assign any such rights to Merck (or its applicable Affiliate), to the extent legally permissible, and, to the extent not legally permissible, waive such rights.

2.4 No Implied Licenses; Retained Rights.

2.4.1 Except as expressly provided herein, nothing in this Agreement grants either Party or vests in either Party any right, title or interest in or to the Know-How, Patent Rights, Confidential Information, Trademarks or other intellectual property of the other Party (either expressly or by implication or estoppel), other than the licenses and rights expressly granted hereunder and the assignments expressly made hereunder.

2.4.2 SeaGen hereby expressly retains (on behalf of itself and its Affiliates) the right, title and interest in and to the SeaGen Technology to (i) conduct its and their Development, Manufacturing and Commercialization activities for the Licensed Compounds and the Licensed



Product as are allocated to SeaGen under the applicable Development Plan, Manufacturing Plan and Commercialization Plan, in accordance with this Agreement, and (ii) practice such SeaGen Technology outside the scope of the license grant in Section 2.2.1 for products other than Licensed Compounds and Licensed Products (subject to the terms and conditions of this Agreement, including Section 2.9). Merck hereby expressly retains (on behalf of itself and its Affiliates) the right, title and interest in and to the Merck Technology to (i) conduct its and their Development, Manufacturing and Commercialization activities for the Licensed Compounds and the Licensed Product as are allocated to Merck under the applicable Development Plan, Manufacturing Plan and Commercialization Plan, in accordance with this Agreement, and (ii) practice such Merck Technology outside the scope of the license grant in Section 2.3.1 for products other than Licensed Compounds and Licensed Products (subject to the terms and conditions of this Agreement, including Section 2.9).

2.5 Third Party In-License Agreements.

2.5.1 Generally. The licenses granted under Sections 2.2 and 2.3 may include certain rights licensed by a Third Party to the license-granting party (or its Affiliate) (the "Licensor Party") under Third Party In-License Agreements. Any sublicense of Third Party intellectual property rights granted by the Licensor Party pursuant to Sections 2.2 and 2.3 to the other Party (the "Licensee Party") shall be subject to the terms and conditions of the Third Party In-License Agreement applicable to sublicensees under which such sublicense is granted, subject to Section 2.5.2.

2.5.2 New Third Party In-License Agreements After Effective Date. During the Term, without the approval of the JSC, neither Party nor any of its Affiliates may enter into any Third Party In-License Agreement with respect to any intellectual property rights that will be used for the Development, Commercialization or Manufacture of the Licensed Compounds or the Licensed Product hereunder; provided that, for clarity, the foregoing shall not apply to a Party with respect to intellectual property related to any of its Proprietary Products for use in a Proprietary Combination to the extent that all costs and expenses under any such license agreement are borne by such Party. For the avoidance of doubt, any license or other similar agreement between a Party (or its Affiliate) and a Third Party pursuant to which such Party (or its Affiliates) obtains a license or similar right in any Know-How or Patent Right that was entered into in violation of the provisions of this Section 2.5.2 shall not be a "Third Party In-License Agreement" for purposes of this Agreement, unless the other Party approves in writing the inclusion of such license or other similar agreement as a "Third Party In-License Agreement", in such other Party's discretion.

2.5.3 Third Party In-License Agreements as of the Effective Date. As of the Effective Date, the SeaGen Existing In-Licenses are the only Third Party In-License Agreements. No amounts paid or payable by either Party under any other license or other similar agreement between a Party (or its Affiliate) and a Third Party, in existence as of the Effective Date, pursuant to which such Party (or its Affiliates) has obtained a license or similar right in any Know-How or Patent Right shall be deemed to be a "Third Party Payment" for purposes of this Agreement, unless the other Party approves in writing the inclusion of such license or other similar agreement as a "Third Party In-License Agreement", in such other Party's discretion, in which case (a) such license or similar agreement shall thereafter be a "Third Party In-License Agreement" hereunder



and (b) the applicable payments pursuant to such Third Party In-License Agreement made thereafter shall be included hereunder as "Third Party Payments" (to the extent such payments otherwise fall within the definition of "Third Party Payments").

2.6 Sublicense Rights by Licensee; Further Grants of Licenses by Licensor.

2.6.1 Sublicenses by Licensee. Each Party may grant sublicenses (through multiple tiers) of the license to it under Section 2.2 or 2.3 to any Affiliates and Third Parties; provided, however, that (a) each such sublicense is consistent with the applicable terms of this Agreement, (b) each such sublicense terminates upon the termination (but not upon expiration) of this Agreement (except to the extent that the license under which such sublicense was granted survives such termination), and (c) with respect to any sublicenses to a Third Party, a sublicense to a Third Party to (i) Develop the Licensed Compounds or the Licensed Product must be approved by the JSC (or otherwise expressly set forth in the Development Plan), (ii) Manufacture the Licensed Compounds or the Licensed Product must be approved by the JSC (or otherwise expressly set forth in the Manufacturing Plan) or (iii) Commercialize the Licensed Product in any of the Collaboration Territory, China, Brazil or Japan (or any country or region in any of the foregoing) must be approved by the JSC (or otherwise expressly set forth in the Commercialization Plan), in each case of this clause (c), prior to entering into any such license agreement with a Third Party; provided, however, that no such consent shall be required pursuant to this clause (c) for any sublicense, in whole or in part, to a Third Party contractor (e.g., a contract research organization or a contract manufacturer) to carry out activities hereunder on behalf of the applicable Party in accordance with this Agreement (including, in all cases, Section 2.7). In no event shall any sublicense granted pursuant to Section 2.2 or 2.3 diminish, reduce or eliminate any of the obligations of the sublicensing Party under this Agreement. Any sublicense granted pursuant to Section 2.2 or 2.3 shall be subject to, and consistent with, the applicable terms and conditions of this Agreement and shall require each sublicensee to comply with all applicable terms and conditions of this Agreement (including, for clarity, Section 12.3). Notwithstanding the foregoing, the applicable Party may grant sublicenses (through multiple tiers) of the license to it under Section 2.2.3 and 2.2.4 to any Affiliates or Third Parties without consent or approval of the other Party to the extent that the applicable sublicensee obtains rights or licenses to such Party's Proprietary Product, as applicable, and solely in connection with such Party's Proprietary Product for use in the applicable Proprietary Combination.

2.6.2 Further License Grants by Licensor to Co-Exclusive IP. Subject to the terms and conditions of this Agreement, with respect to any Co-Exclusive licenses granted by a Party to the other Party pursuant to Section 2.2 or 2.3, as applicable, the Party that is the license grantor party shall have the same rights to grant additional licenses under such Co-Exclusively licensed intellectual property (within the scope of the license grants to the licensee Party) as the licensee party would have to grant sublicenses of such intellectual property in accordance with Section 2.6.1, mutatis mutandis (i.e., the license grantor Party may only grant such further licenses to the extent permitted under and in compliance with Section 2.6.1 as if such license grantor Party were the licensee granting a sublicense). For clarity, subject to the terms and conditions of this Agreement (including Section 2.9), the grant of a Co-Exclusive license to the other Party as set forth herein shall not restrict the license grantor Party from exploiting such Co-Exclusively



licensed intellectual property, including by granting licenses, outside the scope of the license grants to the licensee Party.

2.7 Use of Subcontractors. Each Party shall have the right to engage Third Party subcontractors to perform its rights and obligations hereunder with respect to the Licensed Compounds and the Licensed Product hereunder (provided that such engagement is consistent with the Development Plan, Manufacturing Plan, Commercialization Plan, and the applicable Merck Supply Agreement or SeaGen Supply Agreement, as applicable); provided that (a) neither Party shall have the right to use a contract sales force to Promote the Licensed Product in the Collaboration Territory, unless specifically set forth in the Commercialization Plan, (b) neither Party shall have the right to use a Distributor to distribute or sell the Licensed Product unless (i) approved by the JSC, (ii) specifically set forth in the Commercialization Plan or (iii) for a country set forth on Schedule 2.7, (c) neither Party shall have the right to use a Third Party contract manufacturer to Manufacture any Licensed Compound or the Licensed Product unless specifically set forth in the Manufacturing Plan (or, in the case of SeaGen, is an existing contract manufacturer engaged by SeaGen pursuant to a SeaGen Existing CMO Agreement to Manufacture any Licensed Compound or the Licensed Product (or any component thereof) as of the Effective Date, but subject to 7.7) and (d) neither Party shall have the right to use a contract research organization to perform any material activities with respect to the Development of a Licensed Compound or the Licensed Product unless specifically set forth in the Development Plan. Subject to Section 13.3.3, in no event shall any subcontracting hereunder diminish, reduce or eliminate any of the obligations of the subcontracting Party hereunder, and any such subcontracting shall be subject and to and consistent with, the applicable terms and conditions of this Agreement and shall require each such subcontractor to comply with all applicable terms and conditions of this Agreement (including, for clarity, Section 12.3). Subject to Section 13.3.3, any act or omission of a Party's Third Party subcontractor in the performance of activities hereunder shall constitute the act or omission of such Party for purposes of this Agreement.

2.8 No Outside Development, Manufacture or Commercialization of Licensed Compounds and the Licensed Product.

2.8.1 Notwithstanding anything to the contrary contained herein, but subject to Sections 2.8.2 and 2.9.2, unless and until this Agreement expires or is terminated, during the Term, neither Merck nor SeaGen shall, and each of Merck and SeaGen shall cause their respective Affiliates not to, directly or indirectly, by itself or with or through any Third Party, Develop, Manufacture or Commercialize any Licensed Compound or the Licensed Product, including as a monotherapy or for use in any combination (including concomitant or sequential therapy) with other products, or grant a Third Party any rights to do so, except as permitted under, and in accordance with, this Agreement and the Development Plan, Manufacturing Plan, and Commercialization Plan, as applicable.

2.8.2 Subject to Section 2.4.1, Section 2.9 (with respect to Competing Products), and Article 9, as applicable: (a) nothing contained herein shall prohibit or otherwise restrict in any way a Party or its Affiliates, itself or with or through any Third Parties, from researching, developing, using, importing, exporting, making, having made, offering to sell or selling any of its Proprietary Products, and (b) nothing herein shall grant a Party (or any of its Affiliates) any right



to research, develop, use, import, export, make, have made, offer to sell or sell the other Party's Proprietary Products or to determine any prices or reimbursements or to share in any revenues with respect thereto, and (c) each Party and its Affiliates retain all rights to develop (including seeking regulatory approval for) and commercialize (including determining pricing and reimbursement for) its Proprietary Products, and nothing contained herein shall limit a Party's and its Affiliate's rights to develop (including seeking regulatory approval for) or commercialize (itself or with or through any Third Parties) any of its Proprietary Products anywhere in the Territory; provided that, in each case ((a), (b) and (c)), the Development, Manufacture and Commercialization of the Licensed Product for use in any combination (including concomitant or sequential use) with any Proprietary Product, including in any Proprietary Combination, shall be subject to the provisions of this Agreement. In addition, subject to Section 2.4.1, Section 2.9 (with respect to Competing Products), and Article 9, nothing contained herein shall prohibit or otherwise restrict in any way SeaGen or its Affiliates, itself or with or through any Third Parties, from researching, developing, using, importing, exporting, making, having made, offering to sell or selling any payload or linker component of any Licensed Compound or the Licensed Product, in each case, alone or as components in other products but excluding the use thereof in any Licensed Compound, Licensed Product or Competing Product.

2.9 Exclusivity.

2.9.1 Exclusivity. During the Term, neither Party (nor any of its Affiliates) will (and such Party will ensure that its Affiliates do not) [*]. Notwithstanding the foregoing, the provisions of this Section 2.9.1 will not apply to, and a Party and its Affiliates will not be prohibited under this Section 2.9.1 from, (i) clinically developing, selling or otherwise commercializing the Licensed Compounds and the Licensed Product in accordance with this Agreement (including the Development Plan, Manufacturing Plan and Commercialization Plan, as applicable), (ii) granting rights to Third Party sublicensees and subcontractors to clinically develop, sell or otherwise commercialize the Licensed Compounds and the Licensed Product in accordance with this Agreement (including Sections 2.6 and 2.7), (iii) with respect to Merck (and its Affiliates), from and after the [*] year anniversary of the Effective Date, carrying out activities (alone or with any Third Party) to [*], and (iv) without limiting the foregoing clause (iii), with respect to Merck (and its Affiliates), from and after the [*] year anniversary of the Effective Date, carrying out activities (alone or with any Third Party) to [*].

2.9.2 SeaGen Pre-Clinical Research of Competing Products. Notwithstanding Section 2.9.1, and subject to Section 2.9.3 and Section 5.2.4(a), SeaGen and its Affiliates (itself, but not with or through any Third Party) may conduct, at its cost, pre-clinical development (prior to GLP Tox Studies) of a Competing Product (including SGN-LIV-1-B and SGN-LIV-1-C) for purposes of identifying alternative or "next generation" compounds to potentially be included as a Licensed Compound under this Agreement (each such Competing Product, a "Next Generation Compound"), subject to the remainder of this Section 2.9.2. SeaGen shall use Commercially Reasonable Efforts to pre-clinically develop (prior to GLP Tox Studies) each of SGN-LIV-1-B and SGN-LIV-1-C. SeaGen shall update the JSC by providing a summary overview of such activities for each Next Generation Compound on a quarterly basis (and any other reasonable information requested by the JSC with respect thereto) and shall consider in good faith any comments of Merck with respect to such activities. SeaGen shall notify



Merck in writing of any Next Generation Compound that SeaGen or its Affiliate pre-clinically develops (and in all cases, prior to initiating any GLP Tox Study for such Next Generation Compound) that it reasonably believes is suitable for further Development in GLP Tox Studies, such notice including all data generated from the pre-clinical development, including all data supporting or establishing SeaGen's belief that the Next Generation Compound is suitable for further Development in GLP Tox Studies (each, a "Next Generation Compound Notice"). Merck shall have [*] days from receipt of the Next Generation Compound Notice to notify SeaGen in writing if Merck desires to include such Next Generation Compound Candidate as a "Licensed Compound" under this Agreement ("Licensed Compound Notice"). During such [*] day period, SeaGen shall use reasonable efforts to answer Merck's questions with respect to such Next Generation Compound, including, if applicable, providing additional information necessary or reasonably useful for Merck to decide whether to include such Next Generation Compound hereunder as a "Licensed Compound". If Merck timely provides SeaGen with a Licensed Compound Notice, then the Next Generation Compound that is the subject of such Licensed Compound Notice shall be included as a "Licensed Compound" hereunder as of the date of such notice. Notwithstanding the foregoing, with respect to SGN-LIV-1-C, if Merck does not issue a Licensed Compound Notice within [*] days from receipt of the Next Generation Compound Notice for SGN-LIV-1-C, but the Next Generation Compound Notice for SGN-LIV-1-C includes sufficient data (as determined by the JSC) showing that SGN-LIV-1-C has met the "Criteria for Go to GLP Tox Studies" set forth in part 1 of Schedule 2.9.2, then unless the Parties mutually agree otherwise, Merck shall be deemed to have issued a Licensed Compound Notice for SGN-LIV-1-C, and SGN-LIV-1-C shall be included as a "Licensed Compound" hereunder, as of the date of expiration of such [*] day period. For clarity, in all cases, SeaGen and its Affiliates (itself or with or through any Third Party) shall have no right to, and shall not, conduct any GLP Tox Studies or any clinical development or commercialization of any Next Generation Compound unless and until Merck provides a Licensed Compound Notice with respect to the applicable Next Generation Compound, and in such case, such GLP Tox Studies and any further Development and Commercialization thereof shall be conducted under and in accordance with this Agreement, including the applicable Development Plan and Commercialization Plan.

2.9.3 Acquired Competing Products. If after the Effective Date, (i) a Party (or any of its Affiliates) acquires any Third Party (or business or assets of a Third Party) (by merger, purchase of assets, stock acquisition or otherwise) and, as a result of such transaction, obtains rights (via ownership or otherwise) to a Competing Product, or (ii) a Party is acquired by a Third Party (by merger, purchase of assets, stock acquisition or otherwise, including as a result of a Change of Control with a Person who (itself or any of its affiliates) owns or controls a Competing Product) that owns or controls a Competing Product immediately prior to such transaction, and, as a result of such transaction under the preceding sub-clause (i) or (ii), such Party (or any of its Affiliates) (the "Acquiring Competing Product Party") would be in breach of the provisions of Section 2.9.1 (such Competing Product, an "Acquired Competing Product"), then such Acquiring Competing Product Party (and its Affiliates) will not be deemed to be in breach of Section 2.9.1 so long as such Acquiring Competing Product Party (and its Affiliates, as applicable) no later than [*] months following such transaction, undertakes at least one of the following:

(a) sells, transfers and assigns to a Third Party all of the Acquiring Competing Product Party's (and its Affiliates') rights to such Acquired Competing Product



(provided that, for the avoidance of doubt, the Acquiring Competing Product Party may continue to retain an economic interest therein (e.g., upfront payments, milestone payments, royalties, etc.));

(b) ceases and terminates the activities with respect to the Acquired Competing Product during the Term which are in breach of the provisions of Section 2.9.1;

(c) within [*] months following the consummation of the applicable acquisition transaction, offers in writing to the other Party to include such Acquired Competing Product as a "Licensed Compound" under this Agreement (on financial terms to be discussed, in addition to the sharing of future Allowable Development Costs, Allowable Commercialization Costs and Allowable Joint IP Costs, as set forth herein, if such Acquired Competing Product is included as a Licensed Compound hereunder), in which case such other Party shall have [*] days following receipt of such written offer to notify the Acquiring Competing Product Party in writing if it desires to so include such Acquired Competing Product, and if such other Party so notifies the Acquiring Competing Product Party in writing that such Acquired Competing Product should be included as a "Licensed Compound" hereunder, then the Acquired Competing Product will thereafter automatically be a "Licensed Compound" for purposes of this Agreement, and the Parties shall enter into an amendment to this Agreement to so include such Acquired Competing Product as a "Licensed Compound" hereunder; provided that if such other Party does not so notify the Acquiring Competing Product Party that the Acquired Competing Product should be included under this Agreement within such time period, then the Acquired Competing Product Party shall complete a different applicable alternative under this clause 2.9.3 with respect to such Acquired Competing Product no later than [*] months following the consummation of the applicable acquisition transaction; or

(d) solely with respect to Merck as the Acquiring Competing Product Party, Merck provides notice of termination of this Agreement in accordance with Section 14.2 at least [*] months prior to expiration of such [*]-month period.

2.9.4 Interim Activities for Acquired Competing Products. For clarity, the Acquiring Competing Product Party will not be in breach of its obligations under Section 2.9.1 with respect to an Acquired Competing Product as long as the Acquiring Competing Product Party complies with the provisions of Section 2.9.3; provided that, during the [*] month period during which the Acquiring Competing Product Party is permitted to undertake the alternatives set forth in Section 2.9.3, the Acquiring Competing Product Party shall be permitted to continue to conduct the development, manufacturing and commercialization of the Acquired Competing Product (the "Interim Permitted Competing Activities") so long as (a) such Interim Permitted Competing Activities will be conducted separately from any activities conducted under this Agreement, including the maintenance of separate lab notebooks and records; (b) no personnel or contractors of the Acquiring Competing Product Party or any of its Affiliates who have conducted activities pursuant to this Agreement shall be involved in any Interim Permitted Competing Activities; (c) the Acquiring Competing Product Party shall establish reasonable firewall protections and safeguards (that are reasonably acceptable to the other Party) designed to ensure that the Interim Permitted Competing Activities are segregated from the activities conducted hereunder; (d) the Acquiring Competing Product Party shall not use (or permit to be used) in the conduct of any Interim Permitted Competing Activities any Confidential Information of the other Party,



Development Data or Program Know-How, and the Acquiring Competing Product Party shall ensure that none of the foregoing are provided to or otherwise disclosed to any Person that is involved in the conduct of any Interim Permitted Competing Activities; and (e) the conduct of the Interim Permitted Competing Activities do not delay or otherwise inhibit the conduct of the Acquiring Competing Product Party's obligations hereunder or the conduct of activities under any Development Plan, Manufacturing Plan or Commercialization Plan.

2.9.5 Combination Therapies.

(a) [*]. For clarity, during the Term, [*] shall be [*]

(b) [*]. Notwithstanding anything to the contrary (including Section 5.2.4(b)) hereunder, but subject to Section 3.2.4(b)(vi), after the [*] anniversary of the Effective Date, if SeaGen proposes a Clinical Trial for use of the Licensed Product in combination (including concomitant or sequential therapy) with a [*] (alone or in further combination with one or more other products approved for the applicable tumor type) for consideration by the JSC under Section 5.2.4(b), and such Clinical Trial for such combination is not approved to be included in the Development Plan by Merck through the JSC within [*] days following SeaGen's request, then SeaGen (or its Affiliates) may carry out such Clinical Trial (alone or with any Third Party) for the Licensed Product for use in combination (including concomitant or sequential therapy) with such [*] (such Clinical Trial, a [*] and such combination therapy, a [*]), provided that (i) SeaGen (and its Affiliates), as applicable, [*] and (ii) SeaGen (and its Affiliates) [*]. Notwithstanding anything to the contrary hereunder, Section [*] shall apply [*]. For purposes of [*].

ARTICLE 3 GOVERNANCE

3.1 Committees. The Parties shall establish a Joint Steering Committee and appropriate Subcommittees to oversee the Development, Manufacture and Commercialization of Licensed Compounds and the Licensed Product, as more particularly described in this Article 3. Notwithstanding the foregoing, with respect to the Licensed Compounds and the Licensed Product, and the Development, Manufacturing and Commercialization thereof, each Party shall retain the rights, powers and discretion granted to it under this Agreement and the Ancillary Agreements and no such rights, powers or discretion shall be delegated to or vested in the JSC or any Subcommittee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Ancillary Agreements or the Parties expressly so agree in writing. Notwithstanding anything to the contrary in this Agreement, in no circumstances shall the JSC (including pursuant to Section 3.2.4(b)) or any Subcommittee have any power to amend, modify or waive compliance with this Agreement or any Ancillary Agreements. The Parties hereby agree and acknowledge that, for purposes of efficiency, if agreed to by the Parties, one or more (or all) of each Party's representatives appointed to the JSC (or any of the other Subcommittees) hereunder may also be appointed by such Party to any committee under any other collaboration agreement(s) between the Parties (or their respective Affiliates), and, in such case, meetings of such committees shall be coordinated to discuss the applicable issues under the various collaboration agreement(s).

3.2 Joint Steering Committee.



3.2.1 Formation. Within [*] days after the Effective Date, the Parties shall establish a Joint Steering Committee (the "JSC" or "Joint Steering Committee") to oversee, review, manage and coordinate the Development, Manufacture and Commercialization of Licensed Compounds and the Licensed Product and to facilitate communications between the Parties in connection therewith.

3.2.2 Composition of the Joint Steering Committee. The Joint Steering Committee shall be composed of [*] employees of Merck or its Affiliates as representatives of Merck and [*] employees of SeaGen or its Affiliates as representatives of SeaGen. Each Party may change one or more of its representatives to the JSC from time to time in its sole discretion, effective upon notice to the other Party of such change. Within [*] days after the Effective Date, the Parties shall each appoint their initial [*] representatives to the JSC. Each Party's representatives shall have appropriate technical credentials, experience and knowledge for their specific role within the JSC, and ongoing familiarity with the Licensed Compounds and the Licensed Product and shall be duly authorized under their respective company's internal governance procedures to make the decisions or carry out the activities given to them under this Agreement. If agreed by the JSC, the JSC may invite non-members to participate in the discussions and meetings of the JSC; provided that such participants are under obligations of confidentiality consistent with this Agreement and shall have no voting authority at the JSC. The JSC shall be co-chaired by representatives of each Party. The role of the co-chairpersons shall be to convene and preside in person or telephonically at meetings of the JSC, to prepare and circulate agendas and to ensure the preparation of minutes (all such responsibilities to alternate between each Party's co-chairperson on an annual basis), but the co-chairpersons shall have no additional powers or rights beyond those held by the other JSC representatives.

3.2.3 Specific Responsibilities of the JSC. With respect to Licensed Compounds and the Licensed Product, in addition to its general responsibilities to oversee, review, manage and coordinate the Development, Manufacture and Commercialization of Licensed Compounds and the Licensed Product, the JSC shall, subject to the terms of this Agreement, in particular:

(a) oversee the collaborative activities of the Parties under this Agreement for the Licensed Compounds and the Licensed Product, including to coordinate the overall strategy for the Development, Manufacture and Commercialization of Licensed Compounds and the Licensed Product in the Field in the Territory, including to address any matters that would otherwise be under the purview of a given Subcommittee prior to the establishment of such Subcommittee;

(b) facilitate the transition of any applicable Development, Manufacturing and Commercialization activities for Licensed Compounds and the Licensed Product between the Parties;

(c) review the progress of each Development Plan, Manufacturing Plan and Commercialization Plan;

(d) discuss reports from the Subcommittees and provide guidance thereto;



(e) review, discuss and approve (i) any amendments to the Development Plan (including the Development Budget), including the Regulatory Plan contained therein (and also including, for clarity, any matter requiring the approval of the JSC under Section 5.2.4), (ii) the initial Commercialization Plan (including the Commercialization Budget) and any amendments thereto, and (iii) the initial Manufacturing Plan (including the Manufacturing Data) and any amendments thereto;

(f) review, discuss and approve any Regional Commercialization Sub-Plans and any amendments thereto (provided that the approval of Regional Commercialization Sub-Plans for the SeaGen Territory and the Merck Territory shall be limited to approval for consistency with the applicable approved Commercialization Plan (but allowing for differences in regional and local factors to be addressed) and the Commercialization Budget);

(g) review, discuss and approve the Commercialization Guidelines and any amendments thereto for the Licensed Product;

(h) review, discuss and approve [*] following the receipt of Marketing Authorization, [*], for such country;

(i) discuss and determine, consistent with Section 4.1.1, which Party shall be the Lead Study Party for a given Clinical Trial of the Licensed Product (and, for clarity, a Party may be the Lead Study Party for a given Clinical Trial notwithstanding the use of resources, assistance or services of Third Parties (as permitted in accordance with this Agreement) or the other Party in connection with such Clinical Trial);

(j) discuss and determine (i) [*];

(k) discuss and determine whether to put in place a second source supply (including by a Third Party or by a Party) for the Licensed Compound and for the Licensed Product in accordance with Section 7.4.4;

(l) approve the licensing of any intellectual property from a Third Party in order to gain rights to use such Third Party's intellectual property in the Development, Manufacture or Commercialization of a Licensed Compound or Licensed Product under this Agreement in accordance with Section 2.5.2;

(m) approve the grant of sublicenses with respect to the Development, Manufacture and Commercialization of the Licensed Product as set forth in Section 2.6;

(n) discuss and agree on any patient assistance program (or the like) for the Licensed Product for the Territory;

(o) establish such additional Subcommittees with respect to Licensed Compounds and the Licensed Product as it deems necessary to achieve the objectives and intent of this Agreement (including, if determined by the JSC, (x) separate Subcommittees for separate therapeutic areas (e.g., separate JDCs, JCCs and JMCs per therapeutic area), (y) separate regional commercial Subcommittees for the Commercialization of the Licensed Product in different



regions, and (z) separate Subcommittees with respect to a Companion Diagnostic for use in connection with the Licensed Product), and to determine if any Subcommittee should be disbanded;

(p) attempt to resolve issues presented to it by, and disputes within, any Subcommittee; and

(q) perform such other functions with respect to Licensed Compounds and the Licensed Product designated to the JSC as expressly set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

3.2.4 Decision Making.

(a) Decision Making; Escalation. The JSC shall act by unanimous consent. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. In the event that the JSC cannot or does not, after good faith, reasonable efforts, reach agreement on any issue within the purview of the JSC (and, for clarity, any matter that is within the purview of any Subcommittee shall also be deemed to be within the purview of the JSC) within [*] Business Days after the JSC first considers such issue, either Party (through the Alliance Managers) may elect to formally submit such issue to the Parties' applicable Senior Executives for resolution (and, for the avoidance of doubt, references in this Agreement to decisions or approvals by the JSC or a Subcommittee shall include such decision or approval mutually made by the Senior Executives pursuant to this Section 3.2.4(a), to the extent applicable). In the event that the Senior Executives are unable to resolve a given issue referred to the Senior Executives in accordance with this Section 3.2.4(a) within [*] Business Days after the dispute is formally submitted to the Senior Executives for resolution, then either Party (through the Alliance Managers) may elect to formally submit such issue to the Parties' respective [*] for resolution (and, for the avoidance of doubt, references in this Agreement to decisions or approvals by the JSC or a Subcommittee shall include such decision or approval mutually made by such [*] pursuant to this Section 3.2.4(a), to the extent applicable).

(b) Final Resolution. In the event that the Parties' respective [*] are unable to resolve a given issue referred to the [*] in accordance with Section 3.2.4(a) within [*] Business Days after the dispute is formally submitted to the [*] for resolution, then the resolution or course of conduct shall be determined as follows (and, for the avoidance of doubt, references in this Agreement to decisions or approvals by the JSC or a Subcommittee shall include such decision or approval made pursuant to this Section 3.2.4(b), to the extent applicable):

(i) with respect to matters related to the Development of the Licensed Product (including the Development Plan and any amendments thereto, including any dispute as to whether to add a new Clinical Trial to the Development Plan or to discontinue any existing Clinical Trial), subject to Section 3.2.4(b)(ii) and Section 3.2.4(b)(vi), such dispute shall [*] and will [*] (and, for clarity, except as otherwise set forth in [*], if such matter is [*], then [*];

(ii) All decisions as to whether to include the Development of the Licensed Product for use in any Combination Therapy (including with a Merck Proprietary



Product, SeaGen Proprietary Product or Third Party product) in the Development Plan must be approved in writing by each of the Parties, and any dispute with respect thereto shall [*]; provided, however, the Development of the Licensed Product for use in Combination Therapy [*] is hereby deemed to be mutually approved by the Parties as of the Effective Date. If the Parties mutually agree to include the Development of the Licensed Product for use in Combination Therapy with a Merck Proprietary Product or SeaGen Proprietary Product, as applicable, then the following shall apply:

(1) if the Parties approve the Development of the Licensed Product for use in Combination Therapy with a SeaGen Proprietary Product, then in the event of a dispute with respect to matters related to the [*]; and

(2) if the Parties approve the Development of the Licensed Product for use in Combination Therapy with a Merck Proprietary Product, then in the event of a dispute with respect to matters related to the [*];

(iii) with respect to matters related to the Commercialization of the Licensed Product for the Territory (including the Commercialization Plan and any amendments thereto and any Regional Commercialization Sub-Plan and any amendments thereto), subject to Section 3.2.4(b)(iv) and 3.2.4(b)(vi), such dispute shall [*] and will [*] (and, for clarity, except as otherwise set forth in [*], if such matter is [*], then [*]); provided however that, subject to Section 3.2.4(b)(iv) and 3.2.4(b)(vi), (x) with respect to a dispute related to the contents of a Regional Commercialization Sub-Plan for the SeaGen Territory, SeaGen shall have final decision-making authority with respect to such dispute, provided that in all cases the contents of such Regional Commercialization Sub-Plan are consistent with the Commercialization Plan (including the Commercialization Budget) as applied to the SeaGen Territory and (y) with respect to a dispute related to the contents of a Regional Commercialization Sub-Plan for the Merck Territory, Merck shall have final decision-making authority with respect to such dispute, provided that in all cases the contents of such Regional Commercialization Sub-Plan are consistent with the Commercialization Plan (including the Commercialization Budget) as applied to the Merck Territory;

(iv) if the Licensed Product is being Commercialized hereunder for use in a Proprietary Combination, then with respect to matters related to any Promotional Materials and Other Field-Based Materials for the Licensed Product to the extent related to the Proprietary Product or Proprietary Combination (including any information related to the Proprietary Product contained therein), but subject always to the Promotional Materials Guidelines and the Other Field-Based Materials Guidelines, [*];

(v) with respect to all other matters related to a Licensed Compound or the Licensed Product for the Territory within the purview of the JSC (including (A) the Manufacturing Plan, and any amendments thereto, or (B) any dispute regarding entering into a Third Party In-License Agreement as set forth in Section 2.5.2), subject to Section 3.2.4(b)(vi), such dispute shall [*] and will [*] (and, for clarity, if such matter is [*] then [*];

(vi) notwithstanding the provisions of Sections 3.2.4(b)(i), 3.2.4(b)(iii) and 3.2.4(b)(v), (A) if a Party reasonably and in good faith believes that there is a



Safety Issue with respect to the Licensed Product being used in a given Clinical Trial that is being conducted hereunder, then such Party shall have the right to require the other Party to suspend, and such other Party shall suspend as so required, such Clinical Trial (subject to the other Party's obligation to comply with legal and regulatory requirements) until such Safety Issue is reasonably resolved, or (B) if a Party reasonably and in good faith believes that (x) a change to the Development Plan, Commercialization Plan or Manufacturing Plan, as applicable, is required in order for such Party to reasonably perform the Development, Commercialization or Manufacturing activities allocated to such Party for the Licensed Product under the Development Plan, Commercialization Plan or Manufacturing Plan, as applicable, in compliance with Applicable Law (or to satisfy a specific Regulatory Authority request), or (y) a change to the Core Data Sheet is required in order to comply with Applicable Law (or to satisfy a specific Regulatory Authority request), then such Party shall notify the other Party thereof in writing, including a reasonably detailed description of such changes and requirements to comply with Applicable Law (or to satisfy a specific Regulatory Authority request), and the Parties shall use good faith efforts to mutually agree in writing on any such required changes to the then-current Development Plan, Commercialization Plan, Manufacturing Plan or Core Data Sheet, as applicable; provided that the determination as to whether such changes are required to comply with Applicable Law or satisfy a Regulatory Authority request shall be subject to Section 16.8.

(c) Operational Discretion. Subject to Section 3.2.4(b), the Party to which an activity under any Development Plan, Commercialization Plan or Manufacturing Plan is assigned shall have the right to make final operational decisions with respect to how such activity is conducted from an operational perspective; provided that (i) such decisions are consistent with this Agreement and the Development Plan (including Development Budget), Manufacturing Plan (including Manufacturing Data) or Commercialization Plan (including Commercialization Budget), as applicable (and, for the avoidance of doubt, the foregoing provisions of this Section 3.2.4(c) shall not be interpreted to empower such Party to make final decisions with respect to any changes to the Development Plan (including Development Budget), Manufacturing Plan (including Manufacturing Data) or the Commercialization Plan (including Commercialization Budget)), and (ii) such decisions are consistent with customary business practices for other of such Party's similar products.

(d) Proprietary Products. Notwithstanding the foregoing provisions of this Section 3.2.4, the Joint Steering Committee shall have no decision-making authority with respect to any matters related to a Party's Proprietary Products (other than with respect to the Development and Commercialization of the Licensed Product for use in a Proprietary Combination), and, for clarity, any such matters shall not be subject to the foregoing provisions of this Section 3.2.4, and all development, manufacturing and commercialization activities with respect to any Proprietary Product (other than with respect to the Development and Commercialization of the Licensed Product for use in a Proprietary Combination) shall be at the determination of the Proprietary Product Party as set forth in Section 2.8.2.

(e) Limitation of Authority. The JSC (and each Subcommittee) shall only have the powers expressly assigned to it in this Article 3 and elsewhere in this Agreement and shall not have the authority to: (i) modify or amend the terms and conditions of this Agreement, (ii) waive either Party's compliance with, or determine that either Party has or has not fulfilled,

the terms and conditions of this Agreement, (iii) make a decision that is stated to require the mutual agreement or mutual consent of the Parties (or that is subject to the determination of the other Party as set forth herein), or (iv) determine any issue in a manner that would conflict with, expand, or reduce the express terms and conditions of this Agreement.

3.2.5 Meetings. The Parties shall endeavor to have their first meeting of the JSC within thirty (30) days after the formation thereof. Thereafter, the JSC shall meet in accordance with a schedule established by the JSC, but no less frequently than [*] times per Calendar Year, unless the JSC determines a different frequency, with the location for such meetings to be determined by the JSC. The JSC may meet in person, or alternatively, the JSC may meet by means of teleconference, videoconference or other similar communications equipment. Either Party may also call a special meeting of the JSC by at least ten (10) Business Days' prior written notice to the other Party in the event such requesting Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such requesting Party shall provide the JSC no later than five (5) Business Days prior to the special meeting with materials reasonably adequate to enable an informed decision on the relevant matter; provided that for time sensitive matters, a Party may call a special meeting of the JSC and provide relevant materials with less than [*] Business Days' notice if the Parties agree that an issue warrants an expedited meeting. No later than [*] Business Days prior to any meeting of the JSC (other than a special meeting as described above), the designated co-chairperson of the JSC shall prepare and circulate an agenda for such meeting to all members of the JSC; provided, however, that either Party shall be free to include additional topics on such agenda, either prior to or, if representatives of each Party are present at a meeting, during the course of such meeting. Each Party shall bear its own costs and expenses related to the attendance of such meetings by its representatives. The designated co-chairperson of the JSC will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect, without limitation, material decisions made at such meetings. The designated JSC co-chairperson shall send draft meeting minutes to each member of the JSC for review and approval within [*] Business Days after each JSC meeting. Such minutes will be deemed approved unless one or more members of the JSC objects to the accuracy of such minutes within [*] Business Days of receipt.

3.3 Joint Development Committee.

3.3.1 Composition of the Joint Development Committee. Within [*] days after the Effective Date, the Parties shall establish a committee to oversee Development of the Licensed Compounds and the Licensed Product for the Territory in accordance with the Development Plan and to coordinate the Development and regulatory activities of the Parties with respect to the Licensed Compounds and the Licensed Product (the "JDC" or "Joint Development Committee"). Each Party shall initially appoint [*] employees of such Party or its Affiliates as representatives to the JDC, with each Party's representatives having appropriate technical credentials, experience and knowledge for their specific role within the JDC for the development of products, and having sufficient seniority within the applicable Party to make decisions arising within the scope of the JDC's responsibilities and being duly authorized under their respective company's internal governance procedures to make the decisions or carry out the activities given to them under this Agreement. The JDC may change its size from time to time by mutual, unanimous consent of its members; provided that the JDC shall consist at all times of an equal



number of representatives of each of Merck and SeaGen. Each Party may replace one or more of its JDC representatives at any time in its sole discretion upon written notice to the other Party. If agreed by the JDC, the JDC may invite non-members to participate in the discussions and meetings of the JDC; provided that such participants are under obligations of confidentiality consistent with this Agreement and shall have no voting authority at the JDC. The JDC shall be co-chaired by representatives of each Party. The role of the co-chairpersons shall be to convene and preside at meetings of the JDC, to prepare and circulate agendas and to ensure the preparation of minutes (all such responsibilities to alternate between each Party's co-chairperson on an annual basis), but the co-chairpersons shall have no additional powers or rights beyond those held by the other JDC representatives.

3.3.2 Specific Responsibilities of the JDC. In addition to its general responsibilities, with respect to Licensed Compounds and the Licensed Product, the JDC shall, subject to the terms of this Agreement, in particular:

(a) discuss, prepare and approve for submission to the JSC amendments to the Development Plan (including the Development Budget and the Regulatory Plan);

(b) review and update quarterly financial forecasts for Development of the Licensed Product (including timing of expenditures) to endeavor to ensure actual and anticipated expenditure is within the approved Development Budget for the relevant Calendar Year and make recommendations to the JSC for approval of any variances before additional expenditures are incurred;

(c) create, implement and review the overall strategy for Development of the Licensed Product (including the Regulatory Plan) and the design and objectives of all Clinical Trials and non-clinical studies conducted under the Development Plan;

(d) review and approve the protocols for all Clinical Trials conducted under the Development Plan and any material amendments thereto (including any amendments which would change the primary endpoint of such Clinical Trial, dosage or similar matters); provided that such review and approval shall be conducted within a timeframe that does not unduly delay any Clinical Trial;

(e) review and discuss the Next Generation Compound Notices and related data;

(f) decide timing for filing or withdrawal of any registration application or any submission to conduct investigative studies for the Licensed Product, including any IND or MAA;

(g) oversee the conduct of any Clinical Trial under the Development Plan, including discuss, coordinate and share information regarding operational activities associated with such Clinical Trials, including study feasibility, study-specific key opinion leader (KOL) engagement, country and site selection, site contracting, use of contract research organizations (including preparation of guidelines with respect to the use of contract research



organizations) or the resources of the other Party, site opening and enrollment (including steps to effectively address over or under enrollment);

(h) oversee the forecasting of quantities of Licensed Product required for Clinical Trials for incorporation into the Manufacturing Plan and Development Plan;

(i) discuss and agree on the overall regulatory filing strategy for obtaining Marketing Authorizations for the Licensed Product for the Territory and for maintaining such Marketing Authorizations (including post-approval commitments), including overseeing the strategy for submission and maintenance of the registration dossiers (including MAAs) for the Licensed Product;

(j) review, discuss, coordinate and approve Phase IV Clinical Trials, local clinical evaluations and outcomes research activities, including the allocation of budgeted resources thereto (to the extent applicable) and the priorities thereof (subject to consultation with the JCC regarding funding decisions) for the Licensed Product;

(k) (i) review and discuss, in consultation with the JCC, medical affairs activities for the Licensed Product, including field-based medical education activities by either Party, use of medical liaisons and grant-based medical education programs for Licensed Product, medical affairs materials to be used by the Parties, plans for investigator-initiated studies, and grant plans; and (ii) discuss, prepare and approve guidelines specifying the content of the Other Field-Based Materials (including, for clarity, with respect to medical liaison and other medical affairs activities) with respect to use of the Licensed Product as a monotherapy or in any Combination Therapy (the "Other Field-Based Materials Guidelines") and any amendments thereto; provided that the Proprietary Product Party will determine the content of the Other Field-Based Materials Guidelines relating to its Proprietary Product;

(l) discuss and approve plans for development of Companion Diagnostics, if any, specifically for use in connection with any Licensed Compound or the Licensed Product;

(m) review, discuss and approve, in consultation with the JCC, strategies for distribution of Licensed Product for "compassionate use" or as free goods;

(n) review, discuss, coordinate and approve a global publication strategy for the Licensed Products (including a strategy for the publication of Development Data developed under this Agreement from the conduct of Clinical Trials for the Licensed Products) ("Global Publication Strategy");

(o) discuss, coordinate and approve a strategy for the Development of the Licensed Product for use in a Combination Therapy with pharmaceutical product(s) other than the Initial Merck Proprietary Product (including testing and conducting Clinical Trials for the Licensed Product for use in a Combination Therapy with [*]) reasonably in advance of loss of patent exclusivity with respect to the composition of matter of the Initial Merck Proprietary Product;



(p) establish working teams to advise the JDC on matters within the purview of the JDC; and

(q) perform such other functions with respect to Licensed Compounds or the Licensed Product as may be appropriate to further the purposes of this Agreement, as directed by the JSC.

3.4 Joint Manufacturing Committee.

3.4.1 Composition. Within [*] days after the Effective Date, the Parties shall establish a committee to oversee CMC Development activities and Manufacturing of clinical and commercial supplies of Licensed Compounds and the Licensed Product for the Territory (the "JMC" or "Joint Manufacturing Committee"). Each Party shall initially appoint [*] employees of such Party or its Affiliates as representatives to the JMC, with each Party's representatives having appropriate technical credentials, experience and knowledge in the manufacturing of products similar to the Licensed Product for their specific role within the JMC, and having sufficient seniority within the applicable Party to make decisions arising within the scope of the JMC's responsibilities and being duly authorized under their respective company's internal governance procedures to make the decisions or carry out the activities given to them under this Agreement. The JMC may change its size from time to time by mutual, unanimous consent of its members; provided that the JMC shall consist at all times of an equal number of representatives of each of Merck and SeaGen. Each Party may replace one or more of its JMC representatives at any time in its sole discretion upon written notice to the other Party. If agreed by the JMC, the JMC may invite non-members to participate in the discussions and meetings of the JMC; provided that such participants are under obligations of confidentiality consistent with this Agreement and shall have no voting authority at the JMC. The JMC shall be co-chaired by representatives of each Party. The role of the co-chairpersons shall be to convene and preside at meetings of the JMC, to prepare and circulate agendas and to ensure the preparation of minutes (all such responsibilities to alternate between each Party's co-chairperson on an annual basis), but the co-chairpersons shall have no additional powers or rights beyond those held by the other JMC representatives.

3.4.2 Specific Responsibilities of the Joint Manufacturing Committee. In addition to its general responsibilities, with respect to Licensed Compounds and the Licensed Product, the Joint Manufacturing Committee shall, subject to the terms of this Agreement, in particular:

(a) oversee clinical and commercial Manufacture of Licensed Compounds and the Licensed Product, including coordination of the Manufacturing activities of the Lead Manufacturing Party with respect to Licensed Compounds and the Licensed Product and developing the overall manufacturing strategy, including considerations around supply redundancy and resiliency as well as life cycle management initiatives;

(b) discuss, prepare and approve for submission to the JSC each Manufacturing Plan (including the Manufacturing Data) and any amendments thereto for Licensed Compounds and the Licensed Product;



(c) oversee implementation of each Manufacturing Plan for Licensed Compounds and the Licensed Product;

(d) with respect to the Manufacturing activities of the Lead Manufacturing Party prior to the JSC's approval of the initial Manufacturing Plan, review, discuss and approve any matter related to the Manufacture of a Licensed Compound or the Licensed Product that would otherwise have been set forth in the Manufacturing Plan (prior to the Lead Manufacturing Party commencing the applicable Manufacturing activity);

(e) review forecasts provided in the Commercialization Plan for the Licensed Product and oversee development of, and discuss and agree on, logistical strategies, including capacity planning and appropriate inventory levels of Licensed Compounds and the Licensed Product to maintain consistency with the forecasts;

(f) establish a sales and operations planning team to coordinate the Parties' supply activities;

(g) oversee the conduct of the CMC Development for Licensed Compounds and the Licensed Product, and facilitate the flow of information between the Parties with respect to CMC Development;

(h) oversee development of, and recommend to JSC for approval, strategies for second sourcing for the Manufacture of Licensed Compounds and the Licensed Product;

(i) discuss, prepare and approve (in coordination with the JDC) for submission to the JSC proposed annual and interim amendments to CMC Development activities within the Development Plan, if any;

(j) discuss and oversee (in coordination with the JDC) CMC regulatory-related activities and maintenance of regulatory submissions, including INDs and MAAs, for the Licensed Product to ensure regulatory compliance and timely management of responses to any Regulatory Authority queries pre- and post-approval as well as during regulatory review processes;

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

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

(m) discuss and approve any Manufacturing sites or testing sites proposed to be established following the Effective Date for the Licensed Compounds or the Licensed Product; provided, however, that in performing such review and approval, the JMC shall take into consideration any then-existing supply or quality agreements established with Third Party



manufacturing sites for the Licensed Compounds or the Licensed Product in accordance with this Agreement, and seek to avoid conflicts with the provisions thereof;

(n) discuss and approve changes to the specifications or any changes to the manufacturing process (including any change that may affect the quality of Licensed Compounds or the Licensed Product, or change in Third Party contract manufacturer or key material vendor) for the Licensed Compounds or the Licensed Product; provided, however, that the Parties may agree in writing upon an alternate mechanism for Manufacturing change controls that is reasonably acceptable to both Parties with the goal of being timely and efficient;

(o) review any proposals for any capital expenditure, manufacturing site transfer costs or other non-recurring costs or expenses in relation to the Manufacture of the Licensed Compounds and the Licensed Product and approve any such capital expenditures or other costs and expenses and a budget therefor (including the allocation thereof related to the applicable Licensed Compounds and the Licensed Product), which shall then be set forth in the Manufacturing Plan; provided that, [*];

(p) review and agree on the Cost of Goods Manufactured (including a breakdown of the components thereof, as well as the methodologies for allocating indirect costs) on an annual basis, and review manufacturing processes on an annual basis, with a goal towards minimizing Cost of Goods Manufactured for Licensed Compounds and the Licensed Product, while ensuring continuous fully-compliant supply to maintain consistency with the forecasts and required inventory and safety stock levels;

(q) subject to Section 13.3.3, discuss ways to prevent, mitigate, respond to [*] failed batches of Licensed Product (or Licensed Compound) at a Third Party contract manufacturer; [*];

(r) coordinate with the JDC regarding (i) allocation of amounts under Development Budget to CMC Development activities for the Licensed Product, (ii) strategies for new indications, formulations and delivery systems for the Licensed Product, and (iii) other Development matters related to the Manufacture of the Licensed Product;

(s) establish working teams to advise the JMC on matters within the purview of the JMC; and

(t) perform such other functions with respect to Licensed Compounds or the Licensed Product as may be appropriate to further the purposes of this Agreement, as directed by the JSC.

3.5 Joint Commercialization Committee.

3.5.1 Composition. No later than the earlier of [*] or [*], the Parties shall establish a committee to oversee Commercialization of the Licensed Product (other than commercial manufacture) for the Territory (the "JCC" or "Joint Commercialization Committee"). Each Party shall initially appoint [*] employees of such Party or its Affiliates as representatives to the JCC, with each Party's representatives having appropriate technical



credentials, experience and knowledge in the commercialization of products similar to the Licensed Product for their specific role within the JCC, and having sufficient seniority within the applicable Party to make decisions arising within the scope of the JCC's responsibilities and being duly authorized under their respective company's internal governance procedures to make the decisions or carry out the activities given to them under this Agreement. The JCC may change its size from time to time by mutual, unanimous consent of its members; provided that the JCC shall consist at all times of an equal number of representatives of each of Merck and SeaGen. Each Party may replace one or more of its JCC representatives at any time in its sole discretion upon written notice to the other Party. If agreed by the JCC, the JCC may invite non-members to participate in the discussions and meetings of the JCC; provided that such participants are under obligations of confidentiality consistent with this Agreement and shall have no voting authority at the JCC. The JCC shall be co-chaired by representatives of each Party. The role of the co-chairpersons shall be to convene and preside at meetings of the JCC, to prepare and circulate agendas and to ensure the preparation of minutes (all such responsibilities to alternate between each Party's co-chairperson on an annual basis), but the co-chairpersons shall have no additional powers or rights beyond those held by the other JCC representatives.

3.5.2 Specific Responsibilities of the Joint Commercialization Committee. In addition to its general responsibilities, with respect to Licensed Compounds and the Licensed Product, the Joint Commercialization Committee shall, subject to the terms of this Agreement, in particular:

(a) discuss, prepare and approve for submission to the JSC the initial Commercialization Plan (including the Commercialization Budget) and amendments thereto for the Licensed Product;

(b) discuss, prepare and approve for submission to the JSC guidelines (including the Pricing Guidelines), policies and procedures to be followed by the Parties in connection with the Commercialization of the Licensed Product and any amendments thereto (collectively, the "Commercialization Guidelines");

(c) discuss, prepare and approve guidelines specifying the content of the Promotional Materials (including, for clarity, with respect to the Promotion of the Licensed Product as a monotherapy or for use in any Combination Therapy) (the "Promotional Materials Guidelines") and any amendments thereto; provided that the Proprietary Product Party will determine the content of the Promotional Materials Guidelines relating to its Proprietary Product;

(d) review revenue forecasts and review the Commercialization Budget (including timing of expenditures) for the Territory at least on a quarterly basis to endeavor to ensure actual and anticipated spend is within the approved Commercialization Budget;

(e) review and discuss the Commercialization activities of SeaGen and Merck with respect to the Licensed Product for the Territory and coordinate the Commercialization activities of Merck and SeaGen with respect to the Licensed Product Promoted under this Agreement in the Territory, including pre- and post-launch activities and any other Promotion activities by the Parties for the Licensed Product in the Territory;



(f) following the receipt of Marketing Authorization, [*], in a given country [*], review the commercial strategy and discuss, prepare and submit a recommendation to the JSC [*];

(g) in order to assist with, among other things, Licensed Product supply forecasts as well as decisions to commit and allocate resources to the activities hereunder, but subject in all cases to Applicable Law, establish [*] for the Licensed Product for the Territory (collectively, the "Pricing Guidelines"), which Pricing Guidelines shall be established [*];

(h) discuss general market access strategies for the Licensed Product;

(i) discuss and determine (i) if Merck (rather than SeaGen) should be the Lead Distribution Party (or the Lead Trademark Party) for the Licensed Product in any portion of the SeaGen Territory or the US Collaboration Territory or the European Collaboration Territory and (ii) if SeaGen (rather than Merck) should be the Lead Distribution Party (or the Lead Trademark Party) for the Licensed Product in any portion of the Merck Territory;

(j) establish a process by which the Parties will review and comment on training materials and programs and training of the Parties' sales forces for the Commercialization of the Licensed Product in the Territory;

(k) prepare Licensed Product forecasts to be shared with the JMC for planning of inventory levels of Licensed Compounds and the Licensed Product;

(l) discuss and approve global brand positioning and messaging for the Licensed Product;

(m) discuss and approve plans for commercialization of Companion Diagnostics, if any, specifically for use in connection with the Licensed Product;

(n) oversee implementation of the Commercialization Plan;

(o) establish working teams to advise the JCC on matters within the purview of the JCC; and

(p) perform such other functions with respect to Licensed Compounds or the Licensed Product as may be appropriate to further the purposes of this Agreement, as directed by the JSC.

3.6 Financial Managers; Joint Finance Committee.

3.6.1 Financial Managers. Within [*] days after the Effective Date, each Party shall appoint an employee of that Party or its Affiliate who shall oversee the financial calculations (including accounting matters), financial reporting and payments hereunder with respect to the Licensed Compounds and the Licensed Product (each, a "Financial Manager"). Such persons shall facilitate clear and responsive communication between the Parties and the effective exchange of information with respect to such matters hereunder, and may serve as a single point of contact



for any such matters. Each Party may designate a replacement Financial Manager for such Party in its sole discretion by notice in writing to the other Party.

3.6.2 Composition of the Joint Finance Committee. Within [*] days after the Effective Date, the Parties shall establish a committee to coordinate financial matters with respect to Licensed Compounds and the Licensed Product and to support the JSC, the JDC, the JCC and the JMC in connection therewith (the "JFC" or "Joint Finance Committee"). Each Party shall initially appoint [*] employees of such Party or its Affiliates as representatives to the JFC, with each Party's representatives having appropriate technical credentials, experience and knowledge for their specific role within the JFC, and having sufficient seniority within the applicable Party to make decisions arising within the scope of the JFC's responsibilities and being duly authorized under their respective company's internal governance procedures to make the decisions or carry out the activities given to them under this Agreement. The JFC may change its size from time to time by mutual, unanimous consent of its members; provided that the JFC shall consist at all times of an equal number of representatives of each of Merck and SeaGen. Each Party may replace one or more of its JFC representatives at any time in its sole discretion upon written notice to the other Party. If agreed by the JFC, the JFC may invite non-members to participate in the discussions and meetings of the JFC; provided that such participants are under obligations of confidentiality consistent with this Agreement and shall have no voting authority at the JFC. The JFC shall be co-chaired by representatives of each Party. The role of the co-chairpersons shall be to convene and preside at meetings of the JFC, to prepare and circulate agendas and to ensure the preparation of minutes (all such responsibilities to alternate between each Party's co-chairperson on an annual basis), but the co-chairpersons shall have no additional powers or rights beyond those held by the other JFC representatives.

3.6.3 Specific Responsibilities of the JFC. In addition to its general responsibilities, with respect to Licensed Compounds and the Licensed Product, the JFC shall, subject to the terms of this Agreement and subject to the oversight of the JSC, in particular:

(a) work with the JSC and the other Subcommittees to assist in financial, budgeting and planning matters as required, including assisting in the preparation of budgets and annual and long term plans with respect to the Licensed Product;

(b) recommend, for approval by the JSC, procedures, formats and timelines consistent with this Agreement for reporting financial data as well as additional or alternative reporting procedures concerning financial aspects of the collaboration with respect to the Licensed Product;

(c) prepare such reports on financial matters as are approved by the JSC for the implementation of the financial aspects of the collaboration with respect to the Licensed Product;

(d) coordinate audits of financial data where appropriate and required or allowed by this Agreement with respect to the Licensed Product;

(e) address issues of implementation relating to the financial mechanics and calculations under this Agreement and the Ancillary Agreements with respect to the Licensed Product;

(f) recommend, for approval by the JSC, a means of reconciling, one to the other, the internal reporting and accounting standards of each of the Parties where necessary and methods of charging costs and expenses of each of the Parties, in each case, with respect to the Licensed Product;

(g) review the appropriate allocation of costs and expenses with respect to Allowable Commercialization Costs, Allowable Development Costs and Allowable Joint IP Costs;

(h) propose to the JSC adjustments to the Development FTE Rates, Medical Affairs FTE Rates, Promotion FTE Rates and Field Force FTE Rates annually;

(i) establish working teams to advise the JFC on matters within the purview of the JFC; and

(j) perform such other functions with respect to Licensed Compounds or the Licensed Product as may be appropriate to further the purposes of this Agreement, as directed by the JSC.

3.7 Meetings of Subcommittees. Each Subcommittee shall meet at least one (1) time per Calendar Quarter at a time mutually agreed by the Parties, spaced at regular intervals unless the applicable Subcommittee determines a different frequency, with the location for such meetings to be determined by the applicable Subcommittee. Each Subcommittee may meet in person, or alternatively, such Subcommittee may meet by means of teleconference, videoconference or other similar communications equipment. Either Party may also call a special meeting of the applicable Subcommittee by at least ten (10) Business Days' prior written notice to the other Party in the event such requesting Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such requesting Party shall provide the applicable Subcommittee no later than five (5) Business Days prior to the special meeting with materials reasonably adequate to enable an informed decision on the relevant matter; provided that for time sensitive matters, a Party may call a special meeting of the applicable Subcommittee and provide relevant materials with less than five (5) Business Days' notice if the Parties agree that an issue warrants an expedited meeting. No later than ten (10) Business Days prior to any meeting of the applicable Subcommittee (other than a special meeting as described above), the designated co-chairperson of the applicable Subcommittee shall prepare and circulate an agenda for such meeting to all members of the applicable Subcommittee; provided, however, that either Party shall be free to include additional topics on such agenda, either prior to or, if representatives of each Party are present at a meeting, during the course of such meeting. Each Party will bear the expense of its respective Subcommittee members' participation in the meetings of the applicable Subcommittee. The designated co-chairperson of the applicable Subcommittee shall be responsible for keeping reasonably detailed written minutes of all meetings of such Subcommittee that reflect all decisions made at such meetings. The designated Subcommittee co-chairperson shall send meeting minutes to each member of the applicable Subcommittee for review and approval within ten (10) Business



Days after each meeting of such Subcommittee. Minutes will be deemed approved unless one or more members of the applicable Subcommittee objects to the accuracy of such minutes within ten (10) Business Days of receipt.

3.8 Decision Making of Subcommittees. Each Subcommittee shall act by unanimous consent. For a given Subcommittee, the representatives from each Party on such Subcommittee will have, collectively, one (1) vote on behalf of that Party. If a given Subcommittee cannot or does not, after good faith, reasonable efforts, reach unanimous consent on an issue that comes before such Subcommittee and over which such Subcommittee has oversight within [*] Business Days after such issue is first considered by such Subcommittee, then such matter shall be raised to the JSC for resolution in accordance with Section 3.2.4.

3.9 Alliance Managers.

3.9.1 Alliance Managers. Each Party shall appoint one or more employees of it or its Affiliate who shall oversee interactions between the Parties for all matters related to this Agreement and any Ancillary Agreements between the Parties or their Affiliates (each, an "Alliance Manager"). Such persons shall endeavor to assure clear and responsive communication between the Parties and the effective exchange of information, and shall serve as a single point of contact for any matters arising under this Agreement. The Alliance Managers shall have the right to attend all Committee meetings as non-voting participants and may bring to the attention of the applicable Committee any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as the Parties may mutually agree in writing; provided that the Alliance Manager shall not count toward the number of representatives that each Party may have on each such Committee. Each Party may designate a replacement Alliance Manager for such Party in its sole discretion by notice in writing to the other Party.

3.9.2 Responsibilities. The Alliance Managers shall have the responsibility of creating and maintaining a constructive work environment between the Parties. Without limiting the generality of the foregoing, each Alliance Manager shall:

- (a) identify and bring disputes and issues that may result in disputes (including any asserted occurrence of a breach by a Party) to the attention of the Parties in a timely manner, and function as the point of first referral in all matters of conflict resolution;
- (b) provide a single point of communication for seeking consensus both internally within the Parties' respective organizations and between the Parties;
- (c) plan and coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement; and
- (d) take responsibility for ensuring that governance meetings and the production of meeting agendas and minutes occur as set forth in this Agreement (and the Alliance Managers shall facilitate such activities on behalf of the co-chairs of the JSC or other relevant Subcommittee), and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.



ARTICLE 4 ALLOCATION OF RESPONSIBILITIES

4.1 General. In the allocation of roles and responsibilities under this Agreement pursuant to the Development Plan and Commercialization Plan, whether by the JSC or by the Parties, the Parties intend to adhere to the following principles:

4.1.1 Development. The Parties desire to work together in good faith, through the JSC and the other Subcommittees and otherwise in accordance with this Agreement, to promote the efficient and coordinated Development of the Licensed Compounds and Licensed Product by the Parties. The Parties have agreed upon an allocation of certain roles and responsibilities between the Parties as of the Effective Date with respect to the Development of the Licensed Compounds and Licensed Product, such that, unless otherwise determined by the JSC (or as otherwise expressly set forth herein), (a) SeaGen shall be the Lead Regulatory Party in the US Collaboration Territory and the SeaGen Territory; and (b) Merck shall be the Lead Regulatory Party in the European Collaboration Territory and the Merck Territory. Subject to the foregoing allocation of responsibilities, and subject further to the applicable Party having or being able to procure (through itself, its Affiliates and permitted subcontractors) the relevant capabilities and infrastructure, the Parties, acting through the JSC and otherwise in accordance with this Agreement, shall seek to equitably allocate any remaining roles and responsibilities under this Agreement with respect to the Development of the Licensed Compounds and Licensed Product in the Territory, such that each Party will have responsibility for approximately [*] (the exact amount to be determined on a commercially reasonable basis) of the remaining Development activities for the Licensed Product in the Territory; provided that, in all cases (unless otherwise determined by the JSC), SeaGen shall be the Lead Study Party with respect to the Ongoing Clinical Trials. For clarity, the Parties acknowledge and agree that, through the JSC, either Party may be appointed as the Lead Study Party for a particular Clinical Trial of the Licensed Product notwithstanding that such Clinical Trial may (i) be conducted in one or more countries in the other Party's portion of the Territory (in the case of Merck, the Merck Territory, and, in the case of SeaGen, the SeaGen Territory), (ii) be conducted in a country where the other Party is the Lead Regulatory Party, or (iii) involve a Proprietary Combination with the other Party's Proprietary Product.

4.1.2 Commercialization (including Promotion) in the Collaboration Territory. The Parties desire to work together in good faith, through the JSC and the other Subcommittees and otherwise in accordance with this Agreement, with the intent to promote the efficient and coordinated Commercialization of the Licensed Product by the Parties. Unless otherwise determined by the JSC (or as otherwise expressly set forth herein), the Lead Distribution Party for each region of the Territory has been agreed upon between the Parties as of the Effective Date such that (a) SeaGen shall be the Lead Distribution Party for the US Collaboration Territory, the European Collaboration Territory and the SeaGen Territory, and (b) Merck shall be the Lead Distribution Party for the Merck Territory. Subject to the foregoing allocation of responsibilities and subject further to the applicable Party beginning launch planning activities at least [*] prior, and having or being able to procure (in each case, through itself, its Affiliates and permitted subcontractors) by a commercially reasonable period of time prior to be able to execute successfully on such plan, to the anticipated first commercial sale of the applicable Licensed Product in the US Collaboration Territory or the European Collaboration Territory (as applicable)



the relevant capabilities and infrastructure, for all other Promotion activities (and other Commercialization activities, but excluding Distribution) in the US Collaboration Territory or the European Collaboration Territory (as applicable), consistent with the Commercialization Plan (and the Regional Commercialization Sub-Plan) for the Collaboration Territory, the Parties, acting through the JSC and otherwise in accordance with this Agreement, shall seek to equitably allocate any remaining roles and responsibilities under this Agreement with respect to such Promotion (and other Commercialization) of the Licensed Product in the US Collaboration Territory or the European Collaboration Territory (as applicable), such that each Party will have responsibility for approximately [*] (the exact amount to be determined on a commercially reasonable basis) of the Promotion activities (and other Commercialization activities, but excluding Distribution) for the Licensed Product in the US Collaboration Territory or the European Collaboration Territory (as applicable), including through Co-Promotion and other allocation of Commercialization activities of the Licensed Product; provided that the Parties intend that such allocation shall enable SeaGen, in addition to being the Lead Distribution Party in the European Collaboration Territory, to meaningfully employ its European Commercialization infrastructure in support of Promotion or other Commercialization activities for the Licensed Product in the European Collaboration Territory.

4.2 Technology Transfers to Enable Collaboration. The Parties agree and acknowledge that SeaGen has been responsible for the Development of the Licensed Compound and the Licensed Product prior to the Effective Date. In order to facilitate Merck's involvement in the Development and Commercialization of the Licensed Product in accordance with this Agreement, the following shall apply:

4.2.1 Provision of Information. Promptly after the Effective Date, the JDC will develop and implement a plan for the secure transfer of SeaGen Know-How from SeaGen to Merck under this Agreement. During the Term as reasonably requested by Merck from time to time, SeaGen will transfer to Merck such SeaGen Know-How that is necessary or reasonably useful for Merck to perform its Development or Commercialization obligations for the Licensed Product hereunder. For clarity, SeaGen's obligations under this section shall exclude the obligation to transfer any SeaGen Know-How specific to Manufacturing of the Licensed Product, which are included in the SeaGen Supply Agreement and 7.4.4(c), as applicable.

4.2.2 Copies of Regulatory Materials. Promptly after the Effective Date (but in all cases within [*] thereafter), SeaGen shall provide to Merck true, correct and complete electronic copies of any and all material Regulatory Documentation (as well as such other Regulatory Documentation reasonably requested by Merck that is necessary or reasonably useful for Merck to perform its Development and Commercialization obligations hereunder) related to the Licensed Product held or generated by or on behalf of SeaGen or its Affiliates (the "Existing Regulatory Materials"), including providing copies of all documents submitted to the applicable Regulatory Authority in connection therewith.

4.2.3 Transition; Transition Leads and Transition Plan. The Parties shall work together and cooperate in good faith, using Commercially Reasonable Efforts, to transition from SeaGen to Merck those Development and Commercialization activities with respect to the Licensed Product to be performed by Merck in accordance with this Agreement as of the Effective



Date and thereafter during the term if any role, task or activity is reassigned in accordance with this Agreement, and each Party shall provide the other Party with assistance as reasonably requested by such other Party in connection with any such transition of the Development and Commercialization of the Licensed Product hereunder. Within thirty (30) days after the Effective Date, each Party shall appoint an employee of it or its Affiliate who shall oversee the transition (each, a "Transition Lead"). The Transition Leads shall endeavor to assure clear and responsive communication between the Parties with respect to the transition, and shall serve as a single point of contact for any matters arising in connection with the transition. Each Party may designate a replacement Transition Lead for such Party in its sole discretion by notice in writing to the other Party. In order to facilitate any such transition, at the request of either Party, the Parties shall work together in good faith and establish a transition plan setting forth transition activities to be undertaken by or on behalf of each Party in order to assist with such transition (a "Transition Plan"). Once established, each Party shall use Commercially Reasonable Efforts to expeditiously perform its activities under the Transition Plan.

ARTICLE 5 DEVELOPMENT

5.1 Development. All Development activities for Licensed Compounds and the Licensed Product (including as a monotherapy as well as for use in any Combination Therapy, including for use in any Proprietary Combination) for use in the Field in the Territory will be performed by the Parties in accordance with this Agreement and the applicable Development Plan. Subject to the terms of this Agreement, each Party shall use Commercially Reasonable Efforts to perform the activities allocated to such Party under the applicable Development Plan. During the Term, neither Party (nor their respective Affiliates) shall undertake any Development activities with respect to any Licensed Compounds or the Licensed Product for use in the Field in the Territory, except to the extent consistent with the applicable Development Plan.

5.2 Development Plans for the Licensed Product.

5.2.1 General. The Development of the Licensed Compounds and the Licensed Product for the Territory shall be conducted pursuant to a comprehensive, Territory-wide development plan approved by the JSC (each, a "Development Plan"). Each Development Plan shall include a Development Budget and shall describe (a) the overall program of Development for the Licensed Compounds and Licensed Product, including non-clinical studies, Clinical Trials, the Regulatory Plan and other elements for obtaining and maintaining Marketing Authorization(s) for the Licensed Compounds and the Licensed Product and fulfilling other regulatory obligations, including post-approval commitments, and associated timelines and priorities, (b) for the key countries in the Territory, timelines for key Regulatory Authority interactions, filing of applications for Marketing Authorizations, and the receipt and maintenance of Marketing Authorizations, (c) subject to Section 4.1.1, the anticipated tasks and responsibilities and resource allocation of each Party for such Development, (d) subject to Section 4.1.1, the Lead Study Party for each such Clinical Trial and a reasonably detailed description of each such Clinical Trial, including the estimated timeline therefor and (e) the allocation of the Development Budget for all such activities. For clarity, the Development Plan may also include activities with respect to the Development of Companion Diagnostics for use in connection with the Licensed Product. Both Parties shall have the right to propose to the JDC, for approval by the JSC, additional Development



activities with respect to Licensed Compounds and the Licensed Product, including expansion of a Development Plan to include any new indication(s) or new formulation(s) for the Licensed Product, or new Combination Therapies (including any Proprietary Combination) or Combination Products, or any other amendment to a Development Plan, but such proposal shall be included, and the Development Plan revised, only if approved by the JSC. In the event of any inconsistency between the Development Plan and this Agreement, the terms of this Agreement shall prevail.

5.2.2 Initial Development Plan. The initial Development Plan (including the initial Development Budget) is attached hereto as Exhibit A (the "Initial Development Plan"). The Initial Development Plan shall be effective from the Effective Date until amended and updated by the JDC, and approved by the JSC, in accordance with this Agreement.

5.2.3 Amendments to Development Plan. On an annual basis, or more often as the Parties may deem appropriate, the JDC shall prepare proposed amendments to the then-current Development Plan, and, subject to this Agreement, the corresponding Development Budget, for approval of the JSC no later than December 1 of each Calendar Year. Such amended Development Plan shall cover the applicable period as set forth therein and shall contain corresponding updates to the Development Budget included therein, which shall appropriately itemize the costs and expenses separately for each Development activity, to the extent practicable. Such updated and amended Development Plan shall reflect any changes, re-prioritization of studies within, reallocation of resources with respect to, or revisions to the then-current Development Plan. In addition, the JDC may prepare amendments to the Development Plan and corresponding allocation of the Development Budget for the JSC's approval from time to time during the Calendar Year in order to reflect changes in such plan and budget, in each case, in accordance with the foregoing. Once approved by the JSC, the amended Development Plan (and Development Budget) shall become effective for the applicable period on the date approved by the JSC (or such other date as the JSC shall specify). Any JSC-approved amended Development Plan (and Development Budget) shall supersede the previous Development Plan (and Development Budget) for the applicable period. Notwithstanding the foregoing, in the event that the JSC does not approve a given amended Development Plan (or Development Budget, as applicable), then the then-current Development Plan (or Development Budget, as applicable) shall continue in effect without modification (i.e., no changes shall be made to the Development Plan (and Development Budget) unless and until agreed to by the JSC) such that only the Development activities set forth in the then-current Development Plan shall continue (in accordance with the then-current Development Budget, as applicable, without any additional budget changes being made).

5.2.4 Additional Development of Next Generation Compounds, Combination Therapies, Combination Products and Companion Diagnostics.

(a) In the event that Merck provides a Licensed Compound Notice pursuant to Section 2.9.2 for SGN-LIV-1-B, SGN-LIV-1-C or any other Next Generation Compound (or, with respect to SGN-LIV-1-C, Merck is deemed to have provided a Licensed Compound Notice pursuant to Section 2.9.2 for SGN-LIV-1-C) such that such Next Generation Compound is included as a "Licensed Compound" hereunder, then the Parties shall be deemed to have agreed to initiate a GLP Tox Study therefor and the JSC will promptly (and in any event within [*] days after SeaGen's receipt of the applicable Licensed Compound Notice), amend the



Development Plan to include GLP Tox Studies for such Licensed Compound. In addition, in the event that Merck provides (or is deemed to have provided) a Licensed Compound Notice pursuant to Section 2.9.2 for SGN-LIV-1-C such that SGN-LIV-1-C is included as a "Licensed Compound" hereunder, then, upon successful completion of such GLP Tox Studies for SGN-LIV-1-C (as determined by the JSC; provided that, with respect to SGN-LIV-1-C, GLP Tox Studies for SGN-LIV-1-C shall have been successfully completed if the JSC determines that the data from the GLP Tox Studies for SGN-LIV-1-C shows that SGN-LIV-1-C has met the "Criteria of Go to Phase I Clinical Evaluation" set forth in part 2 of Schedule 2.9.2), unless otherwise agreed by both Parties, each Party shall be deemed to have agreed to initiate at least one (1) Phase I Clinical Trial for SGN-LIV-1-C (which Phase I Clinical Trial would have as its aim, unless otherwise determined by the JDC, to [*]) and the JSC will promptly (and within [*] days after first presentation of the final results of such successful GLP Tox Studies to the JSC), amend the Development Plan to include at least one (1) Phase I Clinical Trial therefor, the design of and protocol for which Phase I Clinical Trial shall be mutually agreed by the Parties via the JDC in accordance with Section 3.3.2(c) and 3.3.2(d), respectively.

(b) In the event that a Party desires to develop (i) a Licensed Compound or the Licensed Product for any Combination Therapy with, or as a Combination Product with, (A) a product of a Third Party or (B) a Merck Proprietary Product or (C) a SeaGen Proprietary Product (including, in each case ((A), (B) and (C)), marketed products or pipeline products), or (ii) any Companion Diagnostic for a Licensed Compound or the Licensed Product, such Party may propose including such Combination Therapy, Combination Product or Companion Diagnostic in the Development Plan, but such proposal shall be included only if agreed to by the JSC. With respect to any development for use in a Combination Therapy or as a Combination Product with a product of a Third Party or development of a Companion Diagnostic of a Third Party, the Parties, through the JSC, shall discuss and agree upon any agreements to be entered into with the applicable Third Party for use of such Third Party's product in combination or in connection with the Licensed Product; provided that any such agreement with such Third Party shall be subject to the approval of the JSC. With respect to any development for use in a Proprietary Triple Combination Therapy, the Parties shall, in good faith prior to the time Development commences in relation to such Proprietary Triple Combination Therapy, discuss in good faith and mutually agree upon any additional terms or other amendments to this Agreement with respect to the proposed Development and Commercialization of the Licensed Product for use in such Proprietary Triple Combination Therapy [*].

(c) For clarity, in the event that (i) a Next Generation Compound is included as a Licensed Compound pursuant to Section 2.9.2 or an Acquired Competing Product is included as a Licensed Compound pursuant to Section 2.9.3(c), or (ii) a Combination Therapy (including any Proprietary Combination), Combination Product or Companion Diagnostic is approved by the JSC pursuant to Section 5.2.4(b) for inclusion in the Development Plan; then, in each case (i) and (ii), any further Development activities with respect to such Licensed Compound or for such Licensed Product for use in such Combination Therapy or as a Combination Product, or such Companion Diagnostic, as applicable, shall be in accordance with the Development Plan as approved by the JSC and the other terms and conditions of this Agreement.



(d) [*]. The Parties agree (and in the case of Merck, Merck agrees on behalf of Merck and MCI) as follows with respect to [*]: (i) as of the Effective Date, [*]; (ii) in the event that [*] for purposes of this Agreement [*]; and (iii) except as aforesaid in sub-clause (ii)[*] the [*] shall [*].

5.2.5 Development Responsibilities. Subject to the terms and conditions of this Agreement (including Section 10.4), each Party shall use Commercially Reasonable Efforts to conduct the Development of the Licensed Product in accordance with the then-approved Development Plan and shall use Commercially Reasonable Efforts to do so within the corresponding Development Budget allocations. Subject to Section 3.2.4(b)(vi) and Section 8.2, unless otherwise approved by the JSC, neither Party may unilaterally (a) discontinue the Development of the Licensed Product, (b) terminate any Development Plan, or (c) fail to Initiate, or terminate after Initiation, any Clinical Trial set forth in a Development Plan.

5.2.6 Development Costs; Costs in Excess of Development Budget.

(a) Sharing. The Parties shall share Allowable Development Costs as set forth in Section 10.4.

(b) Proprietary Product Costs. For clarity, with respect to any Development of the Licensed Product for use in a Proprietary Combination, except as otherwise set forth in the Development Plan (as approved by the JSC), the Proprietary Product Party shall manufacture and supply such Proprietary Product Party's Proprietary Product for use in such Development (including Clinical Trials of the Licensed Product for use in a Proprietary Combination) and [*]. For clarity, unless otherwise set forth in the Development Plan, such Proprietary Product will be delivered in unpackaged, unlabeled form for use in the Clinical Trials and both (i) the costs of packaging and labeling such Proprietary Product for use in such Clinical Trials, and (ii) the transportation costs to deliver such Proprietary Product to the Clinical Trial sites, shall, in each case (i) and (ii)), be Allowable Development Costs.

(c) Permitted Development Overage. The Party that is responsible for the performance of activities described in the Development Plan shall use Commercially Reasonable Efforts to ensure that the actual costs and expenses for such Development activities for Licensed Compounds and the Licensed Product in a Calendar Year do not exceed [*] percent ([*]%) of the estimated allocated costs and expenses budgeted for such activity for such Calendar Year as set forth in the Development Budget (i.e., the costs and expenses for the performance of a specific activity described in the Development Plan may exceed the estimated allocated costs and expenses therefor as set forth in the Development Budget by up to [*] percent ([*]%) (the "Permitted Development Overage") and such costs and expenses, to the extent such costs and expenses are within the Permitted Development Overage and would otherwise have been included as Allowable Development Costs but for the budget overage, shall be included as Allowable Development Costs). If either Party believes that the actual costs and expenses in relation to a particular Development activity in a Calendar Year will exceed the allocated budget (plus the Permitted Development Overage) for such activity during such Calendar Year as set forth in the Development Budget, such Party may request the JSC to review and approve an amendment to the Development Budget before incurring such excess cost. In the event that the JSC does not approve



an increase in the Development Budget for such activity, the Party performing such Development activity shall be solely responsible for the costs and expenses for Development it incurs which are in excess of the Development Budget (plus the Permitted Development Overage) (and any such excess shall not be Allowable Development Costs hereunder); provided that, to the extent such excess costs and expenses are attributable to reasonable activities performed as a direct result of [*] and in each case of [*] have been [*] but for the [*].

5.2.7 Activities under the Existing CTC. The Parties hereby agree and acknowledge that (a) from and after the Effective Date, all activities that were being conducted by the Parties pursuant to the CTC as of the Effective Date shall thereafter be deemed to be conducted pursuant to this Agreement (including that the clinical trials being conducted by the Parties pursuant to the CTC as of the Effective Date are included in the Initial Development Plan hereunder), and will be subject to the terms and conditions of this Agreement (rather than the CTC) and (b) as of the Effective Date, the CTC shall terminate and be of no further force and effect (provided that, for clarity, the activities conducted under the CTC prior to such termination shall continue to be governed by the applicable provisions of the CTC, including any provisions thereof that survive the termination of the CTC).

5.3 Development Reports; Development Data and Records.

5.3.1 Reports and Data. Each Party shall keep the JDC reasonably informed regarding the progress and results of Development activities for the Licensed Compounds and the Licensed Product performed by such Party, including a quarterly report of results achieved versus the Development Plan. Such reports shall also include all Development Data generated since the last report from any Development activities for a Licensed Compounds or the Licensed Product hereunder, including Clinical Trials. Each Party will promptly respond to the other Party's reasonable questions regarding any such reports, and shall provide updates on Development activities for the Licensed Compounds and the Licensed Product to the other Party from time to time as such other Party may reasonably request. Notwithstanding the foregoing, a Party shall not be required to disclose or otherwise provide to the other Party or the JSC (or any Subcommittee) any Development Data that specifically relates to such Party's Proprietary Product (but not specifically related to the use or method of using the applicable Proprietary Combination).

5.3.2 Use of Development Data. Prior to publication of Development Data in accordance with this Agreement, neither Party shall use the Development Data for any purpose other than (a) to seek Marketing Authorization for the Licensed Product in accordance with this Agreement, (b) to file and prosecute the Joint Program Patents and enforce any resulting patents pursuant to this Agreement, (c) with respect to Merck (provided that Merck may not so use Development Data that is a SeaGen Proprietary Product Program Invention), (i) to file and prosecute the Merck Program Patents and enforce any resulting patents pursuant to this Agreement, (ii) with respect to any Merck Proprietary Product used in a Proprietary Combination, to seek Marketing Authorization for such Merck Proprietary Product, (d) with respect to SeaGen (provided that SeaGen may not so use Development Data that is a Merck Proprietary Product Program Invention), (i) to file and prosecute the SeaGen Program Patents and enforce any resulting patents pursuant to this Agreement, (ii) with respect to any SeaGen Proprietary Product used in a Proprietary Combination, to seek Marketing Authorization for such SeaGen Proprietary Product,



or (e) for internal research purposes (provided that Merck may not so use Development Data that is a SeaGen Proprietary Product Program Invention and SeaGen may not so use Development Data that is a Merck Proprietary Product Program Invention); provided, however, that the foregoing restrictions shall no longer apply to any Development Data that becomes available to the public.

5.3.3 Study Reports. The Lead Study Party (as the sponsor) for a given Clinical Trial for the Licensed Product pursuant to a Development Plan shall provide the other Party with an electronic draft of the final study report for such Clinical Trial as soon as reasonably practicable after completion of the Clinical Trial, for such other Party to provide comments to the Lead Study Party, which comments shall be provided within [*] days of receipt of the draft of such final study report. The Lead Study Party shall consider in good faith such comments and, at either Party's reasonable request, the Parties shall meet in person or via teleconference within ten (10) Business Days after the Lead Study Party's receipt of such comments to discuss such comments in good faith. The Lead Study Party shall provide the other Party with a copy of the final study report for a given study promptly after such final study report is available. In the event that a given Clinical Trial under the Development Plan is for a Proprietary Combination, the Lead Study Party shall not include any statements in the study report relating to the applicable Proprietary Product which have not been approved by the applicable Proprietary Product Party, unless otherwise required by Applicable Law.

5.3.4 Records. Each Party shall maintain (and shall cause its Affiliates and subcontractors performing Development activities with respect to the Licensed Product to maintain) records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved in the performance of the Development of the Licensed Product. Each Party shall have the right, during normal business hours and upon reasonable (and, in any event, not less than thirty (30) days') prior written notice, not more than once per Calendar Year (unless for cause), to inspect all such records of the other Party (which may be redacted for information that is not related to this Agreement, including, (a) with respect to records of Merck and its Affiliates, redactions for information specific to the Merck Proprietary Product and not related to a Merck Proprietary Combination, and (b) with respect to records of SeaGen and its Affiliates, redactions for information specific to the SeaGen Proprietary Product and not related to a SeaGen Proprietary Combination or specific to the SeaGen Linker Technology that is not relevant for the Licensed Product or a Licensed Compound) to the extent reasonably requested for the purposes of this Agreement. Such records and the information disclosed therein shall be maintained in confidence in accordance with Section 9.1.

5.3.5 Data Integrity. Each Party agrees that it shall carry out all Development activities for the Licensed Product and collect and record any data generated therefrom in compliance with Applicable Law and in a manner consistent with the following: (a) data will be generated using sound scientific techniques and processes, (b) data will be accurately recorded in accordance with good scientific practices by persons conducting research hereunder; (c) data will be analyzed appropriately without bias in accordance with good scientific practices, and (d) data and results will be stored securely and in a manner that can be easily retrieved.

5.4 Lead Study Party; Conduct of Clinical Trials.



5.4.1 With respect to a Clinical Trial of Licensed Product to be conducted pursuant to the Development Plan, the Lead Study Party shall prepare and submit to the JDC for review, discussion and approval in accordance with Section 3.3.2(d) the protocol (and any material amendments thereto) for any such Clinical Trial.

5.4.2 The Lead Study Party for a Clinical Trial shall have operational control of all applicable Development activities (provided that such activities are consistent with the Development Plan and this Agreement) and shall act as the sponsor of such Clinical Trial. The Lead Study Party shall be responsible for obtaining all necessary approvals and clearances, including IRB approvals, INDs and other regulatory approvals and customs clearances necessary for the conduct of such Clinical Trials, in each case, in accordance with this Agreement, and the Lead Study Party shall ensure that all such approvals and clearances are obtained prior to initiating performance of the applicable Clinical Trial. The Lead Study Party shall ensure that the Clinical Trial is performed in accordance with the protocol and all Applicable Laws, including cGCPs.

5.4.3 The Lead Study Party shall be responsible for selecting the Clinical Trial sites and clinical trial investigators for the Development activities and entering into clinical trial agreements in connection therewith. The clinical trial agreements shall require the Clinical Trial sites to comply with all Applicable Laws and will contain provisions in accordance with industry standards, including those relating to confidentiality, data and results, intellectual property and publications; provided that, in all cases, such agreement shall require that all Know-How specifically related to the Licensed Product (or any Proprietary Product), including improvements or modifications thereof, shall be assigned to the Lead Study Party (and thereafter subject to further assignment as between the Parties as provided for herein).

5.4.4 The Lead Study Party shall prepare and obtain the patient informed consent forms for the Clinical Trials as part of the Development activities, which shall comply with Applicable Law. The Lead Study Party shall ensure that all patient authorizations and consents in connection with the Clinical Trials permit, in accordance with Applicable Law, sharing of clinical trial data with the other Party in accordance with this Agreement.

5.5 Regulatory and Safety Responsibility for the Licensed Product.

5.5.1 Approval of MAAs and Core Data Sheet.

(a) MAA. The JDC in collaboration with the JMC shall review and approve (1) the contents of each MAA for the Licensed Product in the Collaboration Territory, and (2) the CMC components of any MAA for the Licensed Product in the Territory. If the CMC components of any MAA for the Licensed 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 material changes are made to such components or additional CMC information is required to be submitted together with such components, approval under this Section 5.5.1(a) shall be required.

(b) Core Data Sheet. Merck will lead the preparation and update of the Core Data Sheet for the Licensed Product, in consultation with SeaGen. The initial Core Data Sheet and any changes to the Core Data Sheet shall be agreed between the Parties. In the event



that the Parties cannot agree upon the content of the Core Data Sheet or any changes thereto, either Party may escalate the matter as follows: (i) if such matter relates to safety labelling, either Party (through the Alliance Managers) may elect to formally submit such issue to Merck's [*] (or a person in an equivalent position at Merck) and SeaGen's [*] (or a person in an equivalent position at SeaGen) for resolution; and (ii) for all other such matters, and for any matter not resolved as provided in the foregoing clause (i) within [*] Business Days after formal submission of such matter under the foregoing clause (i) for resolution, either Party may elect to submit such issue to the JSC for final resolution in accordance with Section 3.2.4. The Lead Regulatory Party in the applicable country shall be responsible for creating and updating the local product information for the Licensed Product in the applicable country; provided that the Lead Regulatory Party shall submit such information to the JDC for approval by the JDC if any material deviations are made from the Core Data Sheet. Any changes to the local product information required by Applicable Laws or a Governmental Authority shall be communicated by the applicable Party to the JDC in a timely manner. For purposes of this Agreement, "Core Data Sheet" means a document setting forth information relating to safety, efficacy, indications, dosing, pharmacology, and other information concerning the Licensed Product.

5.5.2 Lead Regulatory Party.

(a) The regulatory strategy for the Licensed Product in the Territory shall be governed by the applicable portion of the Development Plan related to regulatory matters (the "Regulatory Plan"). The Regulatory Plan shall only be amended upon approval by the JSC. The Lead Regulatory Party with respect to a given country in the Territory shall be responsible for, and shall use Commercially Reasonable Efforts to, conduct the activities pursuant to the Regulatory Plan for the applicable Licensed Product in such country, which shall include the Parties' plan for filing MAAs for the applicable Licensed Product in such country, including any supplements and amendments thereto.

(b) The applicable Lead Regulatory Party shall be responsible for taking the lead with all interactions with Regulatory Authorities (meetings, telephone, etc.) in a given country in the Territory and for other regulatory matters related to the Licensed Product in such country in the Territory [*]. To the extent permitted by the applicable Regulatory Authority and Applicable Law, the non-Lead Regulatory Party shall be entitled to have [*] to the [*] with [*] in the [*] for the Licensed Product and (ii) to the extent [*] for the [*] (and in each case, [*]), the Lead Regulatory Party shall provide notice to the other Party sufficiently in advance of any such meeting or interaction unless such advance notice is not possible due to the urgency of the situation, in which case the Lead Regulatory Party shall inform the other Party of the content of such a meeting as soon as reasonably possible after the meeting has taken place).

(c) Subject to Section 5.5.1(b) with respect to the Core Data Sheet, the Lead Regulatory Party for a country shall also be responsible for preparing all Regulatory Documentation for the applicable Licensed Product in such country in the Territory [*]. The non-Lead Regulatory Party shall have the right to review and comment upon (which comments shall be made in a timely manner and shall be considered in good faith by the Lead Regulatory Party) all material Regulatory Documentation for the Licensed Product in the Territory (which material Regulatory Documentation shall be provided by the Lead Regulatory Party to the other Party



reasonably prior to submission thereof). The Lead Regulatory Party shall promptly provide to the non-Lead Regulatory Party a copy of (i) all material correspondence from any Regulatory Authority for the Licensed Product, and (ii) final material Regulatory Documentation submitted to a Regulatory Authority for the Licensed Product after submission thereof. Without limiting the foregoing, if the non-Lead Regulatory Party receives any material correspondence from a Regulatory Authority from a Regulatory Authority for the Licensed Product, it shall promptly provide copies thereof to the other Party.

(d) The Lead Regulatory Party for a country in the Territory shall also be responsible, in accordance with this Agreement, for submitting and thereafter maintaining (including all routine maintenance) all (subject to Section 5.5.3) investigational study applications (including INDs) and all registration dossiers (including MAAs) and all Marketing Authorizations related to the applicable Licensed Product in such country in the Territory (including with respect to Pricing Approvals and health technology assessments for the Licensed Product, as applicable), and all such INDs, MAAs and Marketing Authorizations (including with respect to Pricing Approvals and health technology assessments for the Licensed Product, as applicable) shall be in the name of the Lead Regulatory Party (or its Affiliate or sublicensee, or if required under Applicable Law in a given country, a local Distributor). The Lead Regulatory Party shall not withdraw (and shall cause its Affiliates not to withdraw) any Marketing Authorization for the Licensed Product in the Territory without the prior consent of the JSC.

(e) The Lead Regulatory Party for a country in the Territory shall also be responsible, in accordance with this Agreement, for activities to support the registration of the Licensed Product, including post-marketing surveillance programs, in accordance with the Development Plan.

(f) With respect to Pricing Approvals and health technology assessments for the Licensed Product, the following shall apply to the extent permitted by Applicable Law and the applicable Regulatory Authority:

(i) The Lead Regulatory Party shall seek to obtain Pricing Approvals for the Licensed Product from the applicable Regulatory Authorities, [*]; provided, however, that [*] in the event that the [*] then, before doing so [*] shall [*] and shall [*] with respect thereto, however, [*].

(ii) The Parties hereby agree and acknowledge that the foregoing provisions of this Section 5.5.2 do not give the non-Lead Regulatory Party the right to receive, review and comment on Regulatory Documentation or other correspondence with Regulatory Authorities with respect to, or attend meetings or other interactions with Regulatory Authorities in connection with, [*]; provided, however, that in lieu thereof, (w) the Lead Regulatory Party shall provide to the JCC [*], (x) the Lead Regulatory Party shall provide periodic updates to the JCC on [*], (y) the Lead Regulatory Party [*] shall provide to the non-Lead Regulatory Party's [*], and (z) the Lead Regulatory Party shall provide to the JCC a copy of all final Pricing Approvals (and any amendments thereto) for the Licensed Product promptly following receipt from the applicable Regulatory Authority. Notwithstanding the foregoing provisions of this Section

5.5.2(f)(ii), at least [*] months prior to the launch of the Licensed Product in the Collaboration Territory, [*].

(iii) As set forth in Section 3.5.2(f), upon the Lead Regulatory Party's receipt of Marketing Authorization, [*], for a particular country [*], the JCC shall [*] to the JSC regarding [*]. Upon receipt of such recommendation, the JSC shall, in accordance with Section 3.2.3(h), review, discuss and determine whether to approve, as appropriate, [*].

(g) The Parties shall reasonably cooperate, and shall provide such reasonable assistance as may be reasonably requested by the other Party, in connection with the activities relating to the Licensed Product described in this Section 5.5.2.

5.5.3 Lead Study Party. Notwithstanding Section 5.5.1, if the Lead Study Party for a given Clinical Trial is not the Lead Regulatory Party in a certain country, then such Lead Study Party shall be responsible for regulatory matters in such country with respect to such Clinical Trial, including obtaining and maintaining the IND for such Clinical Trial in its (or its Affiliate's) name; provided that the Parties shall cooperate and coordinate with respect to all communications, filings and meetings with respect to such Clinical Trial as provided in Section 5.5.2; provided, further, that if one Party is the Lead Study Party and the other Party is the Lead Regulatory Party, then, at the Lead Study Party's reasonable request, the Lead Study Party may exercise the rights of reference granted to it under Article 2 to reference the Lead Regulatory Party's existing INDs for the applicable Licensed Product, in connection with the applicable Clinical Trial, and, in any case, the Lead Regulatory Party shall execute the necessary documents and provide necessary information to permit such reference to its Regulatory Documentation.

5.5.4 References to Proprietary Product in Licensed Product Regulatory Documentation and Communications. Notwithstanding Section 5.5.1, 5.5.2 or 5.5.3, the Proprietary Product Party shall have the right to review and approve (and if the other Party is the Lead Regulatory Party or Lead Study Party, as applicable, such other Party shall afford the Proprietary Product Party the right to review and approve) the content of any Regulatory Documentation for the Licensed Product and other regulatory correspondence for the Licensed Product to the extent that, in each case, such content refers to its Proprietary Product. Without limiting the foregoing, with respect to Regulatory Documentation or communications with a Regulatory Authority for the Licensed Product that specifically pertain to a Proprietary Product Party's Proprietary Product (in the event the other Party is the Lead Regulatory Party or Lead Study Party, as applicable), the other Party (as the Lead Regulatory Party or Lead Study Party, as applicable) shall provide to the Proprietary Product Party any comments or other inquiries from a Regulatory Authority it receives that specifically pertain to the Proprietary Product Party's Proprietary Product, and the Proprietary Product Party shall promptly review and respond to such comment or inquiry and such other Party (as the Lead Regulatory Party or Lead Study Party, as applicable) shall forward such response to the Regulatory Authority on the Proprietary Product Party's behalf. The Parties agree to work together in good faith to provide responses in a timely manner such that each Party is able to meet deadlines for submissions to Regulatory Authorities.

5.5.5 Regulatory Documentation for Proprietary Products. The provisions of this Section 5.5.5 shall apply only with respect to submissions, documents and other



correspondence submitted to Regulatory Authorities with respect to a Proprietary Product Party's Proprietary Product for use in a Proprietary Combination (and, for clarity, shall not apply with respect to submissions, documents and other correspondence submitted to Regulatory Authorities for the Licensed Product itself for use in the Proprietary Combination, which shall be governed by the foregoing provisions of this Section 5.5).

(a) Notwithstanding the foregoing provisions of this Section 5.5, the applicable Proprietary Product Party shall be responsible for preparing all submissions, documents and other correspondence submitted to applicable Regulatory Authorities for such Proprietary Product Party's Proprietary Products for use in a Proprietary Combination in the Territory, including INDs, MAAs and Marketing Authorizations (including product labeling and including in connection with pricing/reimbursement approvals and health technology assessments), in each case, for the Proprietary Product, and amendments and supplements thereto (collectively, the "Proprietary Product Regulatory Documentation").

(b) The applicable Proprietary Product Party shall (i) promptly provide to the other Party a copy of those portions of all material correspondence from any Regulatory Authority with respect to Proprietary Product Regulatory Documentation to the extent specifically pertaining to the Licensed Compound or Licensed Product (but excluding pricing/reimbursement approvals and health technology assessments for the Proprietary Product, as applicable), (ii) promptly provide to the other Party a copy of those portions of final material Proprietary Product Regulatory Documentation that specifically pertain to Licensed Compound or Licensed Product after submission thereof (but excluding pricing/reimbursement approvals and health technology assessments for the Proprietary Product, as applicable) and (iii) keep the other Party informed regarding all material regulatory matters that specifically pertain to the Licensed Compound or the Licensed Product for use in the applicable Proprietary Combinations (but excluding pricing/reimbursement-related and health technology assessment-related submissions, communications and approvals, in each case, for the Proprietary Product, as applicable).

(c) For clarity, notwithstanding Section 5.5.2(b), the non-Proprietary Product Party shall not be entitled to have representatives present at meetings or other interactions with Regulatory Authorities for the other Party's Proprietary Products; provided, however, that the Proprietary Product Party shall provide updates to the other Party with respect to such meetings or other material interactions with Regulatory Authorities to the extent specifically pertaining to the Licensed Compound or the Licensed Product (but excluding pricing/reimbursement-related and health technology assessment-related meetings or other interactions, in each case, for the Proprietary Product, as applicable).

(d) Except as expressly set forth in the foregoing provisions of this Section 5.5.5, the non-Proprietary Product Party shall have no right to review or receive any regulatory documentation with respect to any of the Proprietary Product Party's Proprietary Products.

5.5.6 Components of Proprietary Combinations Sold Separately. For the avoidance of doubt, with respect to a Proprietary Combination, the Parties expect and intend for the Licensed Product and the applicable Proprietary Product in such Proprietary Combination to



be priced and sold separately, and, as between the Parties, the applicable Proprietary Product Party shall have the sole right, in its discretion (unless and solely to the extent the applicable Proprietary Combination is a Combination Product hereunder, in which case the Parties will discuss in good faith and mutually agree on how to handle establishing the terms and conditions relating to the sale of such Combination Product), to sell its Proprietary Product and establish any terms and conditions relating to the sale thereof, including the price (including discounts, rebates and other forms of price concessions), which activities with respect to such Proprietary Product shall be deemed to be outside the scope of this Agreement (and, for clarity, the Proprietary Product Party shall not be required to share with the non-Proprietary Product Party any pricing information (including any information with respect to Pricing Approvals and health technology assessments for its Proprietary Product) with respect to such Proprietary Product Party's Proprietary Products).

5.5.7 Safety Reporting.

(a) Within [*] days after the Effective Date, the Parties (or their respective Affiliates) shall initiate negotiations to enter into a pharmacovigilance agreement for the Licensed Product (the "Pharmacovigilance Agreement") for exchanging adverse event and other safety information relating to the Licensed Product worldwide. In the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement, the terms of this Agreement shall prevail and govern, except to the extent such conflicting terms relating directly to the pharmacovigilance responsibilities of the Parties (including the exchange of safety data), in which case the terms of the Pharmacovigilance Agreement shall prevail and govern.

(b) SeaGen (or its Affiliate) shall provide Merck an electronic copy to include [*] for all legacy data of applicable adverse events for the Licensed Product that is within SeaGen's (or its Affiliate's) possession, for inclusion in Merck's safety database for the Licensed Product.

(c) Upon receipt and completion of processing of all legacy data as set forth in the foregoing clause (b), Merck will assume the role of global safety database holder for the Licensed Product. SeaGen may continue to hold a mirror safety database for the Licensed Product.

(d) Each Party hereto agrees to notify the other Party of any information of which such Party becomes aware concerning any adverse events with respect to the Licensed Product. All serious adverse events shall be exchanged as a processed case (on a CIOMS-1 form in English) within [*] calendar days of receipt and all non-serious adverse events shall be exchanged as a processed case (on a CIOMS-1 form in English) within [*] calendar days of receipt. Adverse events with respect to the Licensed Product from Clinical Trials that are drug-related, fatal and life threatening shall be exchanged (on a CIOMS-1 form in English) within [*] calendar days. The Pharmacovigilance Agreement shall ensure that adverse event and other safety information is exchanged according to a schedule that will permit each Party to comply with Applicable Law, including any local regulatory requirements.

(e) It is understood and agreed that these safety reporting requirement provisions are based on the policies and procedures of the Parties and regulatory reporting



requirements. In the event of changes to regulatory requirements for safety reporting, the Parties agree to comply with any such reasonably required revised notification requirements.

5.5.8 Regulatory Agreement. At the request of either Party, the Parties shall negotiate in good faith and enter into a regulatory agreement setting forth additional details with respect to regulatory matters related to Licensed Compound and Licensed Product and any Proprietary Product that is the subject of a Proprietary Combination (the "Regulatory Agreement").

ARTICLE 6 COMMERCIALIZATION

6.1 Commercialization. All Commercialization activities for Licensed Compounds and the Licensed Product for use in the Field in the Territory will be performed by the Parties in accordance with this Agreement and the applicable Commercialization Plan. Subject to the terms of this Agreement, each Party shall use Commercially Reasonable Efforts to perform the activities allocated to such Party under the applicable Commercialization Plan. During the Term, neither Party (nor their respective Affiliates) shall undertake any Commercialization activities with respect to any Licensed Compounds or the Licensed Product for use in the Field in the Territory, except to the extent consistent with the applicable Commercialization Plan and Commercialization Guidelines.

6.2 Commercialization Plan.

6.2.1 Commercialization Plan. The Commercialization of the Licensed Compounds and the Licensed Product for the Territory shall be conducted pursuant to a comprehensive, Territory-wide commercialization plan approved by the JSC (which shall be broken down by region, including, at a minimum, for the SeaGen Territory, Merck Territory and Collaboration Territory) (each, a "Commercialization Plan"); provided that with respect to the SeaGen Territory and the Merck Territory, the Commercialization Plan shall be a higher level plan (with more specific details to be set forth in the applicable Regional Commercialization Sub-Plans as set forth in Section 6.2.4). Each Commercialization Plan shall include (i) a Commercialization Budget (which shall be further broken down by region, including, at a minimum, for the SeaGen Territory, Merck Territory and Collaboration Territory), (ii) the Licensed Product forecast for Commercialization purposes and (iii) a plan for the launch sequence of the Licensed Product in the applicable countries in the Territory. The Commercialization Plan shall (a) subject to Section 4.1.2, allocate Commercialization activities between the Parties in the Collaboration Territory (including the Promotion of the Licensed Product in and the preparation of the Promotional Materials and Other Field-Based Materials for, in each case, the applicable countries or regions in the Collaboration Territory), including an allocation of the Commercialization Budget for such activities, (b) unless otherwise agreed to by the Parties in writing, allocate all Commercialization activities in the SeaGen Territory (including the Promotion of the Licensed Product in and the preparation of the Promotional Materials and Other Field-Based Materials for, in each case, the SeaGen Territory) to SeaGen, and (c) unless otherwise agreed to by the Parties in writing, allocate all Commercialization activities in the Merck Territory (including the Promotion of the Licensed Product in and the preparation of the Promotional Materials and Other Field-Based Materials for, in each case, the Merck Territory) to Merck, but in all cases, the Commercialization Plan shall be



consistent with Sections 6.4, 6.5 and 6.6. For clarity, the Commercialization Plan may also include activities with respect to the Commercialization of a Companion Diagnostic. Both Parties shall have the right to propose to the JCC additional Commercialization activities with respect to the Licensed Product not then part of the applicable Commercialization Plan. In the event of any inconsistency between the Commercialization Plan and this Agreement, the terms of this Agreement shall prevail.

6.2.2 Initial Commercialization Plan. The initial Commercialization Plan (including Commercialization Budget) for the Licensed Product shall be prepared jointly by the Parties and submitted to the JCC for its review (and ultimately submitted to the JSC for its review and approval) at least [*] prior to the anticipated issuance of the first Marketing Authorization by a Regulatory Authority for such Licensed Product (each, an "Initial Commercialization Plan"). The Initial Commercialization Plan for the Licensed Product shall be effective from the date approved by the JSC until amended and updated by the JCC, and approved by the JSC, in accordance with this Agreement. For the avoidance of doubt, no Commercialization of the Licensed Product in the Territory shall occur unless and until the JSC approves the Initial Commercialization Plan with respect thereto.

6.2.3 Amendments to Commercialization Plan. On an annual basis, or more often as the Parties may deem appropriate, the JCC shall prepare proposed amendments to the then-current Commercialization Plan for the Licensed Product and the corresponding Commercialization Budget, for approval of the JSC no later than [*] of each Calendar Year. Such amended Commercialization Plan shall cover the applicable period as set forth therein and shall contain corresponding updates to the Commercialization Budget included therein, which shall appropriately itemize the costs and expenses separately for each Commercialization activity for the applicable Licensed Product, to the extent practicable. Such updated and amended Commercialization Plan shall reflect any changes, reallocation of resources with respect to, or additions to the then-current Commercialization Plan. In addition, the JCC may prepare amendments to the Commercialization Plan and corresponding allocation of the Commercialization Budget for the JSC's approval from time to time during the Calendar Year in order to reflect changes in such plan and budget, in each case, in accordance with the foregoing. Once approved by the JSC, the amended Commercialization Plan (and Commercialization Budget) shall become effective for the applicable period on the date approved by the JSC (or such other date as the JSC shall specify). Any JSC-approved amended Commercialization Plan (and Commercialization Budget) for the Licensed Product shall supersede the previous Commercialization Plan (and Commercialization Budget) for such Licensed Product for the applicable period. Notwithstanding the foregoing, in the event that the JSC does not approve a given amended Commercialization Plan (or Commercialization Budget, as applicable) for the Licensed Product, then the then-current Commercialization Plan and Commercialization Budget (for the preceding Calendar Year) for such Licensed Product, as applicable, shall be deemed to be automatically renewed for the upcoming Calendar Year.

6.2.4 Regional Commercialization Plans. Following the preparation of the Commercialization Plan for a given Calendar Year, no later than [*] of each applicable Calendar Year, (a) SeaGen, for the SeaGen Territory, (b) Merck, for the Merck Territory, and (c) the Parties jointly, for the Collaboration Territory, shall prepare regional commercialization plans with



additional details related to the Commercialization of the applicable Licensed Product in the SeaGen Territory, Merck Territory or Collaboration Territory, as applicable (each, a "Regional Commercialization Sub-Plan"), for submission to and review by the JCC, and approval by the JSC (provided that, with respect to the Regional Commercialization Sub-Plan for the Merck Territory and the SeaGen Territory, such approval by the JSC shall only be for consistency with the overall approved Commercialization Plan for the applicable Calendar Year, but allowing for differences in regional and local factors to be addressed). In all cases, the Party(ies) preparing a given Regional Commercialization Sub-Plan shall ensure that such Regional Commercialization Sub-Plan is consistent with the Commercialization Plan (including Commercialization Budget) for the applicable Calendar Year, and the Party(ies) preparing a given Regional Commercialization Sub-Plan may (but shall not be required to) further break down such Regional Commercialization Sub-Plan on a country-by-country basis. In addition, the Party that prepared the applicable Regional Commercialization Sub-Plan (or either Party for the Regional Commercialization Sub-Plan for the Collaboration Territory) may propose amendments to a given Regional Commercialization Sub-Plan from time to time during the Calendar Year in order to reflect changes in such plan, and shall submit such proposed amendments to the JSC for review and approval (provided that, with respect to the Regional Commercialization Sub-Plan for the Merck Territory and the SeaGen Territory, such approval by the JSC shall only be for consistency with the overall approved Commercialization Plan, but allowing for differences in regional and local factors to be addressed). Once approved by the JSC, the applicable Regional Commercialization Sub-Plan (and any amendments thereto) shall become effective for the applicable period on the date approved by the JSC (or such other date as the JSC shall specify). Any JSC-approved amended Regional Commercialization Sub-Plan for the Licensed Product shall supersede the previous Regional Commercialization Sub-Plan for the applicable region for such Licensed Product for the applicable period. Notwithstanding the foregoing, in the event that the JSC does not approve a Regional Commercialization Sub-Plan for the Licensed Product for a given Calendar Year for a given region, then (a) any portion (if any) of the Regional Commercialization Sub-Plan for such Licensed Product for such Calendar Year for such region that is approved by the JSC shall be deemed to be the Regional Commercialization Sub-Plan for such Licensed Product for such Calendar Year for such region, and (b) if no such portion is so approved, there shall be no Regional Commercialization Sub-Plan for such Licensed Product for such Calendar Year for such region (provided that, for clarity, in each case ((a) and (b)), the overall Commercialization Plan for such Licensed Product for such Calendar Year shall continue to apply with respect to the applicable region). In the event of a conflict between the Commercialization Plan and a given Regional Commercialization Sub-Plan, the Commercialization Plan shall control.

6.2.5 Commercialization Responsibilities. Subject to the terms and conditions of this Agreement (including Section 10.4), each Party shall use Commercially Reasonable Efforts to conduct the Commercialization of the Licensed Product in accordance with the then-approved Commercialization Plan (and the applicable Regional Commercialization Sub-Plan, if applicable) and shall use Commercially Reasonable Efforts to do so within the corresponding Commercialization Budget allocations.

6.2.6 Commercialization Costs; Costs in Excess of the Commercialization Budget.



(a) With respect to Commercialization of the Licensed Product for the Territory, the Parties shall share Allowable Commercialization Costs as set forth in Section 10.4.

(b) The Party that is responsible for the performance of activities described in the Commercialization Plan shall use Commercially Reasonable Efforts to ensure that the actual costs and expenses for such Commercialization activities for the Licensed Product in a Calendar Year do not exceed [*] percent ([*]%) of the estimated allocated costs and expenses budgeted for such activity for such Calendar Year as set forth in the Commercialization Budget (i.e., the costs and expenses for the performance of a specific activity described in the Commercialization Plan may exceed the estimated allocated costs and expenses therefor as set forth in the Commercialization Budget by up to [*] percent ([*]%) (the "Permitted Commercialization Overage") and such costs and expenses, to the extent such costs and expenses are within the Permitted Commercialization Overage and would otherwise have been included as Allowable Commercialization Costs but for the budget overage, shall be included as Allowable Commercialization Costs). If either Party believes that the actual costs and expenses in relation to a particular Commercialization activity in a Calendar Year will exceed the allocated budget (plus the Permitted Commercialization Overage) for such activity during such Calendar Year as set forth in the Commercialization Budget, such Party may request the JSC to review and approve an amendment to the Commercialization Budget before incurring such excess cost. In the event that the JSC does not approve an increase in the Commercialization Budget for such activity, then the Party performing such Commercialization activity shall be solely responsible for the costs and expenses for Commercialization it incurs which are in excess of the Commercialization Budget (plus the Permitted Commercialization Overage) (and any such excess shall not be Allowable Commercialization Costs hereunder); provided that, to the extent such excess costs and expenses are attributable to reasonable activities performed as a direct result of [*] have been [*] for the [*].

6.3 Commercialization Reports. Each Party shall keep the JCC reasonably informed regarding the progress and results of Commercialization activities for the Licensed Product for the Territory performed by such Party, including a [*] report of material activities performed versus the Commercialization Plan (which [*] reports shall be in a form, and include such content, as determined by the JCC). Each Party will promptly respond to the other Party's reasonable questions regarding any such reports, and shall provide updates on Commercialization activities for the Licensed Product to the other Party from time to time as such other Party may reasonably request.

6.4 Lead Distribution Party.

6.4.1 Certain Rights and Responsibilities of Lead Distribution Party. The Lead Distribution Party for the Licensed Product in a given country shall be solely responsible for (a) handling all order processing, invoicing and collection, distribution, returns, inventory and receivables arising from sales to Third Parties (collectively, "Distribution") and (b) for booking of sales of such Licensed Product in such country.

6.4.2 Terms of Sale to Customers. To the extent permitted by Applicable Law, the Lead Distribution Party shall have the right and responsibility for establishing and modifying



the terms and conditions of sale of the Licensed Product to customers in the applicable countries, including any terms and conditions relating to the price at which the Licensed Product will be sold to customers (including discounts, rebates and other forms of price concessions); provided that, in connection therewith, the following shall apply:

(a) subject to Applicable Law, the Lead Distribution Party shall not [*];

(b) in those countries where Regulatory Authorities issue Pricing Approvals for the Licensed Product, such pricing decisions and terms and conditions shall in all cases comply with all applicable Pricing Approvals from the applicable Regulatory Authorities in the country of sale as may be obtained by the Lead Regulatory Party as set forth in Section 5.5.2; and

(c) such pricing decisions and terms and conditions shall, to the extent permitted by Applicable Law, also [*] (but subject in all cases to Section 6.4.2(b) if applicable, which shall control in the event of a conflict); provided, however, that in the event that the [*] then, before doing so, [*] shall [*] and shall [*] with respect thereto, however, [*], but subject in all cases to Section 6.4.2(b).

6.4.3 Distribution Model in the European Collaboration Territory. Given that SeaGen is the Lead Distribution Party and Merck is the Lead Regulatory Party in the European Collaboration Territory, prior to the launch of the Licensed Product in the European Collaboration Territory, the Parties (or their respective Affiliates) shall negotiate in good faith and enter into a distribution agreement for the Licensed Product in the European Collaboration Territory (the "European Collaboration Territory Distribution Agreement") for Merck to appoint SeaGen as the distributor of the Licensed Product in the European Collaboration Territory and to allocate and coordinate certain additional specific rights and responsibilities between the Parties with respect to the Licensed Product with the goal of ensuring that SeaGen can exercise its rights and perform its obligations as the Lead Distribution Party and Merck can exercise its rights and perform its obligations as the Lead Regulatory Party in the European Collaboration Territory.

6.5 Promotional Materials; Other Field-Based Materials.

6.5.1 General. Subject to Sections 6.5.2 and 6.5.3, the Party allocated the applicable task pursuant to the Commercialization Plan for a given country in the Territory, shall be responsible for preparing the Promotional Materials and the Other Field-Based Materials for the applicable Licensed Product (including, for clarity, any such Promotional Materials and Other Field-Based Materials for the Licensed Product for use in any Combination Therapy) in such country. All Promotional Materials shall comply with the Promotional Materials Guidelines, all Other Field-Based Materials shall comply with the Other Field-Based Materials Guidelines, and all Promotional Materials and all Other Field-Based Materials shall also, in each case, be consistent with the Commercialization Guidelines and the Commercialization Plan. The Party that prepares the applicable Promotional Materials or Other Field-Based Materials shall be responsible for ensuring that such Promotional Materials or Other Field-Based Materials comply with Applicable Law.



6.5.2 Materials other than Proprietary Combination Materials.

(a) Subject to Section 6.5.3, with respect to Promotional Materials or Other Field-Based Materials, as applicable, for the Collaboration Territory, the Parties shall reasonably cooperate and coordinate in connection with the preparation of such Promotional Materials and Other Field-Based Materials, as applicable (such Promotional Materials for the Collaboration Territory, the "Joint Promotional Materials" and such Other Field-Based Materials for the Collaboration Territory, the "Joint Other Field-Based Materials"). The Party responsible for preparing Joint Promotional Materials or Joint Other Field-Based Materials, as applicable, shall provide proposed versions of such Joint Promotional Materials or Joint Other Field-Based Materials to the other Party for review and approval, in particular, for compliance with Applicable Law and the Promotional Materials Guidelines or Other Field-Based Materials Guidelines, as applicable. Neither Party shall use any Promotional Materials to Promote the Licensed Product in the Collaboration Territory other than Joint Promotional Materials that have been reviewed and approved by the other Party as aforesaid; provided that for clarity, each Party shall have the right to Promote the Licensed Product to the approved labeling for such Licensed Product in accordance with Applicable Laws. Neither Party shall use any other field based materials [*] to conduct the applicable field-based activities [*] for the Licensed Product in the Collaboration Territory other than Joint Other Field-Based Materials that have been reviewed and approved by the other Party as aforesaid.

(b) Subject to Section 6.5.3, unless otherwise set forth in the Commercialization Plan, SeaGen, with respect to the SeaGen Territory, and Merck, with respect to the Merck Territory, shall be responsible for preparing the local Promotional Materials and local Other Field-Based Materials, as applicable, for the SeaGen Territory and Merck Territory, respectively; provided that, in each case, unless otherwise agreed to by the JCC, such local Promotional Materials and local Other Field-Based Materials shall be based on the Joint Promotional Materials and Joint Other Field-Based Materials with such changes as may be reasonably required to translate such materials into local language and to otherwise comply with local requirements, guidelines and customs in the applicable country (provided that, in all cases, such materials shall comply with the Promotional Materials Guidelines or Other Field-Based Materials Guidelines, as applicable). The Party that prepares the applicable local Promotional Materials or local Other Field-Based Materials shall be responsible for ensuring that such Promotional Materials or Other Field-Based Materials comply with Applicable Law.

6.5.3 Proprietary Combination Materials for use under this Agreement. Notwithstanding the foregoing provisions of this Section 6.5 or any other provision of this Agreement:

(a) With respect to the Promotion and other field-based activities for the Licensed Product for use in a Merck Proprietary Combination to be conducted by the Parties hereunder, Merck shall lead the preparation of the Promotional Materials and Other Field-Based Materials, including preparing all revisions, updates and translations thereof, as applicable, for the Licensed Product for use in a Merck Proprietary Combination (such Promotional Materials, the "Merck Licensed Product Combination Promotional Materials" and such Other Field-Based Materials, the "Merck Licensed Product Combination Other Field-Based Materials")



throughout the Territory, in each case, in consultation with SeaGen. All Merck Licensed Product Combination Promotional Materials and Merck Licensed Product Combination Other Field-Based Materials shall comply with the Promotional Materials Guidelines and Other Field-Based Materials Guidelines, respectively, and, in each case, be consistent with the Commercialization Guidelines and the Commercialization Plan. Merck shall ensure that the Merck Licensed Product Combination Promotional Materials and Merck Licensed Product Combination Other Field-Based Materials comply with Applicable Law. Merck shall provide the proposed versions of such Merck Licensed Product Combination Promotional Materials or Merck Licensed Product Combination Other Field-Based Materials [*] to SeaGen for review and comment, in particular for compliance with Applicable Law and the Promotional Materials Guidelines or Other Field-Based Materials Guidelines, as applicable, and Merck shall [*] by SeaGen. Notwithstanding anything to the contrary contained herein, nothing contained herein shall be deemed to grant to SeaGen (and its Affiliates) any right to promote any Merck Proprietary Product (whether as a standalone product or in combination with any other product); provided that, for clarity, SeaGen shall have the right to Promote the Licensed Product for use in a Merck Proprietary Combination in accordance with this Agreement and the applicable Commercialization Plan.

(b) With respect to the Promotion and other field-based activities for the Licensed Product for use in a SeaGen Proprietary Combination to be conducted by the Parties hereunder, SeaGen shall lead the preparation of the Promotional Materials and Other Field-Based Materials, including preparing all revisions, updates and translations thereof, as applicable, for the Licensed Product for use in a SeaGen Proprietary Combination (such Promotional Materials, the "SeaGen Licensed Product Combination Promotional Materials" and such Other Field-Based Materials, the "SeaGen Licensed Product Combination Other Field-Based Materials") throughout the Territory, in each case, in consultation with Merck. All SeaGen Licensed Product Combination Promotional Materials and SeaGen Licensed Product Combination Other Field-Based Materials shall comply with the Promotional Materials Guidelines and Other Field-Based Materials Guidelines, respectively, and, in each case, be consistent with the Commercialization Guidelines and the Commercialization Plan. SeaGen shall ensure that the SeaGen Licensed Product Combination Promotional Materials and SeaGen Licensed Product Combination Other Field-Based Materials comply with Applicable Law. SeaGen shall provide the proposed versions of such SeaGen Licensed Product Combination Promotional Materials or SeaGen Licensed Product Combination Other Field-Based Materials [*] to Merck for review and comment, in particular for compliance with Applicable Law and the Promotional Materials Guidelines or Other Field-Based Materials Guidelines, as applicable, and SeaGen shall [*] by Merck. Notwithstanding anything to the contrary contained herein, nothing contained herein shall be deemed to grant to Merck (and its Affiliates) any right to promote any SeaGen Proprietary Product (whether as a standalone product or in combination with any other product); provided that, for clarity, Merck shall have the right to Promote the Licensed Product for use in a SeaGen Proprietary Combination in accordance with this Agreement and the applicable Commercialization Plan.

6.5.4 Proprietary Combination Materials for use Outside this Agreement. Notwithstanding the foregoing provisions of this Section 6.5 or any other provision of this Agreement:



(a) With respect to the promotion and other field-based activities for a Merck Proprietary Product for use in a Merck Proprietary Combination to be conducted by or on behalf of Merck outside of this Agreement (i.e., outside of the promotion and other field-based activities for the Licensed Product under this Agreement), [*], for any Merck Proprietary Product for use in a Merck Proprietary Combination, including such materials that refer to the Licensed Product (such Promotional Materials, the “Merck Proprietary Combination Outside Promotional Materials” and such Other Field-Based Materials, the “Merck Proprietary Combination Outside Other Field-Based Materials”) throughout the Territory, and SeaGen shall [*], respectively. Merck shall ensure that the Merck Proprietary Combination Outside Promotional Materials and Merck Proprietary Combination Outside Other Field-Based Materials comply with Applicable Law and shall be responsible for the use thereof. For clarity, the Merck Proprietary Combination Outside Promotional Materials and Merck Proprietary Combination Outside Other Field-Based Materials shall be used by or on behalf of Merck for use in the promotion of the applicable Merck Proprietary Product for use in the Merck Proprietary Combination, and not for the Promotion of the Licensed Product for use in the Merck Proprietary Combination.

(b) With respect to the promotion and other field-based activities for a SeaGen Proprietary Product for use in a SeaGen Proprietary Combination to be conducted by or on behalf of SeaGen outside of this Agreement (i.e., outside of the promotion and other field-based activities for the Licensed Product under this Agreement), SeaGen [*], for any SeaGen Proprietary Product for use in a SeaGen Proprietary Combination, including such materials that refer to the Licensed Product (such Promotional Materials, the “SeaGen Proprietary Combination Outside Promotional Materials” and such Other Field-Based Materials, the “SeaGen Proprietary Combination Outside Other Field-Based Materials”) throughout the Territory, and Merck shall [*], respectively. SeaGen shall ensure that the SeaGen Proprietary Combination Outside Promotional Materials and SeaGen Proprietary Combination Outside Other Field-Based Materials comply with Applicable Law and shall be responsible for the use thereof. For clarity, the SeaGen Proprietary Combination Outside Promotional Materials and SeaGen Proprietary Combination Outside Other Field-Based Materials shall be used by or on behalf of SeaGen for use in the promotion of the applicable SeaGen Proprietary Product for use in the SeaGen Proprietary Combination, and not for the Promotion of the Licensed Product for use in the SeaGen Proprietary Combination.

6.6 Promotion for the Licensed Product.

6.6.1 Inside the Collaboration Territory.

(a) General. Subject to Section 4.1.2, the Parties intend that each Party will have responsibility for approximately [*] (the exact amount to be determined on a commercially reasonable basis) of the Promotion activities for the Licensed Product in each of (i) the US Collaboration Territory and (ii) the European Collaboration Territory, through Co-Promotion of the Licensed Product; provided that a Party shall only be allocated Promotion activities to the extent such Party has reasonable commercial capabilities to perform such Promotion activities. All Promotion activities for the Licensed Product (including for use in



Proprietary Combinations) in the Collaboration Territory shall be consistent with the applicable Commercialization Plan.

(b) Promotion Agreement. The Parties will enter Promotion agreements to coordinate the Promotion activities for the Licensed Product in the countries (or regions) in the Collaboration Territory (each, a "Promotion Agreement"), which shall also include provisions for establishing call plans (and consequences of call shortfalls) and allocating Field Force FTE Costs, as well as agreed target customers or stakeholders on a regional basis. The Parties will use good faith efforts to enter into a Promotion Agreement at least [*] months prior to the anticipated First Commercial Sale of the Licensed Product in the applicable country or region in the Collaboration Territory.

6.6.2 SeaGen Territory. For clarity, as between the Parties, SeaGen (in addition to being the Lead Distribution Party) shall have the sole right to conduct Promotion activities for the Licensed Product in the SeaGen Territory in accordance with this Agreement and the Commercialization Plan.

6.6.3 Merck Territory. For clarity, as between the Parties, Merck (in addition to being the Lead Distribution Party) shall have the sole right to conduct Promotion activities for the Licensed Product in the Merck Territory in accordance with this Agreement and the Commercialization Plan.

6.7 Unsolicited Requests for Medical Information. Each Party will respond to unsolicited requests for information from health care professionals in the Territory with respect to the Licensed Product in a manner consistent with such Party's current business practices and Applicable Law. Notwithstanding the foregoing, unless otherwise set forth in the Commercialization Plan, the Lead Distribution Party in a given country shall develop and approve, in consultation with the other Party, responses relating to the Licensed Product for use by both Parties in addressing these information requests in such country, which responses will be used by the responding Party in responding to such requests unless otherwise required by Applicable Law. Nothing in this Agreement shall prohibit or limit either SeaGen or Merck from responding to unsolicited requests for information with respect to any of their other respective pharmaceutical products in accordance with its customary business practices and Applicable Law.

6.8 Recalls.

6.8.1 Licensed Product.

(a) Each Party shall promptly provide notice to the other Party (a) if it is considering withdrawing or recalling or taking similar action (including any product distribution hold, recall, clinical hold, or market withdrawal; each a "Recall") with respect to the Licensed Product in a country of the Territory or (b) of any newly identified safety issue or safety signal or adverse event related to the Licensed Product or any circumstance arising in such Party's studies of the Licensed Product, for which the Party reasonably believes that an action warranting the Licensed Product Recall may be required to protect public health. Such notice shall be given by telephone and e-mail (which notice shall be provided within [*], unless such Recall involves an adverse event, in which case, such notice shall be provided immediately) and confirmed in writing



promptly thereafter. The Parties shall promptly meet (either in person or by teleconference or videoconference, or by other means as agreed to by the Parties) and discuss in good faith the reason the notifying Party is considering a Recall (including any safety issues or signals), the scope thereof and the process for undertaking such Recall (provided that such discussions do not delay any action required to protect public health) and work to jointly implement a strategy and any actions that may be required to protect public health, with respect to the Licensed Product in one or more countries in the Territory.

(b) If the Parties agree to commence a Recall (whether instituted at the request of a Regulatory Authority or, subject to the remaining provisions of this Section 6.8, voluntarily instituted by either Party), then the Party holding the Marketing Authorization for the applicable Licensed Product in the applicable country shall implement a Recall (the "Recalling Party"). If the Parties are unable to agree as to whether to commence a Recall, then either Party may determine (provided that such determination is made reasonably and in good faith) that a Recall is necessary in which case the Recalling Party shall institute a Recall; provided that, notwithstanding the foregoing, the Party that is not the holder of the Marketing Authorization in the applicable country in the Territory may only unilaterally determine that a Recall is necessary with respect to such Licensed Product in such country in the event that such Party determines, reasonably and in good faith, that (A) such Licensed Product in such country is not in compliance with cGMPs, Applicable Law or applicable specifications or is adulterated or misbranded within the meaning of the Act or any similar Applicable Law of any applicable jurisdiction or (B) there is a Safety Issue with respect to such Licensed Product in such country, in which case the Party holding the Marketing Authorization for the applicable Licensed Product in such country shall institute a Recall (and shall be the Recalling Party) and the other Party shall provide reasonable assistance in connection therewith; provided that, for clarity, the Party that does not hold the Marketing Authorization for the applicable Licensed Product in the applicable country shall have no right by itself to institute any Recall with respect to the Licensed Product in such country (other than to cause the Party holding the Marketing Authorization to institute the Recall in accordance with this Section 6.8). The other Party shall fully cooperate with the Recalling Party and comply with the Recalling Party's reasonable instructions for assistance in carrying out the Recall, and if the Recalling Party is not the Lead Distribution Party, then, at the request of the Recalling Party and to the extent permitted pursuant to Applicable Law, the Lead Distribution Party shall implement the Recall that was instituted by the Recalling Party. The costs and expenses of implementing any Recall shall be shared by the Parties equally unless (x) such costs and expenses are subject to an indemnification obligation by one Party to the other Party under this Agreement (in which case, such costs and expenses are addressed pursuant to Section 13.1 or Section 13.2 (but subject to Section 13.3, as applicable)) or (y) such costs and expenses are allocated to a Party pursuant to the terms set forth in Schedule 6.8.

6.8.2 Proprietary Product. For clarity, (a) Merck shall have the sole right, in its discretion and at its own expense, to handle any and all Recalls of Merck Proprietary Product, and nothing contained herein is granting SeaGen any rights in connection therewith; and (b) SeaGen shall have the sole right, in its discretion and at its own expense, to handle any and all Recalls of SeaGen Proprietary Product, and nothing contained herein is granting Merck any rights in connection therewith.



ARTICLE 7 MANUFACTURE

7.1 Manufacture Generally.

7.1.1 Licensed Compounds and the Licensed Product. All Manufacture and supply of Licensed Compounds and Licensed Product shall be conducted pursuant to a comprehensive, Territory-wide manufacturing plan (the "Manufacturing Plan") that sets forth (i) activities for the scale-up and manufacturing process validation for Licensed Compounds and the Licensed Product, including the timeline therefor, as well as risk management and other related activities, (ii) all significant work necessary to establish Manufacturing capacity for the Development and Commercialization of Licensed Compounds and Licensed Product, including capital expenditures in relation to the Manufacture of Licensed Compounds or the Licensed Product (provided that, for clarity, any such capital expenditures which also benefit other products in addition to the Licensed Compounds and the Licensed Product will be allocated among the Licensed Compounds and Licensed Products, on the one hand, and such other products on the other hand, as agreed to by the Parties in good faith), (iii) any Third Party contract manufacturers to be utilized to Manufacture Licensed Compounds or the Licensed Product, (iv) the anticipated tasks and responsibilities and resource allocation of the Parties for the Manufacture of Licensed Compounds and the Licensed Product for Development and Commercialization, (v) matters related to safety stock, back-up manufacturers and other back-up plans for Manufacturing Licensed Compounds and the Licensed Product, (vi) the quantity of, and schedule for delivery for, clinical supplies of the Licensed Product necessary to conduct all Clinical Trials (which shall be consistent with the Development Plan), (vii) a unit forecast for Licensed Compounds and the Licensed Product to be Manufactured in the following Calendar Year on behalf of the Lead Manufacturing Party for Commercialization purposes and (viii) a non-binding estimate of the Cost of Goods Manufactured on a unit basis for the Licensed Product for the following Calendar Year (clauses (vi), (vii) and (viii), collectively referred to herein as "Manufacturing Data").

7.1.2 Diligence. Each Party shall use Commercially Reasonable Efforts to conduct (i) the Manufacture of Licensed Compounds and the Licensed Product for Development and Commercialization hereunder to the extent such Manufacture is assigned to such Party in the Manufacturing Plan and (ii) the other activities allocated to such Party under the Manufacturing Plan, and in each case, such Manufacture shall be in accordance with the Manufacturing Plan, this Agreement and the Merck Supply Agreement or SeaGen Supply Agreement, as applicable. During the Term, neither Party (nor their respective Affiliates) shall undertake any Manufacturing activities with respect to any Licensed Compounds or the Licensed Product for use in the Field in the Territory, except to the extent consistent with the applicable Manufacturing Plan.

7.2 Manufacturing Plan for the Licensed Product.

7.2.1 Initial Manufacturing Plan. The initial Manufacturing Plan (including the Manufacturing Data) shall be prepared jointly by the Parties and submitted to the JMC for its review (and ultimately submitted to the JSC for its review and approval), within such time as determined by the JMC (the "Initial Manufacturing Plan"). The Initial Manufacturing Plan shall be effective from the date approved by the JSC until amended and updated by the JMC, and approved by the JSC, in accordance with this Agreement. Subject to Section 3.4.2(d), until the



Initial Manufacturing Plan is approved by the JSC, SeaGen shall, under the direction of the JMC, conduct the Manufacturing activities for Licensed Compound or the Licensed Product in accordance with SeaGen's normal practices during the [*] period immediately prior to the Effective Date, and otherwise in accordance with the terms of this Agreement.

7.2.2 Amendments to Manufacturing Plan. On an [*] basis, or more often as the Parties may deem appropriate, the JMC shall prepare proposed amendments to the then-current Manufacturing Plan (including the Manufacturing Data), for approval of the JSC in accordance with Section 3.2.3(e) no later than [*] of each Calendar Year. Such amended Manufacturing Plan shall cover the applicable period as set forth therein. Such updated and amended Manufacturing Plan shall reflect any changes, re-prioritization of activities within, reallocation of resources with respect to, or additions to, the then-current Manufacturing Plan. In addition, the JMC may prepare amendments to the Manufacturing Plan for the JSC's approval in accordance with Section 3.2.3(e) from time to time during the Calendar Year in order to reflect changes in such plan, in each case, in accordance with the foregoing. Once approved by the JSC (or the JMC, as applicable), the amended Manufacturing Plan (including the amended Manufacturing Data) shall become effective for the applicable period on the date approved by the JSC (or the JMC, as applicable) (or such other date as the JSC (or the JMC, as applicable) shall specify). Any JSC (or JMC, as applicable)-approved amended Manufacturing Plan shall supersede the previous Manufacturing Plan for the applicable period. Notwithstanding the foregoing, in the event that the JSC (or the JMC, as applicable) does not approve any amended Manufacturing Plan (including any amended Manufacturing Data), the then-current Manufacturing Plan shall continue in effect without modification (i.e., no changes shall be made to the Manufacturing Plan unless and until agreed to by the JSC (or the JMC, as applicable)); provided that the Manufacturing Data shall be deemed to be automatically be renewed for the subsequent Calendar Year.

7.2.3 Cost of Goods Manufactured for Licensed Product. The Lead Manufacturing Party shall use Commercially Reasonable Efforts to minimize the Cost of Goods Manufactured for the applicable Licensed Product to the extent reasonably practicable, while ensuring continuous fully-compliant supply to maintain consistency with the forecasts and required inventory and safety stock levels.

7.3 Development Supply for Licensed Product.

7.3.1 Calculation of Cost of Goods Manufactured for Development. Cost of Goods Manufactured for Development activities hereunder shall be equal to the Lead Manufacturing Party's Cost of Goods Manufactured for manufacturing and supplying the Licensed Product.

7.3.2 Supply Agreement for Development Use by Merck. Within [*] days after the Effective Date (or such other time as determined by the JMC), the Parties will enter into a SeaGen Supply Agreement, pursuant to which SeaGen (as the Lead Manufacturing Party for the applicable Licensed Product) will Manufacture and supply such Licensed Product to Merck (or its Affiliate) for any Development to be conducted by or on behalf of Merck (or its Affiliates) pursuant to this Agreement. For clarity, such Licensed Product will be supplied to Merck by SeaGen in [*] vials, and Merck shall be responsible for all [*] and any other specific Manufacturing



responsibilities for the Licensed Product as set forth in and designated to Merck in the Manufacturing Plan.

7.3.3 Supply for Development Use by SeaGen. SeaGen (as the Lead Manufacturing Party) shall perform its Manufacturing obligations with respect to the Licensed Product for use by or on behalf of SeaGen (or its Affiliates) for Development activities hereunder (e.g., if SeaGen is the Lead Study Party), in accordance with this Agreement.

7.3.4 Allocation of Cost of Goods Manufactured for Development. With respect to the Manufacture and supply of Licensed Product for use in the Development activities hereunder, the Cost of Goods Manufactured shall be included in Allowable Development Costs (to the extent included in the Development Budget (plus any Permitted Development Overage)) to the extent such quantities of Licensed Product were in accordance with the Manufacturing Plan. For clarity, if SeaGen is supplying Licensed Product to Merck for use in the Development activities hereunder pursuant to the applicable SeaGen Supply Agreement, there will not be a separate charge for such supply under such agreement (i.e., the quantities of Licensed Product supplied under the applicable SeaGen Supply Agreement shall be supplied under such agreements free of charge).

7.3.5 Efforts. The Lead Manufacturing Party shall use Commercially Reasonable Efforts to Manufacture and supply those quantities of Licensed Product as set forth in the Manufacturing Plan for use in the Development activities hereunder, which Manufacture and supply shall be in accordance with the Manufacturing Plan, this Agreement and the Merck Supply Agreement or SeaGen Supply Agreement, as applicable.

7.4 Commercial Supply for Licensed Product.

7.4.1 Commercial Supply. Subject to the oversight of the JMC as described in Section 3.4, SeaGen or its Affiliates shall Manufacture and supply the commercial requirements for the Licensed Product in fully packaged and labelled, finished form (except as may otherwise set forth in the European Collaboration Territory Distribution Agreement or as otherwise set forth in the Manufacturing Plan) in accordance with the terms hereof (and the SeaGen Supply Agreement contemplated by Section 7.4.2, as applicable) for Commercialization worldwide by each Party; provided that Merck shall be responsible for any specific Manufacturing responsibilities for the Licensed Product as set forth in and designated to Merck in the Manufacturing Plan. For clarity, such Licensed Product shall be labelled in accordance with the labelling specifications provided by Merck for the Merck Territory, provided by SeaGen for the SeaGen Territory and as agreed upon between the Parties for the Collaboration Territory. With respect to the Licensed Product for sale in a given country: (a) in the Merck Territory, Merck shall be responsible for ensuring that such labelling complies with the approved label and Applicable Laws for the applicable country in the Merck Territory; (b) in the SeaGen Territory, SeaGen shall be responsible for ensuring that such labelling complies with the approved label and Applicable Laws for the applicable country in the SeaGen Territory; (c) in the US Collaboration Territory, SeaGen shall be responsible for ensuring that such labelling complies with the approved label and Applicable Laws in the US Collaboration Territory; and (d) in the European Collaboration Territory, each Party shall be responsible for ensuring that such labelling complies with the approved label and Applicable Laws for the applicable country in the European Collaboration



Territory in accordance with the activities assigned to each of the Parties pursuant to this Agreement.

7.4.2 Supply Agreement for Commercial Use by Merck. Prior to the commencement of the [*] for the Licensed Product (or such other time as determined by the JMC), the Parties will enter into a SeaGen Supply Agreement, pursuant to which SeaGen (as the Lead Manufacturing Party for the applicable Licensed Product) will Manufacture and supply such Licensed Product to Merck (or its Affiliate) for any Commercialization to be conducted by or on behalf of Merck (or its Affiliates) pursuant to this Agreement (i.e., if Merck is the Lead Distribution Party in any portion of the Territory (including the Merck Territory)).

7.4.3 Supply for Commercial Use by SeaGen. SeaGen (as the Lead Manufacturing Party) shall perform its Manufacturing obligations with respect to Licensed Product for use by or on behalf of SeaGen (or its Affiliates) for Commercialization activities hereunder (i.e., if SeaGen is the Lead Distribution Party in any portion of the Territory), in accordance with this Agreement.

7.4.4 Second Source for Commercial Supply.

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

(b) Second Source. If at any time the JSC agrees that it is necessary or desirable to establish a second or additional source for the Manufacture (in whole or in part) of the Licensed 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 JMC as described in Section 3.4, then Merck will have the first right and option, exercisable upon written notice to SeaGen within [*] days of the JSC's agreement, to (a) establish contracts and maintain arrangements with Third Parties approved by the JMC (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 Person Manufacturing the Licensed Product (including Merck 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 Merck exercises such option, then (i) if Merck will be supplying any quantities of Licensed Product to SeaGen for Commercialization purposes, then the Parties shall enter into a Merck Supply Agreement to provide for such Manufacturing and the supply of Licensed Product or applicable components from Merck to SeaGen under terms and conditions substantially similar to those applicable for supply from SeaGen to Merck, and (ii) the relevant activities and budget therefor shall be included in the Development Plan. If Merck does not exercise such option within such [*] day period, or if Merck fails to use Commercially Reasonable Efforts to establish such second or additional source Manufacturing within the time period mutually agreed by the Parties in the Development Plan, then SeaGen shall have the right to (A)



establish contracts and maintain arrangements with Third Parties approved by the JMC (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 (x) any such Person Manufacturing the Licensed Product (including SeaGen 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 and (y) SeaGen shall use Commercially Reasonable Efforts to establish such second or additional source Manufacturing within the time period mutually agreed by the Parties in the Development Plan.

(c) Manufacturing Technology Transfer. In the event that Merck at any time elects to establish a second or additional source of Manufacture pursuant to this Section 7.4.4(b), SeaGen and its Affiliates shall provide or cause their Third Party subcontractors to provide all assistance reasonably requested by Merck to conduct a technical transfer of Manufacturing to Merck 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 necessary or reasonably useful to enable Merck 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 JMC.

(d) Contract Volumes; Inventory. If the JSC establishes any second or additional sources of supply of Licensed Product, unless otherwise agreed to by the JMC, the JMC shall continue to allocate sourcing under the Manufacturing Plan, as between the existing sources and any second or additional sources, with the intent to maintain Manufacturing volumes at existing Third Party Manufacturing sites at or above the minimum level necessary to avoid the imposition of penalties (i.e., any “take or pay” or minimum volume requirements for the Manufacture of the Licensed Product) against a Party or its Affiliate(s). In such case, each Party shall provide a report of their respective inventory of Licensed Product (including components thereof) to the JMC on a Calendar Quarterly basis or as otherwise determined by the JMC.

7.4.5 Costs.

(a) Calculation of Commercial Cost of Goods Manufactured. Prior to the start of the Calendar Year in which the First Commercial Sale of the Licensed Product is anticipated to occur, and prior to the start of each Calendar Year thereafter (in each case, no later than [*] of the preceding Calendar Year), the Parties, through the JFC and JMC, shall establish the estimated Cost of Goods Manufactured (per unit) of Licensed Product for the commercial Manufacture of the Licensed Product for the upcoming Calendar Year based on the estimated Cost of Goods Manufactured as calculated pursuant to Schedule 1.39 (the “Estimated COGS”), which Estimated COGS for a given Calendar Year shall thereafter be subject to true-up at the end of the applicable Calendar Year as set forth in the remainder of this Section 7.4.5(a). Within [*] days following the end of a given Calendar Year, the Parties, through the JFC and JMC, shall determine the actual Cost of Goods Manufactured (per unit) for the commercial Manufacture of Licensed Product incurred during such Calendar Year as calculated pursuant to Schedule 1.39 (the “Actual COGS”), and such Actual COGS shall serve as the basis for an [*] reconciliation between Estimated COGS established prior to the start of the Calendar Year and Actual COGS for the



quantities of Licensed Product Manufactured for commercial sale for such Calendar Year, which reconciliation shall be reflected in the calculation of the final payment made between the Parties with respect to such Calendar Year (or the following Calendar Quarter if data necessary to determine such reconciliation is not available in time to reflect in the final payment for such Calendar Year); provided, however, that notwithstanding the foregoing, [*]. A mechanism for the reconciliation process will be agreed to by the JFC. The Parties shall each track their respective inventory of Licensed Product (including components thereof) and their respective Cost of Goods Manufactured, and each Party shall provide a report of such inventory and its Cost of Goods Manufactured for Licensed Product to the JFC and JMC on a [*] basis or as otherwise determined by the JMC.

(b) Allocation of Commercial Cost of Goods Manufactured:

(i) Supply by Lead Manufacturing Party for Commercialization by Lead Manufacturing Party. If the Lead Manufacturing Party for the Licensed Product is also the Lead Distribution Party for such Licensed Product in the applicable portions of the Territory, then, with respect to the Manufacture and supply of such Licensed Product for use in the Commercialization activities hereunder by or on behalf of such Lead Distribution Party (or its respective Affiliates), the Cost of Goods Manufactured (based on the Estimated COGS and reconciliations for the applicable Calendar Year as set forth in Section 7.4.5(a)) shall be included in Allowable Commercialization Costs (even if not included in the Commercialization Budget) to the extent such quantities of Licensed Product were in accordance with the Manufacturing Plan.

(ii) Supply by Lead Manufacturing Party for Commercialization by Other Party. If the Lead Manufacturing Party is supplying Licensed Product to the other Party (for those portions of the Territory where such other Party is the Lead Distribution Party) for use in the Commercialization activities hereunder pursuant to a Merck Supply Agreement or SeaGen Supply Agreement, as applicable, then such Licensed Product shall be supplied to the Lead Distribution Party under such supply agreement at the Cost of Goods Manufactured (based on the Estimated COGS and reconciliations for the applicable Calendar Year as set forth in Section 7.4.5(a)) (and such costs incurred by the Lead Manufacturing Party shall not be separately included in Allowable Commercialization Costs); provided that, for clarity, any such amounts paid by the Lead Distribution Party to the Lead Manufacturing Party under a Merck Supply Agreement or SeaGen Supply Agreement, as applicable, shall be included in Allowable Commercialization Costs (even if not included in the Commercialization Budget) of the Lead Distribution Party.

7.4.6 Efforts. The Lead Manufacturing Party shall use Commercially Reasonable Efforts to Manufacture and supply those quantities of Licensed Product as set forth in the Manufacturing Plan for Commercialization by the Lead Distribution Party in the Territory, which Manufacture and supply shall be in accordance with the Manufacturing Plan, this Agreement and the Merck Supply Agreement or SeaGen Supply Agreement, as applicable. In the event that there is excess market demand in the Territory for commercial supply of the applicable Licensed Product beyond what is set forth in the Manufacturing Plan, then the JMC shall discuss in good faith amendments to such Manufacturing Plan to address such excess demand.



7.5 Continuity of Supply for Licensed Compounds and the Licensed Product. The Lead Manufacturing Party for Licensed Product shall, in coordination with the JMC, establish and put in place reasonable mechanisms to assure continuity of supply of the Licensed Compounds and the Licensed Product, which may include holding safety stock or other mechanisms in each case as specified in the applicable Manufacturing Plan.

7.6 Compliance for Licensed Compounds and the Licensed Product. Without limitation of the terms of any Merck Supply Agreement or SeaGen Supply Agreement, as applicable, the Lead Manufacturing Party shall ensure that all Manufacturing activities with respect to any Licensed Compounds and the Licensed Product for which it is the Lead Manufacturing Party shall be conducted in accordance with cGMPs and Applicable Law as well as in accordance with the specifications for the applicable Licensed Compounds or the Licensed Product, and shall ensure that upon delivery thereof (which shall be defined in accordance with the Merck Supply Agreement or SeaGen Supply Agreement, as applicable, with respect to supply to the other Party, or otherwise shall be when the Licensed Compound or Licensed Product, as applicable, leaves the manufacturing facility) the Licensed Compounds and the Licensed Product are not adulterated or misbranded within the meaning of the Act or any similar Applicable Law of any applicable jurisdiction.

7.7 Audits and Oversight of Manufacturing Facilities for Licensed Compounds and the Licensed Product.

7.7.1 The Lead Manufacturing Party will reasonably cooperate with the non-Lead Manufacturing Party with respect to the oversight of any of the Lead Manufacturing Party's Third Party contract manufacturers involved in the Manufacture of Licensed Compound or Licensed Product to be supplied by or on behalf of the Lead Manufacturing Party (or its Affiliates) for Development or Commercialization activities hereunder, including pursuant to the SeaGen Supply Agreement or Merck Supply Agreement, as applicable, and in connection therewith, (a) the Lead Manufacturing Party shall keep the non-Lead Manufacturing Party fully informed with respect to any compliance issues related to any such Third Party contract manufacturer, (b) at the request of the non-Lead Manufacturing Party, the Lead Manufacturing Party shall meet with the non-Lead Manufacturing Party to discuss any compliance or deficiency issues, and (c) at the request of the non-Lead Manufacturing Party, the Lead Manufacturing Party shall provide to the non-Lead Manufacturing Party information reasonably available to the Lead Manufacturing Party (or any of its Affiliates) in connection with the activities of such Third Party contract manufacturers related to the Manufacture of Licensed Compound or Licensed Product.

7.7.2 The non-Lead Manufacturing Party shall have the right to audit (including quality audits and environmental health and safety (EHS) audits) any facilities involved in the Manufacture of Licensed Compound or Licensed Product, including the facilities of any Third Party contract manufacturer engaged by the Lead Manufacturing Party, but subject to the provisions of Section 7.7.3. Such audit rights shall be exercised at reasonable times and for a reasonable duration; provided that the non-Lead Manufacturing Party shall not audit a given facility more than [*] (unless for cause); provided that, in addition to the foregoing audit rights, with respect to any of SeaGen's Third Party contract manufacturers under any SeaGen Existing CMO Agreements (each, an "Existing SeaGen CMO"), SeaGen shall afford Merck the right to



conduct an initial audit of each such Existing SeaGen CMO, which audit must be requested by Merck within [*] days after the Effective Date. In all cases, SeaGen shall afford Merck the right to initiate such audit within [*] days after Merck's request to conduct such audit. Following any such audit, (a) the non-Lead Manufacturing Party will provide an audit report to the Lead Manufacturing Party, and the Parties shall promptly thereafter meet to discuss the audit findings and observations, (b) within [*] days after such meeting, the Lead Manufacturing Party shall provide to the non-Lead Manufacturing Party a corrective action plan to reasonably address the audit findings and observations for the non-Lead Manufacturing Party's review and approval, and (c) once approved by the non-Lead Manufacturing Party, the Lead Manufacturing Party shall use Commercially Reasonable Efforts to (or use Commercially Reasonable Efforts to cause its Third Party contract manufacturer to, as applicable) implement such corrective action plan to the non-Lead Manufacturing Party's reasonable satisfaction (and, if such corrective action plan is not implemented to the non-Lead Manufacturing Party's reasonable satisfaction with a reasonable period of time, then, unless otherwise determined by the JMC, the Lead Manufacturing Party shall no longer use such source of supply for the Manufacture of Licensed Compounds or the Licensed Product, as applicable). The Parties will work together in good faith to expedite all such audits and the implementation of any applicable corrective action plan. The Merck Supply Agreement or SeaGen Supply Agreement, as applicable, shall contain additional provisions with respect to such audit rights.

7.7.3 Notwithstanding the provisions of Section 7.7.2, with respect to any Existing SeaGen CMO, Merck shall only have the right to perform the audits set forth in Section 7.7.2 to the [*]; provided that, in connection therewith, the following shall apply: [*] and, [*] to the [*] to the [*] and in any event, [*] to the [*].

7.8 Changes to Specifications and Manufacturing Process for Licensed Compound or Licensed Product. Prior to implementing any changes to the specifications or any changes to the manufacturing process that may affect the quality or regulatory filings of any Licensed Compound or the Licensed Product, the Lead Manufacturing Party shall prepare a description and plan for the implementation of any such changes, and shall submit such plan and changes to the JMC for review and approval; provided, however, that the Parties may agree in writing upon an alternate mechanism for Manufacturing change controls that is reasonably acceptable to both Parties with the goal of being timely and efficient. The Lead Manufacturing Party shall not (and shall ensure that its Affiliates and Third Party manufacturers do not) make any such changes unless and until approved by the JMC or as otherwise agreed pursuant to the Merck Supply Agreement or SeaGen Supply Agreement, as applicable, and the Lead Manufacturing Party shall provide to the Lead Regulatory Party all information in its Control that is reasonably necessary for the Lead Regulatory Party to support the review and update of applicable Regulatory Documentation as a result of any such change. The Lead Manufacturing Party shall use Commercially Reasonable Efforts to ensure that, during the Term, the Manufacturing process for any Licensed Compound or Licensed Product, as applicable, will be qualified and validated in accordance with cGMPs.

7.9 Supply Agreements for Supply of Licensed Product. Each SeaGen Supply Agreement and Merck Supply Agreement entered into under this Agreement shall reflect the terms set forth on Schedule 7.9 and such other customary terms and conditions for the supply and quality



of pharmaceutical products in the biopharmaceutical industry in the context of a cost and profit sharing arrangement as reasonably agreed to by the Parties, including with respect to forecasting and ordering, compliance audits, the engagement of subcontractors, a fair and equitable allocation of Licensed Product between the Parties and their Affiliates in the event of Licensed Product shortfalls, and representations and warranties.

7.10 Supply of Proprietary Product for Clinical Trial of Proprietary Combination. In the event that for the Parties agree to conduct a Clinical Trial of the Licensed Product for use in a Proprietary Combination, then the Parties shall negotiate in good faith and enter into a supply agreement pursuant to which the Proprietary Product Party (or its Affiliate) shall supply (or have supplied), at the [*], the applicable Proprietary Product to the other Party for use in each Clinical Trial for which such other Party is the Lead Study Party. For the avoidance of doubt, notwithstanding anything to the contrary contained herein (including the provisions of Section 7.7), nothing contained herein is intended to grant the non-Proprietary Product Party any rights to audit any manufacturing or supply activities with respect to the manufacture or supply of the other Party's Proprietary Products. The Proprietary Product Party shall be solely responsible for the Manufacture and supply of its Proprietary Product for use in such Clinical Trial in accordance with the terms of such supply agreement.

ARTICLE 8 COMPLIANCE

8.1 Compliance with Applicable Law and Ethical Business Practices.

8.1.1 In conducting its activities hereunder and under each Ancillary Agreement, each Party shall (and shall cause its Affiliates, sublicensees and contractors to) comply in all respects with Applicable Law and accepted pharmaceutical industry business practices, including, if and to the extent applicable to such Person or its activities hereunder, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), the Public Health Service Act (42 U.S.C. § 201 et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b), Civil Monetary Penalty Statute (42 U.S.C. § 1320a-7a), the False Claims Act (31 U.S.C. § 3729 et seq.), comparable state statutes, the regulations promulgated under all such statutes, and the regulations issued by the FDA or other applicable Governmental Authority. Each Party shall promptly notify the other Party in writing of any material deviations from Applicable Law with respect to activities under this Agreement.

8.1.2 Each Party hereby certifies that it has not and will not employ or otherwise use in any capacity the services of any person or entity debarred under 21 U.S.C. § 335a (or equivalent foreign provisions) in performing any activities under this Agreement or any Ancillary Agreement. Each Party shall notify the other Party, in writing, immediately if any such debarment occurs or comes to its attention, and shall, with respect to any person or entity so debarred, promptly remove such person or entity from performing any further activities under this Agreement or any Ancillary Agreement, as applicable.

8.1.3 Each Party's corporate policy requires that business must be conducted within the letter and spirit of the Applicable Law. Accordingly, Merck and SeaGen agree to conduct the activities contemplated herein in a manner which is consistent with both Applicable Law and good business ethics.



8.1.4 Each Party acknowledges that no employee of the other Party or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by such Party or its agents to any Third Party in violation of the terms of this or any other provision of this Agreement.

8.1.5 Each Party will:

(a) in connection with its activities under or in connection with this Agreement strictly comply with the OECD Anti-Bribery Convention on combating bribery of foreign public officials in international business transactions, the United States Foreign Corrupt Practices Act of 1977, the United Kingdom Bribery Act 2010 and any other equivalent Applicable Law in the Territory for the prevention of fraud, corruption, racketeering, money laundering and terrorism, in each case as may be amended from time to time (such Applicable Law, the "Anti-Corruption Laws"), including such Party's own internal policies in connection therewith. Each Party shall require any Affiliates, contractors, subcontractors, distributors or other persons or entities that provide services to such Party in connection with this Agreement to comply with such Party's obligations under this Section;

(b) not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a Public Official or any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws; and

(c) no later than [*], or shall provide details of any exception to the foregoing; and maintain records (financial and otherwise) and supporting documentation related to the subject matter of this Agreement in order to document or verify compliance with the provisions of this Section 8.1.5 and upon request of the other Party, up to [*] per year and upon reasonable advance notice, shall provide the other Party or its representative with access to such records for purposes of verifying compliance with the provisions of this Section 8.1.5.

8.1.6 In connection with this Agreement, each Party has implemented and agrees to maintain and enforce a compliance and ethics program designed to prevent and detect violations of Applicable Law, including the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), the Public Health Service Act (42 U.S.C. § 201 et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b), Civil Monetary Penalty Statute (42 U.S.C. § 1320a-7a), the False Claims Act (31 U.S.C. § 3729 et seq.) and anti-corruption Applicable Law, throughout its operations (including subsidiaries) and the operations of its contractors and subcontractors that have responsibility for products, payments or services provided under this Agreement. Merck agrees to comply with Merck's internal code of conduct for such program and SeaGen agrees to comply with SeaGen's internal code of conduct for such program. The Alliance Managers will facilitate discussions and the sharing of information and experiences between the Parties respective compliance and ethics organizations, as part of which SeaGen will provide updates relating to the development of its anti-bribery and corruption compliance program.

8.1.7 In connection with this Agreement, each Party has implemented, and will maintain and enforce, a system of internal accounting controls designed to ensure the making and



keeping of accurate books, records, and accounts with respect to any products, payments or services provided under this Agreement. In connection with this Agreement, each Party has implemented and will at all times during the Term maintain an adequate internal audit program, and will conduct periodic internal audits in each case in accordance with its established policies and procedures to ensure compliance with applicable legal requirements and the terms of this Agreement.

8.1.8 With respect to the activities contemplated under this Agreement:

(a) each Party has been and will, for the Term, be in compliance with all Applicable Law relating to international trade, including economic sanctions, import and export controls and customs procedures; and

(b) neither Party has, on its own behalf or in acting on behalf of any other Person, engaged and will not for the Term engage, directly or indirectly, in any transactions, or otherwise deal with, except to the extent permissible under applicable United States law or other Applicable Law, any country or Person targeted by United States or other relevant economic sanctions Applicable Law, including any Person designated on the Specially Designated Nationals List in connection with any activities related to the services under this Agreement.

8.1.9 Each Party agrees that it will not use (and will cause its Affiliates and Third Party contractors not to use) any Person (including any employee, officer, director or Third Party contractor) who is (or has been) on the Exclusions Lists, or who is (or has been) in Violation, in the performance of any activities hereunder or under any Ancillary Agreement. Each Party certifies to the other Party that, as of the Effective Date, it has screened itself, and its officers and directors (and its Affiliates and Third Party contractors (acting in connection with this Agreement) and their respective officers and directors) against the Exclusions Lists and that it has informed the other Party in writing whether it, or any of its officers or directors (or any of its Affiliates or any of their respective officers and directors) has been in Violation. After the Effective Date, each Party will notify the other Party in writing immediately if any such Violation occurs or comes to its attention.

8.1.10 SeaGen and Merck shall (a) track and collect financial disclosure information from all "clinical investigators" involved in the clinical trials hereunder and (b) prepare and submit the certification or disclosure of the same in accordance with all Applicable Law, including Part 54 of Title 21 of the United States Code of Federal Regulations (Financial Disclosure by Clinical Investigators) and related FDA Guidance Documents. Prior to the initiation of clinical activities hereunder, SeaGen and Merck shall determine, in writing, whether each Party shall track and collect separate certification or disclosure forms for each of Merck and SeaGen or use one (1) "combined" certification or disclosure form for both Merck and SeaGen. For purposes of this Section 8.1.10, the term "clinical investigators" shall have the meaning set forth in Part 54.2(d) of Title 21 of the United States Code of Federal Regulations.

8.1.11 The Lead Study Party (as the sponsor) for a given Clinical Trial hereunder will be responsible for reporting payments and other transfers of value made to health care professionals (e.g., investigators, steering committee members, data monitoring committee members, consultants) in connection with the Clinical Trial in accordance with reporting



requirements under Applicable Law (including the Physician Payment Sunshine Act and state gift Applicable Law, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code) and such Party's applicable policies. The value of the Licensed Product shall be determined by mutual agreement between the Parties in accordance with Applicable Law. The Proprietary Product Party shall provide all information required for such reporting regarding the value of such Proprietary Product Party's Proprietary Products provided for use in Clinical Trials of Proprietary Combinations. With respect to any Clinical Trial of a Proprietary Combination conducted under the Development Plan, if the Proprietary Product Party is not the sponsor of such Clinical Trial, the Proprietary Product Party shall provide the Lead Study the necessary information regarding the value of its Proprietary Products under such Clinical Trial within [*] following approval of the protocol for such Clinical Trial. In the event that, at any time during the Term while such Clinical Trial is ongoing, the value of the applicable Proprietary Product provided for such Clinical Trial hereunder changes, such Proprietary Product Party shall notify the Lead Study Party (that is the sponsor of such Clinical Trial) of such revised value, and the effective date of such revised value, within [*] following such change. Such information shall be provided to the Lead Study Party's point of contact who is identified to the other Party in writing following the Effective Date and thereafter promptly following any change to such point of contact.

8.1.12 The Lead Study Party (as the sponsor) for a given Clinical Trial hereunder shall be responsible for ensuring compliance with the requirements for registering such Clinical Trial and posting results of such Clinical Trial on clinicaltrials.gov, and any applicable foreign equivalent.

8.2 Safety or Legal Issues. Notwithstanding anything to the contrary contained herein, neither Party hereto (nor its Affiliates) shall be required to perform any obligation hereunder to the extent that (a) such Party reasonably believes that the performance of such obligation would be prohibited by, or would otherwise not comply with, Applicable Law or (b) such Party reasonably believes that there is a Safety Issue with respect to the performance of such obligation; provided, however, that the provisions of this Section 8.2 shall not limit a Party's payment obligations under this Agreement. In such case, the Parties shall use reasonable best efforts to replace such obligation with an alternative obligation that would not be prohibited by Applicable Law or would not lead to a Safety Issue, as applicable, insofar as practical, to implement the purposes of this Agreement.

8.3 Data Privacy.

8.3.1 Each Party shall: (i) comply with all Data Protection Laws with respect to the collection, use, transfer, storage, destruction, aggregation or other use of Personal Data (as defined in the applicable Data Protection Laws, collectively, "Personal Data") in connection with its activities under or in connection with this Agreement and the Ancillary Agreements, including the Development and Commercialization of the Licensed Product hereunder; (ii) implement appropriate and reasonable security processes and controls in connection with its activities under or in connection with this Agreement and the Ancillary Agreements so as to protect the security and privacy of Personal Data in accordance with Data Protection Laws, and (iii) take such steps as necessary to comply with Data Protection Laws to permit such Party to disclose Personal Data to



the other Party and to permit the other Party to use and disclose such Personal Data in accordance with this Agreement and the Ancillary Agreements;

8.3.2 The Parties (or their respective Affiliates, as applicable) entered into that certain Data Protection Agreement with an effective date of [*] (the "Existing DPA"). The Parties will amend the Existing DPA to cover the collection, storage, transfer, processing and use of Personal Data by the Parties and their Affiliates under this Agreement as contemplated by this Agreement within [*] of the Effective Date (the Existing DPA, as amended, the "DPA").

ARTICLE 9 CONFIDENTIALITY AND PUBLICATION

9.1 Nondisclosure Obligation. During the Term and for a period of [*] years thereafter, all Confidential Information disclosed by one Party or any of its Affiliates to the other Party or any of its Affiliates hereunder or under an Ancillary Agreement shall be maintained in confidence by the receiving Party and its Affiliates and shall not be (a) disclosed to any Third Party without the prior written consent of the disclosing Party, except as set forth herein, or (b) used for any purpose except as set forth herein (including for the exercise of the rights and licenses granted to such Party hereunder (including the right to use and exercise the Joint Program Know-How and the Joint Program Patents as set forth in Section 12.3.5), but it being understood that this clause (b) shall not create or imply any rights or licenses not expressly granted under this Agreement) without the prior written consent of the disclosing Party. The Parties agree that the terms of this Agreement and the Ancillary Agreements will be treated as Confidential Information of both Parties and may only be disclosed as permitted herein. Notwithstanding the foregoing, the confidentiality and non-use obligations with respect to Confidential Information under this Article 9 shall not apply with respect to any information of the disclosing Party to the extent that:

9.1.1 such information (except for Development Data or Program Know-How) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;

9.1.2 such information is in the public domain by use or publication before its receipt from the disclosing Party, or thereafter enters the public domain through no fault of the receiving Party;

9.1.3 such information is subsequently disclosed to the receiving Party by a Third Party, which Third Party may lawfully make such disclosure and is not under an obligation of confidentiality to the disclosing Party with respect to such information; or

9.1.4 such information (except for Development Data or Program Know-How) is developed by the receiving Party independently of Confidential Information received from the disclosing Party, as documented by the receiving Party's business records.

9.1.5 Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party.



9.2 Permitted Disclosure. Notwithstanding the provisions of Section 9.1, a receiving Party shall be permitted to disclose the Confidential Information of the disclosing Party to the extent such Confidential Information:

9.2.1 is disclosed to Governmental Authorities in order to (a) obtain or maintain Patent Rights in relation to the Licensed Compounds, Licensed Product or Companion Diagnostics in accordance with the terms hereof or (b) obtain or maintain approval to (i) conduct Clinical Trials for the Licensed Product or Companion Diagnostics or (ii) market the Licensed Product or Companion Diagnostics; provided that (in each case ((a) or (b)), such disclosure may be only to the extent reasonably necessary to obtain or maintain such Patent Rights or approval in accordance with the provisions of this Agreement; provided that, to the extent practicable, the disclosing Party shall notify the other Party prior to making such disclosure; provided, further, that this Section 9.2.1 shall not permit (A) SeaGen to disclose any Confidential Information of Merck specific to any Merck Proprietary Product that is not specifically related to a Merck Proprietary Combination; and (B) Merck to disclose any Confidential Information of SeaGen specific to any SeaGen Proprietary Product that is not specifically related to a SeaGen Proprietary Combination;

9.2.2 is deemed necessary by a Party to be disclosed to its Related Parties, agent(s), consultant(s), or other Third Parties for the Development, Manufacture or Commercialization of Licensed Compounds or the Licensed Product for the Territory, or for such Person to determine their interest in performing such activities, in accordance with this Agreement on the condition that such Related Parties, agent(s), consultant(s), or other Third Parties agree to be bound by confidentiality and non-use obligations that are no less stringent than those confidentiality and non-use obligations contained in this Agreement; provided, however, that the term of confidentiality for any Third Party shall be no less than [*] years; provided, further, that this Section 9.2.2 shall not permit the non-Proprietary Product Party to disclose any Confidential Information of the Proprietary Product Party that is specific to such Proprietary Product Party's Proprietary Product but not specifically related to a Proprietary Combination;

9.2.3 with respect to the Proprietary Product Party, is disclosed to governmental or other regulatory agencies in order to (a) obtain or maintain Patent Rights in relation to the Proprietary Party's Propriety Products for use in a Proprietary Combination in accordance with Article 12 or (b) obtain or maintain approval to (i) conduct Clinical Trials for the Proprietary Party's Proprietary Products for use in a Proprietary Combination or (ii) market such Party's Proprietary Products for use in a Proprietary Combination; provided that (in each case (a) and (b)), such disclosure may be only to the extent reasonably necessary to obtain or maintain such Patent Rights or approval;

9.2.4 with respect to each Proprietary Product Party, is deemed necessary by such Proprietary Product Party to be disclosed to its Related Parties, agent(s), consultant(s), or other Third Parties for the development, manufacture or commercialization of such Party's Proprietary Products for use in a Proprietary Combination for the Territory, or for such Person to determine their interest in performing such activities, in accordance with this Agreement on the condition that such Related Parties, agent(s), consultant(s), or other Third Parties agree to be bound by confidentiality and non-use obligations that are no less stringent than those confidentiality and



non-use obligations contained in this Agreement; provided, however, that the term of confidentiality for any Third Party shall be no less than ten (10) years;

9.2.5 with respect to Joint Program Know-How (including Biomarker Joint Program Know-How), is disclosed to (a) Governmental Authorities in order to (i) obtain or maintain Joint Program Patents in accordance with the terms hereof in connection with products and diagnostics (other than the Licensed Product or any Companion Diagnostic) or (ii) obtain or maintain approvals in connection with products and diagnostics (other than the Licensed Product or any Companion Diagnostic); provided that (in each case (i) or (ii)), such disclosure may be only to the extent reasonably necessary to obtain or maintain such Patent Rights or approvals or (b) actual or potential collaborators, licensees, sublicensees or contractors in connection with a Party's exercise of its rights to use the Joint Program Know-How (including Biomarker Joint Program Know-How) as set forth in Section 12.3.5 on the condition that such actual or potential collaborators, licensees, sublicensees or contractors agree to be bound by confidentiality and non-use obligations that are no less stringent than those confidentiality and non-use obligations contained in this Agreement, provided, however, that the term of confidentiality for any Third Party shall be no less than [*] years;

9.2.6 is deemed necessary by a Party to be disclosed to its actual or potential acquirors, investment bankers, investors, lenders, or other similar sources of financing solely for the purpose of evaluating or carrying out an actual or potential investment or acquisition, in each case, on the condition that such Person agrees to be bound by confidentiality and non-use obligations that are no less stringent than those confidentiality and non-use obligations contained in this Agreement; or

9.2.7 is deemed necessary by counsel to the receiving Party to be disclosed to such Party's external attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party, on the condition that such attorneys, independent accountants and financial advisors agree to be bound by confidentiality and non-use obligations that are no less stringent than those confidentiality and non-use provisions contained in this Agreement; provided, however, that the term of confidentiality for such attorneys, independent accountants and financial advisors shall be no less than [*] years.

9.3 Disclosures Required by Applicable Law. If a Party is required by Applicable Law or judicial or administrative process to disclose Confidential Information that is subject to the non-disclosure provisions of Section 9.1, such Party may disclose such Confidential Information as so required; provided that such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide such other Party an opportunity to challenge or limit the disclosure obligations, and, if requested by the other Party, cooperate in all reasonable respects with the other Party's efforts to obtain confidential treatment or a protective order with respect to any such disclosure. Confidential Information that is disclosed as required by Applicable Law or by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of Section 9.1, and the Party so disclosing Confidential Information shall (a) take all steps reasonably necessary, including seeking to obtain an order of confidentiality, to endeavor to ensure the continued confidential treatment of such Confidential Information and (b) disclose such



Confidential Information only to the extent required by such Applicable Law or judicial or administrative process.

9.4 Program Know-How. (a) Joint Program Know-How shall be considered Confidential Information of both Parties (and both Parties shall be deemed a disclosing Party and a receiving Party with respect thereto) for purposes of this Agreement, (b) Merck Program Know-How shall be considered Confidential Information of Merck for purposes of this Agreement and (c) SeaGen Program Know-How shall be considered Confidential Information of SeaGen for purposes of this Agreement.

9.5 Publication. Merck and SeaGen each acknowledge the other Party's interest in publishing the results of the research and development hereunder with respect to Licensed Compounds and the Licensed Product in order to obtain recognition within the scientific community and to advance the state of scientific knowledge. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade-secret information. Consequently, subject to, and except for disclosures permitted pursuant to, Section 9.2 or 9.3, each Party may make such publications or presentations with respect to Licensed Compounds or the Licensed Product only in accordance with the Global Publication Strategy and this Section 9.5. If either Party, its Affiliates, or their respective employee(s) or consultant(s) wishes to make such a publication or presentation related to a Licensed Compound or Licensed Product (including joint Confidential Information), such Party shall deliver to the other Party for such other Party's review an electronic copy of any proposed written publication at least [*] prior to submission for publication, or an electronic copy of any proposed abstract, poster or other presentations at least [*] prior to submission for publication or presentation. The reviewing Party shall have the right (a) to propose modifications to the publication or presentation for patent reasons, trade-secret reasons or business reasons, which comments will be in writing and considered in good faith, or (b) to request a reasonable delay in publication or presentation in order to protect patentable information, including, in the case of Merck, in connection with the proposed publication of SeaGen Product Specific Know-How. If the reviewing Party requests a delay, the publishing Party shall delay submission or presentation for a period of up to [*] to enable the preparation and filing of patent applications protecting each Party's rights in such information to be filed in accordance with Article 12. Upon expiration of such [*], the publishing Party shall be free to proceed with the publication or presentation. If the reviewing Party requests modifications to the publication or presentation in such written proposals, the publishing Party shall edit such publication to delete Confidential Information (other than Development Data) of the reviewing Party that the reviewing Party identifies for deletion in the reviewing Party's written comments prior to submission of the publication or presentation. Notwithstanding the foregoing, (a) the Parties agree that study information and results shall be posted by the applicable Party in accordance with Section 8.1.12, and such study results required to be posted pursuant to this clause (a) will not constitute Confidential Information of either Party, (b) if such publication or presentation involves a Proprietary Product or a Proprietary Combination, then the applicable portion of such publication or presentation related to the Proprietary Product or Proprietary Combination shall be subject to the review and prior written approval of the applicable Proprietary Product Party, such approval not to be unreasonably withheld, conditioned or delayed, and (c) as between the Parties, the Proprietary Product Party shall have the sole right to make any publications or presentations with respect to such Proprietary Product Party's Proprietary Products



in its discretion and without compliance with this Section 9.5 (and the non-Proprietary Product Party shall have no right to do so), provided that, for clarity, with respect to this clause (c), to the extent the content of such publications or presentations relates to the Licensed Product or the use of such Proprietary Product in a Proprietary Combination, then such publications or presentations shall be subject to the provisions of this Section 9.5. Notwithstanding the foregoing provisions of this Section 9.5, with respect to any SeaGen Know-How that is specific to the Licensed Product (to the extent such SeaGen Program Know-How has not been previously publicly presented or published either (i) prior to the Effective Date or (ii) after the Effective Date in compliance with this Agreement), except as required by Applicable Law, SeaGen shall not publicly present or publish such SeaGen Know-How unless such presentation or publication is approved by Merck in writing, such approval not to be unreasonably withheld, conditioned or delayed; provided that, for clarity, the foregoing shall not limit or prevent SeaGen from publishing or presenting SeaGen Know-How that relates to the SeaGen Linker Technology generally or any SeaGen Proprietary Product that has been clinically developed or commercialized. The Parties will agree on a publication plan for Licensed Compounds and the Licensed Product through the JDC.

9.6 Publicity/Use of Names.

9.6.1 The Parties have mutually approved a joint press release attached hereto as Schedule 9.6.1 with respect to this Agreement and either Party may make subsequent public disclosure of the contents of such press release. Except as may be otherwise provided herein, neither Party shall issue any press release or make any public announcement concerning the terms of this Agreement or the transactions described herein without the prior written consent of the other Party; provided that this Section 9.6 shall not preclude any Party from issuing any such press release or making any such public announcement if such Party reasonably believes that any such release or announcement is (a) required by Applicable Law, or (b) required by the rules of any stock exchange on which such Party's (or such Party's Affiliates') securities are listed. To the extent that a Party concludes in good faith that it is or may be required to make such a release or announcement or file or register this Agreement or a notification thereof with any Governmental Authority (including as may be required by the rules of any stock exchange on which such Party's (or such Party's Affiliates') securities are listed) in accordance with the foregoing clause (a) or (b), as applicable, such Party agrees to consult and coordinate with the other Party with respect to such disclosure in accordance with Section 9.3 and, if applicable, the preparation and submission of a confidential treatment request for this Agreement in accordance with the remainder of this Section 9.6.1. Notwithstanding the foregoing, if a Party is required by Applicable Law to submit a description of the terms of this Agreement to or file a copy of this Agreement with any Governmental Authority as aforesaid and such Party has (i) promptly notified the other Party in writing of such requirement and any respective timing constraints, (ii) provided copies of the proposed disclosure or filing to the other Party reasonably in advance of such filing or other disclosure and (iii) given the other Party a reasonable time under the circumstances to comment upon and request confidential treatment for such disclosure, then such Party will have the right to make such disclosure or filing at the time and in the manner reasonably determined by its counsel to be required by Applicable Law or the applicable Governmental Authority. If a Party seeks to make a disclosure or filing as set forth in this Section 9.6.1 and the other Party provides comments within the respective time periods or constraints specified herein, the Party seeking to make such disclosure or filing will reasonably consider such comments and use good faith efforts to



incorporate such comments in the disclosure or filing; provided that prior to making any such filing of this Agreement, the Parties shall reasonably cooperate and use good faith efforts to agree on a redacted form of this Agreement to be so filed.

9.6.2 Except as may be otherwise provided herein, no Party or its Affiliate shall use the Corporate Marks or any other name or Trademark of the other Party, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Law.

ARTICLE 10 PAYMENTS

10.1 Upfront Payment. In consideration of the licenses and other rights granted to Merck herein by SeaGen, subject to the terms and conditions of this Agreement, Merck shall pay to SeaGen, within [*] Business Days following the Effective Date, a one-time, non-refundable and non-creditable upfront payment in the amount of Six Hundred Million Dollars (\$600,000,000).

10.2 Development Milestones.

10.2.1 Development Milestone Payments. In further consideration for the licenses and other rights granted to Merck herein by SeaGen, subject to the terms and conditions of this Agreement (including Section 16.4.2(b)(viii)), Merck will notify SeaGen within [*] Business Days following the first achievement of each milestone event described below in this Section 10.2.1 (each, a "Development Milestone Event") by the Parties under this Agreement after the Effective Date with respect to the first Licensed Product to achieve the applicable Development Milestone Event, and Merck shall thereafter pay the corresponding payment amounts set forth below associated with the applicable Development Milestone Event in accordance with Section 10.2.2 (each, a "Development Milestone Payment"):

Development Milestone Event	Development Milestone Payment (in U.S. Dollars)
1. [*]	[*]
2. [*]	[*]
3. [*]	[*]
4. [*]	[*]
5. [*]	[*]
6. [*]	[*]
7. [*]	[*]

Development Milestone Event	Development Milestone Payment (in U.S. Dollars)
8. [*]	[*]
9. [*]	[*]
10. [*]	[*]
11. [*]	[*]
12. [*]	[*]
13. [*]	[*]
14. [*]	[*]
15. [*]	[*]
16. [*]	[*]
17. [*]	[*]
18. [*]	[*]
19. [*]	[*]
20. [*]	[*]
21. [*]	[*]
22. [*]	[*]

With respect to the Development Milestone Events the following shall apply:

(a) With respect to Development Milestones Events [*], if a given [*], then Development Milestone Event [*] will be deemed achieved as of [*] and the corresponding Development Milestone Payment shall be due and payable by Merck.

(b) if Development Milestone Event [*] is skipped and not paid, but Development Milestone Event [*] is subsequently achieved [*], then upon achievement of Development Milestone Event [*], Development Milestone Event [*] will be deemed achieved and the corresponding Development Milestone Payment shall be due and payable by Merck with the Development Milestone Payment corresponding to Development Milestone Event 3.

(c) if Development Milestone Event [*] is skipped and not paid, but Development Milestone Event [*] is subsequently achieved [*], then upon achievement of

Development Milestone Event [*], Development Milestone Event [*] will be deemed achieved and the corresponding Development Milestone Payment shall be due and payable by Merck with the Development Milestone Payment corresponding to Development Milestone Event [*].

(d) The achievement of Development Milestone Event [*]. If any one of Development Milestone Events [*] shall be payable at [*].

(e) The achievement of Development Milestone Event [*]. If any one of Development Milestone Events [*] shall be payable at [*].

(f) The achievement of Development Milestone Event [*]. If any one of Development Milestone Events [*] shall be payable at [*].

(g) The achievement of Development Milestone Event [*]. If any one of Development Milestone Events [*] shall be payable at [*].

(h) The achievement of Development Milestone Event [*]. If any one of Development Milestone Events [*] shall be payable at [*].

(i) If [*], then the applicable Development Milestones Events [*].

(j) Notwithstanding the foregoing [*].

(k) Each of the foregoing Development Milestone Payments in this Section 10.2.1 shall be payable a maximum of one (1) time, for the first Licensed Product (which, for clarity, need not be the same Licensed Product that achieved any other Development Milestone Event) to achieve the applicable Development Milestone Event as set forth in the foregoing chart regardless of the number of Licensed Products achieving the applicable Development Milestone Event (i.e., a maximum of [*] Development Milestone Payments may be made pursuant to this Section 10.2.1), and no Development Milestone Payment shall be due hereunder for subsequent or repeated achievement of a given Development Milestone Event ([*]). For the avoidance of doubt, the maximum amount payable by Merck pursuant to this Section 10.2.1 is Eight Hundred and Fifty Million Dollars (\$850,000,000), assuming that each of the Development Milestone Events in this Section 10.2.1 were achieved.

10.2.2 Invoice and Payment of Development Milestone Payments. Following delivery of notification by Merck to SeaGen (or if the JDC determines and notifies the Parties via the JSC) that the applicable Development Milestone Event has been achieved by the Parties (including through their respective Affiliates and sublicensees) pursuant to this Agreement, SeaGen shall invoice Merck for the applicable Development Milestone Payment, and Merck shall pay such Development Milestone Payment within [*] days after receipt of the invoice therefor. Each Development Milestone Payment is non-refundable and non-creditable.

10.3 Commercial Milestones.

10.3.1 Commercial Milestones Payments. In further consideration for the licenses and other rights granted to Merck herein by SeaGen, subject to the terms and conditions



of this Agreement, the JFC will notify the Parties within [*] days after the end of the Calendar Quarter during which a given milestone event described below in this Section 10.3.1 (each, a "Commercial Milestone Event" and together with any Development Milestone Event, each, a "Milestone Event") was first achieved by the Parties under this Agreement after the Effective Date with respect to the first Licensed Product to achieve the applicable Commercial Milestone Event, and Merck shall thereafter pay the applicable amounts set forth below associated with the applicable Commercial Milestone Event in accordance with Section 10.3.2 (each, a "Commercial Milestone Payment" and together with any Development Milestone Payment, each, a "Milestone Payment"):

Commercial Milestone Event [*]	Commercial Milestone Payment (in U.S. Dollars)
1. [*]	[*]
2. [*]	[*]
3. [*]	[*]
4. [*]	[*]
5. [*]	[*]
6. [*]	[*]

Each of the foregoing Commercial Milestone Events in this Section 10.3.1 shall be payable a maximum of one (1) time as set forth in the foregoing chart regardless of the number of times the applicable Commercial Milestone Event was achieved (i.e., a maximum of [*] Commercial Milestone Payments may be made pursuant to this Section 10.3.1), and no Commercial Milestone Payment shall be due hereunder for any subsequent or repeated achievement of a given Commercial Milestone Event ([*]). For the avoidance of doubt, the maximum amount payable by Merck pursuant to this Section 10.3.1 is One Billion Seven Hundred Fifty Million Dollars (\$1,750,000,000), assuming that each of the Commercial Milestone Events in this Section 10.3.1 were achieved. For clarity, (a) [*], including for [*], (b) subject to the foregoing sub-clause (a) of [*] shall [*] and (c) if [*], then the [*] for [*] shall be [*].

10.3.2 Invoice and Payment of Commercial Milestone Payments. Following delivery of notification by the JFC to the Parties that the applicable Commercial Milestone Event has been achieved by the Parties pursuant to this Agreement, SeaGen shall invoice Merck for the applicable Commercial Milestone Payment, and Merck shall pay such Commercial Milestone Payment within [*] days after receipt of the invoice therefor. Each Commercial Milestone Payment is non-refundable and non-creditable.

10.4 Sharing of Costs and Revenues for Licensed Compounds and the Licensed Product Generally.

10.4.1 Generally. With respect to Licensed Compounds and the Licensed Product, (a) on a worldwide basis, the Parties shall share all Allowable Development Costs on the basis of fifty percent (50%) to Merck and fifty percent (50%) to SeaGen; (b) on a worldwide basis,



the Parties shall share all Allowable Joint IP Costs on the basis of fifty percent (50%) to Merck and fifty percent (50%) to SeaGen; (c) on a worldwide basis, the Parties shall share all Allowable Commercialization Costs on the basis of fifty percent (50%) to Merck and fifty percent (50%) to SeaGen; and (d) on a worldwide basis, the Parties shall share Licensed Product Net Sales and Sublicensee Revenues, in each case, received pursuant to this Agreement, on the basis of fifty percent (50%) to Merck and fifty percent (50%) to SeaGen, in each case ((a), (b), (c) and (d)), which shall be paid as set forth in Section 10.4.2. Notwithstanding the financial definitions herein, the Parties acknowledge and agree that no cost or expense, and no revenues, shall be included in the Allowable Development Costs, Allowable Commercialization Costs or Allowable Joint IP Costs, or in the calculation of Cost of Goods Manufactured or Licensed Product Net Sales or Sublicensee Revenues, if inclusion therein would result in a duplication or double-counting of the same cost or expense or the same revenue.

10.4.2 Calculation and Payment of Shared Costs and Revenues. During the Term, the following shall apply:

(a) Within [*] days after the end of each Calendar Quarter, each Party shall provide to the other Party and the Financial Managers, in a format to be mutually agreed by the Financial Managers, (i) a detailed, activity-based statement of its (and its Affiliates') Allowable Development Costs and Allowable Joint IP Costs, including an itemized breakdown of the calculation of Development FTE Costs included in the Allowable Development Costs (each, a "Development Cost Report"), and (ii) a detailed, activity-based statement of its (and its Affiliates) Allowable Commercialization Costs (each, a "Commercialization Cost Report" and, together with the corresponding Development Cost Report, the "Cost Reports"), including an itemized breakdown of the calculation of each element of Allowable Commercialization Costs (including Sales and Marketing Expenses, Allowable Promotion FTE Costs, Allowable Field Force FTE Costs, Cost of Goods Manufactured and Third Party Payments), in each case of (i) and (ii), to the extent incurred in such Calendar Quarter (or a good faith estimate of any portions thereof where actuals are not known as of such time). The Costs Reports shall be in a format to be agreed upon by the Financial Managers. To the extent that any such Allowable Development Costs, Allowable Joint IP Costs or Allowable Commercialization Costs reported pursuant to this Section 10.4.2(a), were estimated, the relevant Party shall provide actual cost information with the next Calendar Quarter's quarterly Development Cost Report or Commercialization Cost Report, as applicable, and the provisions of Section 10.4.2(b) shall apply to properly allocate between the Parties any amount by which such actual costs exceeded or were less than the estimated costs. For clarity, Allowable Development Costs, Allowable Joint IP Costs and Allowable Commercialization Costs for each Calendar Quarter may include accruals/estimates, and those accruals/estimates will be trued up to actual costs each Calendar Quarter as part of the cost reporting for the following Calendar Quarter.

(b) Within [*] days after the end of each Calendar Quarter, the Financial Managers shall provide to Merck, SeaGen and the JSC a written report (each, a "Cost Reconciliation Report") setting forth, in a format to be mutually agreed by the Financial Managers, the calculations of (i) the Allowable Development Costs and Allowable Joint IP Costs, and each Party's share of such Allowable Development Costs and Allowable Joint IP Costs, and (ii) the Allowable Commercialization Costs and each Party's share of such Allowable



Commercialization Costs. Such Cost Reconciliation Report shall include for such Calendar Quarter, the (A) total Allowable Development Costs, total Allowable Joint IP Costs and total Allowable Commercialization Costs incurred by each Party, and each Party's respective proportionate share thereof, and (B) the net payment due from one Party to the other Party in accordance with Section 10.4.1. Each Party shall promptly following receipt of each Cost Reconciliation Report issue an invoice to the other Party for any such net payment due to such Party from such other Party in accordance with Section 10.4.1. Any net payment owed from one Party to the other Party shall be paid within [*] days following receipt of such invoice; provided that if a Party disputes an amount provided in such Cost Reconciliation Report, then such disputed amount shall be reviewed by the JSC (provided, however, that in the event that the JSC is unable to resolve the issue, either Party shall have the right to have an independent auditor examine the applicable records in order to resolve such issue pursuant to Section 10.6, which determination shall be binding on the Parties absent manifest error), and any net payment owed with respect to the undisputed amounts shall be paid within such [*] day period (and the disputed amount, if determined to be owed, shall be paid within [*] Business Days of resolution of the dispute). If requested by Merck or SeaGen, any invoices or other supporting documentation for any payments to a Third Party that individually exceed [*] shall be promptly provided.

(c) Within [*] days after the end of each Calendar Quarter, each Party shall provide to the other Party and the Financial Managers, in a format to be mutually agreed by the Financial Managers, (i) a detailed statement of its (and each of its Affiliate's) Licensed Product Net Sales with respect to the applicable Licensed Product for the Territory (including the calculation thereof, including a breakdown of Licensed Product Net Sales (and the calculation thereof)) and (ii) a detailed statement of Sublicensee Revenues for such Calendar Quarter with respect to the applicable Licensed Product for the Territory, as well as details of any adjustments to be made to the amounts submitted in the previous Calendar Quarter in the previous Revenue Report (each, a "Revenue Report"). The Revenue Report shall be in a format to be agreed upon by the Financial Managers.

(d) Within [*] days after the end of each Calendar Quarter, the Financial Managers shall provide to Merck, SeaGen and the JSC a written report (each, a "Revenue Reconciliation Report") setting forth, in a format to be mutually agreed by the Financial Managers prior to the First Commercial Sale of Licensed Product in the Territory, (i) the total Licensed Product Net Sales and Sublicensee Revenues for the applicable Licensed Product for the Territory, the amount of Licensed Product Net Sales and Sublicensee Revenues for the applicable Licensed Product for the Territory recognized by each Party, and each Party's share of such Licensed Product Net Sales and Sublicensee Revenues for the applicable Licensed Product for the Territory, and (ii) the net payment due from one Party to the other Party in accordance with Section 10.4.1. Each Party shall promptly following receipt of each Revenue Reconciliation Report issue an invoice to the other Party for any such net payment due to such Party from such other Party in accordance with Section 10.4.1. Any net payment owed from one Party to the other Party shall be paid within [*] days following receipt of such invoice; provided that if a Party disputes an amount provided in such Revenue Reconciliation Report, then such disputed amount shall be reviewed by the JSC (provided, however, that in the event that the JSC is unable to resolve the issue, then either Party shall have the right to have an independent auditor examine the applicable records in order to resolve such issue pursuant to Section 10.6, which determination



shall be binding on the Parties absent manifest error), and any net payment owed with respect to the undisputed amounts shall be paid within such [*] day period (and the disputed amount, if determined to be owed, shall be paid within [*] Business Days of resolution of the dispute).

(e) For planning purposes, at least [*] days prior to the end of a given Calendar Quarter, each Party shall report to the other Party and the Financial Managers its non-binding estimated Sublicensee Revenues, Allowable Development Costs, Allowable Joint IP Costs, Allowable Commercialization Costs and, with effect from First Commercial Sale, Licensed Product Net Sales, in each case, for the current Calendar Quarter (which shall be based on the estimated actual amounts for the [*] months of such Calendar Quarter and the forecasted amounts for the last month of such Calendar Quarter); provided that, for clarity, the Parties shall not be required to reconcile such estimates with the actual amounts.

(f) All costs and expenses and revenues pursuant to this Section 10.4.2 shall be recorded and reported consistent with such Party's Accounting Standards, consistently applied, and shall be reported in U.S. Dollars (with currency conversions as set forth in Section 10.5).

(g) The Financial Managers may determine to consolidate the Cost Reconciliation Report and Revenue Reconciliation Report in order to result in one net payment by the applicable Party. In addition, if agreed to by the Parties (such agreement not to be unreasonably withheld, conditioned or delayed), the Parties shall have the right to reconcile amounts within the Cost Reconciliation Report and Revenue Reconciliation Report at the local country level, on a case-by-case basis; provided that any such amounts shall not also be counted in Section 10.4.1 in order to avoid duplication.

(h) The Parties acknowledge and agree that the Cost of Goods Manufactured, the Development FTE Rates, Medical Affairs FTE Rates, Promotion FTE Rates and Field Force FTE Rates represent fair market value for the provision of the applicable services for which such amounts are paid and represent arms'-length negotiated amounts. The Development FTE Rates, Medical Affairs FTE Rates, Promotion FTE Rates and Field Force FTE Rates shall be reviewed annually by the Parties and may be adjusted by mutual written agreement of the Parties to the extent the Parties mutually determine that an adjustment is necessary to comply with the arm's-length standard under Applicable Law.

(i) Notwithstanding anything to the contrary set forth herein, (i) when calculating the Parties' Allowable Commercialization Costs, Allowable Development Costs and Allowable Joint IP Costs, any amount of, or in respect of, recoverable VAT incurred by each Party (or its Affiliates) in respect of any item of expenditure or cost that forms a component of such calculations shall be excluded and (ii) when calculating Licensed Product Net Sales and Sublicensee Revenues, any amount of, or in respect of, VAT in respect of any item of revenue that forms a component of such calculations shall be excluded.

(j) Each Party shall consider in good faith other reasonable procedures proposed by the other Party for sharing applicable financial information hereunder in order to permit each Party to close its books periodically in a timely manner.



10.4.3 Costs other than Allowable Costs. For the avoidance of doubt, each Party shall be solely responsible for any costs and expenses (including any payments arising under any agreements between such Party (or its Affiliates) and Third Party licensors, including such payments arising from the grant of rights to, or exercise of rights by, the other Party (or any of its Affiliates or sublicensees) hereunder) incurred by it (or its Affiliate) in connection with the Development, Manufacture or Commercialization of Licensed Compound and Licensed Product, other than such costs and expenses that are included in the Allowable Development Costs, Allowable Joint IP Costs or Allowable Commercialization Cost as set forth in this Agreement (which shall be shared by the Parties as set forth in this Section 10.4).

10.5 Payment Terms.

10.5.1 Currency Exchange; Offset. All payments to be made by a Party under this Agreement shall be made in U.S. Dollars, by wire transfer, pursuant to the instructions of the Party receiving payment, as designated from time to time. To the extent any costs and expenses shared by the Parties hereunder are incurred in a currency other than U.S. Dollars, the applicable expense shall be converted into U.S. Dollars by the incurring Party on a monthly basis using as a rate of exchange the average actual foreign currency exchange rate for the month in which the expense is incurred according to the exchange rates utilized by the applicable Party in its own internal accounting system, consistently applied. Likewise, to the extent Licensed Product is sold in a currency other than U.S. Dollars, the amount received shall be converted into U.S. Dollars on a monthly basis using as a rate of exchange the average actual foreign currency exchange rate for the month in which the sale is made according to the exchange rates utilized by the applicable Party in its own internal accounting system, consistently applied. Unless otherwise agreed to by the Parties, 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.

10.5.2 Late Payments. Any undisputed payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) [*] or (b) the maximum rate permitted by Applicable Laws; in each case calculated on the number of days such payment is delinquent (provided that if the payment is disputed, such interest shall be calculated from the time that the dispute is resolved), compounded monthly.

10.6 Recordkeeping and Audit.

10.6.1 Each Party and its Affiliates shall maintain complete and accurate books and records of account, in accordance with its applicable Accounting Standards, of all transactions and other business activities under this Agreement and the Ancillary Agreements, sufficient to confirm the accuracy of all financial reports furnished by a Party to the other Party under this Agreement or the Ancillary Agreements, as applicable, and all charges or payments by a Party to the other Party under this Agreement or the Ancillary Agreements. For [*] years after the end of the applicable Calendar Year, upon reasonable written notice to a Party, but no more than once per Calendar Year, such Party shall permit an independent certified public accountant of national standing designated by the other Party to audit such books and records of account of such Party in order to confirm the accuracy and completeness of all such reports and all such charges or



payments. The accounting firm shall disclose to the Party requesting the audit only whether the audited reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to the Party requesting the audit.

10.6.2 The Party requesting an audit shall bear all costs and expenses incurred in connection with any such audit; provided, however, that if any such audit identifies any underpayments by the audited Party hereunder or overpayments by the auditing Party hereunder, in each case, that are the fault of the audited Party, in excess of [*] percent ([*]%) of the amount actually payable, or [*] U.S. Dollars (\$[*]), whichever is greater, then, in addition to paying the full amount of such underpayment or overpayment, the audited Party shall reimburse the other Party for all reasonable costs and expenses incurred by such Party in connection with such audit.

10.6.3 Each Party shall be required to maintain books and records for the greater of (a) [*] or (b) for as long as either Party is required by applicable tax law to maintain such books and records. Upon the expiration of [*] following the end of any Calendar Year, the cost sharing and revenue sharing calculations as set forth in Section 10.4 with respect to such Calendar Year shall be binding and conclusive upon both Parties. Unless an audit is ongoing with respect to such period, the Parties shall be released from any liability or accountability with respect to said calculations for such Calendar Year.

10.6.4 The Party requesting an audit shall treat all financial information subject to review under this Section 10.6 in accordance with the confidentiality and non-use provisions of Article 9, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the audited Party obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

10.7 Taxes.

10.7.1 VAT. Any consideration due under this Agreement is exclusive of VAT. If any VAT will be chargeable on any of the transactions contemplated under this Agreement and is payable to the respective tax authority by the Party making the supply or providing the service for VAT purposes, upon receipt of a valid invoice in accordance with the applicable VAT law from the supplying or service providing Party, the other Party shall pay such VAT in addition to the consideration otherwise due.

10.7.2 Withholding Taxes. Any Party (the "Paying Party") required to make a payment pursuant to this Agreement to the other Party (the "Payee") shall be entitled to deduct or withhold from the amount payable the tax for which the Paying Party is liable to deduct or withhold under any provisions of applicable tax law. If the withholding tax is eliminated, or the withholding tax rate is reduced, in each case, according to the provisions of an applicable double tax treaty or regulations applicable thereto, then no deduction or withholding shall be made or a reduced amount shall be deducted or withheld, in each case as applicable, only if the Paying Party is timely furnished with necessary documents or certification to the effect that the payment is exempt from tax or subject to a reduced tax rate or the Payee otherwise satisfies the requirements to obtain the treaty benefit in question. Any withheld tax shall be treated as having been paid by the Paying Party to the Payee for all purposes of this Agreement. The Paying Party shall timely forward to the Payee any tax receipts received by it or reasonably available to it certifying the payments of



withholding tax on behalf of the Payee. In the event such receipts are not available, the Paying Party shall provide the Payee with such proof of payment of such tax as may be reasonably acceptable to the Payee. If the Paying Party failed to deduct or withhold tax required by Applicable Law, the Payee shall indemnify and hold harmless the Paying Party from any such taxes (including any interest, penalties or additions to tax imposed thereto) and further shall assist the Paying Party with regard to all procedures required in order to obtain relief and, if appropriate, reimbursement by tax authorities (including providing proof, if applicable, that the appropriate tax has in fact been paid by the Payee) or, in case tax authorities will not reimburse withholding tax to the Paying Party, the Payee will immediately pay to the Paying Party (for remittance to the appropriate taxing authority to the extent not previously paid to such authorities by the Paying Party) the amount of such tax (including any interest, penalties or additions to tax imposed thereto) not previously paid by the Payee to the appropriate taxing authority.

10.7.3 Tax Cooperation. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, VAT 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 VAT.

ARTICLE 11 REPRESENTATIONS, WARRANTIES AND COVENANTS

11.1 Representations and Warranties of Each Party. Each Party represents and warrants to the other Party, as of the Effective Date (provided that, solely to the extent a representation below in this Section 11.1 relates to an Ancillary Agreement, such representation shall be deemed to be made as of the date the applicable Ancillary Agreement has been duly executed by each Party (or its or their applicable Affiliates)), that:

11.1.1 it is duly organized, validly existing and in good standing in its jurisdiction of organization;

11.1.2 it and its applicable Affiliates have the requisite corporate or other company power and authority to enter into this Agreement and each Ancillary Agreement to which it is a party and to perform its obligations hereunder and thereunder;

11.1.3 this Agreement has been duly executed by it and is legally binding upon it and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

11.1.4 when each Ancillary Agreement has been duly executed by such Party or its applicable Affiliate, such Ancillary Agreement will be legally binding upon it or its applicable Affiliate and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);



11.1.5 the execution and delivery of this Agreement by it and each Ancillary Agreement by it or its applicable Affiliate and the performance by it or its applicable Affiliate of the transactions contemplated hereby and thereby have been duly authorized by all necessary corporate or other company action and do not violate (a) such Party's or its applicable Affiliate's charter documents, bylaws or other organizational documents, (b) any agreement, instrument or contractual obligation to which such Party or its applicable Affiliate is bound, (c) in any material respect, any Applicable Law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party or its applicable Affiliate or (d) any order, writ, judgment, injunction, decree or award of any Governmental Authority presently in effect and applicable to such Party or its Affiliates; and

11.1.6 except for (a) FDA, EMA or other regulatory approvals, licenses, clearances and the like necessary for the development, manufacture, sales or marketing of pharmaceutical products, and (b) any required filing with the U.S. Securities and Exchange Commission (SEC) or equivalent filings with regard to this transaction in other countries, no authorization, consent, approval, exemption of or filing or registration with (i) any court or Governmental Authority under Applicable Law is or shall be necessary for, or in connection with, the entering into of this Agreement, the Ancillary Agreements or the transactions contemplated hereby or thereby, or for the performance by it and its Affiliates of their respective obligations under this Agreement and the Ancillary Agreements, or (ii) any other Person is or shall be necessary for, or in connection with, the entering into of this Agreement, the Ancillary Agreements or the transactions contemplated hereby or thereby.

11.2 Additional SeaGen Representations and Warranties. Except as otherwise set forth on Schedule 11.2 (the "SeaGen Disclosure Schedules"), SeaGen represents and warrants to Merck, as of the Effective Date, that:

11.2.1 SeaGen has the right, power and authority to grant the rights and licenses granted to Merck hereunder, and SeaGen has obtained all necessary consents and fulfilled all necessary conditions, if any, to grant the rights and licenses to Merck hereunder; and the rights and licenses granted (or purported to be granted) to Merck hereunder does not conflict with any agreement between SeaGen (or its Affiliate) and any Third Party.

11.2.2 The Patent Rights listed on Schedule 1.139 are all included within the SeaGen Patents. To SeaGen's knowledge, all SeaGen Patents listed on Schedule 1.139 are valid and enforceable Patent Rights (or in the case of patent applications, applied for). All SeaGen Patents are filed and maintained properly and correctly and all applicable fees have been paid on or before any final due date for payment. SeaGen has complied with all Applicable Laws, including any duties of candor to applicable patent offices, in connection with the filing, prosecution and maintenance of the SeaGen Patents.

11.2.3 SeaGen is the sole and exclusive owner of, or otherwise Controls, the SeaGen Technology. All of the SeaGen Product-Specific Know-How, the SeaGen Linker Product-Specific Know-How, the SeaGen Product-Specific Patents and the SeaGen Linker Product-Specific Patents (collectively, the "SeaGen Product-Specific Technology") that is owned by SeaGen or its Affiliate are free and clear of liens, charges and encumbrances. Schedule 1.139 sets



forth a complete and accurate list of the SeaGen Patents (including all application number and filing dates, registration numbers and dates, jurisdictions and owner(s)). SeaGen (and its Affiliates) do not own or control (through license or otherwise) any (A) Patent Rights other than those Patent Rights included within the SeaGen Patents and set forth on Schedule 1.139 or (B) any Know-How other than the Know-How included within the SeaGen Know-How, in each case of (A) and (B), that is necessary or reasonably useful to Develop, Manufacture or Commercialize the Licensed Compound or Licensed Product (for clarity, in the form the Licensed Compound and the Licensed Product exist as of the Effective Date).

11.2.4 SeaGen has obtained from each inventor of the SeaGen Patents that are listed on Schedule 1.139 and indicated on Schedule 1.139 as being owned by SeaGen or any of its Affiliates agreements that have assigned to SeaGen or its Affiliate each such inventor's entire right, title and interest in and to the applicable SeaGen Patents, and, to SeaGen's Knowledge, each such agreement is valid and enforceable.

11.2.5 Neither SeaGen nor any of its Affiliates has granted any Third Party, and neither SeaGen nor any of its Affiliates is under any obligation to grant any Third Party any right to research, develop, manufacture or commercialize any Licensed Compound, Licensed Product or Competing Product (including any rights or licenses under the SeaGen Technology to research, develop, manufacture or commercialize any Licensed Compound, Licensed Product or any Competing Product), other than (i) the rights granted to SeaGen's Third Party contract manufacturers to manufacture the Licensed Compound, Licensed Product and Next Generation Compounds on behalf of SeaGen and (ii) the rights granted to SeaGen's Third Party contract research organizations to conduct development activities on behalf of SeaGen with respect to the Licensed Compound, Licensed Product and Next Generation Compounds.

11.2.6 Neither SeaGen nor any of its Affiliates is subject to, or bound by, any exclusivity provisions, non-compete provisions or other similar types of provisions or obligations pursuant to any agreement with a Third Party or otherwise that would limit or restrict in any way SeaGen or any of its Affiliates from researching, developing, making, having made, importing, using, selling, offering to sell or otherwise exploiting the Licensed Compound or Licensed Product as set forth herein, or granting the rights to Merck to do so as set forth herein.

11.2.7 To SeaGen's knowledge, the use or other exploitation of the SeaGen Product-Specific Technology, as contemplated under this Agreement, (i) does not and will not infringe any valid, enforceable and unexpired issued Patent Right of any Third Party or misappropriate any Know-How or other intellectual property of any Third Party and (ii) does not and will not infringe the claims of any published Third Party patent application if such claims were validly issued in their current form. To SeaGen's knowledge, the use, Development, Manufacture and Commercialization of the Licensed Compound or Licensed Product, in each case, as contemplated under this Agreement, (a) does not and will not infringe any valid, enforceable and unexpired issued Patent Right of any Third Party or misappropriate any Know-How or other intellectual property of any Third Party and (b) does not and will not infringe the claims of any published Third Party patent application if such claims were validly issued in their current form.



11.2.8 There is no (a) actual claim, litigation, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action, whether civil, criminal, administrative or regulatory, pending, or, to SeaGen's knowledge, threatened in writing by any Third Party against SeaGen or any of its Affiliates or (b) judgment or settlement against or owed by SeaGen or any of its Affiliates, in each case ((a) or (b)), in connection with the SeaGen Technology or Licensed Compound or Licensed Product, including any of the foregoing that is (i) alleging that the issued patents in the SeaGen Patents are invalid or unenforceable, or the patent applications in the SeaGen Patents will, upon issuance, be invalid or unenforceable, (ii) alleging that the conception, development, generation, reduction to practice, disclosing, copying, making, assigning or licensing of the SeaGen Technology or the practice thereof infringes or would infringe any Patent Rights of any Person or misappropriates or would misappropriate any Know-How or other intellectual property right of any Person, or (iii) relating to any design defect, failure to warn or product liability claim or action for the Licensed Compound or Licensed Product. As used in this section, "proceeding" excludes those pertaining to prosecution of Patent Rights (and communications attendant thereto) between SeaGen (or its Affiliate) and the relevant Governmental Authority without participation of a Third Party contestant or challenger.

11.2.9 Schedule 1.134 sets forth a complete and accurate list of all agreements between SeaGen (or its Affiliate) and a Third Party entered into prior to the Effective Date pursuant to which SeaGen (or its Affiliate) Controls any Patent Rights or Know-How included within the SeaGen Patents or SeaGen Know-How (other than (i) agreements with SeaGen's (or its Affiliate's) employees and agreements with independent contractors and service providers entered into in the ordinary course of SeaGen's (or its Affiliate's) business, in each case, pursuant to which such employee, independent contractor or service provider, as applicable, assigns its right, title and interest to such Patent Rights and Know-How to SeaGen (or its Affiliate), and (ii) agreements entered into in the ordinary course of business with service providers under which SeaGen (or its Affiliate) is granted customary licenses to the provider's proprietary technology). SeaGen has provided Merck with true, correct and complete copies of all SeaGen Existing In-Licenses. Neither SeaGen nor its Affiliates are in breach or default under any SeaGen Existing In-License, nor, to SeaGen's knowledge, is any counterparty thereto in breach of any SeaGen Existing In-License, and neither SeaGen nor its Affiliates have received any written notice of breach or default with respect to any SeaGen Existing In-License. The SeaGen Existing In-Licenses are in full force and effect. There are no terms or conditions in any SeaGen Existing In-License (or any other agreement between SeaGen or any of its Affiliates and a Third Party) that (a) would prevent Merck from exercising, or otherwise conflict with, the rights and licenses granted to Merck under this Agreement, including with respect to the prosecution, maintenance, enforcement or defense of any SeaGen Product-Specific Technology, or (b) would require SeaGen or any of its Affiliates to grant any Third Party rights under any Program Know-How or Program Patents.

11.2.10 Except pursuant to the SeaGen Existing In-Licenses set forth on Schedule 1.134, neither SeaGen nor any of its Affiliates are subject to any payment obligations to Third Parties as a result of the execution or delivery of this Agreement, or as a result of the grant or exercise of any of the rights or licenses granted to Merck under this Agreement.

11.2.11 Schedule 1.133 sets forth a complete and accurate list of all agreements between SeaGen (or its Affiliate) and a Third Party entered into prior to the Effective Date and in



force as of the Effective Date pursuant to which SeaGen (or its Affiliate) has engaged a Third Party to Manufacture the Licensed Compound or Licensed Product. SeaGen has provided Merck with true, correct and complete copies of all SeaGen Existing CMO Agreements. Neither SeaGen nor its Affiliates are in breach or default under any SeaGen Existing CMO Agreement, nor, to SeaGen's knowledge, is any counterparty thereto in breach of any SeaGen Existing CMO Agreement, and neither SeaGen nor its Affiliates have received any written notice of breach or default with respect to any SeaGen Existing CMO Agreement. The SeaGen Existing CMO Agreements are in full force and effect.

11.2.12 SeaGen has provided to Merck, prior to the Effective Date, true, correct and complete copies of all material data and information in SeaGen's or any of its Affiliates' control regarding the quality, efficacy or safety of the Licensed Compound or Licensed Product, and all quality, efficacy and safety data and information provided or otherwise made available to Merck (or any of its Affiliates) is true, correct and complete in all material respects. As of the Effective Date, all information, documents and materials provided or otherwise made available in writing by or on behalf of SeaGen to Merck (or any of its Affiliates) on or prior to the Effective Date in contemplation of this Agreement was and is true, correct and complete in all material respects, and such information, documents and materials do not (a) contain any untrue statement of a material fact or (b) omit any fact that would cause the statements or facts or information contained therein, in light of the circumstances under which they were made, to be misleading in any material respect.

11.3 Additional SeaGen Representations and Warranties with Respect to the Licensed Compound and the Licensed Product. Except as otherwise set forth in the SeaGen Disclosure Schedules, SeaGen further represents and warrants to Merck as of the Effective Date, that:

11.3.1 Schedule 11.3.1 sets forth all of the INDs, MAAs and Marketing Authorizations for the Licensed Compound or Licensed Product, as applicable, in the name of, or otherwise held by or on behalf of, SeaGen or any of its Affiliates in the Territory. To SeaGen's knowledge, except as set forth on such Schedule, no other Person has obtained, or filed for, any INDs, MAAs or Marketing Authorizations for the Licensed Compound or Licensed Product in the Territory. Each of the INDs, MAAs and Marketing Authorizations set forth on Schedule 11.3.1 have been approved by the FDA or other applicable Regulatory Authority and, are in full force and good standing, and neither SeaGen nor any of its Affiliates has received any notice in writing, or otherwise has knowledge of any facts, which have, or would reasonably be expected to have, led SeaGen (or its Affiliate) to believe that any of the INDs, MAAs or Marketing Authorizations relating to the Licensed Compound or Licensed Product are not currently in, or may not with the passage of time remain in, good standing with the FDA or other applicable Regulatory Authority.

11.3.2 SeaGen has provided Merck access to all material correspondence between SeaGen (or any of its Affiliates) and the FDA (or other Regulatory Authority) regarding the Licensed Compound or Licensed Product, including (a) reports of inspection observations from any Regulatory Authority related to manufacturing facilities where the Licensed Compound or Licensed Product are being manufactured, (b) establishment inspection reports from any Regulatory Authority, (c) any FDA Form 483s relating to the Licensed Compound or Licensed Product or any equivalent thereto from any Regulatory Authority in any applicable jurisdiction,



(d) safety inquiries from any Regulatory Authority, (e) any input from any Regulatory Authority related to trial approvability, post-approval obligations, and notice of clinical hold, and (f) any notice, warning letter, regulatory letter, Section 305 notice, or any other similar communication to SeaGen or any of the Affiliates stating that their businesses were or are in material violation of any Applicable Law, or were or are the subject of any material pending, threatened or anticipated administrative agency or governmental or regulatory authority investigation, proceeding, review or inquiry; in each case ((a) through (f)), with respect to the Licensed Compound or Licensed Product.

11.3.3 Neither SeaGen nor any of its Affiliates (alone or with any Third Party) is conducting any clinical development of any Licensed Product or Competing Product except for the Ongoing Clinical Trials.

11.3.4 All research, development (including non-clinical studies and clinical studies) and manufacturing activities with respect to the Licensed Compound or the Licensed Product conducted by or on behalf of SeaGen or any of its Affiliates prior to the Effective Date, have been conducted in all material respects in accordance with all Applicable Law and SeaGen (and its Affiliates) has not employed or otherwise used in any capacity the services of any person or entity debarred under 21 U.S.C. § 335a (or foreign equivalent) in performing any such research, development (including non-clinical studies and clinical studies) or manufacturing activities prior to the Effective Date. Neither SeaGen nor any of its Affiliates, nor any of its or their respective directors, officers or employees, nor to SeaGen's knowledge, any of its or its Affiliates' respective agents, have made a knowingly false or fraudulent statement to any Regulatory Authority with respect to the Development of the Licensed Compound or Licensed Product, or knowingly failed to disclose a material fact required under Applicable Law to be disclosed to any Regulatory Authority with respect to the Development of the Licensed Compound or Licensed Product.

11.3.5 No Licensed Product has been recalled, withdrawn, suspended or discontinued (whether voluntarily or otherwise), and no warning letters or similar notices have been issued with respect to the Licensed Product by any Regulatory Authority, and to SeaGen's knowledge no recall, withdrawal, suspension, discontinuance, warning letters or similar notices with respect to any Licensed Product is pending or threatened.

11.3.6 No funding from any government funding source has been used in the Development or Manufacture, in each case, by or on behalf of SeaGen (or any of its Affiliates), of the Licensed Compound or Licensed Product. No Development or Manufacture, in each case, by or on behalf of SeaGen (or any of its Affiliates), of the Licensed Compound or Licensed Product has been conducted under any government contract. No Know-How, Patent Rights or other intellectual property within the SeaGen Product-Specific Technology is a "subject invention" as defined under 48 CFR 27.301 (or foreign equivalent thereof).

11.4 Additional Covenants of SeaGen. At all times during the Term, SeaGen shall comply with the following:

11.4.1 SeaGen will not assign or otherwise transfer ownership of, or any other right title or interest in and to, any SeaGen Technology, except to the extent such assignment or transfer does not conflict with or adversely affect the licenses or other rights granted to Merck hereunder;



11.4.2 SeaGen will not grant to any Third Party any license or other rights to any SeaGen Technology, any Licensed Compound or the Licensed Product, if such license grant or other rights conflicts with the licenses or other rights granted to Merck hereunder; and

11.4.3 With respect to any SeaGen Existing In-License (or, subject to Section 2.5.2 and 2.5.3, any other Third Party In-License Agreement between SeaGen (or its Affiliate) and a Third Party) or SeaGen Existing CMO Agreement (collectively, the "SeaGen Agreements"), (a) SeaGen shall not (and shall cause its Affiliates not to) breach any SeaGen Agreement, and (b) to the extent within SeaGen's (or its Affiliate's) reasonable control, SeaGen shall (and shall cause its Affiliates to, as applicable) maintain the applicable SeaGen Agreement in full force and effect as it may relate to the Licensed Compound or Licensed Product or the SeaGen Technology (as related to the Licensed Compound or Licensed Product). SeaGen shall (and shall cause its Affiliates to, as applicable) enforce its rights under each SeaGen Agreement to the extent necessary to preserve the licenses, options and other rights granted to Merck under this Agreement. SeaGen shall not (and shall cause its Affiliates not to) amend, modify or terminate any SeaGen Existing In-License in a manner that could adversely impact the rights or licenses granted to Merck hereunder, or otherwise impose any additional obligations (including any increased financial obligations) on Merck hereunder, unless SeaGen obtains Merck's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed). SeaGen shall keep Merck fully informed of any material development pertaining to any SeaGen Agreement (as related to the Licensed Compound or Licensed Product), and SeaGen will provide Merck with prompt written notice of any claim of a breach of which it is aware under any SeaGen Agreement or notice of termination of any SeaGen Agreement.

11.5 Additional Covenants of Merck. At all times during the Term, Merck shall comply with the following:

11.5.1 Merck will not assign or otherwise transfer ownership of, or any other right title or interest in and to, any Merck Technology in the Territory, except to the extent such assignment or transfer does not conflict with or adversely affect the rights granted to SeaGen hereunder; or

11.5.2 Merck will not grant to any Third Party any license or other rights to any Merck Technology in the Territory if such license grant or other rights conflicts with the rights granted to SeaGen hereunder.

11.5.3 Subject to Section 2.5.2 and 2.5.3, with respect to any Third Party In-License Agreement between Merck (or its Affiliate) and a Third Party (collectively, the "Merck Agreements"), (a) Merck shall not (and shall cause its Affiliates not to) breach any Merck Agreement, and (b) to the extent within Merck's (or its Affiliate's) reasonable control, Merck shall (and shall cause its Affiliates to, as applicable) maintain the applicable Merck Agreement in full force and effect as it may relate to the Licensed Compound or Licensed Product. Merck shall (and shall cause its Affiliates to, as applicable) to enforce its rights under each Merck Agreement to the extent necessary to preserve the licenses, options and other rights granted to SeaGen under this Agreement. Merck shall not (and shall cause its Affiliates not to) amend, modify or terminate any Merck Existing In-License in a manner that could adversely impact the rights or licenses granted



to SeaGen hereunder, or otherwise impose any additional obligations (including any increased financial obligations) on SeaGen hereunder, unless Merck obtains SeaGen's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed). Merck shall keep SeaGen fully informed of any material development pertaining to any Merck Agreement as related to the Licensed Compound or Licensed Product, and Merck will provide SeaGen with prompt written notice of any claim of a breach of which it is aware under any Merck Agreement or notice of termination of any Merck Agreement.

11.6 Non-Solicitation. During the period commencing on the Effective Date and ending on the [*] year anniversary of the Effective Date, with respect to the other Party's (or its Affiliate's) employees involved with the negotiation or performance of this Agreement or any Ancillary Agreement (each a "Restricted Employee"), each Party (a "Soliciting Party") shall not, and shall cause its Affiliates (and any other Person engaged by such Soliciting Party or its Affiliate to act on its behalf for such purpose) not to, directly or indirectly, hire any Restricted Employee of the other Party (or any of its Affiliates), or take any action to solicit or encourage any such Restricted Employee to terminate his or her employment with the other Party (or any of its Affiliates), or to seek or accept employment or other affiliation with the Soliciting Party (or any of its Affiliates); provided, however, the Soliciting Party and its Affiliates shall not be restricted from (a) hiring or soliciting any such Restricted Employee of the other Party (or its Affiliates) through a general solicitation of employees (including through the use of general advertisement in the mass media, participation in job fairs or website postings) not specifically directed or targeted at any such persons or (b) hiring any such Restricted Employee of the other Party (or its Affiliates) who contacts the Soliciting Party on his or her own initiative without any direct or indirect solicitation from Soliciting Party (or any of its Affiliates).

11.7 Disclaimer. EACH PARTY ACKNOWLEDGES AND AGREES THAT EXCEPT AS SET FORTH IN THIS AGREEMENT (OR ANY ANCILLARY AGREEMENT), INCLUDING THIS ARTICLE 11, MERCK AND SEAGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT ANY RESEARCH, DEVELOPMENT, MANUFACTURING OR COMMERCIALIZATION EFFORTS WITH REGARD TO THE LICENSED COMPOUNDS, LICENSED PRODUCTS OR NEXT GENERATION COMPOUNDS WILL BE SUCCESSFUL.

ARTICLE 12 INTELLECTUAL PROPERTY

12.1 Intellectual Property Operating Committee.

12.1.1 Composition. Within [*] after the Effective Date, the Parties shall establish a committee to facilitate discussion and cooperation between the Parties with respect to intellectual property matters set forth under this Agreement, including the matters contemplated by this Article 12 (the "IPOC"). Each Party shall initially appoint at least one (1) employee of such Party or its Affiliates as representatives to the IPOC, each such representative (a) having



sufficient seniority and expertise in the prosecution, maintenance, enforcement and defense of Patent Rights or Trademarks to participate on the IPOC, and (b) to be duly authorized under their respective company's internal governance procedures to carry out the activities given to them under this Agreement. The IPOC may change its size from time to time by mutual, unanimous consent of its members; provided that the IPOC shall consist at all times of an equal number of representatives of each of Merck and SeaGen. Each Party may replace one or more of its IPOC representatives at any time in its sole discretion upon written notice to the other Party. If agreed by the IPOC, the IPOC may invite non-members to participate in the discussions and meetings of the IPOC (e.g., trademark specialists from the Parties); provided that such participants are under obligations of confidentiality consistent with this Agreement.

12.1.2 No-Decision Making Authority. The Parties hereby agree and acknowledge that the IPOC shall be a forum for review and robust discussion with respect to the intellectual property matters under the purview of the IPOC, and for making recommendations to the Parties with respect thereto, but the IPOC shall not have specific decision-making authority.

12.1.3 Specific Responsibilities of the Intellectual Property Operating Committee. In addition to its general responsibilities, the IPOC shall, subject to the terms of this Agreement, in particular:

(a) discuss issues relating to inventorship or ownership of Program Know-How in accordance with the terms of Section 12.3;

(b) discuss, develop and coordinate strategies for obtaining, maintaining, defending and enforcing patent protection for the Joint Program Patents, SeaGen Product-Specific Patents and Merck Product-Specific Patents under this Agreement;

(c) facilitate cooperation between the Parties pursuant to Section 12.4.3;

(d) discuss, develop and coordinate strategies in connection with the selection, adoption, use, registration and enforcement of the Collaboration Marks; and

(e) serve as a forum for the prompt disclosure of all material issues relating to the intellectual property that is the subject of this Agreement.

12.1.4 Meetings. The IPOC will meet on a Calendar Quarterly basis (or more or less frequently as the Parties may otherwise mutually agree), with the location for such meetings to be determined by the IPOC. The IPOC may meet in person or, alternatively, the IPOC may meet by means of teleconference, videoconference or other similar communications equipment. Each Party will bear the expense of its respective IPOC members' participation in IPOC meetings. The IPOC shall be responsible for keeping reasonably detailed written minutes of all meetings of the IPOC.

12.1.5 Duration of the IPOC. The IPOC shall endure for the Term, and if mutually agreed to by the Parties, after the end of the Term (for such period of time as agreed to by the Parties).



12.2 Disclosure of Program Know-How.

12.2.1 Disclosure by Merck. Merck shall promptly disclose to SeaGen in writing the development, making, conception or reduction to practice of Joint Program Know-How as well as any Merck Program Know-How (other than Merck Proprietary Product Program Inventions) and any SeaGen Program Know-How.

12.2.2 Disclosure by SeaGen. SeaGen shall promptly disclose to Merck in writing the development, making, conception or reduction to practice of Joint Program Know-How, as well as any SeaGen Program Know-How (other than SeaGen Proprietary Product Program Inventions) and any Merck Program Know-How.

12.3 Ownership of Intellectual Property.

12.3.1 Inventorship. Inventorship of Program Know-How shall be determined by application of U.S. patent law pertaining to inventorship, and, except as otherwise set forth herein, ownership of Program Know-How shall be determined based on inventorship. Except as otherwise set forth herein, ownership of Program Copyrights shall be determined by application of U.S. copyright law pertaining to ownership.

12.3.2 SeaGen Program Intellectual Property. Subject to the rights and licenses granted to Merck hereunder and in the Ancillary Agreements, as between the Parties, the entire right, title and interest in and to the SeaGen Program Know-How and SeaGen Program Patents shall be owned solely by SeaGen or any of its Affiliates, as applicable.

12.3.3 Merck Program Intellectual Property. Subject to the rights and licenses granted to SeaGen hereunder and in the Ancillary Agreements, as between the Parties, the entire right, title and interest in and to the Merck Program Know-How and Merck Program Patents shall be owned solely by Merck or any of its Affiliates, as applicable.

12.3.4 Proprietary Product-Related Promotional Materials.

(a) Subject to the rights and licenses granted to SeaGen hereunder and in the Ancillary Agreements, as between the Parties, the entire right, title and interest in and to (i) the Merck Proprietary Combination Outside Promotional Materials and the Merck Proprietary Combination Outside Other Field-Based Materials, and the copyrights in the content therein, and (ii) the Merck Licensed Product Combination Promotional Materials and Merck Licensed Product Combination Other Field-Based Materials (or other content) created pursuant to this Agreement for a Merck Proprietary Combination, and the Program Copyrights in the content therein, in each case, shall be owned solely by Merck or any of its Affiliates, as applicable.

(b) Subject to the rights and licenses granted to Merck hereunder and in the Ancillary Agreements, as between the Parties, the entire right, title and interest in and to (i) the SeaGen Proprietary Outside Combination Promotional Materials and the SeaGen Proprietary Combination Outside Other Field-Based Materials, and the copyrights in the content therein and (ii) the SeaGen Licensed Product Combination Promotional Materials and SeaGen Licensed Product Combination Other Field-Based Materials (or other content) created pursuant to this



Agreement for a SeaGen Proprietary Combination, and the Program Copyrights in the content therein, in each case, shall be owned solely by SeaGen or any of its Affiliates, as applicable.

12.3.5 Jointly Owned Intellectual Property. Subject to the rights and licenses granted to each Party hereunder and in the Ancillary Agreements, (a) Joint Program Know-How, Joint Program Patents and Joint Program Copyrights shall be owned jointly by Merck and SeaGen and (b) subject to the terms and conditions of this Agreement, including Section 2.9 and Article 9, each Party shall have the right to use and exercise Joint Program Know-How, the Joint Program Patents and Joint Program Copyrights, and grant licenses under its interest in Joint Program Know-How, Joint Program Patents and Joint Program Copyrights, as it deems appropriate without the consent of (and if any such consent is required, such consent is hereby granted), or any obligation to, the other Party, including any duty to account.

12.3.6 Assignment. Each Party shall (and shall cause its Affiliates to), and hereby does, for no additional consideration (and the rights and obligations of the Parties as set forth in this Agreement is deemed sufficient consideration), assign all rights worldwide to the Program Know-How, Program Patents and Program Copyrights to the other Party to effectuate the ownership thereof as set forth in the foregoing provisions of Sections 12.3.2, 12.3.3, 12.3.4 and 12.3.5. Each Party shall reasonably assist the other in recording and perfecting such other Party's rights in and to such Program Know-How and Program Patents.

12.4 Filing, Prosecution and Maintenance of Patent Rights.

12.4.1 Prosecution and Maintenance of SeaGen Product-Specific Patents, Joint Program Patents and Merck Product-Specific Patents. The Lead Patent Party shall have the right, but not the obligation, to prepare, file, prosecute and maintain the SeaGen Product-Specific Patents, Joint Program Patents and Merck Product-Specific Patents, as applicable, worldwide; provided that with respect to Joint Program Patents, such preparation, filing, prosecution and maintenance shall be done through outside counsel mutually agreed to by the Parties. The Lead Patent Party shall keep the other Party reasonably informed of all material steps with regard to the preparation, filing, prosecution and maintenance of the SeaGen Product-Specific Patents, Joint Program Patents and Merck Product-Specific Patents, as applicable, including by providing such other Party with a copy of material communications to and from any patent authority in the Territory regarding such SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable, and the other Party shall be copied on all material correspondence with the Lead Patent Party's patent counsel with respect thereto. The Lead Patent Party shall provide the other Party drafts of any material filings or responses to be made to such patent authorities in the Territory in advance of submitting such filings or responses so as to allow for a reasonable opportunity for such other Party to review and comment thereon, and the Lead Patent Party shall consider in good faith and discuss the requests and suggestions of such other Party with respect to such Lead Patent Party's drafts and with respect to strategies for filing and prosecuting the SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable, in the Territory. The Lead Patent Party shall consult with the other Party reasonably prior to (but at least [*] days prior to) taking or failing to take any substantive action (including making any filings) with respect to the SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable, including any action that would



materially affect the scope or validity of rights under any patent applications or patents within the SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable (such as substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional patent application, abandoning any patent or not filing or perfecting the filing of any patent application in any country). In the event that the Lead Patent Party decides not to prepare, file, prosecute or maintain a SeaGen Product-Specific Patent, Joint Program Patent or Merck Product-Specific Patent, as applicable, in a country in the Territory, the Lead Patent Party shall provide reasonable prior written notice to the other Party of such intention (which notice shall, in any event, be given no later than [*] days prior to the next deadline for any action that may be taken with respect to such Patent Right in such country), the other Party shall thereupon have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution and maintenance of such SeaGen Product-Specific Patent, Joint Program Patent or Merck Product-Specific Patent, as applicable; provided, however, that (a) with respect to any Merck Product-Specific Patent, if Merck determines in good faith that SeaGen's prosecution and maintenance of such Merck Product-Specific Patent is reasonably likely to have a material adverse impact on Merck's overall relevant Patent Rights portfolio, then SeaGen shall not have any right to direct such prosecution and maintenance; and (b) with respect to any SeaGen Product-Specific Patent, if SeaGen determines in good faith that Merck's prosecution and maintenance of such SeaGen Product-Specific Patent is reasonably likely to have a material adverse impact on SeaGen's overall relevant Patent Rights portfolio, then Merck shall not have any right to direct such prosecution and maintenance. Upon such other Party's written exercise of such option, such other Party shall assume the responsibility and control for the preparation, filing, prosecution and maintenance of such SeaGen Product-Specific Patent, Joint Program Patent or Merck Product-Specific Patent, as applicable, and shall thereafter be the Lead Patent Party with respect thereto. In such event, the original Lead Patent Party shall promptly provide the new Lead Patent Party with the appropriate documents for such transfer of responsibility and control and reasonably cooperate with such new Lead Patent Party in such country as provided under Section 12.4.3.

12.4.2 Costs of Prosecution and Maintenance of SeaGen Product-Specific Patents, Joint Program Patents and Merck Product-Specific Patents. All out-of-pocket costs and expenses (including, for clarity, amounts paid to outside counsel in connection with the preparation, filing, prosecution and maintenance of the applicable Patent Rights) actually and reasonably incurred by a Party or its Affiliates in connection with the preparation, filing, prosecution and maintenance of SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents in accordance with Section 12.4.1 shall be deemed to be "Joint Patent Costs".

12.4.3 Cooperation.

(a) The Parties agree to cooperate fully in the preparation, filing, prosecution and maintenance of the SeaGen Product-Specific Patents, Joint Program Patents and Merck Product-Specific Patents. Cooperation shall include the Parties (A) executing all papers and instruments, or requiring its employees or contractors to execute such papers and instruments, so as to enable the other Party to apply for and to prosecute the SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable, in the Territory, to the extent provided for in this Agreement, and (B) promptly informing the other Party of any matters



coming to such Party's attention that may materially affect the preparation, filing, prosecution or maintenance of any such SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable. Without limiting the foregoing, if a Party will be prosecuting any Patent Rights Controlled by the other Party, such other Party shall promptly provide the prosecuting Party with the appropriate documents for such transfer of responsibility and control and reasonably cooperate with prosecuting Party in order for the prosecuting Party to assume such prosecution.

(b) With respect to Joint Program Patents, Merck Program Patents and SeaGen Program Patents, the Parties intend to prepare, file, prosecute and maintain such Patent Rights such that (i) the claims within the Joint Program Patents claim Joint Program Know-How, but do not also claim Merck Program Know-How or SeaGen Program Know-How, (ii) the claims within the Merck Program Patents claim Merck Program Know-How, but do not also claim Joint Program Know-How or SeaGen Program Know-How and (iii) the claims within the SeaGen Program Patents claim SeaGen Program Know-How, but do not also claim Joint Program Know-How or Merck Program Know-How. Notwithstanding the foregoing, if mutually agreed to by the Parties, a Joint Program Patent may claim Merck Program Know-How or SeaGen Program Know-How that is not separately patentable to the extent not including such Merck Program Know-How or SeaGen Program Know-How would render the claims in the Joint Program Patent unpatentable.

(c) Notwithstanding the Party that is designated as the "Lead Patent Party" with respect to a given SeaGen Product-Specific Patent, Joint Program Patent or Merck Product-Specific Patent, as applicable, the Parties may, by mutual written agreement, determine that the other Party should be the "Lead Patent Party" with respect to a given SeaGen Product-Specific Patent, Joint Program Patent or Merck Product-Specific Patent, as applicable, in which case such other Party shall thereafter be the "Lead Patent Party" with respect to the applicable SeaGen Product-Specific Patent, Joint Program Patent or Merck Product-Specific Patent.

12.4.4 Prosecution and Maintenance of SeaGen General Patents. SeaGen shall have the sole right, but not the obligation, to prepare, file, prosecute and maintain the SeaGen General Patents worldwide, at SeaGen's sole cost and expense; provided that if there are any SeaGen General Patents that claim or cover a Licensed Compound or Licensed Product, SeaGen shall reasonably consult with Merck in connection with the prosecution and maintenance thereof.

12.4.5 Prosecution and Maintenance of Merck General Patents. Merck shall have the sole right, but not the obligation, to prepare, file, prosecute and maintain the Merck General Patents worldwide, at Merck's sole cost and expense.

12.5 Patent Term Extension and Supplementary Protection Certificate.

12.5.1 The Parties shall discuss in good faith, through the IPOC, strategies in order to avoid the loss of any rights that may otherwise be available to the Parties for the SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents with respect to supplementary protection certificates or patent term extensions, including under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 or comparable laws outside the United States, in respect of the Licensed Product (any such right, a "Patent Term Extension"). The JSC shall determine, based upon the strategies proposed by the IPOC, which SeaGen Product-



Specific Patent, Joint Program Patent or Merck Product-Specific Patent shall be a Patent Right for which the Parties desire to obtain a Patent Term Extension in respect of the Licensed Product, and the Party that is the Lead Patent Party for such Patent Right shall apply for such Patent Term Extension. The Parties shall reasonably cooperate, including the applicable patent holder taking such actions as are required under any Applicable Law, in connection with the foregoing. Notwithstanding the provisions of 3.2.4, if the JSC is unable to agree on which SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, if any, shall be a Patent Right for which the Parties will seek to obtain a Patent Term Extension in respect of the Licensed Product, as applicable, within [*] Business Days after the JSC first considers the issue, then the following shall apply:

(a) Either Party (through the Alliance Managers) may elect to formally submit such issue to the Parties' applicable Senior Executives for resolution. In the event that the Senior Executives are unable to resolve a given issue referred to the Senior Executives within [*] Business Days after the dispute is formally submitted to the Senior Executives for resolution, then either Party may elect (through the Alliance Managers) to formally submit such issue to the Parties' respective [*] for resolution.

(b) In the event that the [*] are unable to resolve a given issue referred to the [*] within [*] Business Days after the dispute is formally submitted to the [*] for resolution, then either Party may elect to submit such issue to a patent counsel jointly selected by the Parties (provided that such selection shall not be unreasonably withheld, conditioned or delayed) who (and whose firm, if applicable) (i) is not, and was not at any time during the [*] years prior to such dispute, an employee, consultant, legal advisor, officer or director of, and does not have any conflict of interest with respect to, either Party; (ii) has at least [*] years' experience practicing patent law in the life sciences industry; and (iii) possesses expertise with respect to antibody drug conjugates (an "Independent Patent Counsel"). Such Independent Patent Counsel shall determine which SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, if any, shall be a Patent Right for which the Parties will seek to obtain a Patent Term Extension in respect of the Licensed Product, taking into account all relevant factors (including the impact on the exploitation of the Licensed Product and any material adverse impact on a Party's overall relevant intellectual property portfolio), and such Independent Patent Counsel's determination shall be binding upon the Parties. Expenses of the Independent Patent Counsel shall be "Joint Patent Costs";

provided, in each case, (a) and (b), that if a shorter period of time is necessary to take the action that is the subject of the matter requiring resolution, including in order to comply with applicable statutory requirements for seeking a Patent Term Extension or to avoid any loss of rights, the Parties shall modify the time periods set forth in clauses (a) and (b) so as to permit the taking of such action within such shorter period of time.

12.5.2 Notwithstanding the foregoing, (a) SeaGen (and its Affiliates) shall [*] and (b) Merck (and its Affiliates) shall [*].

12.5.3 All out-of-pocket costs and expenses actually and reasonably incurred by a Party or its Affiliates in connection with obtaining any such Patent Term Extensions with respect



to the Licensed Product in accordance with this Section 12.5 shall be deemed to be "Joint Patent Costs".

12.6 Common Ownership Under Joint Research Agreements. Notwithstanding anything to the contrary in this Article 12, neither Party shall have the right to make an election under 35 U.S.C. § 102(c) when exercising its rights under this Article 12 without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. § 100(h).

12.7 Administrative Proceedings.

12.7.1 SeaGen Product-Specific Patents, Joint Program Patents and Merck Product-Specific Patents. Each Party shall promptly notify the other Party in writing upon receipt by such Party of information concerning the request for, or filing or declaration of, any reissue, post-grant review, inter partes review, derivation proceeding, supplemental examination, interference, opposition, reexamination or other administrative proceeding relating to any of the SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable. The Parties shall thereafter consult and reasonably cooperate to determine a course of action with respect to any such proceeding and shall reasonably consult with one another in an effort to agree with respect to decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms; provided, however, that, except as otherwise agreed by the Parties, and except as set forth in Section 12.7.2, [*] shall control and have final decision-making authority with respect to any such proceeding relating to such SeaGen Product-Specific Patent, Joint Program Patent or Merck Product-Specific Patent, as applicable.

12.7.2 Interaction with Invalidity Actions and Infringement Actions. If any proceeding under Section 12.7.1 involves Patent Rights involved in an invalidity or unenforceability action under Section 12.8 or an Infringement Action under Section 12.10, any decisions as to whether to initiate or how to respond to such a proceeding, and the course of action in such proceeding, shall be made by the Party controlling such invalidity or unenforceability action or such Infringement Action as set forth in Section 12.8 or Section 12.10, as applicable.

12.7.3 Costs and Expenses. All out-of-pocket costs and expenses actually and reasonably incurred by a Party or its Affiliates in connection with any proceeding under the provisions of Section 12.7.1 with respect to SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable, will be borne in the same manner as out-of-pocket costs and expenses incurred with respect to prosecution and maintenance of such Patent Rights pursuant to Section 12.4.

12.7.4 Administrative Proceedings with respect to SeaGen General Patents. [*] shall have the [*] to handle any [*] or other administrative proceeding with respect to any SeaGen General Patent [*].



12.7.5 Administrative Proceedings with respect to Merck General Patents. [*] shall have the [*] to handle any [*] other administrative proceeding with respect to any Merck General Patent [*].

12.8 Invalidity or Unenforceability Defenses or Actions.

12.8.1 SeaGen Product-Specific Patents, Joint Program Patents and Merck Product-Specific Patents. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable, by a Third Party, including in a declaratory judgment action or similar action or claim filed by a Third Party or as a defense or as a counterclaim in any Infringement Action under Section 12.10, in each case, of which such Party becomes aware. As between the Parties, and subject to Section 12.10 with respect to defenses or counterclaims in Infringement Actions, as applicable, [*]. The other Party may participate in any such claim, suit or proceeding in the Territory with counsel of its choice; provided that [*] shall retain control of the defense in such claim, suit or proceeding. If [*] elects not to defend or control the defense of the applicable SeaGen Product-Specific Patent, Joint Program Patent or Merck Product-Specific Patent in a claim, suit or proceeding brought in the Territory, or otherwise fails to initiate and maintain the defense of any such claim, suit or proceeding, then the other Party may conduct and control the defense of any such claim, suit or proceeding.

12.8.2 Cooperation. With respect to the SeaGen Product-Specific Patents, Joint Program Patents and Merck Product-Specific Patents, each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its activities set forth in Section 12.8.1, including by being joined as a party in such action or proceeding as is necessary to bring or defend such action or proceeding, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours. In connection with any such defense or claim or counterclaim, the controlling Party shall keep the other Party reasonably informed of any steps taken, and shall provide copies of all documents filed, in connection with such defense, claim or counterclaim. In connection with the activities set forth in Section 12.8.1 with respect to SeaGen Product-Specific Patents, Joint Program Patents and Merck Product-Specific Patents, as applicable, the controlling Party shall consider in good faith any comments from the other Party, and each Party shall consult with the other as to the strategy for the defense of the SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable.

12.8.3 Costs and Expenses. All out-of-pocket costs and expenses actually and reasonably incurred by a Party or its Affiliates in connection with any proceeding under the foregoing provisions of this Section 12.8 with respect to SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable, will be borne in the same manner as out-of-pocket costs and expenses incurred with respect to prosecution and maintenance of such Patent Rights pursuant to Section 12.4.

12.8.4 SeaGen General Patents. [*] shall have the [*] the SeaGen General Patents [*].



12.8.5 Merck General Patents. [*] shall have the [*] Merck General Patents [*].

12.9 Patent Listings.

12.9.1 SeaGen Product-Specific Patents, Joint Program Patents and Merck Product-Specific Patents.

(a) The Parties shall discuss, through the IPOC, strategies with respect to filings with Regulatory Authorities in the Territory for listing SeaGen Product-Specific Patents, Joint Program Patents and Merck Product-Specific Patents for the Licensed Product as required or allowed (a) in the United States, in the FDA's Orange Book or Purple Book, or (b) any other national or international equivalents of any of the foregoing ("Patent Listings"). The JSC shall determine which SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, as applicable, shall be used for any Patent Listings for the Licensed Product. Notwithstanding the provisions of 3.2.4, if the JSC is unable to agree on which SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, if any, shall be used for any Patent Listing for the Licensed Product, as applicable, within [*] Business Days after the JSC first considers the issue, then the following shall apply:

(i) Either Party (through the Alliance Managers) may elect to formally submit such issue to the Parties' applicable Senior Executives for resolution. In the event that the Senior Executives are unable to resolve a given issue referred to the Senior Executives within [*] Business Days after the dispute is formally submitted to the Senior Executives for resolution, then either Party (through the Alliance Managers) may elect to formally submit such issue to the Parties' respective [*] for resolution.

(ii) In the event that the [*] are unable to resolve a given issue referred to the [*] within [*] Business Days after the dispute is formally submitted to the [*] for resolution, then either Party may elect to submit such issue to an Independent Patent Counsel jointly selected by the Parties (provided that such selection shall not be unreasonably withheld, conditioned or delayed). Such Independent Patent Counsel shall determine which SeaGen Product-Specific Patents, Joint Program Patents or Merck Product-Specific Patents, if any, shall be used for Patent Listings in respect of the Licensed Product, taking into account all relevant factors (including the impact on the exploitation of the Licensed Product and any material adverse impact on a Party's overall relevant intellectual property portfolio), and such patent counsel's determination shall be binding upon the Parties. Expenses of the patent counsel shall be "Joint Patent Costs";

provided, in each case, (i) and (ii), that if a shorter period of time is necessary to take the action that is the subject of the matter requiring resolution, including in order to comply with applicable statutory requirements for submitting or obtaining a Patent Listing or to avoid any loss of rights, the Parties shall modify the time periods set forth in clauses (i) and (ii) so as to permit the taking of such action within such shorter period of time.

(b) In addition, to the extent that any SeaGen General Patent or Merck General Patent (i) is required under Applicable Law to be included in a Patent Listing with respect



to the Licensed Product, [*], with respect to such SeaGen General Patent, or [*], with respect to such Merck General Patent, will identify such Patent Right and permit it to be listed, or (ii) is allowed under Applicable Law to be included in a Patent Listing, then [*], with respect to such SeaGen General Patent, or [*], with respect to such Merck General Patent, will have the final decision making authority as to whether to identify such Patent Right to the other Party for listing and permit it to be listed.

(c) Notwithstanding the foregoing, the Parties [*].

(d) The JSC shall determine, subject to the requirements of Applicable Law, whether [*], as applicable, shall make the necessary filings for the Patent Listings for the Licensed Product determined in accordance with this Section 12.9, and such Party shall make all such filings. At the filing Party's reasonable request, the other Party shall provide prompt and reasonable assistance (including by taking such action as patent holder as is required under any Applicable Law) in connection with the foregoing, including (A) providing to the filing Party all necessary information, including a correct and complete list of the applicable SeaGen Patents, Joint Program Patents and Merck Patents claiming the Licensed Product, to enable the filing Party to make such filings with Regulatory Authorities in the Territory with respect to such Patent Rights, and (B) cooperating with the filing Party's reasonable requests in connection therewith, including meeting any submission deadlines.

12.9.2 Costs and Expenses. All out-of-pocket costs and expenses actually and reasonably incurred by a Party or its Affiliates in connection with the Patent Listings pursuant to Section 12.9.1 shall be deemed to be "Joint Patent Costs".

12.10 Enforcement of Patents and Know-How.

12.10.1 Notices. Each Party shall promptly notify the other Party in writing of any known or suspected infringement or misappropriation of any SeaGen Technology or Merck Technology by a Third Party of which such Party becomes aware, in each case, to the extent such alleged infringing or misappropriating activities involve, as to the Licensed Product, [*] with respect thereto (a "Competitive Infringement"). Promptly following [*] the Parties [*] shall [*].

12.10.2 Relevant Infringement IP.

(a) Competitive Infringement (Relevant Infringement IP).

(i) As between the Parties, [*] shall have the first right, but not the obligation, to initiate an infringement or other appropriate claim, suit or proceeding anywhere in the world against any Third Party (an "Infringement Action") with respect to any Competitive Infringement of any (i) Merck Product-Specific Patents or Merck Product-Specific Know-How, (ii) SeaGen Product-Specific Patents or SeaGen Product-Specific Know-How or (iii) Joint Program Patents or Joint Program Know-How ((i), (ii) and (iii), collectively, the "Relevant Infringement IP"); provided that [*] shall not initiate any such Infringement Action with respect to a Competitive Infringement of the Relevant Infringement IP in the foregoing clauses [*], the



Parties shall mutually agree upon the strategy with respect to such Infringement Action and [*] prosecution of such Infringement Action, if any, shall be consistent with such agreed upon strategy.

(ii) Any such prosecution of an Infringement Action with respect to a Competitive Infringement of the Relevant Infringement IP shall be through outside counsel selected by [*] and approved by [*] (such approval not to be unreasonably withheld, conditioned or delayed). In the event [*] prosecutes any such Infringement Action with respect to a Competitive Infringement, [*] shall have the right to join as a party to such Infringement Action in the Territory and participate with its own counsel; provided that [*] shall retain control of the prosecution of such Infringement Action, including the responses to any defense or any counterclaim raised in connection therewith. In connection with any Infringement Action under this Section 12.10.2(a)(ii), [*] shall provide [*] with drafts of all official papers and statements prior to their submission in such Infringement Action, with sufficient time to allow [*] to review, consider and substantively comment thereon, and [*] shall consider such comments in good faith. If [*] does not take steps, using Commercially Reasonable Efforts, to prosecute, an Infringement Action under this Section 12.10.2(a)(ii) with respect to a Competitive Infringement with respect to the Relevant Infringement IP (A) within [*] days following the first notice provided above with respect to such Infringement Action, or (B) no later than [*] days before the time limit, if any, set forth under Applicable Law for filing of such Infringement Actions (provided that such date in this clause (B) occurs after the first such notice of the Infringement Action is provided), whichever comes first, then [*] may, by providing written notice to [*] within [*] Business Days following the earlier to occur of (A) or (B), prosecute such Infringement Action with respect to such Competitive Infringement (and [*] shall have the right to join as a party to such Infringement Action in the Territory and participate with its own counsel); provided that (x) the foregoing provisions of this Section 12.10.2(a)(ii) shall apply with respect to [*] and [*] in connection with such Infringement Action of the Relevant Infringement IP prosecuted by [*], *mutatis mutandis*, and (y) [*] prosecution of such Infringement Action, if any, shall be consistent with the Parties' mutually agreed upon strategy.

(b) Competitive Infringement (Relevant Linker Infringement IP).

(i) As between the Parties, [*] shall have the first right, but not the obligation, to initiate an Infringement Action with respect to any Competitive Infringement of any (i) SeaGen Linker Product-Specific Patents or (ii) SeaGen Linker Product-Specific Know-How ((i) and (ii), collectively, the "Relevant Linker Infringement IP"), in each case subject to [*] the Parties shall mutually agree upon the strategy with respect to such Infringement Action and [*] prosecution of such Infringement Action, if any, shall be consistent with such agreed upon strategy. In connection with any Infringement Action under this Section 12.10.2(b)(i), [*] shall provide [*] with drafts of all official papers and statements prior to their submission in such Infringement Action, with sufficient time to allow [*] to review, consider and substantively comment thereon, and [*] shall consider such comments in good faith.

(ii) If [*] does not take steps, using Commercially Reasonable Efforts, to prosecute, an Infringement Action under this Section 12.10.2(b)(ii) with respect to a Competitive Infringement of the Relevant Linker Infringement IP (A) within [*] days following the first notice provided above with respect to such Infringement Action, or (B) no later than [*]



days before the time limit, if any, set forth under Applicable Law for filing of such Infringement Actions (provided that such date in this clause (B) occurs after the first such notice of the Infringement Action is provided), whichever comes first, then [*] may, by providing written notice to [*] within [*] Business Days following the earlier to occur of (A) or (B), [*] the Parties shall mutually agree upon the strategy with respect to such Infringement Action. Subject to the foregoing, [*] may initiate such Infringement Action; provided that (x) the foregoing provisions of this Section 12.10.2(b)(ii) shall apply with respect to [*] and [*] in connection with such Infringement Action of the Relevant Linker Infringement IP prosecuted by [*], mutatis mutandis, and (y) [*] prosecution of such Infringement Action, if any, shall be consistent with the Parties' mutually agreed upon strategy. [*] shall have the right to join as a party to such Infringement Action in the Territory and participate with its own counsel.

(c) Costs of Competitive Infringement. All out-of-pocket costs and expenses actually and reasonably incurred by a Party or its Affiliates in connection with any Infringement Action for a Competitive Infringement in accordance with Section 12.10.2(a) or 12.10.2(b), as applicable, shall be deemed to be "Joint IP Action Costs".

(d) Non-Competitive Infringement of Joint Program Patents and Joint Program Know-How. With respect to any activities of a Third Party that may constitute an infringement, unauthorized use or misappropriation of any Joint Program Patents or Joint Program Know-How that is not a Competitive Infringement, the Parties shall discuss and agree regarding enforcement of such Joint Program Patents or Joint Program Know-How (including any sharing of recoveries with respect thereto), [*].

(e) Non-Competitive Infringement of SeaGen Patents and SeaGen Know-How. With respect to any activities of a Third Party that may constitute an infringement, unauthorized use or misappropriation of any SeaGen Patents or SeaGen Know-How that is not a Competitive Infringement, [*] shall have the sole right, but not the obligation, at its sole cost, to initiate an Infringement Action anywhere in the world against any Third Party with respect thereto; provided, however, that [*]. As between the Parties, [*] shall be entitled to retain any and all recoveries in connection with any such Infringement Action.

(f) Non-Competitive Infringement of Merck Product-Specific Patents and Merck Product-Specific Know-How; Any Infringement of Merck General Patents and Merck General Know-How. With respect to any activities of a Third Party that may constitute an infringement, unauthorized use or misappropriation of (i) any Merck Product-Specific Patents or Merck Product-Specific Know-How that is not a Competitive Infringement, or (ii) any Merck General Patents or Merck General Know-How, [*] shall have the sole right, but not the obligation, at its sole cost, to initiate an Infringement Action anywhere in the world against any Third Party with respect thereto; provided, however, that [*]. As between the Parties, [*] shall be entitled to retain any and all recoveries in connection with any such Infringement Action.

12.10.3 BPCIA and Biosimilar Applications.

(a) Notwithstanding the foregoing provisions of Section 12.10.2, if either Party receives a copy of a Biosimilar Application referencing the Licensed Product, whether or not such notice or copy is provided under any Applicable Laws (including under the BPCIA,

the United States Patient Protection and Affordable Care Act, or implementing FDA regulations and guidance applicable to the approval or manufacture of any biosimilar product or interchangeable product), or otherwise becomes aware that such a Biosimilar Application has been submitted to a Regulatory Authority for marketing authorization (such as in an instance described in 42 U.S.C. § 262(l)(2)), the remainder of this Section 12.10.3 shall apply. Such Party shall promptly, but in any event within [*] Business Days, notify the other Party. The owner of the relevant Patents shall then seek permission to view the Biosimilar Application, information regarding the process or processes used to manufacture the product that is the subject of the Biosimilar Application, and related confidential information from the filer of the Biosimilar Application if necessary under 42 U.S.C. § 262(l)(1)(B)(iii). If either Party receives any equivalent or similar communication or notice in the United States or any other jurisdiction, the Party receiving such communication or notice shall within five (5) Business Days notify the other Party of such communication or notice to the extent permitted by Applicable Laws. Regardless of the Party that is the “reference product sponsor”, as defined in 42 U.S.C. § 262(l)(1)(A), for purposes of such Biosimilar Application:

(i) [*] (the “Controlling Party” and [*] the “Non-Controlling Party”, provided, however, that [*]) shall discuss and agree in good faith upon an appropriate strategy with respect to such Biosimilar Application and all actions taken with respect to such Biosimilar Action, if any, shall be consistent with such strategy (as may be revised from time to time by prior written agreement of the Parties hereunder).

(ii) The Controlling Party shall have the first right to designate the outside counsel and in-house counsel who shall receive confidential access to the Biosimilar Application, information regarding the process or processes used to manufacture the product that is the subject of the Biosimilar Application, and any related confidential information pursuant to 42 U.S.C. § 262(l)(1)(B)(ii), provided that any such outside counsel shall be consented to in writing by the Non-Controlling Party, such consent not to be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, if the Controlling Party is not permitted, pursuant to Applicable Law, to make such designations (or take any other action as set forth in this Section 12.10.3) due to the fact that the Controlling Party is not the Lead Regulatory Party or the holder of the applicable Patent Rights, as applicable, then the Non-Controlling Party shall make such designations (or take such other actions as set forth in this Section 12.10.3) at the reasonable direction of the Controlling Party.

(iii) In each case, after consulting with the Non-Controlling Party and subject to the then-current strategy agreed upon between the Parties under clause (i) above, the Controlling Party shall have the right to [*]. If the Non-Controlling Party is required pursuant to Applicable Law to execute any of these tasks it shall do so in accordance with the then-current strategy agreed upon between the Parties under clause (i) above and in coordination with the Controlling Party. The Controlling Party shall have the right to [*].

(iv) The Controlling Party shall have the right, after consulting with the Non-Controlling Party and subject to the then-current strategy agreed upon between the Parties under clause (i) above, [*] in any other jurisdiction outside of the United States. If the Non-Controlling Party is required by Applicable Law to execute any of these tasks, it shall do so



in accordance with Controlling Party's reasonable instructions, subject to the then-current strategy agreed upon between the Parties under clause (i) above.

(v) The Non-Controlling Party shall cooperate with the Controlling Party's reasonable requests in connection with the foregoing activities to the extent required or permitted by Applicable Law. The Controlling Party shall notify the Non-Controlling Party of any such lists or communications promptly after they are made.

(vi) Each Party shall within [*] Business Days after receiving any notice of commercial marketing provided by the filer of a Biosimilar Application pursuant to 42 U.S.C. § 262(l)(8)(A), notify the other Party thereof. To the extent permitted by Applicable Law, and subject to clause (i) above, the Controlling Party shall have the first right, but not the obligation, to seek an injunction against such commercial marketing as permitted pursuant to 42 U.S.C. § 262(l)(8)(B) and to file an action for patent infringement, provided that [*]. Except as otherwise provided in this Section 12.10.3, any such action shall be subject to the terms and conditions of Sections 12.10.2, 12.10.4 and 12.10.5.

(vii) The Parties recognize that procedures other than those set forth above in this Section 12.10.3 may apply with respect to Biosimilar Applications. In the event that the Parties determine that certain provisions of Applicable Laws in the United States or in any other country in the Territory apply to actions taken by the Parties with respect to Biosimilar Applications under this Section 12.10.3 in such country, the Parties shall comply with any such Applicable Laws in such country (and any relevant and reasonable procedures established by Parties) in exercising their rights and obligations with respect to Biosimilar Applications under this Section 12.10.3 in a manner to effectuate the intent of this Section 12.10.3.

(b) As used herein, the term "Biosimilar Application" means an application or submission filed with a Regulatory Authority for Marketing Authorization of a pharmaceutical or biological product claimed to be biosimilar or interchangeable to the Licensed Product or otherwise relying on the approval of such Licensed Product, including, for example, an application filed under 42 U.S.C. § 262(k).

12.10.4 Cooperation and Settlement. The Parties agree to cooperate fully in any Infringement Action for a Competitive Infringement with respect to any Relevant Infringement IP or Relevant Linker Infringement IP, as applicable, pursuant to Sections 12.10.2(a), 12.10.2(b) and 12.10.3. If a Party brings such an Infringement Action, [*]. Neither Party shall settle any Infringement Action of any Relevant Infringement IP or Relevant Linker Infringement IP, as applicable, in accordance with Sections 12.10.2(a), 12.10.2(b) and 12.10.3 with respect to a Competitive Infringement [*]. Without limiting the foregoing, the Party commencing the litigation pursuant to Sections 12.10.2(a), 12.10.2(b) and 12.10.3 with respect to any Relevant Infringement IP or Relevant Linker Infringement IP, as applicable, shall provide the other Party with copies of all pleadings and other documents filed with the court.

12.10.5 Recovery. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of an Infringement Action with respect to any Relevant Infringement IP or Relevant Linker Infringement IP, as applicable, brought pursuant to Sections 12.10.2(a), 12.10.2(b) and 12.10.3 (whether by way of settlement or



otherwise) with respect to a Competitive Infringement shall be first allocated to reimburse the Parties for their out-of-pocket costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the Party bringing such Infringement Action; [*].

12.11 SeaGen Existing In-Licenses. Subject to the provisions of this Article 12, in the event that Merck is not fully able to enjoy any of the rights granted to Merck under this Article 12 as a result of such rights being subject to the applicable terms and conditions of a SeaGen Existing In-License, then SeaGen shall use reasonable efforts to allow Merck to exercise and enjoy such rights to the maximum extent possible under the applicable SeaGen Existing In-License, including by (i) promptly providing to Merck any relevant information and correspondence from the counterparty to the applicable SeaGen Existing In-License, (ii) consulting with Merck in connection with any relevant matters and providing Merck's comments thereon to the counterparty to the applicable SeaGen Existing In-License, and (iii) exercising any rights or options (e.g., step-in rights) that SeaGen may have under the applicable SeaGen Existing In-License as reasonably directed by Merck in order to allow Merck to fully exercise its rights under this Article 12.

12.12 Trademarks.

12.12.1 Collaboration Marks for Products. The JSC shall designate one of the Parties (the "Trademark Clearance Party") who shall be responsible, subject to the oversight of and in coordination with the JCC, and with input from the IPOC, for identifying potential Trademarks to be used to identify the Licensed Product and, in connection therewith, the Trademark Clearance Party shall create a list of potential candidate Trademarks. From the list of such potential Trademarks, the Trademark Clearance Party shall be responsible for the legal assessment and testing (market research and regulatory risk assessment) of the potential Trademark candidates, and shall keep the other Party reasonably informed at each step in the process (including through addressing the issues with the IPOC and the JCC), and shall present the lead Trademark candidates before the JCC and the JSC along with the recommendations of the IPOC with respect to such lead Trademark candidates. From the above-referenced list and based on the outcome of the Trademark legal assessment and Trademark testing by the Trademark Clearance Party and input from the IPOC, the JCC shall consider and advise the JSC, and the JSC shall ultimately be responsible for the selection of the actual Trademarks (and any backups) to be used to identify the Licensed Product in each country in the Territory (the "Collaboration Marks"). Once the JSC selects the Collaboration Marks, the Lead Trademark Party in the applicable country shall thereafter be responsible for the filing, registration and maintenance of the Collaboration Marks in the applicable countries in the Territory, and all out-of-pocket costs and expenses associated therewith (or associated with its other activities under this Section 12.12.1) actually and reasonably incurred by the Lead Trademark Party or its Affiliates shall be deemed to be "Joint Trademark Costs". The Lead Trademark Party in the applicable country shall coordinate with and keep the other Party reasonably informed of the status of the Trademark applications and registrations for Collaboration Marks in such country in the Territory, including by providing regular updates on the status of the Trademark applications and registrations for the Collaboration Marks (at a frequency to be determined by the IPOC and otherwise upon reasonable request), and by providing advanced notice to the other Party with sufficient time to respond if a



refusal may make it necessary or advisable to abandon an application for a Collaboration Mark. All uses of the Collaboration Marks in connection with proposed major promotional activities shall be reviewed by the JCC prior to first public display, launch or distribution thereof. Each Party shall ensure that its use of the Collaboration Marks complies with all Applicable Law (including Applicable Law particularly applying to the proper use and designation of Trademarks in the applicable countries or regions in the Territory) and complies with all applicable quality standards and branding guidelines established by the Lead Trademark Party in the applicable country with input from the IPOC for the applicable Collaboration Mark in the applicable country. Each Party acknowledges and agrees that the applicable Lead Trademark Party in the applicable country shall own all applicable Collaboration Marks in such country, including all Trademark registrations and applications therefor (any such Collaboration Marks owned by SeaGen or its Affiliate, a "SeaGen Collaboration Mark" and any such Collaboration Marks owned by Merck or its Affiliate, a "Merck Collaboration Mark"), including all goodwill associated therewith, and should (a) Merck (or its Related Parties) acquire any ownership rights or goodwill in any SeaGen Collaboration Mark, Merck shall (and shall procure that its Related Parties will), and hereby does, assign any such rights to SeaGen (or its applicable Affiliate), to the extent legally permissible, and, to the extent not legally permissible, waive such rights and (b) SeaGen (or its Related Parties) acquire any ownership rights or goodwill in any Merck Collaboration Mark, SeaGen shall (and shall procure that its Related Parties will), and hereby does, assign any such rights to Merck (or its applicable Affiliate), to the extent legally permissible, and, to the extent not legally permissible, waive such rights. Neither Party nor its respective Affiliates shall register or use any Trademark, domain name, URL or social media identifier which consists of or incorporates, in whole or in part, or is confusingly similar to, the Collaboration Marks for any products, services or uses, other than for the Licensed Product hereunder.

12.12.2 Third Party Infringement or Challenge. Each Party shall promptly inform the other Party of any actual, alleged or threatened infringement of, conflict with or challenge to the Collaboration Marks of which such Party has notice, including attempted registration of trademarks that such Party plans to challenge as being confusingly similar to the Collaboration Marks. SeaGen and Merck shall thereafter consult and cooperate in good faith to agree on a course of action (such agreement not to be unreasonably withheld, conditioned or delayed), including the commencement of administrative or civil legal action by either or both SeaGen and Merck; provided that [*]. The out-of-pocket costs and expenses with respect to any such actions or defense actually and reasonably incurred by a Party or its Affiliates shall be deemed to be "Joint Trademark Costs". Any recovery obtained by either or both Merck or SeaGen in connection with or as a result of any action contemplated by this Section 12.12.2 with respect to any Collaboration Marks, whether by settlement or otherwise, shall be shared in order as follows: (a) first to repay each Party's reasonable out-of-pocket costs and expenses (including reasonable attorneys' fees) incurred in connection with the action, which repayment shall be on a pro rata basis if such recovery is insufficient to repay such out-of-pocket costs and expenses of both Parties, and (b) the amount of any recovery remaining, if any, with respect to any such infringement shall be treated in a manner consistent with Section 10.4 as if such recovery were Licensed Product Net Sales. In connection with any action (or defense) contemplated by this Section 12.12.2, the Parties shall reasonably cooperate with each other and will provide each other with such information, documents, powers, instruments, testimony or other assistance as the other Party may reasonably request in connection with the prosecution or defense of any such action or proceeding. Each Party



shall keep the other Party informed of developments in any such action or proceeding, including, to the extent permissible by Applicable Law, consultation on any settlement. Neither Party shall settle any such action or proceeding [*]. The non-prosecuting Party shall have the right to be represented by counsel of its own choice, at its expense.

12.12.3 Merck Proprietary Product Marks for use in Merck Proprietary Combination. As between the Parties, Merck shall be responsible for the filing, registration and maintenance of the Merck Proprietary Product Marks for use in a Merck Proprietary Combination in the Territory, at its cost and expense. SeaGen hereby acknowledges and agrees that Merck shall own all Merck Proprietary Product Marks (and all Trademark registrations and applications therefor) in the Territory, including all goodwill associated therewith, and should SeaGen (or its Related Parties) acquire any ownership rights or goodwill in any Merck Proprietary Product Mark, SeaGen shall (and shall procure that its Related Parties will), and hereby does, assign any such rights to Merck (or its applicable Affiliate), to the extent legally permissible, and, to the extent not legally permissible, waive such rights. Neither SeaGen nor its respective Affiliates shall register or use any Trademark, domain name, URL or social media identifier which consists of or incorporates, in whole or in part, or is confusingly similar to, the Merck Proprietary Product Marks for any products, services or uses.

12.12.4 SeaGen Proprietary Product Marks for use in SeaGen Proprietary Combination. As between the Parties, SeaGen shall be responsible for the filing, registration and maintenance of the SeaGen Proprietary Product Marks for use in a SeaGen Proprietary Combination in the Territory, at its cost and expense. Merck hereby acknowledges and agrees that SeaGen shall own all SeaGen Proprietary Product Marks (and all Trademark registrations and applications therefor) in the Territory, including all goodwill associated therewith, and should Merck (or its Related Parties) acquire any ownership rights or goodwill in any SeaGen Proprietary Product Mark, Merck shall (and shall procure that its Related Parties will), and hereby does, assign any such rights to SeaGen (or its applicable Affiliate), to the extent legally permissible, and, to the extent not legally permissible, waive such rights. Neither Merck nor its respective Affiliates shall register or use any Trademark, domain name, URL or social media identifier which consists of or incorporates, in whole or in part, or is confusingly similar to, the SeaGen Proprietary Product Marks for any products, services or uses.

12.12.5 Use of Trademarks of the Other Party. Except as may be expressly agreed to by the Parties, or except to the extent required to comply with Applicable Law, neither Party shall, without the other Party's prior written consent, use any Trademarks of the other Party (including the other Party's Corporate Marks, or any Collaboration Marks, Merck Proprietary Product Marks or SeaGen Proprietary Product Marks), or any Trademark that is confusingly similar to, any of the other Party's Corporate Marks, Collaboration Marks, Merck Proprietary Product Marks or SeaGen Proprietary Product Marks; provided that the Parties may use the Corporate Marks, Collaboration Marks, Merck Proprietary Product Marks or SeaGen Proprietary Product Marks of the other Party in connection with the Commercialization of the Licensed Product and any Proprietary Combination in accordance with this Agreement (and the applicable Promotion Agreement, if applicable) (as well as, in the case of the applicable Proprietary Product Party, in connection with the commercialization of such Proprietary Product Party's Proprietary Product for use in a Proprietary Combination in accordance with the licenses set forth in Section 2.2.4).



Moreover, neither Party (nor their respective Affiliates) shall register or use (except as expressly permitted herein) any domain name, URL or social media identifier that incorporates, in whole or in part, any of the other Party's Corporate Marks, Merck Proprietary Product Marks or SeaGen Proprietary Product Marks. For clarity, no Merck Corporate Marks or SeaGen Corporate Marks or Merck Proprietary Product Marks or SeaGen Proprietary Product Marks, nor any variants, derivatives, translations or transliterations of any Merck Corporate Marks or SeaGen Corporate Marks or Merck Proprietary Product Marks or SeaGen Proprietary Product Marks, shall be deemed a Collaboration Mark. Without limiting the foregoing, if the Parties agree on a version of a Merck Proprietary Combination Mark or SeaGen Proprietary Combination Mark that combines a Collaboration Mark, on the one hand, and a Merck Proprietary Product Mark or SeaGen Proprietary Product Mark, on the other, for use in connection with a Proprietary Combination, as applicable (provided, that, for clarity, such Merck Proprietary Combination Mark or SeaGen Proprietary Combination Mark and the use thereof shall be subject, in all cases, to Merck's or SeaGen's prior approval, as applicable), such Merck Proprietary Combination Mark or SeaGen Proprietary Combination Mark shall not cause any Merck Proprietary Product Mark or SeaGen Proprietary Product Mark to become a Collaboration Mark and shall not result in SeaGen or Merck (or any of their Affiliates), as applicable, having any ownership rights or independent right to use or enforce any Merck Proprietary Product Mark or SeaGen Proprietary Product Mark, as applicable, of the other Party.

ARTICLE 13 INDEMNIFICATION; LIMITATION ON LIABILITY

13.1 General Indemnification by SeaGen. Subject to Section 13.3.3, SeaGen shall indemnify and hold harmless Merck, its Affiliates and their respective directors, officers, employees and agents, and their respective successors and assigns (collectively, the "Merck Indemnified Parties") from, against and in respect of any and all liabilities, losses, costs and expenses (including reasonable costs and expenses of investigation and defense), damages, fines, penalties, costs and expenses or amounts paid in settlement (including reasonable attorneys' and experts' fees and costs and expenses), in each case, payable to Third Parties (collectively, "Losses"), in each case to the extent resulting from any Action and to the extent such Losses are incurred or suffered by the Merck Indemnified Parties or any of them as a result of, arising out of or directly or indirectly relating to: (a) any breach of this Agreement or any Ancillary Agreement by SeaGen or its Affiliates, (b) the negligence, willful misconduct or violation of Applicable Law by or of SeaGen, its Affiliates or licensees or their respective directors, officers, employees or agents or any of them, in each case, in performing under this Agreement or any Ancillary Agreement, (c) the promotion or other commercialization by or on behalf of SeaGen or its Affiliates or licensees outside of this Agreement of a SeaGen Proprietary Product [*] for use in a SeaGen Proprietary Combination (including the use by or on behalf of SeaGen or any of its Affiliates or licensees of any SeaGen Proprietary Combination Outside Promotional Materials or SeaGen Proprietary Combination Outside Other Field-Based Materials), (d) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of SeaGen or its Affiliates or licensees prior to the Effective Date or after the end of the Term, (e) the conduct of any [*] by or on behalf of SeaGen or any of its Affiliates or licensees, or (f) the conduct of any [*] by or on behalf of SeaGen or any of its Affiliates or licensees; except, in each case ((a), (b), (c), (d), (e) and (f)), to the extent caused by the negligence, willful misconduct, violation of Applicable Law or breach of this Agreement or any Ancillary Agreement



of or by Merck, its Affiliates or any of the other Merck Indemnified Parties. For clarity, Merck (and its Affiliates and sublicensees) shall not be licensees of SeaGen for purposes of this Section 13.1.

13.2 General Indemnification by Merck. Subject to Section 13.3.3 and 13.4, Merck shall indemnify and hold harmless SeaGen, its Affiliates and their respective directors, officers, employees and agents, and their respective successors and assigns (collectively, the "SeaGen Indemnified Parties"), from, against and in respect of any and all Losses in each case, payable to Third Parties, in each case to the extent resulting from any Action and to the extent such Losses are incurred or suffered by the SeaGen Indemnified Parties or any of them as a result of, arising out of or directly or indirectly relating to: (a) any breach of this Agreement or any Ancillary Agreement by Merck or its Affiliates, (b) the negligence, willful misconduct or violation of Applicable Law by or of Merck, its Affiliates or licensees or their respective directors, officers, employees or agents or any of them, in each case, in performing under this Agreement or any Ancillary Agreement, (c) the promotion or other commercialization by or on behalf of Merck or its Affiliates or licensees outside of this Agreement of a Merck Proprietary Product for use in a Merck Proprietary Combination (including the use by or on behalf of Merck of any of its Affiliates or licensees of any Merck Proprietary Combination Outside Promotional Materials or Merck Proprietary Combination Outside Other Field-Based Materials) or (d) the conduct of any [*] by or on behalf of Merck or any of its Affiliates or licensees; except, in each case ((a), (b), (c) and (d)), to the extent caused by the negligence, willful misconduct, violation of Applicable Law or breach of this Agreement or any Ancillary Agreement of or by SeaGen, its Affiliates or any of the other SeaGen Indemnified Parties. For clarity, SeaGen (and its Affiliates and sublicensees) shall not be licensees of Merck for purposes of this Section 13.2.

13.3 Shared Liability Claims; Product Liability Actions for Proprietary Combinations; [*].

13.3.1 Shared Liability Action; Product Liability Actions for Proprietary Combinations.

(a) Shared Liability Action. Subject to Sections 13.1, 13.2, 13.3.1(b), 13.3.3 and 13.4, any and all Losses resulting from any Action brought against any SeaGen Indemnified Party or Merck Indemnified Party as a result of, arising out of or directly or indirectly relating to, any units of Licensed Compound or Licensed Product sold or administered during the Term pursuant to this Agreement for use in the Field for the Territory, including any Product Liability Action, or Action for infringement or misappropriation of intellectual property of a Third Party (in each case, other than such Losses entitled to indemnification under Section 13.1, Section 13.2, Section 13.4 or any Ancillary Agreement, as applicable) (a "Shared Liability Action") shall [*].

(b) Product Liability Actions for Proprietary Combinations. Subject to Sections 13.1, 13.2 and 13.3.3, any and all Losses resulting from any Product Liability Action brought against any SeaGen Indemnified Party or Merck Indemnified Party as a result of units of Licensed Product administered during the Term pursuant to this Agreement in a Proprietary Combination shall be allocated as follows: [*]. For clarity, nothing in this



Section 13.3.1(b) precludes a Party from exercising its right to indemnification under Section 13.1 or Section 13.2, if applicable.

13.3.2 Cooperation. In the event of a Shared Liability Action as set forth in Section 13.3.1, the Parties shall promptly discuss in good faith and agree on how to address such Action. Neither Party shall agree to any settlement of such Action without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed.

13.3.3 [*]. If an [*], as applicable, to [*], then, notwithstanding the provisions of [*], provided that, in the [*], the provisions of [*] shall apply and the provisions of [*] shall not apply) or the provisions of [*], provided that, in [*], the provisions of [*] shall apply and the provisions of [*] shall not apply), [*] that may be [*], that would otherwise be [*] for the [*] in the [*] in accordance with [*], in each case of (i) and (ii), [*] in the [*] pursuant to this Agreement [*] in a [*] and that were [*], and (b) [*] of the [*], then the following shall apply with respect to [*]:

(a) in the event of [*], the Parties shall [*] shall have the [*] with respect to [*]; however, neither Party shall [*], which shall [*];

(b) if [*], then [*] shall [*], with respect to [*]; provided that [*] shall not [*], which shall [*] as a result of [*];

(c) if [*], then [*] shall [*], with respect to any [*] shall not [*] with the [*], which shall [*] as a result of such [*]; and

(d) [*] shall be [*] in connection with [*], and [*] in connection with [*]; provided that, if there are [*] then [*] shall be [*].

For purposes of this Section 13.3.3, [*] shall mean [*] in accordance with this Agreement [*]; provided that [*].

In the event of [*], notwithstanding anything to the contrary [*] or any [*], as set forth in the foregoing provisions of this Section 13.3.3 shall be [*] with respect to any [*], to the extent [*].

Notwithstanding the foregoing provisions of this Section 13.3.3, the provisions of this Section 13.3.3 shall not apply with respect to [*].

13.4 Additional Indemnification by SeaGen. Without limiting the foregoing indemnification obligations of SeaGen pursuant to Sections 13.1 and 13.3, SeaGen hereby agrees to provide such additional indemnifications to the Merck Indemnified Parties as set forth in that certain [*] between the Parties dated as of the date hereof and attached hereto as [*].

13.5 Claims for Indemnification.

13.5.1 A Party seeking indemnification under this Article 13 (an "Indemnified Party") shall give prompt written notification to the Party from whom indemnification is sought



(the "Indemnifying Party") of the commencement of any Action for which indemnification may be sought or, if earlier, upon the assertion of any such Action by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of an Action as provided in this Section 13.5.1 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 prejudiced as a result of such failure to give notice).

13.5.2 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 Action using counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The assumption of a defense by the Indemnifying Party shall not be deemed an admission that the Indemnifying Party has an obligation to defend, indemnify or hold harmless an Indemnified Party from and against any Loss from an Action. If the Indemnifying Party assumes and conducts the defense of an Action as provided above, and if it is ultimately determined pursuant to Section 16.8 that the Indemnifying Party was not obligated to indemnify, defend, or hold harmless an Indemnified Party from and against any Loss from such Action, the Indemnified Party shall reimburse the Indemnifying Party for any and all reasonable and verifiable out-of-pocket costs and expenses (including reasonable attorneys' and experts' fees, costs and expenses) incurred by the Indemnifying Party in connection with defending such Action and all other Losses paid by the Indemnifying Party on behalf of the Indemnified Party in connection with such Action, and if such determination is the result of an arbitration proceeding initiated by the Indemnifying Party pursuant to Section 16.8, then the Indemnified Party also shall reimburse the Indemnifying Party for all of the reasonable and verifiable out-of-pocket costs and expenses (including reasonable attorneys' and experts' fees, costs and expenses and costs and expenses of the arbitration) incurred by the Indemnifying Party in connection with such arbitration proceeding.

13.5.3 The Party not controlling such defense may participate therein at its own expense; provided that if the Indemnifying Party assumes control of such defense and 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 action, suit, proceeding or claim, the Indemnifying Party shall be responsible for the reasonable fees, costs and expenses of counsel to the Indemnified Party solely in connection therewith; provided, further, however, that in no event shall the Indemnifying Party be responsible for the fees, costs and expenses of more than one counsel in any one jurisdiction for all Indemnified Parties.

13.5.4 The Party controlling such defense shall keep the other Party advised of the status of such Action and the defense thereof and shall consider in good faith recommendations made by the other Party with respect thereto.

13.5.5 The Indemnified Party shall not agree to any settlement of such Action without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, conditioned or delayed. The Indemnifying Party shall not agree to any settlement of such Action or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party (and the other Merck Indemnified Parties or SeaGen Indemnified Parties, as applicable) from all liability with respect thereto or that imposes any



liability or obligation on the Indemnified Party (or other Merck Indemnified Parties or SeaGen Indemnified Parties, as applicable) without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld, conditioned or delayed.

13.5.6 If the Indemnifying Party chooses to defend any Action, the Indemnified Party shall cooperate in the defense thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Action and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket costs and expenses in connection therewith.

13.6 Disclaimer of Liability. NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN OR IN ANY ANCILLARY AGREEMENT, EACH PARTY ACKNOWLEDGES AND AGREES THAT IN NO EVENT SHALL ANY PARTY OR ANY OF ITS RESPECTIVE AFFILIATES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, CONSEQUENTIAL OR OTHER SIMILAR DAMAGES SUFFERED BY SEAGEN, MERCK OR ANY OF THEIR RESPECTIVE AFFILIATES IN CONNECTION WITH THIS AGREEMENT OR ANY ANCILLARY AGREEMENT OR OTHERWISE ARISING DIRECTLY OR INDIRECTLY OUT OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT OR ANY ANCILLARY AGREEMENT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE (AND, FOR CLARITY, NEITHER PARTY NOR ANY OF THEIR RESPECTIVE AFFILIATES SHALL BE ENTITLED TO RECOVER FOR ANY LOST PROFIT OR LOST REVENUE DAMAGES, WHETHER SUCH DAMAGES ARE CLAIMED AS DIRECT OR INDIRECT DAMAGES); PROVIDED THAT THIS SECTION 13.6 SHALL NOT APPLY WITH RESPECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS WITH RESPECT TO LOSSES FROM THIRD PARTY ACTIONS UNDER THIS ARTICLE 13.

13.7 Insurance. Each Party shall procure and maintain insurance (or self-insurance), including clinical trials insurance and product liability insurance, as applicable, with respect to its activities hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which the Licensed Product is being clinically tested in human subjects or commercially distributed or sold, as applicable. Except with respect to self-insurance, each Party shall provide the other Party with evidence of such insurance upon request. Such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 13 or otherwise.

ARTICLE 14 TERM AND TERMINATION

14.1 Term. This Agreement shall be effective as of the Effective Date and, unless terminated earlier pursuant to Section 14.2, 14.3, 14.4, 14.5 or 14.6, this Agreement shall continue in full force and effect, until the date on which the Licensed Compounds and the Licensed Product



are no longer being Developed or Commercialized under this Agreement (provided that normal pauses or gaps between or following Clinical Trials or other studies for the analysis of data, preparation of reports and design of future Clinical Trials or preparation of applications for Marketing Authorization and other customary Development functions not constituting Clinical Trials would not constitute cessation of Development) (the "Term").

14.2 Unilateral Termination of Agreement in its Entirety by Merck. Merck shall have the right to terminate this Agreement in its entirety (with or without cause) at any time by giving [*] advance written notice to SeaGen.

14.3 Termination by Mutual Agreement. The Parties shall have the right to terminate this Agreement in its entirety (or in part) upon mutual written agreement. In such case, the Parties shall agree in writing on the effects of such termination (including the costs of transition or wind-down of activities), and the provisions of Section 14.7 shall not apply (unless otherwise mutually agreed to by the Parties).

14.4 Termination for Cause.

14.4.1 Termination by Merck for Cause. Merck shall have the right to terminate this Agreement in its entirety at any time during the Term upon written notice to SeaGen if SeaGen is in material breach of this Agreement, and has not cured such breach within [*] days after notice requesting cure of the breach (provided that if such cure cannot be fully achieved within such [*] day cure period, then such cure period will be extended for an additional period of up to [*] additional days (for a total cure period of [*] days)); provided, however, that in the event of a good faith dispute with respect to the existence of such a material breach, the [*] day cure period (as may be extended pursuant to the foregoing provisions of this Section 14.4.1) shall be tolled until such time as the dispute is resolved pursuant to Section 16.8 and, for clarity, this Agreement shall remain in full force and effect during such period.

14.4.2 Termination by SeaGen for Cause. SeaGen shall have the right to terminate this Agreement in its entirety at any time during the Term upon written notice to Merck if Merck is in material breach of this Agreement, and has not cured such breach within [*] days after notice requesting cure of the breach (provided that if such cure cannot be fully achieved within such [*] day cure period, then such cure period will be extended for an additional period of up to [*] additional days (for a total cure period of [*] days)); provided, however, that in the event of a good faith dispute with respect to the existence of such a material breach, the [*] day cure period (as may be extended pursuant to the foregoing provisions of this Section 14.4.2) shall be tolled until such time as the dispute is resolved pursuant to Section 16.8 and, for clarity, this Agreement shall remain in full force and effect during such period.

14.4.3 Disfavored Remedy. The Parties agree that the remedies under the foregoing Sections 14.4.1 and 14.4.2 are to be invoked only if the applicable material breach cannot be adequately remedied through a combination of specific performance and the payment of money damages as available to the non-breaching Party in accordance with this Agreement.

14.5 Termination For Bankruptcy.



14.5.1 Termination. If a Party (the "Bankruptcy Party") makes a general assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it, in each case, which is not dismissed, discharged, bonded or stayed within [*] after the filing thereof (each, an "Insolvency Event"), the other Party may terminate this Agreement in its entirety, effective immediately upon written notice to such Bankruptcy Party.

14.5.2 Licenses. In the event that this Agreement is terminated due to the rejection of this Agreement by or on behalf of the Bankruptcy Party due to an Insolvency Event, all licenses and rights to licenses granted under or pursuant to this Agreement by the Bankruptcy Party to the other Party are and shall otherwise be deemed to be licenses of rights to "intellectual property" (including for purposes of 365(n) of the United States Bankruptcy Code). The Parties agree that the other Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under any applicable insolvency statute, and that upon commencement of an Insolvency Event by or against the Bankruptcy Party, the other Party shall be entitled to a complete duplicate of or complete access to (as such other Party deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to the other Party (a) upon any such commencement of a bankruptcy proceeding, at the written request therefor by the other Party, unless the Bankruptcy Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, upon the rejection of this Agreement by or on behalf of the Bankruptcy Party, then at the written request therefore. The provisions of this Section 14.5.2 shall be (i) without prejudice to any rights the other Party may have arising under any applicable insolvency statute or other Applicable Law and (ii) effective only to the extent permitted by Applicable Law.

14.6 Termination for Patent Challenge.

14.6.1 In the event that Merck or any of its Affiliates directly takes any action, or knowingly provides financial or other assistance (including direct legal or technical advice) to any Third Party, to challenge in a court or administrative proceeding any claim in any SeaGen Patent as being invalid, unenforceable or otherwise not patentable, SeaGen shall have the right to immediately terminate this Agreement in its entirety, including the rights with respect thereto of any Merck sublicensee, [*] written notice to Merck; provided that SeaGen shall not have the right to terminate this Agreement (a) if Merck withdraws or causes to be withdrawn such action within such [*] period or (b) if Merck (or its Affiliate) or such Third Party challenges any SeaGen Patents in defense of claims raised by or on behalf of SeaGen (or its Affiliate) against Merck (or its Affiliate) or such Third Party, or otherwise in connection with an assertion of a cross-claim or a counter-claim. In the event that SeaGen notifies Merck in writing that any of Merck's sublicensees directly takes any action, or knowingly provides financial or other assistance (including direct legal or technical advice) to any Third Party, to challenge in a court or administrative proceeding any claim in any SeaGen Patent as being invalid, unenforceable or otherwise not patentable, then Merck shall terminate such sublicensee's sublicense in its entirety, unless (i) such action by such sublicensee is withdrawn within [*] after SeaGen notice to Merck thereof or (ii) such sublicensee (or its affiliate) or such Third Party challenges any SeaGen Patents in defense of claims raised by



or on behalf of SeaGen (or its Affiliate) against such sublicensee (or its affiliate) or such Third Party, or otherwise in connection with an assertion of a cross-claim or a counter-claim.

14.6.2 In the event that SeaGen or any of its Affiliates directly takes any action, or knowingly provides financial or other assistance (including direct legal or technical advice) to any Third Party, to challenge in a court or administrative proceeding any claim in any Merck Patent as being invalid, unenforceable or otherwise not patentable, Merck shall have the right to immediately terminate this Agreement in its entirety, including the rights with respect thereto of any SeaGen sublicensee, upon [*] prior written notice to SeaGen; provided that Merck shall not have the right to terminate this Agreement (a) if SeaGen withdraws or causes to be withdrawn such action within such [*] period or (b) if SeaGen (or its Affiliate) or such Third Party challenges any Merck Patents in defense of claims raised by or on behalf of Merck (or its Affiliate) against SeaGen (or its Affiliate) or such Third Party, or otherwise in connection with an assertion of a cross-claim or a counter-claim. In the event that Merck notifies SeaGen in writing that any of SeaGen's sublicensees directly takes any action, or knowingly provides financial or other assistance (including direct legal or technical advice) to any Third Party, to challenge in a court or administrative proceeding any claim in any Merck Patent as being invalid, unenforceable or otherwise not patentable, then SeaGen shall terminate such sublicensee's sublicense in its entirety, unless (i) such action by such sublicensee is withdrawn within [*] after Merck notice to SeaGen thereof or (ii) such sublicensee (or its affiliate) or such Third Party challenges any Merck Patents in defense of claims raised by or on behalf of Merck (or its Affiliate) against such sublicensee (or its affiliate) or such Third Party, or otherwise in connection with an assertion of a cross-claim or a counter-claim.

14.7 Effects of Termination.

14.7.1 Generally. In the event of termination of this Agreement for any reason, except as set forth in this Section 14.6 and for the surviving provisions as set forth in Section 14.9, the rights, licenses and obligations of the Parties hereunder shall terminate and be of no further force or effect as of the effective date of such termination.

14.7.2 Return of Confidential Information. In the event of termination of this Agreement for any reason, no later than [*] days after the effective date of such termination, each Party shall either (a) return or cause to be returned to the other Party or (b) destroy and certify such destruction to the other Party, all Confidential Information of the other Party (other than Joint Program Know-How), except to the extent that such Party needs to retain such Confidential Information to exercise its rights or perform its obligations hereunder that survive termination. Notwithstanding the foregoing, (i) each Party may keep one copy of Confidential Information received from the other Party in its confidential files for record purposes, and (ii) each Party shall be permitted to retain Confidential Information included in any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such Party's standard archiving and back-up procedures.

14.7.3 Transition of Licensed Product Activities.



(a) Subject to Section 14.7.4, in the event of termination of this Agreement for any reason, the Parties shall work together in good faith following such termination in order to effect, as soon as reasonably practicable (but in any event within [*] months) following the effective date of termination, an orderly wind-down or transition in accordance with Sections 14.7.3(b) and 14.7.5 of the ongoing Development, Manufacture and Commercialization responsibilities with respect to the Licensed Product from Merck to SeaGen with respect to those Development, Manufacture and Commercialization activities being performed by Merck hereunder for the Licensed Product as of the date of such termination; provided that (i) except if this Agreement is terminated by Merck under Section 14.2 or by SeaGen pursuant to Section 14.4.2 for Merck's material breach, or as otherwise provided in Section 14.7.3(b) or 14.7.5, SeaGen shall reimburse Merck for any costs and expenses incurred by Merck (or any of its Affiliates) in connection therewith, and (ii) except as expressly set forth in Section 14.7.5, Merck shall not be required to grant any assignments, rights or licenses to any intellectual property or to any other assets or materials of Merck or any of its Affiliates in connection therewith.

(b) Notwithstanding the provisions of Section 14.7.1, the licenses granted to Merck hereunder shall survive during such transition period in order for Merck (and its Related Parties), prior to completion of such transition, to:

(i) unless Merck or SeaGen elects to continue the applicable Clinical Trial under Section 14.7.4 or 14.7.5(b), subject to compliance with Applicable Law (including taking into account patient safety), wind-down any ongoing Clinical Trials that were being conducted by Merck (or any of its Related Parties) as the Lead Study Party with respect to the Licensed Product hereunder at the time of such termination (provided that (A) the costs of winding-down such Clinical Trials shall be Allowable Development Costs and be shared between the Parties in accordance with Section 10.4, *mutatis mutandis* and (B) the provisions of Section 5.3 shall apply to any and all Development Data generated from such Clinical Trials after the effective date of termination, *mutatis mutandis*);

(ii) solely if this Agreement is terminated after the first commercial sale of the Licensed Product in any country where Merck is the Lead Distribution Party, Distribute and otherwise Commercialize any remaining inventory (including Licensed Product Manufactured pursuant to Section 14.7.3(b)(iv)) of the Licensed Product hereunder for such country; provided that, all activities with respect to such Distribution and Commercialization of the Licensed Product shall be done in accordance with the applicable terms and conditions of this Agreement, *mutatis mutandis*, and the Parties shall continue to share the costs and expenses with respect to such Distribution and other Commercialization of such inventory in accordance with Section 10.4, *mutatis mutandis*, and shall share the Licensed Product Net Sales from the sale of such inventory in accordance with Section 10.4, *mutatis mutandis*;

(iii) solely with respect to those countries where Merck is the Lead Regulatory Party, to continue to undertake such Development activities for the Licensed Product designated to Merck as the Lead Regulatory Party, during such transition period, as applicable; provided that all such activities shall be done in accordance with the applicable terms and conditions of this Agreement, *mutatis mutandis*, and the Parties shall continue to share the



costs and expenses with respect to such activities in accordance with Section 10.4, *mutatis mutandis*; and

(iv) if Merck is the Lead Manufacturing Party, to finish any Manufacturing of any work-in-progress of Licensed Product; provided that all such activities shall be done in accordance with the applicable terms and conditions of this Agreement, *mutatis mutandis*, in which case, the Parties shall continue to share the costs and expenses with respect to such activities in accordance with Section 10.4, *mutatis mutandis*;

provided that, for clarity, Merck shall have no obligation to undertake such activities in the foregoing clauses (ii) or (iv) of this Section 14.7.3(b), as applicable.

14.7.4 Election by Parties to Continue Ongoing Conduct of Clinical Trials for Merck Proprietary Combinations under a Clinical Trial Agreement. In the event of termination of this Agreement for any reason, notwithstanding the provisions of Section 14.7.3 or 14.7.5(b), with respect to any Clinical Trial of the Licensed Product for use in a Merck Proprietary Combination that has been Initiated and is ongoing as of the effective date of termination (any such Clinical Trial, an "Ongoing Merck Proprietary Combination Trial"), the following shall apply:

(a) With respect to each Ongoing Merck Proprietary Combination Trial, either Party may elect, on a Clinical Trial-by-Clinical Trial basis, to continue the conduct of such Ongoing Merck Proprietary Combination Trial pursuant to Section 14.7.4(c) and will provide written notice to the other Party of its election before the effective date of termination or within the [*] period immediately thereafter.

(b) With respect to any Ongoing Merck Proprietary Combination Trial that neither Merck nor SeaGen elected to continue pursuant to Section 14.7.4(a) and that is being conducted by Merck (or any of its Related Parties on its behalf) as the Lead Study Party, SeaGen will make an election under Section 14.7.5(b) as to whether to transfer to SeaGen, wind-down or for Merck to continue the applicable Clinical Trial, in each case, in accordance with Section 14.7.5(b).

(c) With respect to each Ongoing Merck Proprietary Combination Trial for which Merck or SeaGen elects to continue pursuant to Section 14.7.4(a) (on a Clinical Trial-by-Clinical Trial basis), the Parties will negotiate in good faith a clinical trial collaboration agreement between the Parties (provided that if the Parties are unable to agree on such clinical trial collaboration agreement within [*] days after the effective date of termination, then the Parties shall use the CTC as the form of such clinical trial collaboration agreement, with such changes as may be necessary to reflect that a different Clinical Trial is being conducted, and also to reflect any potential different roles of the Parties with respect to such Clinical Trial (based on the allocation of such roles under this Agreement) as compared to the CTC) with respect to the continued conduct by the applicable Lead Study Party of such Clinical Trial until completion (other than in the event of a Safety Issue) in accordance with the Development Plan in effect as of the effective date of termination; provided that, for clarity, pending the execution of the clinical trial collaboration agreement, (i) the conduct of such Clinical Trials shall continue in accordance with the terms and conditions of this Agreement (including, for clarity, with respect to sharing of



Allowable Development Costs in connection therewith), *mutatis mutandis*, (ii) the provisions of Section 5.3 shall apply to any and all Development Data generated from such Clinical Trial after the effective date of termination, *mutatis mutandis*, (iii) the Parties' obligations under the Pharmacovigilance Agreement shall remain in full force and effect with respect to such Clinical Trial, and (iv) without limiting the foregoing sub-clause (i), the licenses granted to each Party hereunder shall survive as necessary in order for such Party to continue the conduct of any such Clinical Trials.

14.7.5 Transfers and Licenses from Merck to SeaGen. In the event of termination of this Agreement for any reason, at SeaGen's option, upon written notice to Merck (in each case no later than [*] days after the effective date of termination), Merck shall make the following transfers to SeaGen (except in the case of sub-clauses (a), (c), (d) and (f) below to the extent Merck needs to retain such assets, materials or rights, as applicable, to the extent necessary for Merck to conduct its activities under Sections 14.7.3(b) or 14.7.4, in which case, any activities remaining to be performed under sub-clauses (a), (c), (d) and (f) will be performed promptly upon completion of the applicable Merck activities under Sections 14.7.3(b) or 14.7.4, as applicable, provided that SeaGen had made its election to have such activities performed within the [*] day period after the effective date of termination):

(a) Regulatory Documentation. Merck shall, at SeaGen's cost (provided that if this Agreement is terminated by Merck under Section 14.2 or by SeaGen pursuant to Section 14.4.2 for Merck's material breach, then SeaGen shall not be required to reimburse Merck for such costs), provide SeaGen with copies of and, subject to compliance with Applicable Laws, and to the extent it is legally permitted to do so, Merck shall also transfer and assign to SeaGen (or its designee) any and all (i) Marketing Authorizations (including any and all pricing approval and government reimbursement approvals), and (ii) other material Regulatory Documentation, in each case, that are owned by Merck or its Affiliate (including, solely if Merck has the legal right to do so, any and all of the foregoing that were made or filed by Merck's or its Affiliates' respective sublicensees) and that are solely and exclusively for the Licensed Product (including, if applicable, Licensed Product for use in a SeaGen Proprietary Combination (but excluding any of the foregoing that are related to any Combination Product that is co-formulated with any Merck Proprietary Product, which shall be addressed under a separate agreement between the Parties as set forth in Section 14.7.5(g)), and solely as they exist as of the effective date of termination. In the event of a failure to obtain assignment (and provided that Merck will use Commercially Reasonable Efforts to obtain such assignment), then Merck and its Affiliates hereby consent and grant to SeaGen, its Affiliates and (sub)licensees the right to access and reference (without any further action required on the part of Merck or its Affiliates whose authorization to file such consent with any Regulatory Authority is hereby granted) any such Regulatory Documentation owned by Merck or its Affiliates with respect to the Licensed Product for SeaGen's and its Affiliates' use in connection with the Licensed Product.

(b) Clinical Trials. Subject to Section 14.7.4, if, at the time of such termination, Merck (or any of its Related Parties on its behalf) as the Lead Study Party is conducting any Clinical Trials for the Licensed Product, then, at SeaGen's election on a Clinical Trial-by-Clinical Trial basis, to the extent elected by written notice to Merck before the effective date of termination or within the [*] day period immediately thereafter: (i) to the extent



permissible under Applicable Law and commercially feasible, Merck shall, and shall cause its Related Parties to, at SeaGen's cost (provided that if this Agreement is terminated by Merck under Section 14.2 or by SeaGen pursuant to Section 14.4.2 for Merck's material breach, then SeaGen shall not be required to reimburse Merck for such costs) transfer the conduct of such Clinical Trial to SeaGen (or its designees), and SeaGen shall assume any and all liability for the conduct of such transferred Clinical Trial after the effective date of such transfer (except to the extent arising prior to the transfer date or from any willful misconduct or negligent act or omission by Merck or its Related Parties or their respective employees, agents and contractors), (ii) to the extent permissible under Applicable Laws (and taking into account patient safety matters), Merck shall wind-down the applicable Clinical Trial in accordance with Section 14.7.3 or (iii) to the extent that a given Clinical Trial may not be transferred to SeaGen under the foregoing clause (i) pursuant to Applicable Law (and if clause (ii) is not elected with respect to such Clinical Trial), Merck shall, at SeaGen's cost, continue such Clinical Trial until completion (provided that Merck may discontinue such Clinical Trial for Safety Issues). In furtherance of the foregoing, notwithstanding the provisions of Section 14.7.1, the licenses granted to Merck hereunder shall survive solely to the extent necessary for Merck (and its Related Parties) to finish, transition or otherwise wind-down such Clinical Trials, as applicable. If such costs are to be borne by SeaGen as set forth in this Section 14.7.5(b), then SeaGen shall pay Merck for the costs of such activities, which costs shall be paid by SeaGen to Merck within [*] days after receipt of an invoice and supporting documentation therefor. Notwithstanding the foregoing, in the event of termination of this Agreement by Merck under Section 14.2, with respect to any Ongoing Merck Proprietary Clinical Trial under the Development Plan for a Merck Proprietary Combination with the Initial Merck Proprietary Product that has been Initiated prior to the effective date of termination and that will continue after the effective date of termination pursuant to this Section 14.7.5(b), Merck shall continue to supply the Initial Merck Proprietary Product, at Merck's cost, for use in each such Clinical Trial in accordance with (and for the quantities set forth in) the Development Plan as in existence as of the effective date of termination of this Agreement.

(c) Trademarks. Subject to compliance with Applicable Laws, to the extent it is legally permitted to do so, Merck shall transfer to SeaGen, at SeaGen's cost (provided that if this Agreement is terminated by Merck under Section 14.2 or by SeaGen pursuant to Section 14.4.2 for Merck's material breach, then SeaGen shall not be required to reimburse Merck for such costs), any Merck Collaboration Marks (including all applications therefor), in each case, that are owned by Merck or its Affiliate and that are solely and exclusively for the Licensed Product (but excluding any of the foregoing that are related to any Combination Product that is co-formulated with any Merck Proprietary Product, which shall be addressed under a separate agreement between the Parties as set forth in Section 14.7.5(g)), and solely as they exist as of the effective date of termination (and, following such transfer, such Merck Collaboration Marks shall thereafter be deemed to be SeaGen Collaboration Marks).

(d) Inventory. Merck shall transfer to SeaGen the remaining inventory of Licensed Product (including work-in-progress) owned by, and in the possession of, Merck (or its Affiliate), and, (i) solely if such Licensed Product was manufactured by or on behalf of Merck or its Affiliate, SeaGen shall pay to Merck the Cost of Goods Manufactured of such inventory (and work-in-progress) plus the costs of transportation to SeaGen, or (ii) solely if such Licensed Product was manufactured by or on behalf of SeaGen and paid for by Merck under a SeaGen Supply



Agreement, SeaGen shall pay to Merck the price for such inventory (and work-in-progress) paid by Merck to SeaGen under such SeaGen Supply Agreement plus the costs of transportation to SeaGen (provided that, in each case ((i) and (ii)) if any of the foregoing amounts have already been included in the calculation of Allowable Development Costs or Allowable Commercialization Costs and shared equally between the Parties hereunder (for example, the Cost of Goods Manufactured of any clinical supplies of the Licensed Product that were already included as Allowable Development Costs) then SeaGen shall only be required to pay for the remaining half of the applicable costs in the foregoing clauses (i) and (ii) pursuant to this Section 14.7.5(d)), which costs shall be paid by SeaGen to Merck within [*] days after receipt of an invoice therefor.

(e) Licenses. Merck shall, and effective upon termination of this Agreement hereby does, grant, on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant), to SeaGen under [*] the "Reversion Product") and necessary for SeaGen to continue the Development and Commercialization of the Reversion Product, in each case, with a right to grant and authorize sublicenses through multiple tiers, a non-exclusive, perpetual, irrevocable, royalty-free, fully paid-up, license to import, use, sell, offer to sell and otherwise commercialize the Reversion Product in the Field for the Territory, [*] to the [*], pursuant to this Agreement, [*] has [*] or has [*] for the [*] or [*], the "SeaGen Continuing Combinations"). In addition, the licenses and provisions set forth in Section 2.3.2 shall survive with respect to the use of the Reversion Product in the SeaGen Continuing Combinations, but solely for SeaGen to use those Promotional Materials and packaging and labeling for the SeaGen Continuing Combinations existing as of the effective date of termination to promote and commercialize the SeaGen Continuing Combination (and for no other purposes) and subject to the terms and conditions set forth in Section 2.3.2, *mutatis mutandis*. In addition, Merck shall, and effective upon termination of this Agreement hereby does, grant, on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant), to SeaGen a fully-paid, royalty-free, Co-Exclusive (with Merck and its Affiliates) right and license, with the right to grant sublicenses through multiple tiers (subject to Section 2.6), under [*], to seek and obtain regulatory approval for, import, use, sell and offer to sell (including Commercialize) and otherwise exploit the applicable Licensed Product for use in the corresponding SeaGen Continuing Combination. In furtherance of the foregoing, Merck shall, and hereby does, grant on behalf of itself and its Affiliates (and hereby causes its Affiliates to grant) to SeaGen a right of reference to any INDs, MAAs and Marketing Authorizations for the Reversion Product that are Controlled by Merck or any of its Affiliates as of the effective date of termination, which right of reference shall be for use in connection with the Reversion Product for use in the SeaGen Continuing Combinations in the Field for the Territory. At the request of SeaGen, Merck shall provide to SeaGen a cross-reference letter or similar communication to the applicable Governmental Authority to effectuate such right of reference.

(f) Transition of Contracts. Merck shall, at SeaGen's cost (provided that if this Agreement is terminated by Merck under Section 14.2 or by SeaGen pursuant to Section 14.4.2 for Merck's material breach, then SeaGen shall not be required to reimburse Merck for such costs), assign (to the extent assignable and without penalty to Merck or its Affiliate), upon request of SeaGen within [*] days after the effective date of termination, any agreements with Third Party subcontractors and vendors (including Distributors) that are solely and exclusively for the Licensed Product to Develop, Manufacture or otherwise Commercialize the Licensed Product; provided that, to the extent any such Third Party agreement is not assignable to SeaGen, Merck



shall, at SeaGen's cost, reasonably cooperate with SeaGen to assist SeaGen to arrange to continue to receive such services for a reasonable time (not to exceed [*]) after termination. If such costs are to be borne by SeaGen as set forth in this Section 14.7.5(f), SeaGen shall pay Merck for the costs of such activities, which costs shall be paid by SeaGen to Merck within [*] after receipt of an invoice therefor.

(g) Combination Products with Merck Proprietary Products. In the event that as of the date of termination of this Agreement, the Parties are conducting Clinical Trials hereunder for, or are Commercializing hereunder, a Licensed Product that is a Combination Product that is co-formulated with any Merck Proprietary Product, then the Parties shall negotiate in good faith to enter into a separate agreement to address the rights and responsibilities of the Parties with respect to such Combination Product following termination of this Agreement.

(h) Conditions. Notwithstanding the foregoing provisions of this Section 14.7.5, the foregoing transfers, assignments and licenses by Merck shall be provided on an "as is" basis (without any representations and warranties).

14.7.6 Continuing Payments from SeaGen to Merck. In the event that Merck terminates this Agreement under Section 14.4.1, 14.5 or 14.6, the following shall apply:

(a) SeaGen shall pay to Merck, on a Continuing Product-by-Continuing Product basis, an amount equal to the Applicable Percentage of the aggregate net sales of the applicable Continuing Product sold by any Continuing Party (which net sales shall be calculated, on a Continuing Product-by-Continuing Product basis, in a manner consistent with the definition of "Licensed Product Net Sales" hereunder, mutatis mutandis) during the applicable Continuing Payment Term (which Continuing Product Term shall be determined on a Continuing Product-by-Continuing Product and country-by-country basis) (the "Continuing Product Payments"). For purposes of this Section 14.7.6, the following terms shall have the following meanings:

"Applicable Percentage" means, [*]

- (i) "Continuing Party" means [*].
- (ii) "Continuing Payment Term" means, [*].
- (iii) "Continuing Product" means [*].
- (iv) "Recoupment Amount" means [*].

(b) The Continuing Product Payments shall be paid to Merck on a quarterly basis, and in connection therewith, (i) [*] after the end of each calendar quarter during which any Continuing Product was sold, SeaGen shall provide to Merck a report setting forth the net sales (including the calculation thereof) and the Continuing Product Payments payable thereon, and SeaGen shall remit payment of the Continuing Product Payments to Merck simultaneously with the delivery of each such report, (ii) the provisions of Sections 10.5, 10.6 and 10.7 shall apply, mutatis mutandis, and (iii) from and after such time as the aggregate Continuing Product Payments

for all Continuing Products paid to Merck pursuant to Section 14.7.6(a) equal the Recoupment Amount, the provisions of Schedule 14.7.6 shall apply.

(c) Payment Conditions for Continuing Product. All Continuing Product Payments are subject to the following conditions: (i) only one Continuing Product Payment shall be due with respect to the same unit of Continuing Product; (ii) no Continuing Product Payment shall be due upon the sale or other transfer among SeaGen or its Affiliates or any other Continuing Party for resale purposes, but in such cases the payment shall be due and calculated upon the applicable Continuing Party's net sales of the Continuing Product (which net sales shall be calculated in a manner consistent with the definition of "Licensed Product Net Sales" hereunder, *mutatis mutandis*) to the first independent Third Party; and (iii) no Continuing Product Payments shall accrue on the disposition of Continuing Product by any Continuing Party as samples (promotion or otherwise) or as donations (e.g., to non-profit institutions or government agencies for a non-commercial purpose) or for development (per the defined term "Develop", *mutatis mutandis*) activities.

14.7.7 Licenses from SeaGen to Merck. The licenses and rights of reference granted to Merck as set forth in Section 2.2.3 shall survive any termination of this Agreement with respect to the applicable Merck Proprietary Products for use in each Merck Proprietary Combination, but solely if Merck (or its designee) [*] to the [*] to the [*] for the [*] in such [*] such a [*] pursuant to [*] the "Merck Continuing Combinations"). In addition, the licenses and provisions set forth in Section 2.2.4 shall survive with respect to the applicable Merck Proprietary Products for use in the Merck Continuing Combinations, but subject to the terms and conditions set forth in Section 2.2.4, *mutatis mutandis*.

14.8 Milestone Payments. For clarity, Merck shall still be obligated to make any Milestone Payment to SeaGen with respect to any Milestone Event achieved during the period commencing on the date of notice of termination of this Agreement and ending on the effective date of termination of this Agreement; provided, however, that Merck shall not be obligated to make such Milestone Payments to SeaGen with respect [*] if the [*] is a [*] of such [*] to such [*] of any [*] pursuant to [*].

14.9 Effect of Expiration or Termination; Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing upon or prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other Party accrued or accruing under this Agreement upon or prior to expiration or termination, including the obligation to share Allowable Development Costs, Allowable Commercialization Costs and Allowable Joint IP Costs incurred prior to such expiration or termination in accordance with this Agreement, and to share the Licensed Product Net Sales from Licensed Product sold prior to such expiration or termination, and Sublicensee Revenues received with respect to Licensed Product prior to the date of expiration or termination, and (subject to Section 14.8) the obligation to pay Milestone Payments with respect to Milestone Events achieved prior to the date of expiration or termination, in each case, in accordance with the provisions of Article 10, and in furtherance thereof, the Parties shall conduct a final accounting in accordance with the provisions of Section 10.4 as soon as reasonably practicable following expiration or termination of this Agreement to effectuate such sharing and payments. In addition,



nothing in this Section 14.9 or otherwise shall relieve any Party from liability for any breach of this Agreement occurring prior to such expiration or termination or any Shared Liability Action arising from Licensed Product sold or administered prior to such expiration or termination. In addition, the provisions of Sections 2.4.1, 5.2.7, 5.3.4 (first sentence only, and for a period of time consistent with Applicable Law for record retention), 5.5.7 (with respect to units of Licensed Products administered or sold prior to the expiration or termination of this Agreement), 6.8 (with respect to units of Licensed Products administered or sold prior to the expiration or termination of this Agreement), 7.7 (with respect to units of Licensed Products administered or sold prior to the expiration or termination of this Agreement), 10.5 (with respect to payments that are accrued but unpaid at the time of expiration or termination, or otherwise to the extent applicable), 10.6 (for the period set forth therein), 10.7, 11.6 (for the time period set forth therein), 11.7, 12.3, 14.7, 14.8 and 14.9 and Articles 1 (to the extent the definitions are used in other surviving provisions), 9 (for the time period set forth therein, but not Section 9.5), 13, 15 and 16 (but not Section 16.4.2(b), other than Section 16.4.2(b)(iii)(H)), shall survive any termination of this Agreement.

ARTICLE 15 TAX MATTERS

15.1 Tax Partnership. It is expressly agreed that SeaGen and Merck shall be independent contractors and that neither Party is assuming liability through, and nothing herein is intended to create, any partnership or agency arrangement between SeaGen and Merck for tax purposes in any jurisdiction in which any activities contemplated by this Agreement and associated agreements are undertaken; provided, however, that the Parties intend that the arrangement between the Parties hereunder shall be treated as a partnership for United States federal and state income tax purposes only (the "Tax Partnership"), and in connection therewith, Merck is authorized and shall file an election with the United States Internal Revenue Service (and any applicable state Governmental Authority in the United States) to the extent necessary for the arrangement hereunder to be treated as a partnership for United States federal income tax purposes (and state income tax purposes, as applicable). Except as otherwise agreed to by SeaGen and Merck in writing, neither Merck nor SeaGen shall file any returns or take any tax reporting positions inconsistent with the characterization of the arrangement hereunder as a Tax Partnership.

15.2 Tax Information Sharing. Each Party shall cooperate in providing any information reasonably requested by the other Party to enable such other Party to report the transactions contemplated by this Agreement on any required tax returns (including information returns), to respond to any request for information from the United States Internal Revenue Service or other taxing authority and to comply with its financial reporting obligations in connection with the financial reporting for taxes. In connection the foregoing, Merck shall use commercially reasonable efforts to provide SeaGen with estimates of its share of the Tax Partnership's profit and loss in advance of SeaGen's annual Form 10-K filing deadline.

15.3 Tax Returns of Tax Partnership. Merck shall prepare, or cause to be prepared, and file on a timely basis with the appropriate authorities, annual income and other required tax returns for the Tax Partnership, including IRS Form 1065 and any similar tax returns filed with any state or local jurisdiction, and SeaGen shall reasonably cooperate with Merck in connection therewith, including by timely providing to Merck all documents and information in SeaGen's control or possession that are reasonably requested by Merck and that are required to accurately



fill out the Tax Partnership tax return (including any related information returns) by Merck or any of its Affiliates, it being understood that SeaGen shall have the right to make appropriate redactions of information unrelated to activities undertaken pursuant to this Agreement. Schedule 15.3 sets forth the procedures to be used in allocating tax items of the Tax Partnership to Merck and SeaGen. SeaGen shall have the right to review any tax returns of the Tax Partnership prepared, or caused to be prepared, by Merck, in each case in advance of their submission and Merck shall obtain SeaGen's consent to the filing of such return, including with respect to any elections or other determinations made in such returns, which consent shall not be unreasonably withheld, conditioned or delayed. Merck shall have all powers needed to perform its duties, including the power to retain all attorneys and accountants of its choice in connection therewith, and to make any US federal, state, or local tax elections with SeaGen's consent, which shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, the tax elections listed in Schedule 15.3 shall not require SeaGen's consent. The Tax Partnership shall apply the [*] method of allocation under Section [*] for any contributions of property deemed to be made to the Tax Partnership, except as otherwise agreed by SeaGen and Merck in writing. Merck shall take steps to have the Tax Partnership elect under Section 6221(b) of the U.S. Internal Revenue Code (the "Code"), as amended by the Bipartisan Budget Act of 2015, P.L. 114-74 (together with any subsequent amendments thereto, Treasury Regulations promulgated thereunder, and published administrative interpretations thereof, collectively, the "BBA") (such election, the "6221(b) election") not to be subject to partnership-level audit proceedings. Merck is hereby designated the "partnership representative" of the Tax Partnership for all years governed by this Agreement and the "designated individual" shall be an officer or employee of Merck. To the extent that the Tax Partnership is not eligible to make the 6221(b) election, (a) Merck shall represent the Tax Partnership in any disputes, controversies or proceedings with the Internal Revenue Service or with any state or local taxing authority and is hereby authorized to take any and all actions that it is permitted to take when acting in that capacity, (b) SeaGen shall have the right to participate in all material tax proceedings (including for the avoidance of doubt audits) of the Tax Partnership and shall have the right to consent to the settlement thereof (such consent not to be unreasonably withheld, conditioned or delayed), (c) SeaGen shall have the right to be notified of all tax proceedings, (d) the Tax Partnership shall make the election provided by Section 6226 of the Code in respect of any underpayments of tax resulting from an audit of the Tax Partnership and (e) the foregoing provisions related to the BBA shall survive termination of this Agreement and the termination of the Tax Partnership, and shall remain binding on each party for the period of time necessary to resolve with the Internal Revenue Service (or any other applicable taxing authority) all tax matters relating to the Tax Partnership.

15.4 Additional Matters. Notwithstanding Section 15.1 or any other provision of this Agreement, the Parties do not intend to create a partnership under the laws of any jurisdiction, except the Parties intend to create a Tax Partnership, and the Parties shall take positions accordingly for accounting and tax purposes with any applicable Governmental Authority in any other jurisdiction in which any activities contemplated by this Agreement and associated agreements are undertaken. To the extent that the activities contemplated by this Agreement are treated in any such other jurisdiction as a partnership for purposes of computing Merck's or SeaGen's tax liability in such jurisdiction, the Parties agree that, to the extent permissible under the Applicable Law of such jurisdiction, items of partnership income and deduction will be



allocated in a manner that, as close as possible, places the Parties in the same position as if no deemed partnership were created.

ARTICLE 16 MISCELLANEOUS

16.1 Use of Affiliates. Either Party shall have the right to exercise its rights and perform its obligations under this Agreement and the Ancillary Agreements either itself or through any of its Affiliates. In addition, in each case where a Party's Affiliate has an obligation pursuant to this Agreement or any Ancillary Agreement or performs an obligation pursuant to this Agreement or any Ancillary Agreement, (a) such Party shall cause and compel such Affiliate to perform such obligation and comply with the terms of this Agreement or such Ancillary Agreement and (b) any breach of the terms or conditions of this Agreement or any Ancillary Agreement by such Affiliate shall be deemed a breach by such Party of such terms or conditions.

16.2 Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" and words of similar import shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) 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), (e) any reference herein to any Person shall be construed to include the Person's successors and assigns, (f) 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, (g) all references herein to Sections, Exhibits or Schedules shall be construed to refer to Sections, Exhibits or Schedules of this Agreement, and references to this Agreement include all Exhibits and Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof and (k) the word "or" is disjunctive but not necessarily exclusive.

16.3 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from any event or cause beyond the reasonable control of the affected Party or any of its Affiliates, potentially including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, global shortages of energy, raw materials or supplies, epidemics, pandemics, fire, floods, or other acts of God, or acts, omissions or delays in acting by any Governmental Authority (each such event



or cause, a "Force Majeure"). The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake Commercially Reasonable Efforts necessary to cure such Force Majeure circumstances. Notwithstanding the foregoing, no Force Majeure shall relieve a Party of any payment obligations hereunder.

16.4 Assignment.

16.4.1 Except as provided in this Section 16.4, this Agreement may not be assigned or otherwise transferred (however structured, whether by merger, acquisition, sale of all or substantially all of its assets to which this Agreement relates or otherwise), nor may any right or obligation hereunder be assigned or transferred, by either Party, without the prior written consent of the other Party; provided, however, that (a) Merck or SeaGen may assign this Agreement or any of its rights and obligations hereunder, in whole or in part, to (i) [*] or (ii) [*], provided that in the event of an assignment to [*] the Parties shall [*]; and provided that, in each case of the foregoing clauses (i) and (ii), the assigning Party shall [*], (b) Merck may assign this Agreement and its rights and obligations hereunder to [*], and (c) SeaGen may assign this Agreement and its rights and obligations hereunder to [*], in each case of (a), (b) and (c), without the prior written consent of the other Party. Any attempted assignment not in accordance with this Section 16.4 shall be null, void and unenforceable. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties hereto and their respective successors and permitted assigns.

16.4.2 Change of Control. Whether or not this Agreement is assigned pursuant to Section 16.4.1, the Parties agree as follows:

(a) The rights to Patent Rights, Know-How or other intellectual property rights of any successor-in-interest of a Party as a result of a Change of Control of such Party or any Person that becomes an Affiliate of a Party through any Change of Control of such Party, that were controlled by such successor or Person (and not such Party or any of its Affiliates prior to such Change of Control) immediately prior to such Change of Control (other than as a result of a license or other grant of rights, covenant or assignment by such Party or its other Affiliates to, or for the benefit of, such Person), will not be deemed to be "Controlled" by such Party for purposes of this Agreement and will be automatically excluded from the rights licensed to the other Party under this Agreement, provided in each case except to the extent that any such Patent Rights, Know-How or other intellectual property rights (i) are actually used in the course of such Party's or such Third Party successor-in-interest's performance of activities under this Agreement, or (ii) was otherwise licensed or sublicensed (as applicable) by such Third Party to such Party, or any Persons that were Affiliates of such Party, in each case under this sub-part (ii), prior to such Change of Control (as applicable) (such excluded Know How, Patent Rights or other intellectual property rights, "Acquiring Person Intellectual Property").

(b) In the event of a Change of Control of SeaGen with a Third Party (such Third Party, together with its affiliates immediately prior to the Change of Control,



collectively the "SeaGen Acquiror"), [*], then notwithstanding anything to the contrary contained herein (including Section 4.1) or in any Ancillary Agreement, the following shall apply:

(i) Sensitive Information. Following the consummation of any such Change of Control of SeaGen, SeaGen and its Affiliates (including the SeaGen Acquiror) shall [*] implement reasonable procedures [*] to restrict access to [*] (collectively, the "Sensitive Information") [*]. Without limiting the foregoing, from and after the consummation of the Change of Control, [*]; and

(ii) [*]. With respect to any [*], such [*] shall be performed in accordance with this Agreement [*]; provided that, in connection therewith (and notwithstanding anything to the contrary contained herein), the following shall apply:

(A) with respect to any [*], Merck shall [*] and in the event that Merck [*], the Parties shall [*] in good faith [*], as soon as reasonably practicable, [*];

(B) notwithstanding the provisions of [*] Merck shall [*]; provided that [*] shall not (x) [*] without the consent of [*], or (y) [*] without the consent of [*] unless [*]; and

(C) notwithstanding the foregoing provisions of this Section 16.4.2(b)(ii) or anything to the contrary contained herein, Merck shall [*] in which case such [*] and the provisions of [*] shall apply (in lieu of the provisions of this Section 16.4.2(b)(ii) with respect to [*]).

(iii) [*]. Notwithstanding anything to the contrary contained herein [*] but subject to [*] from and after the consummation of such Change of Control [*], Merck shall [*]; provided that, in connection therewith, the following shall apply:

(A) such [*] shall not be [*]. Merck shall be [*] (and, except for [*] as set forth in the following clause (C), if applicable, SeaGen shall [*];

(B) prior to [*], Merck shall [*];

(C) if SeaGen is [*], SeaGen shall [*]; provided that Merck shall [*] (but, for clarity, such [*] shall not be [*];

(D) Merck shall have [*]; provided that, [*] only the [*] (or such other [*]) shall be [*];

(E) SeaGen shall [*] for the [*];

(F) Merck shall [*]; provided that, notwithstanding the foregoing, Merck shall [*], in each case, [*]. Any [*] shall, as between the Parties, [*] and shall be [*] (and the [*] shall be [*]); provided that such [*] shall be deemed to be [*];

such [*] for [*]; and (G) Merck shall [*]; provided that [*] shall [*] any

(H) notwithstanding the provisions of [*] upon [*] SeaGen shall [*] and Merck shall [*].

For clarity, (1) [*] shall be deemed to be a [*] (notwithstanding that [*] and that such [*]), (2) the Parties hereby agree and acknowledge that the [*] shall apply to [*] notwithstanding that [*], and (3) Merck [*] as set forth in [*].

(iv) [*]. From and after the consummation of such Change of Control, (A) SeaGen shall [*] any [*], in each case, for the [*] and (B) the [*] of such [*], as applicable, in the foregoing clause (A) shall [*]. For clarity, SeaGen shall [*] in accordance with this Agreement; provided that such [*] shall be [*] in accordance with Applicable Laws.

(v) [*]. Notwithstanding anything to the contrary contained herein [*] but subject to [*] from and after the consummation of such Change of Control during the remainder of the Term, SeaGen shall [*]; provided that, in connection therewith, the following shall apply:

(A) such [*] shall not be [*]. SeaGen shall be [*] (and, except for [*] as set forth in the following clause (C), if applicable, Merck shall [*];

(B) prior to [*] SeaGen shall [*];

(C) if Merck is [*], Merck shall [*]; provided that SeaGen shall [*] (but, for clarity, such [*] shall not be [*];

(D) SeaGen shall have [*]; provided that, if [*] only the [*] (or such other [*]) shall be [*];

(E) Merck shall [*] for the [*];

(F) SeaGen shall [*]; provided that, notwithstanding the foregoing, SeaGen shall [*], in each case, [*]. Any [*] shall, as between the Parties, [*] and shall be [*] (and the [*] shall be [*]); provided that such [*] shall be deemed to be [*]; and

(G) SeaGen shall [*]; provided that [*] shall [*] any such [*] for [*].

For clarity, (1) [*] shall be deemed to be a [*] (notwithstanding that [*] and that such [*]), (2) the Parties hereby agree and acknowledge that [*] shall apply to [*] notwithstanding that [*], and (3) SeaGen [*] as set forth in Section 2.4.2, mutatis mutandis.

(vi) [*]. From and after the consummation of such Change of Control, (A) Merck shall [*] any [*], in each case, for the [*] and (B) the [*] of such [*], as applicable, in the foregoing clause (A) shall [*]. For clarity, Merck shall [*] in accordance with this Agreement; provided that [*] shall be [*] in accordance with Applicable Laws.



(vii) [*].

(A) In the event that Merck [*] in any country or region [*] then at the request of Merck, SeaGen [*] shall [*], and the Parties shall promptly update the [*] in connection therewith [*]. For clarity, the [*] shall be [*].

(B) In the event that SeaGen [*] in any country or region [*] then at the request of SeaGen, Merck [*] shall [*], and the Parties shall promptly update [*] in connection therewith [*]. For clarity, the [*] shall be [*].

(viii) [*]. Notwithstanding the provisions of [*] from and after the consummation of such Change of Control with a SeaGen Acquiror, the following shall apply:

(A) if Merck [*], then if [*] as a result of (x) [*] or (y) [*]; and

(B) no [*] shall be [*].

For clarity, notwithstanding the foregoing, all other [*] shall [*] from and after the consummation of such Change of Control with a SeaGen Acquiror (including that [*] as a result of [*] (irrespective of [*]), and, for clarity, without [*]), the [*].

16.5 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of a Party. The Parties shall, in such an instance, use their reasonable best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) that, insofar as practical, implement the purposes of this Agreement.

16.6 Notices. All notices which are required or permitted pursuant to this Agreement shall be in writing in the English language and will be sufficient and deemed to have been duly given when (a) sent by facsimile transmission (receipt verified), provided further that a copy is promptly sent by an internationally recognized overnight delivery service (receipt requested) (although the sending of the fax shall be when the notice is deemed to have been given), or (b) the earlier of when received by the addressee or five (5) Business Days after it was sent, if delivered personally, sent by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to SeaGen, to: Seattle Genetics, Inc.
21823 30th Drive St
Bothell, WA 98021
Fax: [*]
Email: [*]
Attention: General Counsel



if to Merck, to: Merck Sharp & Dohme Corp.
2000 Galloping Hill Road
Kenilworth, NJ 07033-1310
Attention: Office of Secretary
Email: [*]

with a copy to: Merck Sharp & Dohme Corp.
2000 Galloping Hill Road
Mail Stop K-1-4161
Kenilworth, NJ 07033
Attention: SVP, Corporate Development

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. This Section 16.6 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

16.7 Applicable Law. This Agreement shall be governed by and construed in accordance with the Applicable Law of the State of New York, United States, and the patent law of the United States without reference to any rules of conflict of laws or renvoi that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The United Nations Convention on Contracts for the International Sale of Goods (CISG) of 11 April 1980 shall not be applicable.

16.8 Dispute Resolution.

16.8.1 The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or any Ancillary Agreement, including the formation, existence, validity, enforceability, performance, interpretation, breach, or termination hereof or thereof (a "Dispute"). If the Parties do not fully resolve any such Dispute within [*] after a party first notifies the other Party of such Dispute, and a Party wishes to pursue the matter, then, except as otherwise set forth herein, each such Dispute that is not an "Excluded Claim" (as defined below) shall be finally resolved in accordance with Section 16.8.2; provided, however, that, notwithstanding the foregoing, any decisions that are subject to the final decision-making authority of a given Party (or mutual agreement of the Parties, as applicable) or the JSC, as expressly set forth in this Agreement, including Section 3.2.4(b), will not be subject to the provisions of this Section 16.8 so long as such decisions are made in accordance with this Agreement.

16.8.2 Executive Review; Arbitration.

(a) In the event the Parties have not resolved such Dispute within such [*] as set forth in Section 16.8.1 and such Dispute has not previously been submitted to the Senior Executives or [*] for resolution, then either Party (through the Alliance Managers) may elect to formally submit such issue to the Parties' applicable Senior Executives for resolution. In



the event that the Senior Executives are unable to resolve a given issue referred to the Senior Executives in accordance with this Section [*] after the dispute is formally submitted to the Senior Executives for resolution, then either Party (through the Alliance Managers) may elect to formally submit such issue to the Parties' respective [*] for resolution.

(b) In the event that the Parties' respective [*] are unable to resolve a given issue referred to the [*] in accordance with Section 16.8.2(a) within [*] after the dispute is formally submitted to the [*] for resolution, then either Party may submit such Dispute to be finally settled by arbitration administered in accordance with the procedural rules of the American Arbitration Association ("AAA") in effect at the time of submission, as modified by this Section 16.8.2(a). The arbitration will be governed by the Applicable Laws of the state of New York. The arbitration will be heard and determined by three (3) arbitrators who are retired judges or attorneys with at least ten (10) years of relevant experience in the pharmaceutical industry, each of whom will be impartial and independent. Each Party will appoint one (1) arbitrator and the third (3rd) arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement within thirty (30) days following appointment of the second arbitrator, by AAA. Such arbitration will take place in New York, New York. The arbitration award so given will be a final and binding determination of the dispute, will be fully enforceable in any court of competent jurisdiction, and will not include any damages expressly prohibited by Section 13.6. Fees, costs and expenses of arbitration are to be divided by the Parties in the following manner: Merck will pay for the arbitrator it chooses, SeaGen will pay for the arbitrator it chooses, and the Parties will share payment for the third arbitrator. Except in a proceeding to enforce the results of the arbitration or as otherwise required by Applicable Law, neither Party nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both Parties (each such consent not to be unreasonably withheld, delayed or conditioned). In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred, consistent with Section 16.7, by the applicable New York statute of limitations.

(c) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect its rights or property pending the arbitration award.

(d) The Parties agree that, in the event of a good faith dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination, and any cure period shall commence thereafter. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be promptly refunded if an arbitrator determines that such payments are not due.

(e) As used in this Section 16.8, the term "Excluded Claim" means a dispute, controversy or claim that concerns (i) the validity or infringement of a patent, trademark, copyright or trade secret, or (ii) any antitrust, anti-monopoly or competition Applicable Law or



regulation, whether or not statutory. Any action concerning Excluded Claims identified in clauses (i) or (ii) of this Section 16.8.2(e) may be brought in any court having jurisdiction.

16.9 Entire Agreement; Amendments. This Agreement, together with the Schedules and Exhibits hereto, and the Ancillary Agreements and the DPA contain the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof are superseded by the terms of this Agreement, including that certain Mutual Non-Disclosure Agreement between the Parties (or their respective Affiliates) dated as of [*] (as amended, the "Existing CDA"), to the extent that such Existing CDA relates to the subject matter hereof (provided that Confidential Information related to the subject matter hereof and disclosed under such Existing CDA shall be deemed to be disclosed hereunder). In the event of any conflict between the terms and conditions of the CTC and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall govern. The Schedules and Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of each of the Parties. In the event of a conflict between the terms of this Agreement and one or more Ancillary Agreements, the terms of this Agreement shall govern unless the relevant Ancillary Agreement expressly states that, with respect to the terms subject to the conflict, the Ancillary Agreement governs over this Agreement.

16.10 Export Controls. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States, or other countries that may be imposed on or related to the Parties from time to time, in each case, under Applicable Law. 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 approval, without first obtaining the written consent to do so from the appropriate Governmental Authority in accordance with Applicable Law.

16.11 Headings. The captions to the Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the Articles and Sections hereof.

16.12 Independent Contractors. It is expressly agreed that SeaGen and Merck shall be independent contractors hereunder, and neither SeaGen nor Merck shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party. Except as otherwise set forth in Article 15, it is understood and agreed that the relationship of the two Parties shall not constitute a partnership, joint venture or agency for tax or any other purposes.

16.13 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto, and no Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, Sections 13.1 and 13.2 are intended to



benefit, in addition to the Parties, the other SeaGen Indemnified Parties and Merck Indemnified Parties, but this Agreement is enforceable only by the Parties.

16.14 Waiver. The waiver by either Party of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise. Any waivers under this Agreement must be in writing to be effective.

16.15 Cumulative Remedies. Except as expressly set forth in this Agreement, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law or in equity, including the right to seek damages, specific performance and other remedies under Applicable Law or in equity.

16.16 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

16.17 Business Day Requirements. In the event that any notice or other action is required to be taken by a Party under this Agreement on a day that is not a Business Day, then such notice or other action shall be deemed to be required to be taken on the next occurring Business Day.

16.18 Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together, and shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, jpeg or similar attachment to electronic mail (any such delivery, an "Electronic Delivery") shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party hereto shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each Party forever waives any such defense, except to the extent that such defense relates to lack of authenticity.

16.19 Further Actions. Each Party will execute, acknowledge and deliver such further instruments, and do all such other ministerial, administrative or similar acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement.

[Signature page follows]



IN WITNESS WHEREOF, the Parties have executed this License and Collaboration Agreement as of the Effective Date.

MERCK SHARP & DOHME CORP.

BY: /s/ Robert M. Davis

NAME: Robert M. Davis

TITLE: Executive Vice President, Global Services, and
Chief Financial Officer, Merck & Co., Inc. and
Authorized Officer, Merck Sharp & Dohme Corp.

SEATTLE GENETICS, INC.

BY: /s/ Clay B. Siegall

NAME: Clay B. Siegall, Ph.D.

TITLE: President and Chief Executive Officer

Signature Page to License and Collaboration 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 1.26

European Collaboration Territory

[*]

Schedule 1.39

Cost of Goods Manufactured

“Cost of Goods Manufactured” shall mean the fully allocated cost of manufacturing the Licensed Product or Licensed Compound, calculated in a manner that is consistent with the Lead Manufacturing Party’s standard practices for its products, consistently applied and in accordance with Accounting Standards, and consisting of the following components:

[*]

{2 pages omitted}

Schedule 1.133

SeaGen Existing CMO Agreements

[*]

Schedule 1.134

SeaGen Existing In-Licenses

[*]

Schedule 1.139

SeaGen Patents

(see attached)

[*]

{30 pages omitted}

Schedule 1.152

SGN-LIV-1-A

[*]

Schedule 1.153

SGN-LIV-1-B

[*]

Schedule 1.154

SGN-LIV-1-C

[*]

Schedule 2.7

Permitted Distributor Countries

[*]

Schedule 2.9.2

Next Generation Compound Criteria - SGN-LIV-1-C

[*]

{2 pages omitted}

Schedule 6.8

Certain Costs of Recalls

[*]

Schedule 7.9
Certain Terms for Supply Agreements
(see attached)

[*]

{11 pages omitted}

Schedule 9.6.1

Press Release

(see attached)



Seattle Genetics and Merck Announce Two Strategic Oncology Collaborations

Companies to Co-Develop and Co-Commercialize Seattle Genetics' Antibody-Drug Conjugate Ladiratumumab Vedotin Globally; Merck to Acquire \$1 Billion Equity Stake in Seattle Genetics Common Stock

Companies Enter Exclusive License and Co-Development Agreement to Accelerate Global Reach of TUKYSA for HER2-Positive Cancers in Regions Outside the United States, Canada and Europe

Seattle Genetics to Host Conference Call Today at 9:00 a.m. ET

BOTHELL, Wash. and KENILWORTH, N.J. - September 14, 2020 - Seattle Genetics, Inc. (Nasdaq: SGEN) and Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced two new strategic oncology collaborations.

The companies will globally develop and commercialize Seattle Genetics' ladiratumumab vedotin, an investigational antibody-drug conjugate (ADC) targeting LIV-1, which is currently in phase 2 clinical trials for breast cancer and other solid tumors. The collaboration will pursue a broad joint development program evaluating ladiratumumab vedotin as monotherapy and in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in triple-negative breast cancer, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors. Under the terms of the agreement, Seattle Genetics will receive a \$600 million upfront payment and Merck will make a \$1.0 billion equity investment in 5.0 million shares of Seattle Genetics common stock at a price of \$200 per share. In addition, Seattle Genetics is eligible for progress-dependent milestone payments of up to \$2.6 billion.

Separately, Seattle Genetics has granted Merck an exclusive license to commercialize TUKYSA® (tucatinib), a small molecule tyrosine kinase inhibitor, for the treatment of HER2-positive cancers, in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Seattle Genetics will receive \$125 million from Merck as an upfront payment and is eligible for progress-dependent milestones of up to \$65 million.

"Collaborating with Merck on ladiratumumab vedotin will allow us to accelerate and broaden its development program in breast cancer and other solid tumors, including in combination with Merck's KEYTRUDA, while also positioning us to leverage our U.S. and European commercial operations," said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. "The strategic

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collaboration for TUKY SA will help us reach more patients globally and benefit from the established commercial strength of one of the world's premier pharmaceutical companies."

"These two strategic collaborations will enable us to further diversify Merck's broad oncology portfolio and pipeline, and to continue our efforts to extend and improve the lives of as many patients with cancer as possible," said Dr. Roger M. Perlmutter, President, Merck Research Laboratories. "We look forward to working with the team at Seattle Genetics to advance the clinical program for ladiratumumab vedotin, which has shown compelling signals of efficacy in early studies, and to bring TUKY SA to even more patients with cancer around the world."

Ladiratumumab Vedotin Collaboration Details

Under the terms of the agreement, Seattle Genetics and Merck will collaborate and equally share costs on the global development of ladiratumumab vedotin and other LIV-1-targeting ADCs. The companies have agreed to jointly develop and share future costs and profits for ladiratumumab vedotin on a 50:50 basis worldwide. Merck will pay Seattle Genetics \$600 million upfront and make a \$1.0 billion equity investment in 5.0 million shares of Seattle Genetics common stock at a price of \$200 per share. In addition, Seattle Genetics will be eligible to receive up to \$2.6 billion in milestone payments, including \$850 million in development milestones and \$1.75 billion in sales milestones.

The companies will jointly develop and commercialize ladiratumumab vedotin and equally share profits worldwide. The companies will co-commercialize in the U.S. and Europe. Seattle Genetics will be responsible for marketing applications for approval in the U.S. and Canada, and will record sales in the U.S., Canada and Europe. Merck will be responsible for marketing applications for approval in Europe and in countries outside the U.S. and Canada, and will record sales in countries outside the U.S., Europe and Canada. Including the upfront payment, equity investment proceeds and potential milestone payments, Seattle Genetics is eligible to receive up to \$4.2 billion.

The closing of the equity investment is contingent on completion of review under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act).

TUKY SA Collaboration Details

Under the terms of the agreement, Merck has been granted exclusive rights to commercialize TUKY SA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Seattle Genetics retains commercial rights and will record sales in the U.S., Canada and Europe. Merck will be responsible for marketing applications for approval in its territory, supported by the positive results from the HER2CLIMB clinical trial.

Merck will also co-fund a portion of the TUKY SA global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers, including breast, colorectal, gastric and other cancers set forth in a global product development plan. Seattle Genetics will continue to lead ongoing TUKY SA global development planning and operational execution. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territory.

Seattle Genetics will receive from Merck \$125 million as an upfront payment and is eligible to receive progress-dependent milestones of up to \$65 million. Seattle Genetics will also receive \$85 million in prepaid research and development payments to be applied to Merck's global development funding obligations. In addition, Seattle Genetics would receive tiered royalties on sales of TUKY SA in Merck's territory.

The financial impact of these collaborations is not included in Seattle Genetics' 2020 guidance.

Seattle Genetics Conference Call Details

Seattle Genetics' management will host a conference call to discuss these collaborations today at 6:00 a.m. Pacific Time (PT); 9:00 a.m. Eastern Time (ET). The event will be simultaneously webcast and available for replay from the Seattle Genetics website at www.seattlegenetics.com, under the Investors section. Investors may also participate in the conference call by calling 844-763-8274 (domestic) or +1 412-717-9224 (international). The conference ID is 10147850.

About Ladiratumab Vedotin

Ladiratumab vedotin is a novel investigational ADC targeted to LIV-1. Most metastatic breast cancers express LIV-1, which also has been detected in several other cancers, including lung, head and neck, esophageal and gastric. Ladiratumab vedotin utilizes Seattle Genetics' proprietary ADC technology and consists of a LIV-1-targeted monoclonal antibody linked to a potent microtubule-disrupting agent, monomethyl auristatin E (MMAE) by a protease-cleavable linker. This novel ADC is designed to bind to LIV-1 on cancer cells and release the cell-killing agent into target cells upon internalization. Ladiratumab vedotin may also cause antitumor activity through other mechanisms, including activation of an immune response by induction of immunogenic cell death.

About TUKY SA (tucatinib)

TUKY SA is an oral, small molecule tyrosine kinase inhibitor (TKI) of HER2, a protein that contributes to cancer cell growth. TUKY SA in combination with trastuzumab and capecitabine was approved by the U.S. Food and Drug Administration (FDA) in April 2020 for adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. In addition, TUKY SA received approval in Canada, Singapore, Australia and Switzerland under the Project Orbis initiative of the FDA Oncology Center of Excellence that provides a framework for concurrent submission and review of oncology products among international partners. A marketing application is under review in the European Union.

TUKY SA is being evaluated in several ongoing clinical trials and additional studies are planned. Current trials include the following:

- [HER2CLIMB-02](#): a randomized, double-blind phase 3 trial evaluating TUKY SA in combination with T-DM1 (trastuzumab emtansine; Kadcyla[®]) versus T-DM1 in first- and second-line metastatic HER2-positive breast cancer.
- [CompassHER2 RD](#): a randomized, double-blind phase 3 trial of TUKY SA in combination with T-DM1 versus T-DM1 in the adjuvant breast cancer setting for patients at high risk of relapse.
- [MOUNTAINEER](#): a pivotal phase 2 trial evaluating TUKY SA in combination with trastuzumab (Herceptin[®]) in metastatic HER2-positive colorectal cancer.
- [MOUNTAINEER-02](#): a randomized phase 2/3 trial evaluating TUKY SA in combination with trastuzumab, ramucirumab and paclitaxel versus ramucirumab and paclitaxel in second-line metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma (GEC).
- [Gastrointestinal cancers](#): a phase 1 trial evaluating TUKY SA in combination with trastuzumab and oxaliplatin-based chemotherapy in metastatic HER2-positive colorectal, gastric/ gastroesophageal junction and gallbladder cancers.

For additional information, visit www.clinicaltrials.gov.

TUKYSA Important Safety Information

Warnings and Precautions

- Diarrhea – TUKYSA can cause severe diarrhea including dehydration, hypotension, acute kidney injury, and death. In HER2CLIMB, 81% of patients who received TUKYSA experienced diarrhea, including 12% with Grade 3 diarrhea and 0.5% with Grade 4 diarrhea. Both patients who developed Grade 4 diarrhea subsequently died, with diarrhea as a contributor to death. The median time to onset of the first episode of diarrhea was 12 days and the median time to resolution was 8 days. Diarrhea led to dose reductions of TUKYSA in 6% of patients and discontinuation of TUKYSA in 1% of patients. Prophylactic use of antidiarrheal treatment was not required on HER2CLIMB.

If diarrhea occurs, administer antidiarrheal treatment as clinically indicated. Perform diagnostic tests as clinically indicated to exclude other causes of diarrhea. Based on the severity of the diarrhea, interrupt dose, then dose reduce or permanently discontinue TUKYSA.

- Hepatotoxicity – TUKYSA can cause severe hepatotoxicity. In HER2CLIMB, 8% of patients who received TUKYSA had an ALT increase $>5 \times \text{ULN}$, 5% had an AST increase $>5 \times \text{ULN}$, and 1.5% had a bilirubin increase $>3 \times \text{ULN}$ (Grade ≥ 3). Hepatotoxicity led to dose reduction of TUKYSA in 8% of patients and discontinuation of TUKYSA in 1.5% of patients.

Monitor ALT, AST, and bilirubin prior to starting TUKYSA, every 3 weeks during treatment, and as clinically indicated. Based on the severity of hepatotoxicity, interrupt dose, then dose reduce or permanently discontinue TUKYSA.

- Embryo-Fetal Toxicity – TUKYSA can cause fetal harm. Advise pregnant women and females of reproductive potential risk to a fetus. Advise females of reproductive potential, and male patients with female partners of reproductive potential, to use effective contraception during TUKYSA treatment and for at least 1 week after the last dose.

Adverse Reactions

Serious adverse reactions occurred in 26% of patients who received TUKYSA. Serious adverse reactions in $\geq 2\%$ of patients who received TUKYSA were diarrhea (4%), vomiting (2.5%), nausea (2%), abdominal pain (2%), and seizure (2%). Fatal adverse reactions occurred in 2% of patients who received TUKYSA including sudden death, sepsis, dehydration, and cardiogenic shock.

Adverse reactions led to treatment discontinuation in 6% of patients who received TUKYSA; those occurring in $\geq 1\%$ of patients were hepatotoxicity (1.5%) and diarrhea (1%). Adverse reactions led to dose reduction in 21% of patients who received TUKYSA; those occurring in $\geq 2\%$ of patients were hepatotoxicity (8%) and diarrhea (6%).

The most common adverse reactions in patients who received TUKYSA ($\geq 20\%$) were diarrhea, palmar-plantar erythrodysesthesia, nausea, fatigue, hepatotoxicity, vomiting, stomatitis, decreased appetite, abdominal pain, headache, anemia, and rash.

Lab Abnormalities

In HER2CLIMB, Grade ≥ 3 laboratory abnormalities reported in $\geq 5\%$ of patients who received TUKYSA were: decreased phosphate, increased ALT, decreased potassium, and increased AST. The mean increase

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in serum creatinine was 32% within the first 21 days of treatment with TUKY SA. The serum creatinine increases persisted throughout treatment and were reversible upon treatment completion. Consider alternative markers of renal function if persistent elevations in serum creatinine are observed.

Drug Interactions

- Strong CYP3A or Moderate CYP2C8 Inducers: Concomitant use may decrease TUKY SA activity. Avoid concomitant use of TUKY SA.
- Strong or Moderate CYP2C8 Inhibitors: Concomitant use of TUKY SA with a strong CYP2C8 inhibitor may increase the risk of TUKY SA toxicity; avoid concomitant use. Increase monitoring for TUKY SA toxicity with moderate CYP2C8 inhibitors.
- CYP3A Substrates: Concomitant use may increase the toxicity associated with a CYP3A substrate. Avoid concomitant use of TUKY SA where minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, decrease the CYP3A substrate dosage.
- P-gp Substrates: Concomitant use may increase the toxicity associated with a P-gp substrate. Consider reducing the dosage of P-gp substrates where minimal concentration changes may lead to serious or life-threatening toxicity.

Use in Specific Populations

- Lactation: Advise women not to breastfeed while taking TUKY SA and for at least 1 week after the last dose.
- Renal Impairment: Use of TUKY SA in combination with capecitabine and trastuzumab is not recommended in patients with severe renal impairment (CL_{Cr} <30 mL/min), because capecitabine is contraindicated in patients with severe renal impairment.
- Hepatic Impairment: Reduce the dose of TUKY SA for patients with severe (Child-Pugh C) hepatic impairment.

For more information, please see the full Prescribing Information for TUKY SA [here](#).

About KEYTRUDA® (pembrolizumab) Injection, 100 mg

KEYTRUDA is an anti-PD-1 therapy that works by increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA is a humanized monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumor cells and healthy cells.

Merck has the industry's largest immuno-oncology clinical research program. There are currently more than 1,200 trials studying KEYTRUDA across a wide variety of cancers and treatment settings. The KEYTRUDA clinical program seeks to understand the role of KEYTRUDA across cancers and the factors that may predict a patient's likelihood of benefitting from treatment with KEYTRUDA, including exploring several different biomarkers.

Selected KEYTRUDA® (pembrolizumab) Indications

Melanoma

KEYTRUDA is indicated for the treatment of patients with unresectable or metastatic melanoma.

KEYTRUDA is indicated for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection.

Non-Small Cell Lung Cancer

KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.

KEYTRUDA, in combination with carboplatin and either paclitaxel or paclitaxel protein-bound, is indicated for the first-line treatment of patients with metastatic squamous NSCLC.

KEYTRUDA, as a single agent, is indicated for the first-line treatment of patients with NSCLC expressing PD-L1 [tumor proportion score (TPS) $\geq 1\%$] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, and is stage III where patients are not candidates for surgical resection or definitive chemoradiation, or metastatic.

KEYTRUDA, as a single agent, is indicated for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS $\geq 1\%$) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA.

Small Cell Lung Cancer

KEYTRUDA is indicated for the treatment of patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least 1 other prior line of therapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Head and Neck Squamous Cell Cancer

KEYTRUDA, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC).

KEYTRUDA, as a single agent, is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [combined positive score (CPS) ≥ 1] as determined by an FDA-approved test.

KEYTRUDA, as a single agent, is indicated for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy.

Classical Hodgkin Lymphoma

KEYTRUDA is indicated for the treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma (cHL), or who have relapsed after 3 or more prior lines of therapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Primary Mediastinal Large B-Cell Lymphoma

KEYTRUDA is indicated for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after 2 or more prior lines of therapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. KEYTRUDA is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy.

Urothelial Carcinoma

KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC) who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [combined positive score (CPS) ≥ 10], as determined by an FDA-approved test, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

KEYTRUDA is indicated for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

Microsatellite Instability-High or Mismatch Repair Deficient Cancer

KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

- solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or
- colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established.

Microsatellite Instability-High or Mismatch Repair Deficient Colorectal Cancer

KEYTRUDA is indicated for the first-line treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC).

Gastric Cancer

KEYTRUDA is indicated for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Esophageal Cancer

KEYTRUDA is indicated for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy.

Cervical Cancer

KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Hepatocellular Carcinoma

KEYTRUDA is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Merkel Cell Carcinoma

KEYTRUDA is indicated for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Renal Cell Carcinoma

KEYTRUDA, in combination with axitinib, is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

Tumor Mutational Burden-High

KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. The safety and effectiveness of KEYTRUDA in pediatric patients with TMB-H central nervous system cancers have not been established.

Cutaneous Squamous Cell Carcinoma

KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation.

Selected Important Safety Information for KEYTRUDA

Immune-Mediated Pneumonitis

KEYTRUDA can cause immune-mediated pneumonitis, including fatal cases. Pneumonitis occurred in 3.4% (94/2799) of patients with various cancers receiving KEYTRUDA, including Grade 1 (0.8%), 2 (1.3%), 3 (0.9%), 4 (0.3%), and 5 (0.1%). Pneumonitis occurred in 8.2% (65/790) of NSCLC patients receiving KEYTRUDA as a single agent, including Grades 3-4 in 3.2% of patients, and occurred more frequently in patients with a history of prior thoracic radiation (17%) compared to those without (7.7%). Pneumonitis occurred in 6% (18/300) of HNSCC patients receiving KEYTRUDA as a single agent,

including Grades 3-5 in 1.6% of patients, and occurred in 5.4% (15/276) of patients receiving KEYTRUDA in combination with platinum and FU as first-line therapy for advanced disease, including Grades 3-5 in 1.5% of patients.

Monitor patients for signs and symptoms of pneumonitis. Evaluate suspected pneumonitis with radiographic imaging. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold KEYTRUDA for Grade 2; permanently discontinue KEYTRUDA for Grade 3 or 4 or recurrent Grade 2 pneumonitis.

Immune-Mediated Colitis

KEYTRUDA can cause immune-mediated colitis. Colitis occurred in 1.7% (48/2799) of patients receiving KEYTRUDA, including Grade 2 (0.4%), 3 (1.1%), and 4 (<0.1%). Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 or greater colitis. Withhold KEYTRUDA for Grade 2 or 3; permanently discontinue KEYTRUDA for Grade 4 colitis.

Immune-Mediated Hepatitis (KEYTRUDA) and Hepatotoxicity (KEYTRUDA in Combination With Axitinib)

Immune-Mediated Hepatitis

KEYTRUDA can cause immune-mediated hepatitis. Hepatitis occurred in 0.7% (19/2799) of patients receiving KEYTRUDA, including Grade 2 (0.1%), 3 (0.4%), and 4 (<0.1%). Monitor patients for changes in liver function. Administer corticosteroids for Grade 2 or greater hepatitis and, based on severity of liver enzyme elevations, withhold or discontinue KEYTRUDA.

Hepatotoxicity in Combination With Axitinib

KEYTRUDA in combination with axitinib can cause hepatic toxicity with higher than expected frequencies of Grades 3 and 4 ALT and AST elevations compared to KEYTRUDA alone. With the combination of KEYTRUDA and axitinib, Grades 3 and 4 increased ALT (20%) and increased AST (13%) were seen. Monitor liver enzymes before initiation of and periodically throughout treatment. Consider more frequent monitoring of liver enzymes as compared to when the drugs are administered as single agents. For elevated liver enzymes, interrupt KEYTRUDA and axitinib, and consider administering corticosteroids as needed.

Immune-Mediated Endocrinopathies

KEYTRUDA can cause adrenal insufficiency (primary and secondary), hypophysitis, thyroid disorders, and type 1 diabetes mellitus. Adrenal insufficiency occurred in 0.8% (22/2799) of patients, including Grade 2 (0.3%), 3 (0.3%), and 4 (<0.1%). Hypophysitis occurred in 0.6% (17/2799) of patients, including Grade 2 (0.2%), 3 (0.3%), and 4 (<0.1%). Hypothyroidism occurred in 8.5% (237/2799) of patients, including Grade 2 (6.2%) and 3 (0.1%). The incidence of new or worsening hypothyroidism was higher in 1185 patients with HNSCC (16%) receiving KEYTRUDA, as a single agent or in combination with platinum and FU, including Grade 3 (0.3%) hypothyroidism. Hyperthyroidism occurred in 3.4% (96/2799) of patients, including Grade 2 (0.8%) and 3 (0.1%), and thyroiditis occurred in 0.6% (16/2799) of patients, including Grade 2 (0.3%). Type 1 diabetes mellitus, including diabetic ketoacidosis, occurred in 0.2% (6/2799) of patients.

Monitor patients for signs and symptoms of adrenal insufficiency, hypophysitis (including hypopituitarism), thyroid function (prior to and periodically during treatment), and hyperglycemia. For adrenal insufficiency or hypophysitis, administer corticosteroids and hormone replacement as clinically indicated. Withhold KEYTRUDA for Grade 2 adrenal insufficiency or hypophysitis and withhold or discontinue KEYTRUDA for Grade 3 or Grade 4 adrenal insufficiency or hypophysitis. Administer



hormone replacement for hypothyroidism and manage hyperthyroidism with thionamides and beta-blockers as appropriate. Withhold or discontinue KEYTRUDA for Grade 3 or 4 hyperthyroidism. Administer insulin for type 1 diabetes, and withhold KEYTRUDA and administer antihyperglycemics in patients with severe hyperglycemia.

Immune-Mediated Nephritis and Renal Dysfunction

KEYTRUDA can cause immune-mediated nephritis. Nephritis occurred in 0.3% (9/2799) of patients receiving KEYTRUDA, including Grade 2 (0.1%), 3 (0.1%), and 4 (<0.1%) nephritis. Nephritis occurred in 1.7% (7/405) of patients receiving KEYTRUDA in combination with pemetrexed and platinum chemotherapy. Monitor patients for changes in renal function. Administer corticosteroids for Grade 2 or greater nephritis. Withhold KEYTRUDA for Grade 2; permanently discontinue for Grade 3 or 4 nephritis.

Immune-Mediated Skin Reactions

Immune-mediated rashes, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) (some cases with fatal outcome), exfoliative dermatitis, and bullous pemphigoid, can occur. Monitor patients for suspected severe skin reactions and based on the severity of the adverse reaction, withhold or permanently discontinue KEYTRUDA and administer corticosteroids. For signs or symptoms of SJS or TEN, withhold KEYTRUDA and refer the patient for specialized care for assessment and treatment. If SJS or TEN is confirmed, permanently discontinue KEYTRUDA.

Other Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue in patients receiving KEYTRUDA and may also occur after discontinuation of treatment. For suspected immune-mediated adverse reactions, ensure adequate evaluation to confirm etiology or exclude other causes. Based on the severity of the adverse reaction, withhold KEYTRUDA and administer corticosteroids. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Based on limited data from clinical studies in patients whose immune-related adverse reactions could not be controlled with corticosteroid use, administration of other systemic immunosuppressants can be considered. Resume KEYTRUDA when the adverse reaction remains at Grade 1 or less following corticosteroid taper. Permanently discontinue KEYTRUDA for any Grade 3 immune-mediated adverse reaction that recurs and for any life-threatening immune-mediated adverse reaction.

The following clinically significant immune-mediated adverse reactions occurred in less than 1% (unless otherwise indicated) of 2799 patients: arthritis (1.5%), uveitis, myositis, Guillain-Barré syndrome, myasthenia gravis, vasculitis, pancreatitis, hemolytic anemia, sarcoidosis, and encephalitis. In addition, myelitis and myocarditis were reported in other clinical trials, including classical Hodgkin lymphoma, and postmarketing use.

Treatment with KEYTRUDA may increase the risk of rejection in solid organ transplant recipients. Consider the benefit of treatment vs the risk of possible organ rejection in these patients.

Infusion-Related Reactions

KEYTRUDA can cause severe or life-threatening infusion-related reactions, including hypersensitivity and anaphylaxis, which have been reported in 0.2% (6/2799) of patients. Monitor patients for signs and symptoms of infusion-related reactions. For Grade 3 or 4 reactions, stop infusion and permanently discontinue KEYTRUDA.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)



Immune-mediated complications, including fatal events, occurred in patients who underwent allogeneic HSCT after treatment with KEYTRUDA. Of 23 patients with cHL who proceeded to allogeneic HSCT after KEYTRUDA, 6 (26%) developed graft-versus-host disease (GVHD) (1 fatal case) and 2 (9%) developed severe hepatic veno-occlusive disease (VOD) after reduced-intensity conditioning (1 fatal case). Cases of fatal hyperacute GVHD after allogeneic HSCT have also been reported in patients with lymphoma who received a PD-1 receptor-blocking antibody before transplantation. Follow patients closely for early evidence of transplant-related complications such as hyperacute graft-versus-host disease (GVHD), Grade 3 to 4 acute GVHD, steroid-requiring febrile syndrome, hepatic veno-occlusive disease (VOD), and other immune-mediated adverse reactions.

In patients with a history of allogeneic HSCT, acute GVHD (including fatal GVHD) has been reported after treatment with KEYTRUDA. Patients who experienced GVHD after their transplant procedure may be at increased risk for GVHD after KEYTRUDA. Consider the benefit of KEYTRUDA vs the risk of GVHD in these patients.

Increased Mortality in Patients With Multiple Myeloma

In trials in patients with multiple myeloma, the addition of KEYTRUDA to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of these patients with a PD-1 or PD-L1 blocking antibody in this combination is not recommended outside of controlled trials.

Embryofetal Toxicity

Based on its mechanism of action, KEYTRUDA can cause fetal harm when administered to a pregnant woman. Advise women of this potential risk. In females of reproductive potential, verify pregnancy status prior to initiating KEYTRUDA and advise them to use effective contraception during treatment and for 4 months after the last dose.

Adverse Reactions

In KEYNOTE-006, KEYTRUDA was discontinued due to adverse reactions in 9% of 555 patients with advanced melanoma; adverse reactions leading to permanent discontinuation in more than one patient were colitis (1.4%), autoimmune hepatitis (0.7%), allergic reaction (0.4%), polyneuropathy (0.4%), and cardiac failure (0.4%). The most common adverse reactions ($\geq 20\%$) with KEYTRUDA were fatigue (28%), diarrhea (26%), rash (24%), and nausea (21%).

In KEYNOTE-002, KEYTRUDA was permanently discontinued due to adverse reactions in 12% of 357 patients with advanced melanoma; the most common ($\geq 1\%$) were general physical health deterioration (1%), asthenia (1%), dyspnea (1%), pneumonitis (1%), and generalized edema (1%). The most common adverse reactions were fatigue (43%), pruritus (28%), rash (24%), constipation (22%), nausea (22%), diarrhea (20%), and decreased appetite (20%).

In KEYNOTE-054, KEYTRUDA was permanently discontinued due to adverse reactions in 14% of 509 patients; the most common ($\geq 1\%$) were pneumonitis (1.4%), colitis (1.2%), and diarrhea (1%). Serious adverse reactions occurred in 25% of patients receiving KEYTRUDA. The most common adverse reaction ($\geq 20\%$) with KEYTRUDA was diarrhea (28%).

In KEYNOTE-189, when KEYTRUDA was administered with pemetrexed and platinum chemotherapy in metastatic nonsquamous NSCLC, KEYTRUDA was discontinued due to adverse reactions in 20% of 405 patients. The most common adverse reactions resulting in permanent discontinuation of KEYTRUDA were pneumonitis (3%) and acute kidney injury (2%). The most common adverse reactions ($\geq 20\%$) with



KEYTRUDA were nausea (56%), fatigue (56%), constipation (35%), diarrhea (31%), decreased appetite (28%), rash (25%), vomiting (24%), cough (21%), dyspnea (21%), and pyrexia (20%).

In KEYNOTE-407, when KEYTRUDA was administered with carboplatin and either paclitaxel or paclitaxel protein-bound in metastatic squamous NSCLC, KEYTRUDA was discontinued due to adverse reactions in 15% of 101 patients. The most frequent serious adverse reactions reported in at least 2% of patients were febrile neutropenia, pneumonia, and urinary tract infection. Adverse reactions observed in KEYNOTE-407 were similar to those observed in KEYNOTE-189 with the exception that increased incidences of alopecia (47% vs 36%) and peripheral neuropathy (31% vs 25%) were observed in the KEYTRUDA and chemotherapy arm compared to the placebo and chemotherapy arm in KEYNOTE-407.

In KEYNOTE-042, KEYTRUDA was discontinued due to adverse reactions in 19% of 636 patients with advanced NSCLC; the most common were pneumonitis (3%), death due to unknown cause (1.6%), and pneumonia (1.4%). The most frequent serious adverse reactions reported in at least 2% of patients were pneumonia (7%), pneumonitis (3.9%), pulmonary embolism (2.4%), and pleural effusion (2.2%). The most common adverse reaction ($\geq 20\%$) was fatigue (25%).

In KEYNOTE-010, KEYTRUDA monotherapy was discontinued due to adverse reactions in 8% of 682 patients with metastatic NSCLC; the most common was pneumonitis (1.8%). The most common adverse reactions ($\geq 20\%$) were decreased appetite (25%), fatigue (25%), dyspnea (23%), and nausea (20%).

Adverse reactions occurring in patients with SCLC were similar to those occurring in patients with other solid tumors who received KEYTRUDA as a single agent.

In KEYNOTE-048, KEYTRUDA monotherapy was discontinued due to adverse events in 12% of 300 patients with HNSCC; the most common adverse reactions leading to permanent discontinuation were sepsis (1.7%) and pneumonia (1.3%). The most common adverse reactions ($\geq 20\%$) were fatigue (33%), constipation (20%), and rash (20%).

In KEYNOTE-048, when KEYTRUDA was administered in combination with platinum (cisplatin or carboplatin) and FU chemotherapy, KEYTRUDA was discontinued due to adverse reactions in 16% of 276 patients with HNSCC. The most common adverse reactions resulting in permanent discontinuation of KEYTRUDA were pneumonia (2.5%), pneumonitis (1.8%), and septic shock (1.4%). The most common adverse reactions ($\geq 20\%$) were nausea (51%), fatigue (49%), constipation (37%), vomiting (32%), mucosal inflammation (31%), diarrhea (29%), decreased appetite (29%), stomatitis (26%), and cough (22%).

In KEYNOTE-012, KEYTRUDA was discontinued due to adverse reactions in 17% of 192 patients with HNSCC. Serious adverse reactions occurred in 45% of patients. The most frequent serious adverse reactions reported in at least 2% of patients were pneumonia, dyspnea, confusional state, vomiting, pleural effusion, and respiratory failure. The most common adverse reactions ($\geq 20\%$) were fatigue, decreased appetite, and dyspnea. Adverse reactions occurring in patients with HNSCC were generally similar to those occurring in patients with melanoma or NSCLC who received KEYTRUDA as a monotherapy, with the exception of increased incidences of facial edema and new or worsening hypothyroidism.

In KEYNOTE-087, KEYTRUDA was discontinued due to adverse reactions in 5% of 210 patients with cHL. Serious adverse reactions occurred in 16% of patients; those $\geq 1\%$ included pneumonia, pneumonitis, pyrexia, dyspnea, GVHD, and herpes zoster. Two patients died from causes other than



disease progression; 1 from GVHD after subsequent allogeneic HSCT and 1 from septic shock. The most common adverse reactions ($\geq 20\%$) were fatigue (26%), pyrexia (24%), cough (24%), musculoskeletal pain (21%), diarrhea (20%), and rash (20%).

In KEYNOTE-170, KEYTRUDA was discontinued due to adverse reactions in 8% of 53 patients with PMBCL. Serious adverse reactions occurred in 26% of patients and included arrhythmia (4%), cardiac tamponade (2%), myocardial infarction (2%), pericardial effusion (2%), and pericarditis (2%). Six (11%) patients died within 30 days of start of treatment. The most common adverse reactions ($\geq 20\%$) were musculoskeletal pain (30%), upper respiratory tract infection and pyrexia (28% each), cough (26%), fatigue (23%), and dyspnea (21%).

In KEYNOTE-052, KEYTRUDA was discontinued due to adverse reactions in 11% of 370 patients with locally advanced or metastatic urothelial carcinoma. Serious adverse reactions occurred in 42% of patients; those $\geq 2\%$ were urinary tract infection, hematuria, acute kidney injury, pneumonia, and urosepsis. The most common adverse reactions ($\geq 20\%$) were fatigue (38%), musculoskeletal pain (24%), decreased appetite (22%), constipation (21%), rash (21%), and diarrhea (20%).

In KEYNOTE-045, KEYTRUDA was discontinued due to adverse reactions in 8% of 266 patients with locally advanced or metastatic urothelial carcinoma. The most common adverse reaction resulting in permanent discontinuation of KEYTRUDA was pneumonitis (1.9%). Serious adverse reactions occurred in 39% of KEYTRUDA-treated patients; those $\geq 2\%$ were urinary tract infection, pneumonia, anemia, and pneumonitis. The most common adverse reactions ($\geq 20\%$) in patients who received KEYTRUDA were fatigue (38%), musculoskeletal pain (32%), pruritus (23%), decreased appetite (21%), nausea (21%), and rash (20%).

In KEYNOTE-057, KEYTRUDA was discontinued due to adverse reactions in 11% of 148 patients with high-risk NMIBC. The most common adverse reaction resulting in permanent discontinuation of KEYTRUDA was pneumonitis (1.4%). Serious adverse reactions occurred in 28% of patients; those $\geq 2\%$ were pneumonia (3%), cardiac ischemia (2%), colitis (2%), pulmonary embolism (2%), sepsis (2%), and urinary tract infection (2%). The most common adverse reactions ($\geq 20\%$) were fatigue (29%), diarrhea (24%), and rash (24%).

Adverse reactions occurring in patients with MSI-H or dMMR CRC were similar to those occurring in patients with melanoma or NSCLC who received KEYTRUDA as a monotherapy.

Adverse reactions occurring in patients with gastric cancer were similar to those occurring in patients with melanoma or NSCLC who received KEYTRUDA as a monotherapy.

Adverse reactions occurring in patients with esophageal cancer were similar to those occurring in patients with melanoma or NSCLC who received KEYTRUDA as a monotherapy.

In KEYNOTE-158, KEYTRUDA was discontinued due to adverse reactions in 8% of 98 patients with recurrent or metastatic cervical cancer. Serious adverse reactions occurred in 39% of patients receiving KEYTRUDA; the most frequent included anemia (7%), fistula, hemorrhage, and infections [except urinary tract infections] (4.1% each). The most common adverse reactions ($\geq 20\%$) were fatigue (43%), musculoskeletal pain (27%), diarrhea (23%), pain and abdominal pain (22% each), and decreased appetite (21%).



Adverse reactions occurring in patients with hepatocellular carcinoma (HCC) were generally similar to those in patients with melanoma or NSCLC who received KEYTRUDA as a monotherapy, with the exception of increased incidences of ascites (8% Grades 3-4) and immune-mediated hepatitis (2.9%). Laboratory abnormalities (Grades 3-4) that occurred at a higher incidence were elevated AST (20%), ALT (9%), and hyperbilirubinemia (10%).

Among the 50 patients with MCC enrolled in study KEYNOTE-017, adverse reactions occurring in patients with MCC were generally similar to those occurring in patients with melanoma or NSCLC who received KEYTRUDA as a monotherapy. Laboratory abnormalities (Grades 3-4) that occurred at a higher incidence were elevated AST (11%) and hyperglycemia (19%).

In KEYNOTE-426, when KEYTRUDA was administered in combination with axitinib, fatal adverse reactions occurred in 3.3% of 429 patients. Serious adverse reactions occurred in 40% of patients, the most frequent ($\geq 1\%$) were hepatotoxicity (7%), diarrhea (4.2%), acute kidney injury (2.3%), dehydration (1%), and pneumonitis (1%). Permanent discontinuation due to an adverse reaction occurred in 31% of patients; KEYTRUDA only (13%), axitinib only (13%), and the combination (8%); the most common were hepatotoxicity (13%), diarrhea/colitis (1.9%), acute kidney injury (1.6%), and cerebrovascular accident (1.2%). The most common adverse reactions ($\geq 20\%$) were diarrhea (56%), fatigue/asthenia (52%), hypertension (48%), hepatotoxicity (39%), hypothyroidism (35%), decreased appetite (30%), palmar-plantar erythrodysesthesia (28%), nausea (28%), stomatitis/mucosal inflammation (27%), dysphonia (25%), rash (25%), cough (21%), and constipation (21%).

Adverse reactions occurring in patients with TMB-H cancer were similar to those occurring in patients with other solid tumors who received KEYTRUDA as a single agent.

Adverse reactions occurring in patients with cSCC were similar to those occurring in patients with melanoma or NSCLC who received KEYTRUDA as a monotherapy.

Lactation

Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 4 months after the final dose.

Pediatric Use

There is limited experience in pediatric patients. In a trial, 40 pediatric patients (16 children aged 2 years to younger than 12 years and 24 adolescents aged 12 years to 18 years) with various cancers, including unapproved usages, were administered KEYTRUDA 2 mg/kg every 3 weeks. Patients received KEYTRUDA for a median of 3 doses (range 1-17 doses), with 34 patients (85%) receiving 2 doses or more. The safety profile in these pediatric patients was similar to that seen in adults; adverse reactions that occurred at a higher rate ($\geq 15\%$ difference) in these patients when compared to adults under 65 years of age were fatigue (45%), vomiting (38%), abdominal pain (28%), increased transaminases (28%), and hyponatremia (18%).

Please see Prescribing Information for KEYTRUDA (pembrolizumab) at https://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf and Medication Guide for KEYTRUDA at https://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_mg.pdf

About Seattle Genetics

Seattle Genetics, Inc. is a global biotechnology company that discovers, develops and commercializes



transformative cancer medicines to make a meaningful difference in people's lives. ADCETRIS® (brentuximab vedotin) and PADCEV® (enfortumab vedotin-ejfv) use the company's industry-leading antibody-drug conjugate (ADC) technology. ADCETRIS is approved in certain CD30-expressing lymphomas, and PADCEV is approved in certain metastatic urothelial cancers. TUKYSA® (tucatinib), a small molecule tyrosine kinase inhibitor, is approved in certain HER2-positive metastatic breast cancers. The company is headquartered in the Seattle, Washington area, with locations in California, Switzerland and the European Union. For more information on our robust pipeline, visit www.seattlegenetics.com and follow @SeattleGenetics on Twitter.

Merck's Focus on Cancer

Our goal is to translate breakthrough science into innovative oncology medicines to help people with cancer worldwide. At Merck, the potential to bring new hope to people with cancer drives our purpose and supporting accessibility to our cancer medicines is our commitment. As part of our focus on cancer, Merck is committed to exploring the potential of immuno-oncology with one of the largest development programs in the industry across more than 30 tumor types. We also continue to strengthen our portfolio through strategic acquisitions and are prioritizing the development of several promising oncology candidates with the potential to improve the treatment of advanced cancers. For more information about our oncology clinical trials, visit www.merck.com/clinicaltrials.

About Merck

For more than 125 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals - including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases - as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit www.merck.com and connect with us on [Twitter](#), [Facebook](#), [Instagram](#), [YouTube](#) and [LinkedIn](#).

Forward Looking Statements for Seattle Genetics

Certain of the statements made in this press release are forward looking, such as those, among others, relating to Seattle Genetics' sale of shares of its common stock to Merck, receipt of upfront payments and potential receipt of milestone payments under the ladiratumab vedotin and TUKYSA collaborations and potential royalty payments under the TUKYSA collaboration; the potential to broaden and advance the development of ladiratumab vedotin and TUKYSA and accelerate the availability of TUKYSA to additional cancer patients around the world; as well as any other statements that are not historical fact. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, without limitation, risks and uncertainties related to: the completion of the sale of Seattle Genetics common stock to Merck including the ability to obtain clearance under the HSR Act; Seattle Genetics' ability to maintain the ladiratumab vedotin and TUKYSA collaborations, including the risk that if Merck were to breach or terminate either collaboration, Seattle Genetics would not obtain the anticipated financial and other benefits of the collaboration and the development and/or commercialization of ladiratumab vedotin or TUKYSA could be delayed, perhaps substantially; the possibility that Seattle Genetics and Merck may not be successful in their development efforts under either collaboration and that, even if successful, Seattle Genetics and Merck may be unable to successfully commercialize ladiratumab vedotin and TUKYSA; and the duration and severity of the COVID-19 pandemic and resulting global economic, financial, and healthcare system disruptions. More information about the risks and uncertainties faced by Seattle Genetics is

[*] = 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



contained under the caption "Risk Factors" included in the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 filed with the Securities and Exchange Commission. Seattle Genetics disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, NJ., USA

This news release of Merck & Co., Inc., Kenilworth, NJ., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2019 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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CONTACTS:

Seattle Genetics

Investors:

Peggy Pinkston, 425-527-4160

ppinkston@seagen.com

Media:

Monique Greer, 425-527-4641

mgreer@seagen.com

Merck

Investors:

Peter Dannenbaum, 908-740-1037

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Peter.dannenbaum@merck.com

Media:

Pam Eisele, 267-305-3558

Pamela.eisele@merck.com

Schedule 11.2

SeaGen Disclosure Schedules

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Schedule 11.3.1

Regulatory Documentation

[*]

Schedule 13.4

[*]

(See Attached)

[*]

{4 pages omitted}

Schedule 14.7.6

Continuing Product Payment Reduction

The provisions of this Schedule 14.7.6 shall only apply [*].

(a) **Generic Product.** If in a particular Calendar Quarter during the Continuing Payment Term in a given country, one or more Third Parties is or are selling a Generic Product in the Field in a country and the aggregate net sales of the [*] Continuing Product sold by the Continuing Parties (which net sales shall be calculated in a manner consistent with the definition of "Licensed Product Net Sales" hereunder, mutatis mutandis) in such country during such Calendar Quarter (or any Calendar Quarter thereafter) are less than [*] percent ([*]%) of the average quarterly aggregate net sales of the Continuing Product (which net sales shall be calculated in a manner consistent with the definition of "Licensed Product Net Sales", mutatis mutandis) sold by the Continuing Parties in such country over the [*] immediately prior to the Calendar Quarter during which the first such Generic Product was sold in such country (the "Generic Reduction Trigger"), then in such case the Applicable Percentage for calculation of the Continuing Product Payment for such Continuing Product in such country during the Continuing Payment Term shall, commencing with such Calendar Quarter in which the Generic Reduction Trigger occurred and thereafter for the remainder of the Continuing Payment Term in such country, be reduced by [*] percent ([*]%) of the amount otherwise payable under Section 14.7.6, subject to clause (c) of this Schedule 14.7.6. For purposes of the foregoing, "Generic Product" means with respect to a Continuing Product, a product: (A) with the same pharmaceutically active ingredient(s); (B) that has obtained Marketing Authorization (excluding Pricing Approval) from the applicable Regulatory Authority by means of a procedure for establishing equivalence to the Continuing Product or otherwise in reliance on data generated for the Continuing Product; and (C) is legally marketed in such country by or under the authority of an entity other than the Continuing Party.

(b) **Third Party Payments.** If any Continuing Party believes that it is necessary or reasonably useful to obtain a license or similar rights to intellectual property rights of a Third Party or Third Parties in order for such Continuing Party to Develop, Manufacture or Commercialize the Continuing Product ("Third Party License(s)"), then SeaGen shall have the right to credit [*] ([*]%) percent of [*] actually paid by any Continuing Party with respect to the Continuing Product under any such Third Party License(s) against Continuing Product Payments otherwise payable hereunder with respect to units of Continuing Product subject to such payment obligations under such Third Party License. Subject to clause (c) of this Schedule 14.7.6, such credit against Continuing Product Payments payable hereunder shall be allocated as follows: (a) [*] percent ([*]%) of [*] payable under a Third Party License with respect the Continuing Product shall be creditable against Continuing Product Payments payable under Section 14.7.6 with respect to units of the Continuing Product; and (b) [*] percent ([*]%) of [*] shall be creditable against Continuing Product Payments payable under Section 14.7.6 with respect units of the Continuing Product. Notwithstanding the foregoing, if SeaGen is not able to fully credit any of the amounts paid by any Continuing Party in a given Calendar Quarter, then SeaGen shall be entitled to carry forward such right of credit to future Calendar Quarters with respect to such excess amount and continue applying such credit on a Calendar Quarterly basis thereafter until fully utilized.



(c) Royalty Floor. The reductions in clauses (a) and (b) of this Schedule 14.7.6 are cumulative, provided that in no event shall the Applicable Percentage applicable to net sales of the Continuing Product (which net sales shall be calculated in a manner consistent with the definition of "Licensed Product Net Sales", mutatis mutandis) sold by any Continuing Party in such country during any Calendar Quarter in the Continuing Payment Term on a country-by-country basis, fall below (as a result of the reductions in clauses (a) and (b) of this Schedule 14.7.6) a rate that is [*] percent ([*]%) of the Applicable Percentage rates otherwise payable pursuant to Section 14.7.6. Notwithstanding the foregoing, if SeaGen is not able to fully utilize any of the reductions or credits in clauses (a) and (b) of this Schedule 14.7.6 in a given Calendar Quarter as a result of the foregoing limitation, then SeaGen shall be entitled to carry forward such reduction or credit to future Calendar Quarters with respect to such excess amount and continue applying such reduction or credit on a Calendar Quarterly basis thereafter until fully utilized.

Schedule 15.3

Partnership Tax Related Provisions

[*]

{7 pages omitted}

Annex 1 to Schedule 15.3

Initial Capital Accounts

[*]

Exhibit A
Initial Development Plan

[*]

[*] = 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

Execution Version

STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (“Agreement”) is entered into as of September 13, 2020 (the “Execution Date”), by and between Merck Sharp & Dohme Corp., a New Jersey corporation, having a place of business at 2000 Galloping Hill Road Kenilworth, NJ 07033-1310 (“Merck”), and Seattle Genetics, Inc., a Delaware corporation, having a place of business at 21823 30th Drive S.E., Bothell, WA 98021 (“Seagen”). The capitalized terms used herein and not otherwise defined have the meanings given to them in Appendix 1.

RECITAL

Seagen has agreed to sell, and Merck has agreed to purchase, shares of Common Stock subject to and in accordance with the terms and provisions of this Agreement.

AGREEMENT

For good and valuable consideration, Merck and Seagen agree as follows:

Section 1. SALE AND PURCHASE OF STOCK

1.1 Purchase of Stock. Subject to the terms and conditions of this Agreement, at the Closing, Seagen will issue and sell to Merck, and Merck will purchase from Seagen, 5,000,000 shares of Common Stock (the “Shares”) at a price per share equal to (i) the volume-weighted average trading price of Seagen’s Common Stock during the 30-day period ending on the Business Day that is four Business Days prior to the Execution Date rounded to the nearest dollar, to be calculated and agreed to by each of Merck and Seagen (the “Base Price”), plus (ii) the amount that shall cause the total per share purchase price to equal \$200.00 (such amount, the “Premium”), resulting in an aggregate purchase price of \$1,000,000,000 (the Base Price plus the Premium, the “Purchase Price”). Seagen and Merck acknowledge and agree that [*] or in any administrative or legal proceedings concerning [*].

1.2 Payment. At the Closing, Merck will pay the Purchase Price by wire transfer of immediately available funds in accordance with wire instructions provided by Seagen to Merck at least two (2) Business Days prior to the Closing, and Seagen will deliver the Shares in restricted book-entry form to Merck and Seagen shall cause the transfer agent to deliver written confirmation of the book-entry delivery of the Shares to Merck.

1.3 Closing.

(a) Closing. The closing of the transaction contemplated by Section 1.1 (the “Closing”) will be held at the offices of Seagen within three (3) Business Days after the conditions to closing set forth in Section 6 are satisfied or waived for the Closing (other than

those conditions that by their nature are to be satisfied or waived at the Closing) or at such other place, time and/or date as may be jointly designated by Merck and Seagen for the Closing.

(b) Closing Deliverables.

(i) At the Closing, Seagen will deliver to Merck:

(1) a duly executed cross-receipt in form and substance reasonably satisfactory to each party (the "Cross-Receipt");

(2) a legal opinion of Seagen's counsel dated as of the Closing Date, in the form of Exhibit A hereto; and

(3) a certificate of the secretary of Seagen dated as of the Closing Date certifying that attached thereto is a true and complete copy of all resolutions adopted by the Board authorizing the execution, delivery and performance of this Agreement and the transactions contemplated hereby and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby as of the Closing Date.

(ii) At the Closing, Merck will deliver to Seagen a duly-executed Cross-Receipt.

Section 2. REPRESENTATIONS AND WARRANTIES OF SEAGEN

Except as otherwise specifically contemplated by this Agreement, Seagen hereby represents and warrants to Merck that:

2.1 **Private Placement.** Neither Seagen nor any person acting on its behalf, has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under any circumstances that would require registration of the Shares under the Securities Act. Subject to the accuracy of the representations made by Merck in Section 3, the Shares will be issued and sold to Merck in compliance with applicable exemptions from the registration and prospectus delivery requirements of the Securities Act.

2.2 **Organization and Qualification.** Seagen and each of its Subsidiaries have been duly organized or formed, as applicable, and are validly existing and in good standing (where such concept is recognized under the laws of the jurisdiction in which they are organized and formed) under the laws of their respective jurisdictions of organization, with full corporate power and authority to conduct their respective businesses as currently conducted. Seagen and each of its Subsidiaries are duly qualified to do business and is in good standing in every jurisdiction (where such concept is recognized) in which the nature of the business conducted by them or property owned by them makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, would not reasonably be expected to have a Material Adverse Effect.



2.3 Authorization; Enforcement. Seagen has all requisite corporate power and authority to enter into and to perform its obligations under this Agreement, to consummate the transactions contemplated hereby and to issue the Shares in accordance with the terms hereof. The execution, delivery and performance of this Agreement by Seagen and the consummation by it of the transactions contemplated hereby (including the issuance of the Shares at the Closing in accordance with the terms hereof) have been duly authorized by the Board and no further consent or authorization of Seagen, the Board, or its stockholders is required. This Agreement has been duly executed by Seagen and constitutes a legal, valid and binding obligation of Seagen enforceable against Seagen in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, or moratorium or similar Laws affecting creditors' and contracting parties' rights generally.

2.4 Issuance of Shares. The Shares are duly authorized and, upon issuance in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable and will not be subject to preemptive rights or other similar rights of stockholders of Seagen.

2.5 SEC Documents, Financial Statements.

(a) The Common Stock is registered pursuant to Section 12(b) of the Exchange Act. Seagen has delivered or made available (by filing on the SEC's electronic data gathering and retrieval system (EDGAR)) to Merck complete copies of its most recent Annual Report on Form 10-K and its most recent Quarterly Report on Form 10-Q, and any report on Form 8-K, in each case filed with the SEC after January 1, 2020 and prior to the Execution Date (the "SEC Documents"). As of its date, each SEC Document complied in all material respects with the requirements of the Exchange Act, and other Laws applicable to it, and, as of its date, such SEC Documents did not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) The consolidated financial statements, together with the related notes and schedules, of Seagen included in the SEC Documents comply as to form in all material respects with all applicable accounting requirements and the published rules and regulations of the SEC and all other applicable rules and regulations with respect thereto. Such consolidated financial statements, together with the related notes and schedules, have been prepared in accordance with GAAP applied on a consistent basis during the periods involved (except (i) as may be otherwise indicated in such financial statements or the notes thereto or (ii) in the case of unaudited interim statements, to the extent they may not include footnotes or may be condensed or summary statements), and fairly present in all material respects the financial condition of Seagen and its consolidated subsidiaries as of the dates thereof and the results of operations and cash flows for the periods then ended (subject, in the case of unaudited statements, to normal year-end audit adjustments).

(c) The Common Stock is listed on Nasdaq, and Seagen has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from Nasdaq. As



of the date of this Agreement, Seagen has not received any notification that, and has no knowledge that, the SEC or Nasdaq is contemplating terminating such registration or listing.

2.6 Internal Controls; Disclosure Controls and Procedures. Seagen maintains, on its behalf and on behalf of its Subsidiaries, internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Seagen maintains, on its behalf and on behalf of its Subsidiaries, a system of disclosure controls and procedures (as defined in Rules 13a-15(e) under the Exchange Act) that has been designed to ensure that information required to be disclosed by Seagen in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to Seagen's management as appropriate to allow timely decisions regarding required disclosure. Each of the principal executive officer and the principal financial officer of Seagen has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 with respect to all SEC Documents.

2.7 Capitalization and Voting Rights

(a) The authorized capital of Seagen as of the Execution Date consists of: (i) 250,000,000 shares of Common Stock of which, as of September 8, 2020, (x) 175,060,976 shares were issued and outstanding, (y) 10,557,680 shares were reserved for future issuance pursuant to Seagen's equity incentive, long-term incentive and employee stock purchase plans (collectively, the "SGEN Benefit Plans"), and (z) 11,095,160 shares were issuable upon the exercise of stock options outstanding or issuable upon vesting of restricted stock unit awards outstanding, and (ii) 5,000,000 shares of Preferred Stock, of which no shares are issued and outstanding as of the date of this Agreement. All of the issued and outstanding shares of Common Stock (A) have been duly authorized and validly issued, (B) are fully paid and non-assessable and (C) were issued in compliance in all material respects with all applicable federal and state securities Laws and not in violation of any preemptive rights.

(b) All of the authorized shares of Common Stock are entitled to one (1) vote per share.

(c) Except as described or referred to in the SEC Documents, as of September 13, 2020, there were not: (i) any outstanding equity securities, options, warrants, rights (including conversion or preemptive rights) or other agreements pursuant to which Seagen is or may become obligated to issue, sell or repurchase any shares of its capital stock or any other securities of Seagen or any of its Subsidiaries other than equity securities that may have been granted or that Seagen is obligated to grant pursuant to the SGEN Benefit Plans, which plans are described in the SEC Documents, or (ii) any restrictions on the transfer of capital stock of Seagen other than pursuant to federal or state securities Laws or as set forth in this Agreement.

(d) Except as described or referred to in the SEC Documents, Seagen is not a party to or subject to any agreement or understanding relating to the voting of shares of capital stock of Seagen or the giving of written consents by a stockholder or director of Seagen.

2.8 No Conflicts; Government Consents and Permits.



(a) The execution, delivery and performance of this Agreement by Seagen and the consummation by Seagen of the transactions contemplated hereby (including the issuance of the Shares) will not (i) conflict with or result in a violation of any provision of the charter or by-laws or similar organizational documents of Seagen or any of its Subsidiaries, (ii) violate or conflict with, or result in a breach of any provision of, or constitute a default under, any agreement, indenture, or instrument to which Seagen or any of its Subsidiaries is a party, or (iii) result in a violation of any Law (including United States federal and state securities Laws and regulations and regulations of any self-regulatory organizations) applicable to Seagen or any of its Subsidiaries, except in the case of clauses (ii) and (iii) only, for such conflicts, breaches, defaults, and violations as would not reasonably be expected to have a Material Adverse Effect on Seagen or result in a liability for Merck.

(b) Seagen is not required to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency or any regulatory or self-regulatory agency or any other third party in order for it to execute, deliver or perform any of its obligations under this Agreement in accordance with the terms hereof, or to issue and sell the Shares in accordance with the terms hereof other than such as have been made or obtained, and except for (i) any post-closing filings required to be made under federal or state securities Laws, (ii) any required filings or notifications regarding the issuance or listing of additional shares with Nasdaq, and (iii) the applicable premerger notification and waiting period requirements of the HSR Act, and such other Antitrust Law as may be applicable to the Agreement.

2.9 Litigation. Except as set forth in the SEC Documents, there is no action, suit, proceeding or investigation pending (of which Seagen has received notice or otherwise has knowledge) or, to Seagen's knowledge, threatened, against Seagen or any of its Subsidiaries, except where such action, suit, proceeding or investigation, as the case may be, would not reasonably be expected to have a Material Adverse Effect.

2.10 Licenses and Other Rights; Compliance with Laws. Seagen and its Subsidiaries have all franchises, permits, licenses and other rights and privileges ("Permits") necessary to permit them to own their respective properties and to conduct their respective businesses as presently conducted (including all such certificates, authorizations and permits required by the FDA or any other federal, state or foreign agencies or bodies engaged in the regulation of pharmaceuticals or biologics) and are in compliance thereunder, except where the failure to so possess such Permits or to be in compliance thereunder would not reasonably be expected to have a Material Adverse Effect. To Seagen's knowledge, neither Seagen nor any of its Subsidiaries has taken any action that would interfere with their ability to renew all such Permits, except where the failure to renew such Permits would not reasonably be expected to have a Material Adverse Effect. Seagen and each of its Subsidiaries is and has been in compliance with all Laws applicable to its business, properties and assets, and to the approved products sold by it, except where the failure to be in compliance would not reasonably be expected to have a Material Adverse Effect.



2.11 Intellectual Property.

(a) The Intellectual Property that is owned by Seagen or its Subsidiaries is owned free from any liens or restrictions, except for those liens or restrictions that would not reasonably be expected to have a Material Adverse Effect. To Seagen's knowledge, all of Seagen's and its Subsidiaries' Intellectual Property Licenses that are material to Seagen and its Subsidiaries, taken as a whole, are in full force and effect in accordance with their terms, are free of any liens or restrictions except for those liens or restrictions that would not reasonably be expected to have a Material Adverse Effect, and to Seagen's knowledge, neither Seagen nor its Subsidiaries, nor any other party thereto, is in material breach of any such material Intellectual Property License. To Seagen's knowledge, no event has occurred that with notice or lapse of time or both (i) would constitute a breach or default of any such material Intellectual Property License or (ii) would result in the termination thereof, or (iii) would cause or permit the acceleration or other change of any right or obligation or the loss of any benefit thereunder by Seagen or its Subsidiaries except (1) in the case of each of clauses (i) through (iii) as would not reasonably be expected to have a Material Adverse Effect, or (2) as set forth in any such Intellectual Property License.

(b) Except as set forth in the SEC Documents, to Seagen's knowledge, there is no legal claim or demand of any person or any proceeding that is pending or overtly threatened in writing, (i) challenging the right of Seagen or any of its Subsidiaries in respect of any Intellectual Property of Seagen or any of its Subsidiaries, or (ii) claiming that any default exists under any Intellectual Property License, except, in the case of clauses (i) and (ii) above, where any such claim, demand or proceeding would not reasonably be expected to have a Material Adverse Effect.

(c) Except as set forth in the SEC Documents: (i) Seagen or one of its Subsidiaries owns, free of any lien or encumbrance except for those liens or encumbrances that would not reasonably be expected to have a Material Adverse Effect, or, to Seagen's knowledge, has a valid license, or an enforceable right to use, as it is used or held for use, all U.S. and non-U.S. patents, trade secrets, know-how, trademarks, service marks, copyrights, and other proprietary and Intellectual Property rights, and all grants and applications with respect to the foregoing (collectively, the "Proprietary Rights") necessary for the conduct of Seagen's and its Subsidiaries' respective businesses, except where the failure to own or have any of the foregoing would not reasonably be expected to have a Material Adverse Effect (such Proprietary Rights owned by or licensed to Seagen collectively, the "Seagen Rights"); and (ii) to Seagen's knowledge, Seagen and its Subsidiaries have taken reasonable measures to protect the Seagen Rights, consistent with prudent commercial practices in the biotechnology industry, except where failure to take such measures would not reasonably be expected to have a Material Adverse Effect.

2.12 Clinical Trials. Except as would not reasonably be expected to have a Material Adverse Effect, the studies, tests and clinical trials, conducted by or on behalf of Seagen or any of its Subsidiaries that are described in the SEC Documents were and, if still pending, are being conducted in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional scientific standards; the descriptions of the results of



such studies, tests and trials contained in the SEC Documents are accurate in all material respects; and neither Seagen nor any of its Subsidiaries has received any notices or correspondence from the FDA or any foreign, state or local governmental body exercising comparable authority requiring the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of Seagen or any of its Subsidiaries, which termination, suspension or material modification would reasonably be expected to have a Material Adverse Effect.

2.13 Absence of Certain Changes.

(a) Except as disclosed in the SEC Documents filed prior to the Execution Date, since December 31, 2019, no change or event has occurred, except where such change or event has not had, and would not reasonably be expected to have, a Material Adverse Effect on Seagen.

(b) Except as set forth in the SEC Documents filed prior to the Execution Date or as contemplated by this Agreement or the Collaboration Agreements, since December 31, 2019, (i) Seagen has not declared or paid any dividends, or authorized or made any distribution upon or with respect to any class or series of its capital stock, and (ii) neither Seagen nor any of its Subsidiaries has sold, exchanged or otherwise disposed of any of its assets or rights that are material to Seagen and its Subsidiaries taken as a whole.

(c) Since December 31, 2019, neither Seagen nor any of its Subsidiaries has admitted in writing its inability to pay its debts generally as they become due, filed or consented to the filing against it of a petition in bankruptcy or a petition to take advantage of any insolvency act, made an assignment for the benefit of creditors, consented to the appointment of a receiver for itself or for the whole or any substantial part of its property, or had a petition in bankruptcy filed against it, been adjudicated a bankrupt, or filed a petition or answer seeking reorganization or arrangement under the federal bankruptcy Laws or any other Laws of the United States or any other jurisdiction.

2.14 Not an Investment Company. Seagen is not, and after receipt of the Purchase Price, will not be, an "investment company" as defined in the Investment Company Act of 1940, as amended.

2.15 No Integration. Seagen has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act) which is or will be integrated with the Shares sold pursuant to this Agreement in a manner that would require the registration of the Shares under the Securities Act.

2.16 Foreign Corrupt Practices. Neither Seagen nor any Subsidiary of Seagen, nor to Seagen's knowledge, any agent or other person acting on behalf of Seagen, has (a) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (b) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (c) failed to disclose fully any contribution made by Seagen or any of Seagen's Subsidiaries (or made by any person acting on its behalf of which



Seagen is aware) which is in violation of Law, or (d) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable non-U.S. anti-bribery Law.

2.17 Office of Foreign Assets Control. Neither Seagen nor, to Seagen's knowledge, any director, officer, agent, employee or Affiliate of Seagen is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

Section 3. REPRESENTATIONS AND WARRANTIES OF MERCK

Except as otherwise specifically contemplated by this Agreement, Merck hereby represents and warrants to Seagen that:

3.1 Authorization; Enforcement. Merck has the requisite corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby. Merck has taken all necessary corporate action to authorize the execution, delivery and performance of this Agreement. Upon the execution and delivery of this Agreement, this Agreement will constitute a valid and binding obligation of Merck enforceable against Merck in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' and contracting parties' rights generally.

3.2 No Conflicts; Government Consents and Permits.

(a) The execution, delivery and performance of this Agreement by Merck and the consummation by Merck of the transactions contemplated hereby (including the purchase of the Shares) will not (i) conflict with or result in a violation of any provision of Merck's Certificate of Incorporation or Bylaws, (ii) violate or conflict with, or result in a breach of any provision of, or constitute a default under, any agreement, indenture, or instrument to which Merck is a party, or (iii) result in a violation of any Law (including United States federal and state securities Laws and regulations and regulations of any self-regulatory organizations) applicable to Merck, except in the case of clauses (ii) and (iii) only, for such conflicts, breaches, defaults, and violations as would not reasonably be expected to have a Material Adverse Effect on Merck or result in a liability for Seagen.

(b) Merck is not required to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency or any regulatory or self-regulatory agency in order for it to execute, deliver or perform any of its obligations under this Agreement in accordance with the terms hereof, or to purchase the Shares in accordance with the terms hereof other than such as have been made or obtained and except for the applicable premerger notification and waiting period requirements of the HSR Act, and such other Antitrust Law as may be applicable to the Agreement.

3.3 Investment Purpose. Merck is purchasing the Shares for its own account and not with a present view toward the public distribution thereof and has no arrangement or understanding with any other persons regarding the distribution of such Shares except as would not result in a violation of the Securities Act. Merck will not, directly or indirectly, offer, sell,



pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the Shares except in accordance with the Securities Act and to the extent permitted by Section 5.1.

3.4 Reliance on Exemptions. Merck understands that Seagen intends for the Shares to be offered and sold to it in reliance upon specific exemptions from the registration requirements of United States federal and state securities Laws and that Seagen is relying upon the truth and accuracy of, and Merck's compliance with, the representations, warranties, agreements, acknowledgments and understandings of Merck set forth herein in order to determine the availability of such exemptions and the eligibility of Merck to acquire the Shares.

3.5 Accredited Investor; Access to Information. Merck is an "accredited investor" as defined in Regulation D under the Securities Act and is knowledgeable, sophisticated and experienced in making, and is qualified to make decisions with respect to investments in shares presenting an investment decision like that involved in the purchase of the Shares. Merck has been furnished with materials relating to the offer and sale of the Shares, that have been requested by Merck, including the SEC Documents, and Merck has had the opportunity to review the SEC Documents. Merck has been afforded the opportunity to ask questions of Seagen. Neither such inquiries nor any other investigation conducted by or on behalf of Merck or its representatives or counsel will modify, amend or affect Merck's right to rely on the truth, accuracy and completeness of the SEC Documents and Seagen's representations and warranties contained in this Agreement.

3.6 Restricted Securities. Merck understands that the Shares will be characterized as "restricted securities" under the U.S. federal securities Laws inasmuch as they are being acquired from Seagen in a private placement under Section 4(a)(2) of the Securities Act and that under such Laws and applicable regulations such Shares may be resold without registration under the Securities Act only in certain limited circumstances.

3.7 Governmental Review. Merck understands that no United States federal or state agency or any other government or governmental agency has passed upon or made any recommendation or endorsement of the Shares or an investment therein.

Section 4. VOTING AGREEMENT.

4.1 Voting Agreement.

(a) Merck agrees that at any meeting of stockholders of Seagen or any adjournment or postponement thereof, except as permitted by Section 4.1(b) below with respect to Extraordinary Matters, Merck shall (i) after receiving proper notice of any such meeting of stockholders of Seagen (or, if no notice is required or such notice is properly waived, after notice from Seagen is given), be present, in person or by proxy, as a holder of Shares at all such meetings and be counted for the purposes of determining the presence of a quorum at such meetings and (ii) vote (in person or by proxy, as applicable) all Shares as to which Merck has beneficial ownership or as to which Merck otherwise exercises voting or dispositive authority in accordance with the recommendations of the Board with respect to any proposal to be voted upon at such meeting.



(b) Extraordinary Matters. Merck may vote with respect to any or all of the voting securities of Seagen as to which it is entitled to vote or execute a written consent, as it may determine in its sole discretion, with respect to the following matters, if presented to Seagen's stockholders for approval (each such matter being an "Extraordinary Matter"):

(i) any transaction which would result in a Change of Control of Seagen;

(ii) the payment of any dividends to any class of stockholders of Seagen; and

(iii) any liquidation or dissolution of Seagen.

(c) No Revocation. The voting agreements contained in this Section 4 are coupled with an interest and may not be revoked prior to their expiration in accordance with Section 4.1(d).

(d) Expiration. The agreements contained in this Section 4 will expire (i) in part, solely with respect to any Shares sold by Merck to the public or otherwise a non-Affiliate of Merck upon the execution of the sale of such Shares, and (ii) as a whole on the date that Merck, together with its Affiliates, beneficially owns less than 1% of the outstanding Common Stock. For the avoidance of doubt, the agreements contained in this Section 4 shall not limit Merck's ability to transfer or resell any Shares, provided that (A) such transfers or resales are effected in accordance with Section 5.1 or Section 9.10, as applicable, and (B) as a condition to any transfer or resale to an Affiliate of Merck, such Affiliate shall expressly agree to assume Merck's obligations under this Section 4.

Section 5. TRANSFER OR RESALE, LEGENDS AND RULE 144 REPORTING.

5.1 Transfer or Resale. Merck understands and agrees that:

(a) the Shares have not been and are not being registered under the Securities Act or any applicable state securities Laws and, consequently, Merck may have to bear the risk of owning the Shares for an indefinite period of time because the Shares may not be transferred unless (i) the resale of the Shares is registered pursuant to an effective registration statement under the Securities Act; (ii) Merck has delivered to Seagen an opinion of counsel (in form, substance and scope customary for opinions of counsel in comparable transactions) to the effect that the Shares to be sold or transferred may be sold or transferred pursuant to an exemption from such registration; or (iii) the Shares are sold or transferred pursuant to Rule 144; and

(b) any sale of the Shares made in reliance on Rule 144 may be made only in accordance with the terms of Rule 144 and, if Rule 144 is not applicable, any resale of the Shares under circumstances in which the seller (or the person through whom the sale is made) may be deemed to be an underwriter (as that term is defined in the Securities Act) may require compliance with some other exemption under the Securities Act or the rules and regulations of the SEC thereunder.



5.2 Legend. Merck understands the Shares will bear a restrictive legend in substantially the following form (and a stop-transfer order may be placed against transfer of the Shares):

THE SHARES EVIDENCED HEREBY HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED, OR ANY APPLICABLE STATE SECURITIES LAWS. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF A REGISTRATION STATEMENT IN EFFECT WITH RESPECT TO THE SECURITIES UNDER SUCH ACT OR APPLICABLE STATE SECURITIES LAWS OR A CERTIFICATE AND/OR AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED.

5.3 Legend Removal. The Shares shall not be required to bear the legend set forth in Section 5.2 (i) after the sale of such Shares pursuant to an effective registration statement under the Securities Act covering the resale of such Shares, (ii) following any sale of such Shares pursuant to Rule 144 or (iii) if such Shares are eligible for sale under Rule 144 without the need to satisfy the current public information requirement under Rule 144 and without volume or manner-of-sale restrictions. Seagen agrees that following such time as the legend is no longer required under this Section 5.3, no later than two (2) Business Days following the delivery by Merck to Seagen of all of (i) an instrument, whether certificated or uncertificated, representing the Shares issued with a restrictive legend, (ii) a written request addressed to Seagen that such restrictive legend be removed, and (iii) customary broker and representation letters in form and substance reasonably satisfactory to Seagen, Seagen will deliver or cause to be delivered to Merck an instrument, certificated or uncertificated as directed by Merck, representing such Shares that is free from such restrictive legend; provided, however, that each party will be responsible for any fees it incurs in connection with such request and removal.

5.4 Rule 144 Reporting. With a view to making available to Merck the benefits of certain rules and regulations of the SEC which may permit the sale of the Shares to the public without registration, Seagen agrees to use its commercially reasonable efforts to make and keep current public information with respect to Seagen available, as those terms are understood and defined in Rule 144, at all times during the period commencing on the Execution Date and ending on the one-year anniversary of the Closing Date.

Section 6. CONDITIONS TO CLOSING

6.1 Conditions to Obligations of Seagen. Seagen's obligation to complete the purchase and sale of the Shares and deliver the Shares to Merck is subject to the fulfillment or waiver of the following conditions at or prior to the Closing:

(a) Receipt of Funds. Seagen will have received immediately available funds in the full amount of the Purchase Price for the Shares being purchased hereunder.

(b) Absence of Litigation. No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Closing, will have been instituted or be pending before any Governmental Authority.

(c) No Governmental Prohibition; HSR Clearance. The sale of the Shares by Seagen and the purchase of the Shares by Merck will not be prohibited by any applicable Law at the time of Closing. Each of the HSR Conditions shall have been satisfied.

(d) Closing Deliverables. All closing deliverables as required under Section 1.3(b) shall have been delivered by Merck to Seagen.

6.2 Conditions to Merck's Obligations at the Closing. Merck's obligation to complete the purchase and sale of the Shares is subject to the fulfillment or waiver of the following conditions at or prior to the Closing:

(a) Absence of Litigation. No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Closing, will have been instituted or be pending before any Governmental Authority.

(b) No Governmental Prohibition; HSR Clearance. The sale of the Shares by Seagen, and the purchase of the Shares by Merck will not be prohibited by any applicable Law at the time of Closing. Each of the HSR Conditions shall have been satisfied.

(c) Closing Deliverables. All closing deliverables as required under Section 1.3(b) shall have been delivered by Seagen to Merck.

Section 7. TERMINATION.

7.1 Ability to Terminate. This Agreement may be terminated:

- (a) at any time by mutual written consent of Seagen and Merck; or
- (b) by either Seagen or Merck, upon written notice to the other, if the Antitrust Clearance Date has not occurred on or before November 20, 2020.

7.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 7.1, (a) this Agreement (except for this Section 7.2, Section 9.1 and Sections 9.3 through 9.15, and any definitions set forth in this Agreement and used in such Sections) shall forthwith become void and have no effect, without any liability on the part of any party hereto or its Affiliates, and (b) all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; provided, however, that nothing contained in this Section 7.2 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

Section 8. DEMAND REGISTRATION RIGHTS.

8.1 Demand Registrations. At any time beginning on the date that is eighteen (18) months after the Closing Date, Merck will have the right, subject to Section 8.5 below, to request registration of its Registrable Securities (which may, at Merck's request, be shelf registrations pursuant to Rule 415 promulgated under the Securities Act), which request or requests will

specify the number of Registrable Securities intended to be transferred and the intended method of distribution of such Registrable Securities. Upon receipt of such request, and subject to Merck's compliance with Section 8.3 hereof, Seagen will use its commercially reasonable efforts to promptly, but in no event later than [*] following receipt of such request ([*] days following the receipt of such request if Seagen is not then eligible to register for resale the Registrable Securities on Form S-3), effect the registration under the Securities Act of the Registrable Securities so requested to be registered; provided, however, that Seagen will not be required to prepare and file (x) more than [*] registration statements hereunder nor (y) more than one registration statement within any [*], in each case, at the request of Merck pursuant to this Section 8.1. Notwithstanding the foregoing, Seagen may delay the filing or effectiveness of any registration of Registrable Securities pursuant to this Section 8.1 or suspend the use of any registration statement (and Merck hereby agrees not to offer or sell any Registrable Securities pursuant to such registration statement) for a period of not more than [*] if (i) Seagen reasonably believes that there is or may be in existence material nonpublic information or events involving Seagen, the failure of which to be disclosed in the prospectus included in the registration statement could result in a Violation, (ii) all reports required to be filed by Seagen pursuant to the Exchange Act have not been filed by the required date (without regard to any extension), (iii) if Seagen furnishes Merck a certificate signed by the principal executive officer of Seagen stating that in the good faith judgment of the Board, the filing or use of any registration statement covering Registrable Securities would be seriously detrimental to Seagen or its stockholders at such time and that the Board concludes, as a result, that it is in the best interests of Seagen and its stockholders to delay the filing or effectiveness of any registration of Registrable Securities pursuant to this Section 8.1 or suspend the use of any registration statement at such time, provided, however, that Seagen may not delay the filing or effectiveness of any registration of Registrable Securities or suspend the use of any registration statement pursuant to this clause (iii) for a period of more than [*] calendar days, or (iv) the consummation of any business combination by Seagen has occurred or is probable for purposes of Rule 3-05 or Article 11 of Regulation S-X promulgated by the SEC or any similar successor rule. If Seagen will exercise its right to delay the filing or effectiveness or suspend the use of a registration hereunder, the applicable time period during which the registration statement is to remain effective will be extended by a period of time equal to the duration of the suspension period. If so directed by Seagen, Merck will (i) not offer to sell any Registrable Securities pursuant to the registration statement during the period in which the delay or suspension is in effect after receiving notice of such delay or suspension; and (ii) use its commercially reasonable efforts to deliver to Seagen (at Seagen's expense) all copies, other than permanent file copies then in Seagen's possession, of the prospectus relating to such Registrable Securities current at the time of receipt of such notice. Seagen will use its commercially reasonable efforts to maintain the continuous effectiveness of the registration statement for up to [*] following the effective date of such registration statement or, if earlier, until the date on which (i) all of the Registrable Securities included in such registration statement have actually been sold or (ii) Merck, together with its Affiliates, no longer beneficially owns more than [*].

8.2 Registration Expenses. Seagen will pay all Registration Expenses incurred in connection with each registration of Registrable Securities pursuant to this Section 8. [*] to the [*] in connection with each [*].

8.3 Certain Conditions. It will be a condition of Merck's rights hereunder to have Registrable Securities owned by it registered that: (i) Merck will reasonably cooperate with Seagen by supplying information and executing documents relating to Merck or the securities of Seagen owned by Merck in connection with such registration; and (ii) Merck will enter into such undertakings and take such other actions relating to the conduct of the proposed offering that Seagen may request as being necessary to ensure compliance with federal and state securities laws and the securities laws of any applicable jurisdiction and the rules or other requirements of the applicable exchange. In the event of any registration under the Securities Act of any Registrable Securities pursuant to this Section 8, Seagen will indemnify and hold harmless Merck, each of its directors, its officers, and its equity holders against such losses, claims, damages or liabilities (including reimbursement for reasonable and documented legal and other expenses) to which Merck or any such director, officer or equity holder may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such losses, claims, damages or liabilities arise out of or are based upon a Violation; provided, however, that the indemnity agreement contained in this Section 8.3 will not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without Seagen's consent, which consent will not be unreasonably withheld, nor will Seagen be liable in any such case for any such loss, claim, damage, liability or action to the extent that it arises out of or is based upon a Violation that occurs in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by any of such indemnified parties; and provided, further that Merck will indemnify and hold harmless Seagen, each of its directors, its officers, and each person, if any, who controls Seagen within the meaning of the Securities Act, and any underwriter, and any other third party, as applicable, selling securities under such registration statement, against such losses, claims, damages or liabilities (including reimbursement for reasonable and documented legal and other expenses) to which Seagen or any such director, officer, controlling person, underwriter or other third party who may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such losses, claims, damages or liabilities arise out of or are based upon a Merck Violation, in each case, to the extent (and only to the extent) that such Merck Violation occurs in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by any of such indemnifying parties, provided, however, that the indemnity agreement contained in this Section 8.3 will not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without Merck's consent, which consent will not be unreasonably withheld; provided, further, that in no event shall the obligations of Merck in this Section 8.3 exceed the net proceeds received by it from the sale of its Registrable Securities related to the matter in which losses or damages are sought.

8.4 Assignment of Registration Rights. Merck's right to request registration of its Registrable Securities as set forth in Section 8.1 above may be assigned to one or more Affiliates of Merck as provided in Section 9.10, in each case so long as Merck is not relieved of any liability or obligations under this Section 8.

8.5 Termination of Registration Rights. Merck's right to request registration of its Registrable Securities as set forth in Section 8.1 above shall terminate automatically on the date



that is five (5) years following the Closing Date or, if earlier, once Merck, together with its Affiliates, no longer beneficially owns more than [*] of the Shares.

Section 9. GOVERNING LAW; MISCELLANEOUS.

9.1 Governing Law; Jurisdiction. This Agreement will be governed by and interpreted in accordance with the laws of the State of Delaware without regard to the principles of conflict of laws that would require the application of the substantive Laws of another jurisdiction.

9.2 HSR Clearance.

(a) Subject to the terms and conditions of this Agreement, each of Merck and Seagen will use its reasonable best efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary, proper or advisable under applicable Law to consummate the acquisition of the Shares as soon as practicable after the Execution Date, including taking all steps as may be necessary, subject to the limitations in this Section 9.2, to obtain all applicable waiting period expirations or terminations, consents, clearances, waivers, licenses, registrations, permits, authorizations, orders and approvals. In furtherance and not in limitation of the foregoing, each of Merck and Seagen agrees to (i) file or cause to be filed with the FTC and the DOJ any notifications required to be filed under the HSR Act no later than seven (7) Business Days after the Execution Date (unless otherwise mutually agreed to by the parties), and (ii) use reasonable best efforts to obtain as promptly as practicable the termination or expiration of any waiting period under the HSR Act, including by filing as soon as practicable and advisable any supplemental or additional information which may reasonably be requested by the FTC or the DOJ or any other Governmental Authority in connection with applicable Antitrust Law; provided that the obligations in this Section 9.2 shall not require Seagen or Merck or any of its Affiliates to (x) sell, divest (including through a license or a reversion of licensed or assigned rights), hold separate, transfer or dispose of, or commit to any behavioral remedy with respect to, any assets, operations, rights, product lines, businesses or interest therein of Seagen or Merck or any of their Affiliates (or consent to any of the foregoing actions); or (y) litigate or otherwise formally oppose any determination (whether judicial or administrative in nature) by a Governmental Authority seeking to impose any of the restrictions referenced in clause (x). Merck shall be responsible for the payment of filing fees payable under the HSR Act and any other applicable Antitrust Law.

(b) Each of Merck and Seagen shall use reasonable best efforts to provide or cause to be provided promptly all assistance and cooperation to allow Merck and Seagen to prepare and submit any filings or submissions under the HSR Act, including providing to Merck and Seagen, as applicable, any information that it may require for the purpose of any filing, notification, application or request for further information made in respect of any such filing.

(c) Each of Merck and Seagen shall, in connection with the transactions contemplated hereby, and the obtaining of all waiting period expirations or terminations, consents, clearances, waivers, licenses, orders, registrations, approvals, permits and authorizations under the HSR Act or any other applicable Antitrust Law, with respect to actions taken on or after the date of this Agreement, without limitation: (i) promptly notify the other of,



and if in writing, furnish the other with copies of (or, in the case of oral communications, advise the other of) any material communications from or with any Governmental Authority, including the FTC and the DOJ, with respect to the Agreement, (ii) cooperate in all respects and consult with each other in connection with any filing or submission and in connection with any investigation or other inquiry, (iii) permit the other to review and discuss in advance, and consider in good faith the view of the other in connection with, any proposed written or oral communication with any Governmental Authority, (iv) not participate in any substantive meeting or have any substantive communication with any Governmental Authority unless it has given the other party a reasonable opportunity to consult with it in advance and, to the extent permitted by such Governmental Authority, gives the other the opportunity to attend and participate therein, (v) furnish the other party's outside legal counsel with copies of all supplemental filings and substantive communications between it and any such Governmental Authority with respect to the Agreement; provided that neither party will be required to provide the other party with its board of directors or internal committee materials; and any materials subject to this Section 9.2(c) may be restricted to outside counsel and may be redacted or withheld as necessary (A) to comply with contractual arrangements, (B) to address good faith legal privilege concerns and (C) to comply with applicable Law, (vi) furnish the other party's outside legal counsel with such necessary information and reasonable assistance as the other party's outside legal counsel may reasonably request in connection with its preparation of necessary submissions of information to any such Governmental Authority, and (vii) use reasonable best efforts to respond as soon as practicable to reasonable requests for information by any Governmental Authority. Neither Merck nor Seagen shall commit to or agree with any Governmental Authority to stay, toll, or extend any applicable waiting period under the HSR Act or other applicable Antitrust Law, or pull and refile under the HSR Act, without the prior written consent of the other.

9.3 Survival.

(a) Notwithstanding any investigation made by or on behalf of Seagen or Merck prior to, on or after the Closing, the representations and warranties contained in this Agreement (including the exhibits and schedules hereto) and any certificate delivered hereunder shall survive the Closing and shall terminate on the second anniversary of the Closing Date.

(b) The covenants of the parties hereto shall survive until fully performed and discharged, unless otherwise expressly provided herein.

9.4 Counterparts; Electronic Signatures. This Agreement may be executed and delivered (including by facsimile transmission or PDF or any other electronically transmitted signatures such as via DocuSign) in two counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

9.5 Headings. The headings of this Agreement are for convenience of reference only, are not part of this Agreement and do not affect its interpretation.

9.6 Rules of Construction.

(a) For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; the masculine gender shall include the



feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include the masculine and feminine genders.

(b) As used in this Agreement, (i) the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation”, (ii) the words “hereby,” “herein,” “hereunder” and “hereto” shall be deemed to refer to this Agreement in its entirety and not to any specific section of this Agreement and (iii) “or” has the inclusive meaning represented by the phrase “and/or”.

(c) Except as otherwise indicated, all references in this Agreement to “Sections” and “Appendix” are intended to refer to Sections of this Agreement, as appropriate, and Appendix 1 to this Agreement.

(d) As used in this Agreement, the term “days” means calendar days unless otherwise specified. When calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period shall be excluded. If the last day of such period is a non-Business Day, the period in question shall end on the next succeeding Business Day.

(e) Unless otherwise indicated, all monetary amounts herein are in United States dollars.

9.7 Severability. If any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the parties will negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the parties and all other provisions hereof will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

9.8 Entire Agreement; Amendments. This Agreement (including any schedules and appendices hereto and any certificates delivered hereunder) constitute the entire agreement between the parties hereto with respect to the subject matter hereof. There are no restrictions, promises, warranties or undertakings, other than those set forth or referred to herein or therein. This Agreement supersedes all prior agreements and understandings between the parties hereto with respect to the subject matter hereof. No provision of this Agreement may be waived or amended other than by an instrument in writing signed by the party to be charged with enforcement. Any amendment or waiver effected in accordance with this Section 9.8 will be binding upon Merck and Seagen.

9.9 Notices. All notices required or permitted hereunder will be in writing and will be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed email if sent during normal business hours of the recipient, if not, then on the next Business Day, or (c) one Business Day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. The addresses for such communications are:



If to Seagen, addressed to: Seattle Genetics, Inc.
21823 30th Drive S.E.
Bothell, WA 98021
Attention: Chief Executive Officer
E-mail: [*]

with copies to: Seattle Genetics, Inc.
21823 30th Drive S.E.
Bothell, WA 98021
Attention: General Counsel
E-mail: [*]

Cooley LLP
101 California Street, 5th Floor
San Francisco, CA 94111-5800
Attention: Chadwick L. Mills
E-mail: [*]

If to Merck, addressed to: Merck Sharp & Dohme Corp.
2000 Galloping Hill Road
Kenilworth, NJ 07033-1310
Attention: Office of Secretary
Email: [*]

With a copy to: Merck Sharp & Dohme Corp.
2000 Galloping Hill Road
Mail Stop K-1-4161
Kenilworth, NJ 07033
Attention: SVP, Corporate Development

9.10 Successors and Assigns. This Agreement is binding upon and inures to the benefit of the parties and their successors and assigns. Seagen will not assign this Agreement or any rights or obligations hereunder without the prior written consent of Merck, and Merck will not assign this Agreement or any rights or obligations hereunder without the prior written consent of Seagen; provided, however, that Merck may assign this Agreement together with all of the Shares it then owns (subject to Section 4.1(d) and Section 8.4) to any Affiliate of Merck and any such assignee may assign the Agreement together with all of the Shares it then owns (subject to Section 4.1(d) and Section 8.4) to Merck or any other Affiliate of Merck, in any such case, without such consent, provided that the assignee agrees to assume Merck's obligations under Section 4 and Section 8 of this Agreement.

9.11 Third Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto, their respective permitted successors and assigns, and is not for the benefit of, nor may any provision hereof be enforced by, any other person.

9.12 Further Assurances. Each party will do and perform, or cause to be done and performed, all such further acts and things, and will execute and deliver all other agreements, certificates, instruments and documents, as the other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

9.13 No Strict Construction. The language used in this Agreement is deemed to be the language chosen by the parties to express their mutual intent, and no rules of strict construction will be applied against a party.

9.14 Equitable Relief. Seagen recognizes that, if it fails to perform or discharge any of its obligations under this Agreement, any remedy at will not be prohibited by any applicable Law at the time of Closing may prove to be inadequate relief to Merck. Seagen therefore agrees that Merck is entitled to seek temporary and permanent injunctive relief or specific performance in any such case. Merck also recognizes that, if it fails to perform or discharge any of its obligations under this Agreement, any remedy at will not be prohibited by any applicable Law at the time of Closing may prove to be inadequate relief to Seagen. Merck therefore agrees that Seagen is entitled to seek temporary and permanent injunctive relief or specific performance in any such case.

9.15 Expenses. Seagen and Merck are each liable for, and will pay, their own expenses incurred in connection with the negotiation, preparation, execution and delivery of this Agreement, including attorneys' and consultants' fees and expenses.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, Merck and Seagen have caused this Agreement to be duly executed as of the date first above written.

MERCK SHARP & DOHME CORP.

By: /s/ Robert M. Davis

Name: Robert M. Davis

Its: Executive Vice President, Global Services, and Chief Financial Officer, Merck & Co., Inc. and Authorized Officer, Merck Sharp & Dohme Corp.

SEATTLE GENETICS, INC.

By: /s/ Clay B. Siegall

Name: Clay B. Siegall, Ph.D.

Its: President and Chief Executive Officer

[Signature page to Stock Purchase Agreement]

APPENDIX 1

DEFINED TERMS

“Affiliate” of an entity means any corporation, firm, partnership or other entity that directly or indirectly through one or more intermediaries controls, is controlled by or is under common control with it. An entity will be deemed to control another entity if it (i) owns, directly or indirectly, at least 50% of the outstanding voting securities or capital stock (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of such other entity, or has other comparable ownership interest with respect to any entity other than a corporation; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the entity.

“Antitrust Clearance Date” means the date on which all of the HSR Conditions have been met.

“Antitrust Law” means the HSR Act, the Sherman Antitrust Act, as amended, the Clayton Act, as amended, the Federal Trade Commission Act, as amended, and any other applicable Law designed to prohibit, restrict or regulate actions or transactions having the purpose or effect of monopolization, restraint of trade or harm to competition.

“Board” means the board of directors of Seagen.

“Business Day” means a day Monday through Friday on which banks are generally open for business in the State of Washington.

“Change of Control” means, with respect to a party, any (i) direct or indirect acquisition or license of all or substantially all of the assets of such party, (ii) direct or indirect acquisition by a person, or group of persons acting in concert, of 50% or more of the voting equity interests of a party, (iii) tender offer or exchange offer that results in any person, or group of persons acting in concert, beneficially owning 50% or more of the voting equity interests of a party, or (iv) merger, consolidation, other business combination or similar transaction involving a party, pursuant to which any person owns all or substantially all of the consolidated assets, net revenues or net income of a party, taken as a whole, or which results in the holders of the voting equity interests of a party immediately prior to such merger, consolidation, business combination or similar transaction ceasing to hold 50% or more of the combined voting power of the surviving, purchasing or continuing entity immediately after such merger, consolidation, other business combination or similar transaction.

“Closing Date” means the date on which the Closing actually occurs.

“Collaboration Agreements” means (i) that certain License and Collaboration Agreement, dated as of September 13, 2020, by and between Seagen and Merck (the “Liv Agreement”) and (ii) that certain License and Co-Development Agreement, dated as of September 13, 2020, by and between Seagen and Merck and Company, Incorporated.

“Common Stock” means shares of Seagen’s common stock, par value \$0.001 per share.



“DOJ” means the U.S. Department of Justice.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC thereunder.

“FDA” means the U.S. Food and Drug Administration or any successor entity.

“FTC” means the U.S. Federal Trade Commission.

“GAAP” means generally accepted accounting principles in the United States of America as applied by Seagen.

“Governmental Authority” means any Federal, state, provincial, local, municipal, foreign or other governmental or quasi-governmental authority, including any arbitrator and applicable securities exchanges, or any department, minister, agency, commission, commissioner, board, subdivision, bureau, agency, instrumentality, court or other tribunal of any of the foregoing.

“HSR Act” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

“HSR Conditions” means that: (a) the waiting period (and any extensions thereof, including any timing agreements entered into with a Governmental Authority under which the parties agree not to close the transaction) under the HSR Act shall have expired or earlier been terminated; (b) no judicial or administrative proceeding opposing consummation of all or any part of this Agreement shall be pending; and (c) no Law, order or injunction (whether temporary, preliminary or permanent) prohibiting consummation of the transactions contemplated by this Agreement or any material portion hereof shall be in effect.

“Intellectual Property” shall mean trademarks, trade names, trade dress, service marks, copyrights, and similar rights (including registrations and applications to register or renew the registration of any of the foregoing), patents and patent applications, trade secrets, and any other similar intellectual property rights.

“Intellectual Property License” shall mean any license, permit, authorization, approval, contract or consent granted, issued by or with any person relating to the use of Intellectual Property.

“Law” means any federal, state, local or foreign constitution, treaty, law, statute, ordinance, rule, regulation, interpretation, directive, policy, order, writ, decree, injunction, judgment, stay or restraining order of any Governmental Authority, the terms of any permit, and any other ruling or decision of, agreement with or by, or any other requirement of, any Governmental Authority.

“Material Adverse Effect” means any change, effect or circumstance, individually or in the aggregate, (a) that is [*] materially adverse to [*], or (b) that materially impairs [*]; provided, however, that, none of the following (alone or when aggregated any other effects), shall be deemed to be a Material Adverse Effect, and none of the following (alone or when aggregated with any other effects), shall be taken into account for purposes of clause (a) above: (A) (1) general market, economic or political conditions or (2) conditions ([*]), in each case, including



any [*], solely to the extent that [*]; (B) the execution, delivery or performance of this Agreement, the Collaboration Agreements and the transactions contemplated hereby and thereby; or (C) (1) [*] changes resulting from [*]; (2) any [*], with respect to [*]; (3) [*] relating to [*]; or (4) changes in the [*], in and of themselves.

“Merck Violation” means (i) any untrue statement or alleged untrue statement of a material fact contained in such registration statement or incorporated by reference therein, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto, (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by Merck of the Securities Act, the Exchange Act, any state securities law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law in connection with the offering covered by such registration statement.

“Nasdaq” means The Nasdaq Stock Market.

“Preferred Stock” means shares of Seagen’s preferred stock, par value \$0.001 per share.

“Registrable Securities” means the Shares (including any Common Stock that may be issued or distributed in respect thereof by way of dividend or split or other distribution, recapitalization or reclassification); provided, however, that the Shares shall cease to be Registrable Securities upon the sale to the public either pursuant to a registration statement under the Securities Act or under Rule 144 (in which case, only such Shares sold shall cease to be Registrable Securities).

“Registration Expenses” means any and all expenses incurred by Seagen in complying with the provisions of Section 8, including (i) all SEC and stock exchange or financial regulatory authority registration and filing fees, (ii) all fees and expenses of complying with securities or blue sky laws, (iii) all printing, messenger and delivery expenses, (iv) all fees and expenses incurred in connection with the listing of the Registrable Securities on any securities exchange, and (v) the fees and disbursements of counsel for Seagen and of its independent public accountants.

“Rule 144” means Rule 144 promulgated by the SEC pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the SEC having substantially the same effect as such Rule.

“SEC” means the United States Securities and Exchange Commission or any successor entity.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations of the SEC thereunder.

“Selling Expenses” means all (i) underwriting discounts, commissions, or fees of underwriters, selling brokers, dealer managers or similar securities industry professionals applicable to an offering involving Registrable Securities registered pursuant to Section 8 and (ii) fees and expenses of any legal counsel, accountants and any other advisors of Merck.



“Subsidiaries” means those subsidiaries of Seagen listed in Exhibit 21.1 to Seagen’s Annual Report on Form 10-K for the year ended December 31, 2019.

“Violation” means (i) any untrue statement or alleged untrue statement of a material fact contained in such registration statement or incorporated by reference therein, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto, (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by Seagen of the Securities Act, the Exchange Act, any state securities law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law in connection with the offering covered by such registration statement.

EXHIBIT A

[•], 2020

Merck Sharp & Dohme Corp.
2000 Galloping Hill Road
Kenilworth, NJ 07033-1310

Re: Seattle Genetics, Inc.

Ladies and Gentlemen:

We have acted as counsel for Seattle Genetics, Inc., a Delaware corporation (the "Company"), in connection with the sale of 5,000,000 shares of common stock, par value \$0.001 per share (the "Common Stock"), of the Company (the "Shares") pursuant to that certain Stock Purchase Agreement, dated as of September 13, 2020 (the "Purchase Agreement"), by and between the Company and Merck Sharp & Dohme Corp., a New Jersey corporation (the "Purchaser"). We are rendering this opinion to you pursuant to Section 1.3(b)(i)(2) of the Purchase Agreement. Capitalized terms used but not defined herein have the meanings given to them in the Purchase Agreement.

In connection with this opinion, we have examined and relied upon the representations and warranties as to factual matters contained in and made pursuant to the Purchase Agreement by the various parties and originals or copies, certified to our satisfaction, of such records, documents, certificates, opinions, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

In rendering this opinion, we have assumed, without investigation: (a) the authenticity of all documents submitted to us as originals; (b) the conformity to originals of all documents submitted to us as copies; (c) the accuracy, completeness and authenticity of certificates of public officials; (d) the due authorization, execution and delivery of all documents (except the due authorization, execution and delivery by the Company of the Purchase Agreement); (e) the authenticity of all signatures; (f) that all individuals executing and delivering documents had the legal capacity to so execute and deliver; (g) that the Purchase Agreement is a valid and binding obligation, enforceable in accordance with its terms against all parties thereto other than the Company; (h) that there are no extrinsic agreements or understandings among the parties to the Purchase Agreement or to the Reviewed Agreements (as defined below) that would modify or interpret the terms of any such agreements or the respective rights or obligations of the parties thereunder; (i) the valid existence, good standing in the jurisdiction of organization and the corporate or similar power to enter into, and perform the Purchase Agreement in accordance with its terms, of each party to the Purchase Agreement (except that such assumption is not made as to the Company); and (j) compliance by the Purchaser with any state or federal laws applicable to the transactions contemplated by the Purchaser because of the nature of the Purchaser's business.

[*] = 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.

Our opinion is expressed only with respect to the federal laws of the United States of America, the laws of the State of Washington and the General Corporation Law of the State of Delaware (the "DGCL"). We note that the parties to the Purchase Agreement have designated the laws of the State of Delaware as the laws governing the Purchase Agreement. Our opinion below is premised upon the result that would obtain if a Washington court were to apply the internal laws of the State of Washington (notwithstanding the designation of the laws of the State of Delaware) to the interpretation and enforcement of the Purchase Agreement. We express no opinion as to whether the laws of any particular jurisdiction apply, and no opinion to the extent that the laws of any jurisdiction other than those identified above are applicable to the subject matter hereof.

The opinion set forth in this letter is based on the customary practice of lawyers who regularly give, and lawyers who regularly advise opinion recipients regarding, opinions of the kind involved, including customary practice as described in bar association reports. In rendering the opinion below, we are opining only with respect to the specific legal issues expressly set forth in the numbered paragraphs below, and we render no opinion, whether by implication, inference or otherwise, as to any other matter or matters.

We express no opinion with respect to compliance with antifraud laws, rules or regulations relating to securities or the offer and sale thereof; without limiting the generality of the foregoing, we express no opinion as to (a) the accuracy and completeness of the information provided by the Company or its representatives to the Purchaser in connection with the offer and sale of the Shares pursuant to the Purchase Agreement or (b) the past, present or future fair market value of any securities.

We express no opinion with respect to compliance with fiduciary duties by the Company's Board of Directors ("Board") or stockholders or compliance with safe harbors for disinterested Board or stockholder approvals; further, we express no opinion as to whether, and have assumed that, the Purchase Agreement and the transactions contemplated thereby were fair as to the Company within the meaning of Section 144 of the DGCL and all material facts as to the interests of the Company's officers and directors in the Purchase Agreement and the transactions contemplated thereby have been disclosed to the Board as may be required to comply with any applicable safe harbor for disinterested Board approvals.

We are not rendering any opinion or assurance as to: (i) any statute, rule, regulation, ordinance, decree or decisional law relating to antitrust, banking, the environment, land use, pensions, employee benefits, tax, fraudulent transfer, fraudulent conveyance, usury, bankruptcy, insolvency, antiterrorism, money laundering, mail fraud, wire fraud, or other criminal activities, patents, copyrights, trademarks and other intellectual property, health and safety, labor and employment, national and local emergencies, or criminal and civil forfeiture, laws governing the legality of investments for regulated entities, (ii) Regulations T, U or X of the Board of Governors of the Federal Reserve System, (iii) the International Investment and Trade in Services Survey Act or the implementing regulations thereof, (iv) the Defense Production Act of 1950, as amended, (v) the Foreign Investment Risk Review Modernization Act of 2018, including all implementing regulations thereof, (vi) any law, rule or regulation relating to pharmaceutical products or (vii) local law. Furthermore, we express no opinion with respect to state securities or blue sky laws; the Investment Company Act of 1940, as amended (the

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“Investment Company Act”), except to the extent specifically set forth in paragraph 7 below); or laws that place limitations on corporate distributions.

With regard to our opinion in paragraph 1 below with respect to the valid existence and good standing of the Company and the Company’s qualification to do business as a foreign corporation, we have relied solely upon certificates of the Secretaries of State of the indicated jurisdictions as of a recent date.

With regard to our opinion in paragraph 3 below concerning defaults under and any breaches of any agreement identified on Schedule A hereto (the “Reviewed Agreements”), we have relied solely upon (i) inquiries of officers of the Company and (ii) an examination of the Reviewed Agreements in the form provided to us by the Company. We have made no further investigation. Further, with regard to our opinion in paragraph 3 below concerning Reviewed Agreements, we express no opinion as to (a) financial covenants or similar provisions therein requiring financial calculations or determinations to ascertain compliance, (b) provisions therein relating to the occurrence of a “material adverse event” or words of similar import, (c) provisions therein requiring comparisons between the relative rights of the parties thereto with the rights of the Purchaser based upon factual determinations or requiring other factual determinations or the knowledge of facts or other information that are not specifically set forth therein, or (d) any statement or writing that may constitute parol evidence bearing on interpretation or construction of the Reviewed Agreements. We have assumed that the Reviewed Agreements are enforceable in accordance with their terms and that the Reviewed Agreements would be interpreted in accordance with their plain meaning.

With regard to our opinion in paragraphs 3, 4 and 9 below, we have assumed (i) the Purchaser is (a) a “qualified institutional buyer” within the meaning of Rule 144A under the Securities Act of 1933, as amended (the “Securities Act”) or (b) an institutional “accredited investor” within the meaning of Rule 501 or Regulation D under the Securities Act that is (1) a sophisticated investor, experienced in investing in private equity transactions and capable of evaluating investment risks independently, both in general and with regard to all transactions and investment strategies involving a security or securities and (2) has exercised independent judgment in evaluating its participation in the purchase of the Shares; (ii) that the Company has a pre-existing, substantive relationship with the Purchaser that predates the commencement of the offering of the Shares; (iii) the accuracy of the representations and warranties of the Company and the Purchaser contained in the Purchase Agreement and the compliance by the Company and the Purchaser with the covenants contained in the Purchase Agreement; and (iv) that the Company, any person acting on behalf of the Company, has not offered or sold the Shares by any form of “general solicitation or general advertising” within the meaning contemplated by Rule 502(c) of Regulation D promulgated under the Securities Act, including but not limited to in any manner involving a public offering within the meaning of Section 4(a)(2) of the Securities Act with respect to the offer and sale of the Shares. Moreover, our opinion in paragraphs 3, 4 and 9 below addresses the offer and sale of the Shares without regard to any offers or sales of other securities occurring prior to or subsequent to the date hereof.

With regard to our opinion in paragraph 7 below, we have based our opinion, to the extent we consider appropriate, on Rule 3a-8 under the Investment Company Act, and a

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certificate executed by an officer of the Company as to compliance with the requirements of Rule 3a-8. We have conducted no further investigation.

Our opinion is subject to the following additional qualifications and limitations:

- (a) Our opinion is subject to, and may be limited by, (1) applicable bankruptcy, reorganization, insolvency, moratorium, fraudulent conveyance, debtor and creditor, and similar laws which relate to or affect creditors' rights generally, and (2) general principles of equity (including, without limitation, concepts of materiality, reasonableness, good faith and fair dealing) regardless of whether considered in a proceeding in equity or at law;
- (b) Our opinion is subject to the qualification that (1) the enforceability of provisions for indemnification or limitations on liability may be limited by applicable law and by public policy considerations, and (2) the availability of specific performance, an injunction or other equitable remedies is subject to the discretion of the court before which the request is brought; and
- (c) We express no opinion with respect to any provision of the Purchase Agreement that: (1) relates to the subject matter jurisdiction of any federal court of the United States of America to adjudicate any controversy relating to the Purchase Agreement; (2) contains a waiver of an inconvenient forum; (3) provides for liquidated damages, buy-in damages, default interest, late charges, monetary penalties, prepayment or make-whole payments or other economic remedies; (4) relates to advance waivers of claims, defenses, rights granted by law, notice, opportunity for hearing, evidentiary requirements, statutes of limitations, trial by jury, or procedural rights; (5) restricts non-written modifications and waivers; (6) provides for the payment of legal and other professional fees where such payment is contrary to law or public policy; (7) relates to exclusivity, election or accumulation of rights or remedies or would permit the exercise of remedies without consideration of the materiality of the breach by the Company and the consequence of the breach to the party seeking enforcement; (8) authorizes or validates conclusive or discretionary determinations; (9) provides that provisions of the Purchase Agreement are severable to the extent an essential part of the agreed exchange is determined to be invalid and unenforceable; (10) provides that a party's waiver of any breach of any provision of the Purchase Agreement is not to be construed as a waiver by such party of any prior breach of such provision or of any other provision of the Purchase Agreement; (11) provides any party the right to accelerate obligations or exercise remedies without notice; (12) provides for a right or remedy that may be held to be arbitrary or unconscionable, a penalty or otherwise in violation of public policy; (13) relates to choice of law, choice of forum, consent to jurisdiction (both as to personal jurisdiction and subject matter

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jurisdiction) or service of process; (14) requires arbitration; (15) provides for a covenant not to compete; (16) relates to the voting of the Company's capital stock; or (17) specifies provisions that must be waived in writing, to the extent that an oral agreement or implied agreement by trade practice or course of conduct has been created that modifies such provision.

On the basis of the foregoing, in reliance thereon and with the qualifications set forth herein, we are of the opinion that:

1. The Company is a validly existing corporation and in good standing under the laws of the State of Delaware and is qualified to do business as a foreign corporation in the State of Washington.
2. The Company has the corporate power to own or lease, as the case may be, to operate its properties and conduct its business as described in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 and to execute, deliver and perform its obligations under the Purchase Agreement.
3. The execution and delivery of the Purchase Agreement by the Company and the issuance and sale of the Shares pursuant to the Purchase Agreement do not (a) constitute a default under or a breach of any Reviewed Agreement, (b) violate any provision of the certificate of incorporation or bylaws of the Company, or (c) violate the DGCL or any U.S. federal or Washington state statute, law, rule or regulation that in our experience is typically applicable to transactions of the nature contemplated by the Purchase Agreement, in each case of (a) and (c) to the extent the violation of which would materially and adversely affect the Company and its subsidiaries, taken as a whole.
4. All consents, approvals, authorizations, or orders of, and filings, registrations, and qualifications with any U.S. federal or Washington state regulatory authority or governmental body required for the issuance of the Shares has been made or obtained, other than (a) filings required to be made under U.S. federal or state "blue sky" laws that may be made properly after the issuance of the Shares or (b) as provided in Section 9.2 of the Purchase Agreement.
5. The Purchase Agreement has been duly authorized, executed and delivered by the Company and constitutes a valid and binding agreement of the Company enforceable against the Company in accordance with its terms.
6. The Company is not, and, after giving effect to the issue and sale of the Shares, will not be, required to be registered as an "investment company" under the Investment Company Act.
7. The Shares have been duly authorized and upon issuance and delivery against payment therefore in accordance with the terms of the Purchase Agreement, will be validly issued, fully paid and nonassessable.
8. The holders of outstanding shares of capital stock of the Company are not entitled to preemptive rights, rights of first refusal, rights of first offer or other similar rights to

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subscribe for the Shares arising under the DGCL, the certificate of incorporation or bylaws of the Company or any Reviewed Agreement.

9. The offer and sale of the Shares pursuant to the Purchase Agreement are exempt from the registration requirements of Section 5 of the Securities Act.

This opinion is furnished only to you in your capacity as the Purchaser of the Shares under the Purchase Agreement and is solely for your benefit in connection with the transactions referenced in the first paragraph of this letter. This opinion may not be relied upon by you for any other purpose, or furnished to, assigned to, quoted to, or relied upon by any other person, firm or other entity for any purpose (including any person, firm or other entity that acquires Shares from you) without our prior written consent, which may be granted or withheld in our sole discretion.

This opinion is limited to the matters expressly set forth in this letter, and no opinion has been implied, or may be inferred, beyond the matters expressly stated. This opinion speaks only as to law and facts in effect or existing as of the date hereof and we undertake no obligation or responsibility to update or supplement this opinion to reflect any facts or circumstances that may hereafter come to our attention or any changes in any law that may hereafter occur.

Very truly yours,

Cooley LLP

By: _____

SCHEDULE A

REVIEWED AGREEMENTS

Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.

Registration Rights Agreement, dated September 10, 2015, by and between Seattle Genetics, Inc. and the persons listed on Schedule A attached thereto.

Lease Agreement dated December 1, 2000 between Seattle Genetics, Inc. and WCM 132-302, LLC.

First Amendment to Lease dated May 28, 2003 between Seattle Genetics, Inc. and B&N 141-302, LLC.

Second Amendment to Lease dated July 1, 2008 between Seattle Genetics, Inc. and B&N 141-302, LLC.

Third Amendment to Lease dated May 9, 2011 between Seattle Genetics, Inc. and B&N 141-302, LLC.

Fourth Amendment to Lease dated October 24, 2017 between Seattle Genetics, Inc. and SNH Medical Office Properties Trust, as successor in interest to B&N 141-302, LLC.

Office Lease dated May 9, 2011 between Seattle Genetics, Inc. and WCM Highlands II, LLC.

First Amendment to Office Lease dated October 24, 2017 between Seattle Genetics, Inc. and SNH Medical Office Properties Trust, as successor in interest to WCM Highlands II, LLC.

Seattle Genetics, Inc.

Stock Unit Grant Notice
(Amended and Restated 2007 Equity Incentive Plan)

Seattle Genetics, Inc. (the “*Company*”), pursuant to its Amended and Restated 2007 Equity Incentive Plan (the “*Plan*”), hereby awards to Participant a Stock Unit Award for the number of stock units set forth below (the “*Award*”). The Award is subject to all of the terms and conditions as set forth herein and in the Plan and the Stock Unit Agreement (including Exhibit A to the Stock Unit Agreement), both of which are incorporated herein in their entirety. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Plan or the Stock Unit Agreement, as applicable. Except as otherwise explicitly provided herein, in the event of any conflict between the terms in the Award and the Plan, the terms of the Plan shall control; *provided, however*, that the terms of the Award shall control with respect to any terms regarding a Change of Control or a Termination of Employment.

Participant: [insert]

Date of Grant: [insert]

**Target Number of Stock
Units Subject to Award**

(the “*Target Shares*”): [number of shares to be inserted]

**Maximum Number of Stock
Units Subject to Award**

(the “*Maximum Shares*”): [number of shares to be inserted]

Consideration: Participant’s Services

Vesting Schedule: This Award shall vest in accordance with Section 2 of the Stock Unit Agreement and Exhibit A to the Stock Unit Agreement.

Issuance Schedule: The shares of Common Stock to be issued in respect of the Award will be issued in accordance with the issuance schedule set forth in Section 6 of the Stock Unit Agreement.

Sell to Cover Election: By accepting this Award, Participant hereby: (1) elects, effective on the date Participant accepts this Award, to sell shares of Common Stock issued in respect of the Award in an amount determined in accordance with Section 12(b) of the Stock Unit Agreement, and to allow the Agent to remit the cash proceeds of such sale to the Company as more specifically set forth in Section 12(b) of the Stock Unit Agreement (a “*Sell to Cover*”); (2) directs the Company to make a cash payment to satisfy the Withholding Obligation from the cash proceeds of such sale directly to the appropriate taxing authorities; and (3) **represents and warrants that (i) Participant has carefully reviewed Section 12(b) of the Stock Unit Agreement, (ii) on the date Participant accepts this Award he or she is not aware of any material, nonpublic information with respect to the Company or any securities of the Company, is not subject to any legal, regulatory or contractual restriction that would prevent the Agent from conducting sales, does not have, and will not attempt to exercise, authority, influence or control over any sales of Common Stock effected by the Agent pursuant to the Stock Unit Agreement, and is entering into the Stock Unit Agreement**

and this election to Sell to Cover in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1 (regarding trading of the Company's securities on the basis of material nonpublic information) under the Exchange Act, and (iii) it is Participant's intent that this election to Sell to Cover and Section 12(b) of the Stock Unit Agreement comply with the requirements of Rule 10b5-1(c)(1) under the Exchange Act and be interpreted to comply with the requirements of Rule 10b5-1(c) under the Exchange Act. Participant further acknowledges that by accepting this Award, Participant is adopting a 10b5-1 Plan (as defined in Section 12(b) of the Stock Unit Agreement) to permit Participant to conduct a Sell to Cover sufficient to satisfy the Withholding Obligation as more specifically set forth in Section 12(b) of the Stock Unit Agreement.

Additional Terms/Acknowledgements: Participant acknowledges receipt of, and understands and agrees to, this Stock Unit Grant Notice, the Stock Unit Agreement (including the provisions of Section 12(b) thereof with respect to the Sell to Cover and Exhibit A to the Stock Unit Agreement) and the Plan. Participant also acknowledges receipt of the Prospectus for the Plan. Participant further acknowledges that as of the Date of Grant, this Stock Unit Grant Notice, the Stock Unit Agreement (including Exhibit A to the Stock Unit Agreement) and the Plan set forth the entire understanding between Participant and the Company regarding the Award and supersede all prior oral and written agreements on that subject.

Participant's electronic acceptance shall signify Participant's execution of this Stock Unit Grant Notice and understanding that this Award is granted and governed under the terms and conditions set forth herein.

SEATTLE GENETICS, INC.

Clay B. Siegall
Chief Executive Officer

****PLEASE PRINT AND RETAIN THIS AGREEMENT FOR YOUR RECORDS****

Seattle Genetics, Inc.
Amended and Restated 2007 Equity Incentive Plan

Stock Unit Agreement

Pursuant to the Stock Unit Grant Notice (“*Grant Notice*”) and this Stock Unit Agreement (this “*Agreement*”) and in consideration of your services, Seattle Genetics, Inc. (the “*Company*”) has awarded you a Stock Unit Award (the “*Award*”) under its Amended and Restated 2007 Equity Incentive Plan (the “*Plan*”). Your Award is granted to you effective as of the Date of Grant set forth in the Grant Notice for this Award. This Agreement shall be deemed to be agreed to by the Company and you upon your execution of the Stock Unit Grant Notice to which it is attached. Capitalized terms not explicitly defined in this Agreement shall have the same meanings given to them in the Plan or the Grant Notice, as applicable. Except as otherwise explicitly provided herein, in the event of any conflict between the terms in this Agreement and the Plan, the terms of the Plan shall control; *provided, however*, that the terms of this Agreement shall control with respect to any terms regarding a Change of Control or a Termination of Employment. The details of your Award, in addition to those set forth in the Grant Notice and the Plan, are as follows.

1. Grant of the Award. This Award represents the right to be issued on a future date the number of shares of Common Stock that is equal to the number of stock units indicated in the Grant Notice (the “*Stock Units*”), contingent upon the performance criteria and the terms set forth in this Agreement (including Exhibit A to this Agreement). As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the “*Account*”) the maximum number of Stock Units subject to the Award. This Award was granted in consideration of your services to the Company or an Affiliate. Except as otherwise provided herein, you will not be required to make any payment to the Company (other than past and future services to the Company) with respect to your receipt of the Award, the vesting of the Stock Units or the delivery of the Common Stock to be issued in respect of the Award.

2. Vesting.

(a) Subject to the terms of Sections 10, 11 and 12 of this Agreement, your Award will vest, if at all, in accordance with this Section 2 and the vesting terms provided in Exhibit A to this Agreement, provided that you have not incurred a Termination of Employment before the Vesting Date (as defined in Exhibit A to this Agreement). Except as set forth in this Agreement, upon your Termination of Employment, the Stock Units credited to the Account that were not vested on the date of such Termination of Employment will be forfeited at no cost to the Company and you will have no further right, title or interest in the Stock Units or the shares of Common Stock to be issued in respect of the Award. By accepting the grant of this Award, you acknowledge and agree that the terms set forth in this Agreement (including the vesting terms provided in Exhibit A to this Agreement) supersede any contrary terms regarding the vesting of this Award set forth in any notice or other communication that you receive from, or that is displayed by, E*TRADE or other third party designated by the Company.

(b) The Grant Notice sets forth the target and maximum number of Stock Units that shall vest in connection with the achievement of the performance condition determined by the Compensation Committee of the Board of Directors of the Company (the “*Committee*”) and set forth in the Performance Goal Grid in Exhibit A to this Agreement (the “*Performance Goal Grid*”).

(c) The Committee shall certify the level of achievement of the performance condition and the associated number of Stock Units that shall be entitled to vest pursuant to the terms of this Agreement (the “*Certified Shares*”) in accordance with Exhibit A to this Agreement. Subject to the terms of Sections 10 and 11 of this Agreement, no Stock Units subject to your Award shall become Certified Shares unless and until the Committee certifies that the performance condition has been achieved. The Committee will have the full authority to determine whether the performance condition was achieved and approve the Certified Shares in accordance with Exhibit A to this Agreement; *provided, however*, that such Certified Shares may not exceed the Maximum Shares (as set forth in the Grant Notice, subject to Section 3 of this Agreement) and subject to the terms of Sections 10 and 11 of this Agreement, in the event of performance below the Threshold (as defined in Exhibit A to this Agreement), none of the Stock Units will vest and you will have no further right, title or interest in the Stock Units. Any Certified Shares will vest on the Vesting Date (as defined in Exhibit A to this Agreement), subject to the terms of Sections 2(a), 10, 11 and 12 of this Agreement.

(d) Subject to the terms of Sections 10 and 11 of this Agreement, in the event the Compensation Committee determines that the performance condition is not fully or partially achieved, the related Stock Units will not vest and will be forfeited effective as of the last day of the Performance Period (as defined in Exhibit A to this Agreement), subject to earlier forfeiture in the event of your Termination of Employment (except as set forth in this Agreement), and you will have no further right, title or interest in the Stock Units associated with such performance condition.

3. Number of Shares.

(a) The number of Stock Units subject to your Award may be adjusted from time to time for changes in capitalization, as provided in Section 13 of the Plan.

(b) Any additional Stock Units that become subject to the Award pursuant to this Section 3 shall be subject, in a manner determined by the Administrator, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Stock Units covered by your Award.

(c) Notwithstanding the provisions of this Section 3, no fractional shares of Common Stock or rights for fractional shares of Common Stock shall be created pursuant to this Section 3. The Administrator shall, in its discretion, determine an equivalent benefit for any fractional shares of Common Stock or fractional shares of Common Stock that might be created by the adjustments referred to in this Section 3.

4. Securities Law Compliance. You may not be issued any shares of Common Stock in respect of your Award unless either (i) such shares are registered under the Securities Act of 1933, as amended (the “*Securities Act*”); or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award also must comply with other applicable laws and regulations governing the Award, and you will not receive such shares if the Company determines that such receipt would not be in material compliance with such laws and regulations. You represent and warrant that you (a) have been furnished with a copy of the prospectus for the Plan and all information deemed necessary to evaluate the merits and risks of receipt of the Award, (b) have had the opportunity to ask questions concerning the information received about the Award and the Company, and (c) have been given the opportunity to obtain any information you deem necessary to verify the accuracy of any information obtained concerning the Award and the Company.

5. Transfer Restrictions. Your Award is not transferable, except by will or by the laws of descent and distribution. In addition to any other limitation on transfer created by applicable securities laws, you agree not to assign, hypothecate, donate, encumber or otherwise dispose of any interest in any of the shares of Common Stock subject to the Award until such shares are issued to you in accordance with Section 6 of this Agreement. After such shares have been issued to you, you are free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such shares provided that any such actions are in compliance with the provisions herein and applicable securities laws. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, shall thereafter be entitled to receive any distribution of Common Stock to which you were entitled at the time of your death pursuant to this Agreement.

6. Date of Issuance.

(a) If the Award is exempt from application of Section 409A of the Code and any state law of similar effect (collectively “*Section 409A*”), then subject to Section 12, the Company will deliver to you a number of shares of Common Stock equal to the number of Certified Shares, including any additional Certified Shares resulting from any Stock Units received pursuant to Section 3 above, on or within 60 days following the applicable vesting date (the “*Original Issuance Date*”). However, if the Original Issuance Date falls on a date that is not a business day, such delivery date shall instead fall on the next following business day. Notwithstanding the foregoing, if (i) the Original Issuance Date does not occur (1) during an “open window period” applicable to you, as determined by the Company in accordance with the Company’s then-effective policy or policies on trading in Company securities or (2) on a date when you are otherwise permitted to sell shares of Common Stock on the open market; and (ii) the Company elects, prior to the Original Issuance Date, (x) not to satisfy the Withholding Obligation (as defined in Section 12(a) hereof) by withholding shares of Common Stock from the shares of Common Stock otherwise due, on the Original Issuance Date, to you under this Award pursuant to Section 12 hereof, (y) not to permit you to then effect a Sell to Cover under the 10b5-1 Plan (as defined in Section 12(b) of this Agreement), and (z) not to permit you to satisfy the Withholding Obligation in cash, then such shares shall not be delivered on such Original Issuance Date and shall instead be delivered on the first business day of the next

occurring open window period applicable to you or the next business day when you are not prohibited from selling shares of Common Stock on the open market, as applicable (and regardless of whether there has been a Termination of Employment before such time), but in no event later than the 15th day of the third calendar month of the calendar year following the calendar year in which the Stock Units vest. Delivery of the shares of Common Stock pursuant to the provisions of this Section 6(a) is intended to comply with the requirements for the short-term deferral exemption available under Treasury Regulations Section 1.409A-1(b)(4) and shall be construed and administered in such manner. The form of such delivery of the shares of Common Stock (e.g., a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

(b) The provisions of this Section 6(b) are intended to apply if the Award is subject to Section 409A because of the terms of a severance arrangement or other agreement between you and the Company, if any, that provide for acceleration of vesting of the Award upon your separation from service (as such term is defined in Section 409A(a)(2)(A)(i) of the Code (“*Separation from Service*”) and such severance benefit does not satisfy the requirements for an exemption from application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(4) or 1.409A-1(b)(9) (“*Non-Exempt Severance Arrangement*”). If the Award is subject to and not exempt from application of Section 409A due to application of a Non-Exempt Severance Arrangement, the following provisions in this Section 6(b) shall supersede anything to the contrary in Section 6(a).

(i) If the Award vests in the ordinary course before your Termination of Employment in accordance with Section 2 of this Agreement and Exhibit A to this Agreement, without accelerating vesting under the terms of a Non-Exempt Severance Arrangement, in no event will the shares of Common Stock to be issued in respect of your Award be issued any later than the later of: (A) December 31st of the calendar year that includes the applicable vesting date and (B) the 60th day that follows the applicable vesting date.

(ii) If vesting of the Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were in effect as of the date of grant of the Award and, therefore, are part of the terms of the Award as of the date of grant, then the shares of Common Stock will be earlier issued in respect of your Award upon your Separation from Service in accordance with the terms of the Non-Exempt Severance Arrangement, but in no event later than the 60th day that follows the date of your Separation from Service. However, if at the time the shares of Common Stock would otherwise be issued you are subject to the distribution limitations contained in Section 409A applicable to “specified employees,” as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six months following the date of your Separation from Service, or, if earlier, the date of your death that occurs within such six-month period.

(iii) If either (A) vesting of the Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were not in effect as of the date of grant of the Award and,

therefore, are not a part of the terms of the Award on the date of grant, or (B) vesting accelerates pursuant to Section 4(b) of the Plan, then such acceleration of vesting of the Award shall not accelerate the issuance date of the shares of Common Stock (or any substitute property), but such shares (or substitute property) shall instead be issued on the same schedule as set forth in Exhibit A to this Agreement as if they had vested in the ordinary course before your Termination of Employment, notwithstanding the vesting acceleration of the Award. Such issuance schedule is intended to satisfy the requirements of payment on a specified date or pursuant to a fixed schedule, as provided under Treasury Regulations Section 1.409A-3(a)(4).

(c) Notwithstanding anything to the contrary set forth herein, the Company explicitly reserves the right to earlier issue the shares of Common Stock in respect of the Award to the extent permitted and in compliance with the requirements of Section 409A, including pursuant to any of the exemptions available in Treasury Regulations Section 1.409A-3(j)(4)(ix).

(d) The provisions in this Agreement for delivery of the shares of Common Stock in respect of the Award are intended either to comply with the requirements of Section 409A or to provide a basis for exemption from such requirements so that the delivery of such shares will not trigger the additional tax imposed under Section 409A, and any ambiguities herein will be so interpreted.

7. **Dividends.** You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a change in capitalization as provided in Section 3 of this Agreement; *provided, however*, that this sentence shall not apply with respect to any shares of Common Stock that are delivered to you in connection with your Award after such shares have been delivered to you.

8. **Restrictive Legends.** The shares of Common Stock issued in respect of your Award shall be endorsed with appropriate legends determined by the Company.

9. **Award Not a Service Contract.**

(a) Your service with the Company or an Affiliate is not for any specified term and may be terminated by you or by the Company or an Affiliate at any time, for any reason, with or without cause and with or without notice. Nothing in this Agreement (including, but not limited to, the vesting of your Award pursuant to this Agreement (including Exhibit A to this Agreement) or the issuance of the shares of Common Stock in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company or an Affiliate of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) By accepting this Award, you acknowledge and agree that the right to vest in the Award pursuant to this Agreement (including Exhibit A to this Agreement) is earned according to the terms of this Agreement (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a “reorganization”). You further acknowledge and agree that such a reorganization could result in your Termination of Employment, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award, except as otherwise provided in this Agreement. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting terms set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with your right or the Company’s right to terminate your service at any time, with or without cause and with or without notice.

10. Change of Control. Notwithstanding anything to the contrary in this Agreement, the Plan or any written agreement between you and the Company (including the employment agreement between you and the Company, as it may be amended and restated from time to time (the “*Employment Agreement*”), but subject to Section 409A as described in Section 6 above, in the event a Change of Control (as defined in the Employment Agreement) occurs before the last day of the Performance Period (as defined in Exhibit A to this Agreement) and before your Termination of Employment (except as set forth in Section 10(d) of this Agreement), the following shall apply:

(a) **Determination of Certified Shares.** Prior to the effective time of the Change of Control, the Committee will determine the number of Certified Shares in the manner specified in Exhibit A to this Agreement.

(b) **Award May Be Assumed.** If the acquirer or successor (or its parent or subsidiary corporation) in the Change of Control (the “*Acquirer*”) assumes this Award in a manner consistent with Section 13(c) of the Plan, then the Certified Shares will vest on the last day of the Performance Period (as defined in Exhibit A to this Agreement), provided that, except as set forth below, you have not incurred a Termination of Employment prior to such date.

(c) **If Award Is Not Assumed.** If the Acquirer determines that it will not assume the Award in the Change of Control, then the provisions of Section 13(c) of the Plan shall apply with respect to the Certified Shares and references to “fully vested” in such section shall mean the number of Certified Shares determined in accordance with Section 10(a) of this Agreement.

(d) **Change of Control and Involuntary Termination.** If you incur an Involuntary Termination (as defined in the Employment Agreement) immediately prior to or within 12 months after the Change of Control, then the “accelerated vesting” provision of the Employment Agreement shall apply with respect to the Certified Shares and references to “fully

vested” in such provision shall mean the number of Certified Shares determined in accordance with Section 10(a) of this Agreement.

11. Termination of Employment. Except as set forth in Section 10(d) of this Agreement, notwithstanding anything to the contrary in this Agreement, the Plan or any written agreement between you and the Company (including the Employment Agreement), but subject to Section 409A as described in Section 6 above, in the event your Termination of Employment occurs before the last day of the Performance Period (as defined in Exhibit A to this Agreement), the following shall apply:

(a) If such Termination of Employment is due to your death or Disability (as defined in the Employment Agreement) and the Award is outstanding on the date of such Termination of Employment, then the Committee will determine the number of Certified Shares in the manner specified in Exhibit A to this Agreement and the Certified Shares will vest effective as of the date of such Termination of Employment.

(b) If such Termination of Employment is not due to your death or Disability (as defined in the Employment Agreement), then to the extent the Award is outstanding on the date of such Termination of Employment, (i) you will forfeit the Award as of the date of such Termination of Employment and (ii) the Award will terminate as of the date of such Termination of Employment and your eligibility for any future or additional benefits under the Award will terminate as of such date. For clarity, this Section 11 shall supersede the “accelerated vesting” provision of the Employment Agreement which sets forth the treatment of the Award if you incur an Involuntary Termination (as defined in the Employment Agreement), which provisions shall not be applicable for purposes of this Award (other than as provided under Section 10(d) above).

12. Withholding Obligations.

(a) On or before the time you receive a distribution of Common Stock pursuant to your Award, or at any time thereafter as requested by the Company, you hereby authorize any required withholding from the Common Stock issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate which arise in connection with your Award (the “*Withholding Obligation*”).

(b) By accepting this Award, you hereby (i) acknowledge and agree that you have elected a Sell to Cover (as defined in the Grant Notice) to permit you to satisfy the Withholding Obligation and that the Withholding Obligation shall be satisfied pursuant to this Section 12(b) to the fullest extent not otherwise satisfied pursuant to the provisions of Section 12(c) hereof and (ii) further acknowledge and agree to the following provisions:

(i) You hereby irrevocably appoint E*Trade, or such other registered broker-dealer that is a member of the Financial Industry Regulatory Authority as the Company may select, as your agent (the “*Agent*”), and you authorize and direct the Agent to:

(1) Sell on the open market at the then prevailing market price(s), on your behalf, as soon as practicable on or after the date on which the shares of Common Stock are delivered to you pursuant to Section 6 hereof in connection with the vesting of the Stock Units, the number (rounded up to the next whole number) of shares of Common Stock sufficient to generate proceeds to cover (A) the satisfaction of the Withholding Obligation arising from the vesting of those Stock Units and the related issuance of shares of Common Stock to you that is not otherwise satisfied pursuant to Section 12(c) hereof and (B) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto;

(2) Remit directly to the Company and/or any Affiliate the proceeds necessary to satisfy the Withholding Obligation;

(3) Retain the amount required to cover all applicable fees and commissions due to, or required to be collected by, the Agent, relating directly to the sale of the shares of Common Stock referred to in clause (1) above; and

(4) Remit any remaining funds to you.

(i) You acknowledge that your election to Sell to Cover and the corresponding authorization and instruction to the Agent set forth in this Section 12(b) to sell Common Stock to satisfy the Withholding Obligation is intended to comply with the requirements of Rule 10b5-1(c)(1) under the Exchange Act and to be interpreted to comply with the requirements of Rule 10b5-1(c) under the Exchange Act (your election to Sell to Cover and the provisions of this Section 12(b), collectively, the “**10b5-1 Plan**”). You acknowledge that by accepting this Award, you are adopting the 10b5-1 Plan to permit you to satisfy the Withholding Obligation. You hereby authorize the Company and the Agent to cooperate and communicate with one another to determine the number of shares of Common Stock that must be sold pursuant to Section 12(b)(i) to satisfy your obligations hereunder.

(ii) You acknowledge that the Agent is under no obligation to arrange for the sale of Common Stock at any particular price under this 10b5-1 Plan and that the Agent may effect sales as provided in this 10b5-1 Plan in one or more sales and that the average price for executions resulting from bunched orders may be assigned to your account. You further acknowledge that you will be responsible for all brokerage fees and other costs of sale associated with this 10b5-1 Plan, and you agree to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale. In addition, you acknowledge that it may not be possible to sell shares of Common Stock as provided for in this 10b5-1 Plan due to (i) a legal or contractual restriction applicable to you or the Agent, (ii) a market disruption, (iii) a sale effected pursuant to this 10b5-1 Plan that would not comply (or in the reasonable opinion of the Agent’s counsel is likely not to comply) with the Securities Act, (iv) the Company’s determination that sales may not be effected under this 10b5-1 Plan or (v) rules governing order execution priority on the national exchange where the Common Stock may be traded. In the event of the Agent’s inability to sell shares of Common Stock, you will continue to be responsible for the timely payment to the Company of all federal, state, local and foreign taxes that are required by applicable laws and regulations to be withheld, including but not limited to those amounts specified in Section 12(b)(i)(1) above.

(iv) You acknowledge that regardless of any other term or condition of this 10b5-1 Plan, the Agent will not be liable to you for (A) special, indirect, punitive, exemplary, or consequential damages, or incidental losses or damages of any kind, or (B) any failure to perform or for any delay in performance that results from a cause or circumstance that is beyond its reasonable control.

(v) You hereby agree to execute and deliver to the Agent any other agreements or documents as the Agent reasonably deems necessary or appropriate to carry out the purposes and intent of this 10b5-1 Plan. The Agent is a third-party beneficiary of this Section 12(b) and the terms of this 10b5-1 Plan.

(vi) Your election to Sell to Cover and to enter into this 10b5-1 Plan is irrevocable. Upon acceptance of the Award, you have elected to Sell to Cover and to enter into this 10b5-1 Plan, and you acknowledge that you may not change this election at any time in the future. This 10b5-1 Plan shall terminate not later than the date on which the Withholding Obligation arising from the vesting of your Stock Units and the related issuance of shares of Common Stock has been satisfied.

(c) Alternatively, or in addition to or in combination with the Sell to Cover provided for under Section 12(b), you authorize the Company, at its discretion, to satisfy the Withholding Obligation by the following means (or by a combination of the following means):

(i) Requiring you to pay to the Company any portion of the Withholding Obligation in cash;

(ii) Withholding from any compensation otherwise payable to you by the Company; and/or

(iii) Withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date shares of Common Stock are issued pursuant to Section 6) equal to the amount of the Withholding Obligation; *provided, however*, that the number of such shares of Common Stock so withheld shall not exceed the amount necessary to satisfy the Company's or Affiliate's required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income (or such other amount as may be permitted while still avoiding classification of the Award as a liability for financial accounting purposes).

(d) Unless the Withholding Obligation of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to deliver to you any Common Stock.

(e) In the event the Withholding Obligation of the Company arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Withholding Obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

13. Unsecured Obligation. Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares of Common Stock pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares of Common Stock to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. Other Documents. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's policy on trading in Company securities permitting employees to sell shares of Common Stock only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

15. Notices. Any notices provided for in your Award or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. You hereby consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company, the Agent or another third party designated by the Company and agree notice shall be provided upon posting to your electronic account held by the Company, the Agent or another third party designated by the Company.

16. Miscellaneous.

(a) The rights and obligations of the Company under your Award shall be transferable to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by the Company's successors and assigns. Your rights and obligations under your Award may only be assigned with the prior written consent of the Company.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award, and fully understand all provisions of your Award.

(d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

17. Governing Plan Document. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Except as expressly provided herein and other than with respect to any terms set forth in Section 10, Section 11 and Section 12 of the Agreement, in the event of any conflict between the provisions of your Award and those of the Plan, the provisions of the Plan shall control.

18. Severability. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

19. Effect on Other Employee Benefit Plans. The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

20. Amendment. This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Administrator by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that no such amendment adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Administrator reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the grant as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

21. Clawback/Recovery. You acknowledge and agree that, notwithstanding anything to the contrary in this Agreement or the Grant Notice, but subject to applicable law,

your Award will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law, and any other clawback policy that the Company otherwise adopts.

CERTIFICATIONS

I, Clay B. Siegall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Seagen 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: October 29, 2020

